

**The effect of human factors on implementation of accreditation in
the medical laboratories of KwaZulu-Natal.**

By

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Submitted in fulfilment of the requirement for the degree of master of
Health Science in Medical Laboratory Science in the Department of
Biomedical and Clinical Technology at the Durban University of
Technology

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2021

Declaration

I hereby confirm and declare that the work presented in this Master's dissertation, to my belief and knowledge, contains no material previously published or written by another person. The material contained in this dissertation has not been submitted for any other degree nor professional qualification to the university or institution of other higher learning. The work presented in this submission is the result of my own independent work and it has been orally presented at the conferences.

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Acknowledgement

I would firstly give thanks to Jesus Christ my Lord and Saviour; without whom I would not have had the strength to complete this research. I also would like to acknowledge the people who made important contributions towards the completion of this degree:

I wish to extend my sincere gratitude and appreciation to:

1. My supervisor and co-supervisors, Dr Pavitra Pillay, Dr Rogerio Phili and Ms Lindiwe Cele, who consistently and continuously helped me to make this research a success. I sincerely appreciate all the time you took, your expert guidance and support. Without you this project could not have been completed.
2. Dr Thabisile Brenda Mkhize, you became the psychologist I needed at times. You went beyond the call of duty. To all DUT Biomedical and Clinical Technology Lecturers, thank you for your unwavering support and encouragement.
3. Ms Sara Bibi Mitha (Post graduate librarian), thank you for the patience you had with me. You were ever so welcoming whenever I required your assistance, support and professionalism is highly appreciated.
4. My family and friends who became parents to my daughter, for supporting me and forgiving me for missing most of the family events. Thank you for encouraging me and praying with me during the trying times.
5. The NHLS AARQA for allowing me to conduct this research within the NHLS Laboratories.
6. Mr Sibulele Bandezi and MANCO team, your support made it possible for me to complete the research. Mrs Hlengiwe D. Dlamini my line manager, thank you for allowing me time and space to conduct this research, your support does not go un-noticed. Mr Martin Xaba, thank you for your support, assistance and encouraging words.
7. Mrs Patience Dabula and Mr Pree Ganputh thank you for the continuous support and assistance. Your leadership in quality department inspires me. Thank you for believing in us.
8. Mrs Melini Baruth, you have been my greatest cheerleader, prayer partner and a big sister from the time I started, you believed in me when I wanted to give up

- Ngiyabonga. My heartfelt gratitude and appreciation for all the support and assistance.
9. To the KZN training Department: Xoliswa and Sandra, you ladies are the best.
 10. To Mr Vinesh Baruth, thank you for being my unpaid shrink, for calming me and ensuring me that I can still complete this degree.
 11. Mr Silvanus Vengetsamy, words cannot express the gratitude I have for you. You came through for me in more ways than one. Thank you for your unwavering support and assistance. Consider taking IT as your primary profession.
 12. Lastly but not least, thank you to all the participants. I sincerely and humbly appreciate your feedback; without you this research would have not happened at all.

Dedication

This thesis is dedicated to my daughter: Ayabonga Mdletshe, thank you for being the best daughter a mother could ever pray for. Thank you for understanding and forgiving me when I missed your school events while doing field work for this dissertation. Thank you for being my great cheerleader. To my sister: Duduzile Ngubo, you have been a mother to me from the day I was born, and continued to be a mother to my daughter, thank you for your unwavering support and for being my pillar of strength. There are no words that convey my heartfelt gratitude. To all my family members, thank you for the faith you had in me when I wanted to give up, words truly cannot express my gratitude towards you. To God be the Glory

Abstract

Background:

The National Health Laboratory Service (NHLS) provides pathology laboratory services to approximately 80% of the population in South Africa (SA). Despite being the main provider of laboratory service, the NHLS continues to struggle in preparing and ensuring the accreditation of its laboratories. In SA, the SA National Accreditation System (SANAS) is the platform through which laboratories are assessed and granted the accreditation status that certify their adherence to quality and performance standards. The process of preparing and ensuring laboratory accreditation in the NHLS is currently slow. The infrastructural and weak quality management systems are generally the universal barriers to the accreditation of laboratories. However, there is inadequate knowledge of human factors affecting the accreditation of laboratories. This quantitative descriptive study aims to explore the influence of staff motivation, practices and management support to the achievement of SANAS accreditation and to routine laboratory performance.

Methods:

A modified Likert-Scale employee motivation and management support assessment questionnaire was administered to 438 purposively-sampled NHLS employees in selected laboratories in KwaZulu-Natal (KZN). Employee attitudes, practice and behavioural questions as well as cumulative percentages of leadership index questions were used to assess the employee motivation and level of support provided by laboratory management, respectively. Retrospective data of two selected routine indicators of laboratory performance were subsequently evaluated against the employee motivation categories of the laboratories. The laboratories were stratified into accredited and non-accredited streams. Univariate analysis on employee motivation and management support and bivariate analysis on laboratory performance was performed using the SPSS Software. Chi-Square tests were used for comparisons, odds ratios (ORs) and 95% confidence intervals were calculated. Statistical significance was defined as $p < 0,05$ and any variables that achieve a pvalue of <0.05 were analysed using multivariate logistic regression. The study findings were applied to the Stages of Change (SOC) Theoretical Model or Transtheoretical Model (TTM).

Results:

This study included 249/296 participants, resulting in a response rate of 84%. Accredited laboratories had twice the number of staff compliment when compared with non-accredited laboratories. The results indicated that 98% of employees regard NHLS as the employer of choice; they believe they are a critical resource for the organization; they see themselves still working for the NHLS in two years' time and they can recommend NHLS as a great place to work at. Forty-seven percent of the participants did not believe that they have good career opportunities at the NHLS. Most of the participants (82%) stated that there is no work recognition for good performance and 77% of employees indicated that management decisions do not regard quality as the top priority, instead this was turnaround time. About 94% agreed that they believe that laboratory accreditation is necessary and they know their role in accreditation. However, most participants strongly disagreed about the NHLS management motivating them to go beyond what they would in a similar role elsewhere. It was found that 51% of employees did not believe that managers are great role models to the employees. Majority of NHLS employees were not satisfied with financial incentives, with the existing staffing in their laboratories, with the work infrastructure especially in rural settings and with the lack of management support.

Conclusion:

The SOC/ TTM model has five stages: pre-contemplation, contemplation, preparation, action, and maintenance. This model is based on the assumption that behaviour change among people occurs continuously through a cyclical process. This model is also based in the premise that people are at distinct points along the five stages and have different informational needs. In the present study it was found that human factors have an effect on the implementation of accreditation in medical laboratories of KwaZulu-Natal. It was also found that the areas of concern in the NHLS that are likely to be the main cause of the slowness in implementation of accreditation are: inadequate management support and leadership and poor staff morale/ lack of motivation among NHLS employees. It is recommended that the NHLS provide strengthened and ongoing training for employees focusing on the importance of laboratory accreditation.

Managers also need to be capacitated so that they are able to better support staff in gaining and maintaining laboratory accreditation.

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Chapter 1: Introduction

1.1 Background

The National Health Laboratory Service (NHLS) is the biggest diagnostic pathology service in South Africa (SA). The NHLS has the duty of supporting the national and provincial health departments in the delivery of laboratory and related public health services to over 80% of the population. This mandate is done through a national network of laboratories in all nine (9) provinces of SA. NHLS also has specialised institutes that comprise the National Institute for Communicable Diseases (NICD), the National Institute for Occupational Health (NIOH) and the South African Vaccine Producers (SAVP). The NHLS has a workforce of approximately 7000 employees (National Health Laboratory Services 2018a: 35). It has a mandate of providing a cost - effective, efficient and quality laboratory services to all public sector healthcare providers, including conducting health research and training for health sciences (National Health Laboratory Services 2018a).

The NHLS has a historically poor track record of preparing and ensuring the accreditation of its laboratories. Laboratory accreditation is the process whereby an authorized accrediting body gives formal recognition that the laboratory is performing at quality and at the internationally accepted standard. It is also a process whereby an accrediting body certifies that a person or people are competent to perform the set specific tasks. Accreditation of laboratories gives assurance to the public that the results produced by the laboratory are accurate and precise thus deemed reliable. Accreditation is an effective way to prove competence of the laboratory to perform specific tests. Improvement of the quality management system enhance and ensures patient safety, and is one of the critical priorities in laboratory medicine (Zima 2017). The South African National Accreditation System (SANAS) is the only recognized accrediting body of medical laboratories in South Africa. As of 31st of March 2019, the NHLS had only 27% (71/266) of laboratories accredited, despite its targeted accreditation of 97% of National central laboratories (n=49/51) and 75% of Provincial tertiary laboratories (n=4.5/6). The NHLS also failed to achieve targeted percentage

(85%) on annual quality compliance audits which are used to prepare the laboratories that are not SANAS accredited.

The KwaZulu-Natal (KZN) region of the NHLS supports the KZN Provincial Department of Health and other government departments. These departments include, but are not limited to: The Department of Agriculture Forestry and Fishery (DAFF) and Department of Correctional Services (DCS), as well as several non-governmental organizations (NGOs). The KZN region supports eleven (11) health districts. The coverage of 100% of laboratories at hospital level of care (national central hospitals, provincial tertiary hospitals, regional hospitals and district hospitals). At Primary Health Care (PHC) level, there are currently three (3) Community Health Centres (CHCs) that have on-site laboratory services. The PHC clinics that do not have on-site laboratories are serviced through daily specimen collection by outsourced courier service to the nearest laboratory.

There are a total of sixty-four (64) laboratories in KZN made up of ten (10) National central laboratories (Academic complex), Six (6) Provincial tertiary laboratories, seventeen (17) Regional Laboratories and thirty-one (31) District laboratories (Including those laboratories in CHCs). The 64 laboratories are made up of thirty-three (33) rural laboratories, eight (8) peri-rural laboratories and twenty-three (23) urban laboratories. According to the NHLS Annual Report (AR), (National Health Laboratory Services 2018a), 7/10 (70%) of National central laboratories were accredited, 2/6 (33%) Provincial tertiary laboratories were accredited, 6/17 (35%) Regional laboratories were accredited, and 2/30 (6.7%) District laboratories are accredited. Therefore, a total of 19/63 (30%) laboratories were accredited by the end of the 2017/18 financial year, despite the process of accreditation in KZN commencing in 2010. On the 31st of March 2019, there were two more laboratories that were accredited resulting in 21/64 (33%) being accredited (National Health Laboratory Services 2019). Of the 21 laboratories accredited, only 3 (4.7%) are rural laboratories. There are no accredited CHC laboratories, despite the proposed National Health Insurance (NHI) system that prioritises the strengthening of the CHC and PHC system (National Department of Health 2017).

Most of laboratories in the KZN province are located in rural and peri-urban areas and utilize mainly manual analytical systems and human labour compared to urban

laboratories where state of the art equipment and technology are available. The quality of laboratory services in SA is dependent on technical expertise, quality management systems (QMS) and the motivation of healthcare workforce, as is the case in the broader sub-Saharan Africa (Simundic *et al.* 2014). It has been shown that the understanding of human motivational factors is crucial in addressing the problem of poor uptake of accreditation of laboratories (Allam 2017). The current methods that are used for quality management systems (QMS) in the NHLS have been ineffective, particularly in the rural laboratories (only 2/33 laboratories are accredited) and peri-rural laboratories (3/8 laboratories are accredited) (National Health Laboratory Services 2019). The current situation necessitates for the NHLS to rapidly develop innovative strategies to achieve the set accreditation targets. This study was conducted to determine the effect of human factors on the implementation of accreditation.

Many studies have described the influence of poor infrastructure, inadequacy of QMS systems and other resources in enabling the accreditation processes, but few have focussed on human factors affecting the accreditation processes. The human factors that influence the accreditation of laboratories vary according to different population demographics, geographical settings, and resources available (Diamantidis and Chatzoglou 2018). In KZN, most laboratories rely mainly on manual labour to perform diagnostic tests. It is thus critical to understand the role played by employee motivation in facilitating the process of accreditation as employees are a key component of laboratory performance. The current checklists that are used for laboratory accreditation, focus mainly on employee training, qualifications and whether an employee has been deemed competent or not in a particular procedure or test. They do not address the effect of the human factors and how employee motivation impacts the processes required for accreditation.

Human factors (also known as ergonomics) incorporate physical and psychological behaviours in relation to a particular environment, products or services (Dul *et al.* 2012). Human factors focus on what employees are required to do (the task and its characteristics). This includes who is performing the task (the individual and their competence) and where they are employed (the organization and its attributes).

According to World Health Organization (WHO) safety curriculum, “human factors” scrutinize the relationship between employees and the systems with which they interrelate. This is achieved by focusing at improving efficiencies, productivity and job satisfaction, with the goal of minimizing errors (World Health Organization 2009). The lessons and patterns from other industries suggest that using human factor principles, can improve work processes in health care. For example, the common causes of numerous adverse events are due to the miscommunications and actions of the people in the system. The popular assumption is that communication difficulties among the healthcare teams (World Health Organization 2011b) are a result of the fact that each person has a number of tasks that have to be accomplished at one time. However, the study of human factors suggest that what is significant is not the number of tasks but the nature of the tasks being performed (World Health Organization 2011b).

The use of technology in healthcare has rapidly increased, and thereby increasing the significance and relevancy of acknowledgement of human factors influencing employee performance (Mosadeghrad 2014). The higher the human factor risk, the higher the chances are for errors to occur. The potential for harm is great when technology is mishandled (Rodziewicz, Houseman and Hipskind 2020). Human factors integrate the human resource to the tools they are using (including equipment design) and relationship among colleagues such as communication, teamwork and organizational culture (National Health Laboratory Services 2018b; Rosen *et al.* 2018). The main objective of human factors is to ensure that the workplace processes are implemented to minimize the occurrence of errors. It is also to identify the impact of errors on the overall performance of the organization. While human errors cannot be completely eliminated, efforts need to be made to identify the potential risks and actions to mitigate the identified risk (i.e. risk assessment). Human factors aims to understand people limitations and designing the workplace and the equipment used in the organization to allow for variability in humans and human performance. Knowing the effect of factors such as: fatigue, stress, poor communication and inadequate knowledge or skills affect employees, can assist in preventing adverse events and errors which may be caused by such exposure (Bhui *et al.* 2016). Individuals within the organization have different abilities and limitations, thus the study of human factors (or ergonomics) is meant to assist in creating the system that will work and fit the people

to achieve the organizational goals. This not only improves their health and safety but also ensures better managed, happier and more motivated employees which leads to an effective organization (Dul *et al.* 2012).

Many laboratories in sub-Saharan Africa have a shortage of resources, poor management systems, inadequate quality assurance programmes, poor training and poor staff motivation systems (Alemnji, Zeh and Fonjungo 2014). In a study on motivation and retention of health workers that was conducted in Ethiopia (Mesfin *et al.* 2017), the results revealed that motivational factors were country specific. The study also suggested that financial incentives were not enough to motivate the healthcare staff. Another study suggested that staff recognition, adequate resources and appropriate infrastructure were highly influential in health worker motivation (Willis-Shattuck 2008). It is believed that an individual can only accomplish personal and organizational goals if they have relevant knowledge of the tasks they are expected to perform, they feel supported and valued by their line managers or organization management and they have a positive attitude towards the company they work for (Kelechi and Ndugbu 2014).

1.2 Rationale of the Study

There is a paucity of research regarding the factors that influence the slow accreditation of laboratories in KZN apart from the general systemic and infrastructural constraints that exist in various laboratories. Employee participation and support of the accreditation process is a crucial factor affecting the accreditation status of the laboratories, however the impact of employee motivation on the attainment of accreditation within the NHLS has not been evaluated.

In addressing the research problem, the Stages of Change (SOC) Theoretical Model was used to guide the research, document findings and to formulate strategies for improvement and recommendations. The SOC was the most relevant theoretical framework due to its basic premise on the fact that behaviour change is a process, not an event (Prochaska *et al.* 2008). As an individual attempt to change a behaviour, he or she moves through five phases, namely: pre-contemplation, contemplation, preparation, action, and maintenance. The individual at different points along this

continuum have different informational needs, and can only benefit from interventions designed for their specific phase.

1.3 Aims and Objectives

1.3.1 Aim of the Study

The aim of this study was to explore the effect of human factors on the implementation of accreditation in the medical laboratories in KwaZulu-Nata.

1.3.2 Objectives of the Study

1. To determine if there is an association between the level of employee knowledge, attitudes and behaviours with laboratory accreditation.
2. To determine if there is association between the level of support provided by the laboratory management and laboratory accreditation
3. To investigate a correlation between employee motivation and laboratory performance using the performance indicators of laboratory Turnaround Time (TAT) for test results and closure of non-conformance as quality indicators.

The findings of this study will provide baseline information on the human factors and their influence to the slowness of accreditation in the laboratories of KZN. This will form the basis for recommendations to policy and decision makers. The hypothesis of this study is that non-accreditation of the laboratories is a result of poor motivation among staff members as well as a poor support of the accreditation processes and requirements by the managers.

The study tested the following null hypotheses:

- There is no relationship between staff motivation and laboratory accreditation
- There is no relationship between support provided by laboratory managers and laboratory accreditation. Employee motivation does not influence the performance standards of laboratories.

1.4 Structure of the Thesis

This thesis has been written up as follows:

Chapter 1: Background and Introduction of the study

Chapter 2: Literature Review consists of a comprehensive review of literature related to the study.

Chapter 3: Methodology chapter contains a detailed description of the study methods, including a description of the study population, sampling strategy, research design, data collection and data analysis procedures.

Chapter 4: Results chapter consist of the findings from the data collected by means of self-completed questionnaires and other laboratory quality indicators.

Chapter 5: Discussion, in this chapter, the study findings are discussed and related to the aims and objectives of this study.

Chapter 6: Conclusions are drawn based on the findings and relevant recommendations are offered in this chapter.

Chapter 2: Literature Review

2.1 Introduction

Human factors including motivation are the key elements in organizational behaviour (Kopp 2019). According to William (2010), employees have to be motivated to exhibit an attitude or behaviour that will enable the organization to achieve its goals and objectives and thereby improve the overall performance over time. The level of individual motivation is related to contributing human factors (Sekhar, Patwardhan and Singh 2013). This study sought to examine the effect of human factors of laboratory staff on their performance and ability to achieve accreditation in the KZN laboratories.

2.2 Laboratory Accreditation

Laboratory accreditation is the process whereby the laboratory is evaluated by the accreditation body, to ensure that they meet all the requirements of a specific standard. In order for the laboratory to be accredited, it must have evidence that it has implemented a quality management system (QMS) and that it has technical competency to achieve reliable, precise and accurate results. All medical testing laboratories globally aim to comply with requirements of the International Organization for Standardization (ISO) 15189 and all Public Health laboratories have to comply with the requirements of the ISO 17025. All recognized accreditation bodies are part of the International Laboratory Accreditation Cooperation (ILAC). ILAC ensures that there is consistency in the methods and processes when accrediting laboratories. When a laboratory is accredited, it means that its QMS have been confirmed, that its supports and maintains management approach to quality according to international standards. That means the result produced in an accredited laboratory are recognized and accepted internationally.

In South Africa, the South African National Accreditation Standards (SANAS) is the recognized body that confers the accreditation of medical and testing laboratories.

Laboratory accreditation by SANAS certifies the laboratory's adherence to quality standards. The accreditation process provides the means by which improvements in areas such as instrument maintenance and training of staff are accelerated. Although

the accreditation process provides means of checking competency of staff, the checklists used by accrediting bodies such as SANAS, Southern African Development Community Accreditation Services (SADCAS) and WHO, focused on three main areas, namely: staff qualifications, training and competency records. These accreditation processes do not evaluate human factors, neither do they assess the effectiveness and relevance of the training given to staff.

Accreditation processes provide an effective tool for health system improvement. It allows long-term improvement in the quality system to be possible, it enhances the cost effectiveness and sustainability of public health programmes. Through accreditation, laboratories demonstrate high standards of service delivery as this process has a positive influence on performance of the laboratory (Zima 2017). Laboratory results are essential in making medical decisions and diagnosis of patients. It is believed that, an estimated 60% to 80% of patient management decisions are made, based on laboratory results (Peter *et al.* 2010), which is the main reason why accreditation is required. Laboratory testing is thus an essential and critical element in ensuring the accurate and precise healthcare service for patients in resource-limited settings (Peter *et al.* 2010). Reliable and actionable test results are a pre-requisite to ensure a proper, efficient and high-quality service is delivered for patient care (Peter *et al.* 2010). Laboratory accreditation thus provides assurance that results produced by the laboratory are accurate, precise and of high quality.

Studies on laboratory accreditation in Africa have shown that attaining and maintaining accreditation is a challenge. A survey done in the Uganda laboratories revealed that only 0.3% of laboratories (3/954) met international quality standards (Schroeder and Amukele 2014). Another study done in the region of Sub-Saharan Africa (SSA) laboratories in 2013, demonstrated that 380/954 (39.8%) of laboratories are accredited to international standards. Ninety-one percent (91%) of accredited labs are in SA. Thirty-seven (37) out of 49 countries had no laboratories accredited to international quality standards (Schroeder and Amukele 2014).

Studies have indicated that errors occur throughout the testing processes (Schroeder and Amukele 2014). The occurrence of errors in the analytical stage is lower but remains significantly constant, despite years of quality management regulation. The incidence of error occurrence is estimated to be between 7% and 12%. Schroeder and

Amukele (2014) further proposes that an estimated 6% to 12% of laboratory errors put patients at risk of incorrect diagnosis/ prognosis and potentially of adverse events. It is also believed that 26% to 30% of errors have a negative impact on other aspects of patient care (Peter *et al.* 2010).

2.3 Importance of Laboratory Accreditation to the National Health Insurance (NHI)

The NHI is a health financing system that is intended to group funds to provide access to cost effective and quality health services for all South Africans. The NHI aims to provide specific healthcare services, based on individual health needs, irrespective of their socio-economic status (South Africa Department of Health 2017). Currently the health system in SA is highly inequitable. The NHI main objective is to ensure that of health-care services does not result in financial hardship for all SA families (South Africa Department of Health 2017). According to NHI, every SA citizen shall have access to comprehensive healthcare services free of charge and the services obtained at the accredited health facilities such as clinics, hospitals and private health practitioners (South Africa Department of Health 2017). With the advent of the National Health Insurance (NHI), it is critical for every laboratory within NHLS laboratories to achieve SANAS accreditation as the laboratory service will be allocated to accredited providers (South Africa Department of Health 2017). In light of this, the NHLS has been trying to accredit all its laboratories since 2009.

According to the National Health Act, 2003 the NHI is currently being implemented in phases over a 15-year period. Phase one started in 2012 to 2017, it focused on piloting health system strengthening (HSS) initiatives, inception of the NHI Fund and identifying key institutions and moving of central hospitals to the national sphere.

Phase two: 2017 to 2022, the main focus is ensuring that NHI is fully functional. This phase deals with establishing and ensuring that proper management structures and governance structures are established. The main focus in this phase is to implement system that will enable services to be rendered and that people registration can initiate. It also involved presenting the NHI Bill draft to the parliament, which was presented in August 2019. Amendments to several points of the legislation is currently being done.

Phase three is expected to begin between 2022 and 2026, which will be the official implementation of mandatory prepayment and contracting of all accredited hospitals and specialized services such, as but not limited to, medical testing laboratory services (South Africa Department of Health 2017).

The target facilities of the NHI are Regional and District facilities where the majority of SA population access healthcare. Under the NHI system, it is envisaged that the laboratory services will be accessed at appropriate levels of care. It is compulsory that the healthcare service is provided by certified and accredited public and private organizations, hence it is critical for NHLS to ensure that all laboratories are SANAS accredited. Such a situation has placed additional pressure on the NHLS as it is currently struggling to accredit these facilities. The implementation of NHI is reinforced by Vision 2030 of the National Development Plan (NDP). The NDP aims that by 2030, every South African must have access to an equal standard of care, regardless of their income. The expectation thus, is that by 2030 NHLS should have accredited the remaining 45 laboratories. There is a need to find a new innovative way to ensure that all 45 laboratories are able to obtain SANAS accreditation within the next ten (10) years.

Laboratory accreditation will also ensure that the QMS in each laboratory is effective and centered around meeting customer's needs and achieving customer's satisfaction. The NHLS requires a knowledgeable, skilled and motivated workforce to achieve this goal. The introduction of NHI means that all the requirements necessary for laboratory accreditation have to be achieved in all NHLS laboratories.

2.4 Quality Management System (QMS) and Laboratory Accreditation

QMS can be defined as an evidence based system, made up of inter-related processes, to ensure that a quality product or quality service is achieved. Laboratory quality can be defined as correctness, trustworthiness and appropriateness of reported test results (World Health Organization 2011a). For the NHLS to achieve their objectives, they need to have efficient QMS in place. The Quality System that has been intentionally established rather than evolving by chance. This requires top management to view the organization as a complete system, made up by a set of interrelated processes which includes tasks, resources, and consistent employee

behaviours, all working towards organizational objectives (International Standards Organization 2008).

Implementing QMS affects every aspect of an organization's performance. The benefits of proper QMS implementation include: meeting the customer's requirements, which results in customer's satisfaction and in turn leading to more customers, more sales and more repeat business (Khadka and Maharjan 2017). It also enables the organization to meet its objectives and goals. QMS ensures compliance with regulations and provision of products and services in the most cost and resource efficient manner, creating room for expansion, growth and profit (Dentch 2016). The benefits of proper implementation of QMS also enhance good communication within the organization which encourages and improves the ability for the organization to produce uniform and consistent results. Good communication also results in decreased error rate and reduced costs due to ensuring that processes are defined, controlled and continually improving (Dentch 2016). In order for a QMS to be implemented and established for organizations, people (staff) are required, in fact people are the core to making the organization's QMS work or fail. It is thus critical to ensure that people are aware, knowledgeable and are well-trained on QMS during and before its implementation. This will ensure that consistent behaviours are established and maintained. Ensuring that a sound and relevant QMS is implemented in the laboratory is critical, to providing quality results, patient care and is a mandatory requirement for obtaining and maintaining laboratory accreditation in the United State of America (U.S.A.) under Clinical Laboratory Improvement Amendments (CLIA) regulations (World Health Organization 2016).

Mesfin (2017) states that, poor quality and lack of effective QMS in laboratory services results to unnecessary expenses, poor quality or wrong patient care and suffering. It may also lead to failure in disease prevalence due to misdiagnosis (Mesfin *et al.* 2017). Lack of QMS may result in over-treatment such as but not limited to overuse of antibiotics in various clinical circumstances. Overuse of antibiotics may lead to individuals, developing drug resistant microorganisms including multi-drug resistant TB which is one of the epidemic problems in SA (Kurz, Furin and Bark 2016). In order for SA to ensure that patients are properly managed and quality of life improved through proper diagnosis and prognosis, correct, reliable results are essential. Laboratory

accreditation is the only process that can give assurance that results are reliable (Adams 2019).

The quality of the laboratory service is dependent on technical competence of staff to perform their duties, sound QMS and the motivation of human resources. Findings from a study conducted in Sub-Saharan Africa, which involved 213 laboratory professionals advocated that the main factors affecting the laboratory service delivery are: inadequate human resource, lack of effective communication systems, inadequate/failure of equipment, lack of staff motivation, lack of staff training lack of internal quality control (IQC) processes and overall poor infrastructure (Mesfin *et al.* 2017). The study further revealed the different human factors contributing to poor laboratory services, included: poor staff motivation (4.1%), lack of knowledge and skills (23.3%), lack of management support (57.4%) and shortage of resources and budget (64.3%) (Mesfin *et al.* 2017).

The World Health Organization Committee Report (World Health Organization 2011a), stated that achieving high quality service in the laboratory and obtaining laboratory accreditation requires more than a technical approach. It states that employee motivation and morale are also vital in driving and ensuring that quality in laboratories is achieved. The WHO (World Health Organization 2011a) reports continues to propose that failure to change the behaviour and attitudes of people in the organization is the most common cause of ineffective implementation of QMS. It believed that sustained QMS and quality improvements requires a change in attitude to the people who are part of the system and acquisition of a sense of ownership with regard to the quality of services.

The NHLS has utilised several tools to facilitate the process of accrediting laboratories but none of the tools have addressed human factors. Additionally, these tools have not achieved desired results especially in rural and peri-rural laboratories. The tools included the use of different quality improvement programs such as Strengthening Laboratory Management Toward Accreditation (SLMTA). The WHO endorsed structured quality improvement program: SLMTA (Appendix 6) was used in the NHLS and it focused at training the laboratory management and staff on how to implement QMS in a resource-limited environment. After staff have been trained using the SLMTA program, the laboratories with trained staff will go through a process using the Stepwise

Laboratory Quality Improvement Process Towards Accreditation (SLIPTA). SLIPTA (Appendix 7) is the framework/ checklist developed to improve quality of public health laboratories in developing countries to achieve ISO 15189 standards.

The NHLS also has internal Quality training and a different checklist to perform Quality Compliance Audits (QCA) for the laboratories that are not yet SANAS accredited. None of these programs nor the checklists used address or assess human factors and their influence on laboratory accreditation. The current tools that are being used within NHLS, seem to be failing in rural laboratories of NHLS as only three (3) out of thirty-three (33) rural laboratories are accredited in the KZN region. This means only 7% of rural laboratories are accredited, 93% of NHLS rural laboratories in KZN are not accredited where these tools are implemented. This poses a high risk to large population in these areas, where many of the PHCs and CHCs which are targeted by NHI are located. It is thus critical for NHLS to find new innovative ideas to ensure that accreditation is achieved in all laboratories including rural and peri-rural laboratories.

2.5 The Role of Human Factors in Organizational Performance

Human factors that influence organizational performance include three interrelated aspects, namely the job/ profession, the individual performing the job and the organisation culture (Bridger 2017).

The “job” is defined as the type of the task, work volume, the working conditions, the workflow and procedures used (Cain and Saira 2008). It is recommended that for employees to be efficient in performing their tasks, the system within the organization is designed in accordance with ergonomic principles to take account of both human limitations and strengths. This includes ensuring that each task is well defined in an easy to understand procedure. The tasks are assigned to the right individuals matching the requirements of the tasks with the physical and the mental strengths and limitations of people expected to perform the tasks. In medical laboratories, especially in the rural and peri-rural laboratories, staff are expected to multi-task, including performing laboratory diagnostic work as well as to have supervisory roles and the latter is sometimes done without any relevant training. Thus it is important to make sure that when such tasks exist, the people who are expected to perform them, are well equipped and enabled to successfully execute and efficiently carry these tasks.

The employee aspect includes, but is not limited to: an individual's capability (i.e. competence), skills, personality, attitude, and risk awareness (Schmitz 2012). Attributes such as personality of individuals are not easily changed and may not necessarily affect the organization. While other attributes such as: skills and attitudes may be changed or enhanced to improve the performance of the organization (Lorber and Savic 2011).

The "organization" aspect includes work trends, the culture of the organization and leadership. These different aspects that have been mentioned are often ignored when establishing and designing the jobs descriptions and assigning tasks to individuals yet they have a significant influence on individual and group behaviour (Bridger 2017).

People's behaviour in the workplace is affected by the organizational culture (Brief and Weiss 2002). Literature states that employees behaviour is the reflection of the communication and treatment they receive from line managers and immediate supervisors. All these things reflect the culture of the organisation. To manage organization performance and productivity, it is important to consider how management influence affect human behaviour (Kim *et al.* 2013).

The fundamental basis of human factors relates to the issue of how human beings process information. Literature states that humans acquire information from the world around them, interpret and make sense of it and then respond to it (World Health Organization 2011b). According to WHO Safety Curriculum (2011) Human beings are not automated equipment, which is pre-programmed and designed fit for specific use. Automated equipment's, when maintained, are predictable and reliable. In fact, compared to automated system, humans are unpredictable and unreliable. Individuals have the limited ability to process information due to the capacity of human (working) memory. Human beings are distractible, which might pose a risk in following required and necessary processes at work and predisposes one to error (World Health Organization 2011b).

In the health-care setting, the events that are described as mistakes or errors, may lead to loss of lives for patients. These are essential concerns to acknowledge and address because they are reminders that making errors could actually mean death to patients on the receiving end (World Health Organization 2016).

According to the WHO (2016) report, the teachings from human factors obtained from other industries are pertinent to patient safety in all health-care organizations including the laboratories. It is critical to understand the interaction and interrelationship between humans and their working environment. Understanding the risk that comes with each task, individual capabilities and how individual responds to their working environment with different circumstances that may occur assist in designing an efficient risk management to minimize errors. Implementing a proper risk management is essential to knowing how application of human factors principles can improve health care. Successful organizations are the ones that have the ability to achieve high productivity and quality while ensuring health and safety for employees (Collier 2018). Successful businesses are the ones that create systems that will enable the employees to achieve organizational goals. The best systems are based on having a skilled and competent employee and a well-defined job description (Bridger 2017). According to Bridger (2017), the influence of biological, psychological and organizational factors on an individual at work can affect their health, safety, efficiency and productivity.

NHLS has not met the target to achieve SANAS accreditation in all their laboratories, although much effort has been put in ensuring that the QMS is implemented across the organization. A possible gap in the organization's approach to accreditation is that it has not placed much emphasis on the effect that human factors might have on the overall performance of the organization QMS implementation. The present study therefore aimed at investigating various human factors which might have an impact on the implementation of QMS which leads to laboratories obtaining SANAS accreditation.

2.5.1 Effect of Leadership and Supervision on Employee Performance

Studies suggest that supervisor's support can increase job performance (Azman *et al.* 2009). According to Kelepile (2015), productivity and good management are intertwined. A supervisor has a significant influence on an employee's performance. Factors such as enhancing productivity, compliance with procedures, ensuring efficient workflow, communication and organizational culture are usually linked to how management treat their sub-ordinates (Richardson 2014). The supervisory roles include planning and delegating tasks appropriately to ensure a smooth flow of operations. It includes monitoring performance and compliance, providing guidance, support and leadership to employees. Being a leader means ensuring that team work

does not only exist but thrives throughout the organization. To perform management and supervisory functions, requires skill and training. Having the right management that are leaders usually result in low staff turnover and staff shortages. One of the essential qualities of a good leader is good communication skills with all employees effectively (Luthra 2015).

According to Gallup Research, 70% of an employee's motivation is influenced by their line managers (Bradberry 2016). Bradberry (2016) further stated that the research done in the University of California showed that motivated staff are 87% less likely to quit or leave their jobs, this is the study that involved fifty thousand participants from different sectors of employment, including healthcare workers. Supervisory position is a vital role of leading employees, yet many organizations don't invest in training and preparing individuals for key responsibilities which will aid in the management of operations and people. This is the case within the NHLS. Due to the lack of management skills, many managers fail to drive organizations to achieve desired results. This failure usually looks like poor employee performance and seldom question the impact of management on employees. In a study conducted by the Development Dimensions International (DDI), the findings revealed that successful organizations had good leadership which resulted in higher employee retention and engagement rates, for up to three times that of their competitors (Boatman and Wellins 2011) .

Supervisory functions may be shared among employees in a self-managed team (SMT) (Maes and Hootegem 2011). Currently, NHLS has SMTs in most of rural and peri-rural laboratories and most of the employees that are required to perform supervisory functions are junior staff and with no prior supervisory exposure. While SMTs may be beneficial to the organization and might assist in improving job satisfaction for certain employees, it is also argued that the effectiveness of supervision is limited due to lack of supervisory skills (Kaplan, Wiley and Maerrz 2011). Other authors disagree and suggests that the introduction of SMTs improves employee involvement and enhance teamwork (Boakye 2015). Due to shift work in the laboratories, the role of SMTs are not only critical but are inevitable. The role of leadership and management remains a critical organisational factor which contributes to the overall performance of the organization (World Health Organization 2016). Currently NHLS has SMTs in the most rural and peri-rural laboratories. These SMTs although they perform supervisory roles, they are neither trained nor compensated for

these additional tasks. They are not mentored nor guided on how they should fulfil the supervisory roles yet they are expected to perform in these roles. The NHLS needs to address and implement ways to make the current SMTs effective, by ensuring that employees that perform supervisory functions have the skill to perform the task. In this study, the associations between the levels of leadership and support provided by laboratory management will be assessed and the impact it has on the implementation of accreditation.

2.5.2 Effect of Staff Compliment to Quality of Work and Performance

Having the right number of employees, in the right place at the right time is essential for the success of any organization (Stokker and Hallam 2009). According to Wright (2019), in order for the organization to achieve its objectives and goals, it must have a procedure or method to decide whether staffing levels are suitable, based on the workload, complexity of tasks involved in the job and competency of individuals performing that task. Nestor- Harper (2018) stated that under-staffing negatively affects the quality of the product and service delivery. The product and quality of service is compromised when fewer employees are available to serve customers and run production lines (Nestor- Harper 2018). Understaffing causes employees to work faster which increase the risk of errors. Employees may be rushed through training or be required to work without training to ease the workload. When staff are over-worked, they may become overwhelmed and fatigued, which result in increased risks of errors. Eventually service delivery is compromised, which could be deadly in a medical profession such as a pathology laboratory.

Poor quality diminishes an organization's reputation over time and drives away customers. It is thus essential for any organization to determine the right amount of staff for the workload of the organization. There is paucity of studies regarding the effects of staffing levels and how it impacts on staff performance in the laboratory services in SA, and particularly in KZN.

2.5.3 Effect of Workload on Quality of Work and Performance

The 2017 statistics from the study done in the United Kingdom (UK), which included, healthcare workers, lawyers and teachers and reported by Health and Safety Executive (HSE), stated that 23% of full-time employees, between 20 and 60 years of age,

admitted to feeling burned out at work all the time due to high work volumes (Sarner 2018). Another study that was conducted in Geneva which included 1650 randomly selected healthcare professionals including the laboratory personnel showed that these employees experienced high workload and ended up with insomnia and fatigue. Due to the fatigue there was an evident rise in accident rates and errors (Schmidt *et al.* 2015).

It should also be noted that over-staffing can also lead to human performance issues such as monotony, carelessness and negligence. The workload is relevant in making management decisions such as downsizing, rationalization or re-aligning staff during peak hours. It is believed that work volumes are related to staff competence, working hours/shifts and staff complement. A high (or perceived high) workload may adversely affect safety, negatively affects job satisfaction and may eventually contribute to high turnover of staff which will lead to staff shortages (Agezegn, Tefera and Ebrahim 2014).

An assessment of workload is required to determine the staffing norms and to determine if the organization has sufficient staff who are capable and competent to perform the tasks. It is also recommended that workload be assessed when new tasks are introduced and new equipment or system is being implemented (Powell-Cape, Nelson and Patterson 2008). A study to explore the effects of nursing workload, burnout, absenteeism, and quality of patient care, revealed that, high workload, increased the risk of fatigue levels, burnout by up to six times and absenteeism by up to five times. The risk of medical errors for the patients also increased by up to 150% (Farid and Purdy 2019).

2.5.4 Effect of Organizational Culture on Employee Behaviour and Attitude

Organizational culture can be defined as consistent, observable patterns of behaviour in organizations (Watkins 2013). An organisation's culture influences human behaviour and human performance at work (Kelepile 2015). It can also have a considerable influence on productivity. Kelepile (2015) further stated that organizational culture is critical to the business success as it is the process in which organizations develop their internal capacity to ensure that the mandate of that particular organization is effectively achieved. Most organizations have principles and behavioural patterns, that determines how work is done within the organization. This pattern includes interrelations of employees within the organization and how they treat each other.

Individuals who do not adapt to the customs and the norms of the organizations they usually feel like they do not belong and are treated as a “mis-fit” by the other colleagues. They end up making the decision to leave the organization because they don't feel accepted thus become disengaged at work or are dismissed for not demonstrating teamwork (Naong 2009).

The culture and style of management is significant for productivity. Productivity is related to quality, customer's needs and industrial relations, thus an organizational culture can enhance productivity to achieve the organizational goals. Success of implementation of good organizational culture results from good leadership, good employee involvement and good communications (Tsai 2011).

2.5.5 Effect of Employee Knowledge and Skills on Performance

Training results in an improved staff productivity, improved workforce flexibility, savings on costs, and improvement of staff motivation (Naong 2009). Other researchers describe training as the process that allows individuals to obtain relevant knowledge, acquire and improve their skills (Odukah 2016). Effective training leads to improved performance by enabling employees to conduct their tasks, differently and better than before. The literature suggests that trained employees perform duties confidently. Training assists employees to adapt to a position and enhance good attitude and behaviour that will be useful to the organization. Organization with effective training ultimately lead to continuous improvement of systems throughout organizations. Lack of training, and limited access to career development are some of the factors that negatively affect job performance and job motivation (Odukah 2016). The success of an organization is dependent on skills, attitude and behaviours of employees, to complete the daily responsibilities required to attain the company's strategic goals (Vance 2006).

Other studies suggest that employee competencies have a direct impact on service performance and customer care (Hanafi and Ibrahim 2018). According to Boulet (2015), training does not mean competency, just because an individual is trained, it does not mean they are competent. Training is the theoretical knowledge, and acquiring the principles of the specific task/ job. It is possible for one to obtain training but still lack the skills required to apply that knowledge to specific tasks, since knowledge does not necessarily mean one has the skills. Knowledge can thus be

defined as an information obtained through reading, watching, listening and touching while skill is the application of the obtained knowledge (i.e. knowledge is theoretical while skills are practical). The concept of knowledge refers to familiarity with factual information and theoretical concepts. Boulet (2015) further states that skills can be developed easily when one has a basic theory of the tasks to be performed. Human factors need to be considered when training programs are developed in the organization to ensure effectiveness of the training (Andriotis 2018).

Fuller and Farrington (1999) disagrees with the theory that advocates that training enhances employee performance. They believe that with various external factors that affect their performance, which training alone cannot address. The authors further state that, processes throughout the organization should be designed in a way that they all work together to achieve the strategic goals of the organization. This theory suggests that human factors cannot be ignored when the organization attempts to improve performance. According to Fuller and Farrington (1999), the human performance system, begins with organizations inputs to its employees. Organizations have values and the culture that has a direct impact in the human performance.

The study done in Kenya at Coca Cola bottlers, which involved 278 employees provided evidence that training and development of employees, has a positive effect on motivation of staff which results in an improved organizational performance (Odukah 2016). Training on the job is still the method of choice, used by organisations to impart knowledge and develop or improved skills of employees. From the studies and literature that has been mentioned, it can be concluded that knowledge, skills and attitude are related to the performance of the individual.

In order for NHLS to achieve SANAS accreditation, it is thus essential that all employees have necessary knowledge and skills for their specific tasks as this will ensure that productivity and performance is enhanced. It can also assist employees to have positive attitude towards their work and eventually positive behaviour towards the organization. The study evaluates the knowledge, skills and attitudes towards accreditation.

2.5.6 Effect of Employee Attitudes and Behaviours on Performance

In psychology, an attitude is defined as a set of emotions, principles, and behaviours toward a particular incidence. Attitudes are usually the outcome of experience or individual background and they have an effect over behaviour (Offorbike, Nnandi and Agu 2018). Attitude affects behaviours at the workplace, thus organizations that aim to improve employee productivity, need to evaluate the employee's attitude (Open Education Resources services 2017). Published studies suggests that employee attitudes and behaviours are related. When an individual has a negative perception of their tasks and their working environment, they are likely to have poor performance (Zhang *et al.* 2018). The study done in Bangalore also agrees with the theory that employee attitudes and behaviours has a direct impact in the overall performance and productivity of the organization in achieving its goals (Bireswari 2013).

Employee behaviours are influenced by organisation culture and they determine the overall performance of the organization (Naong 2009). According to Naong (2009) performance is evaluated by the organization strategic goals such as eliminating wastage thus reducing cost price, exceeding customer satisfaction or increased productivity. Behaviours are measured in terms of specific actions or activities. What makes organizations successful is achieving the desired objectives and goals. Literature further proposes that employee attitudes and behaviours have a direct effect on employee's performance (Tsai 2011). It is believed that when employees have a positive or good attitude and behaviours, then the performance would also be enhanced which leads to improved productivity, efficiencies and quality. The study results that was done in Abuja metropolis, which involved 40 healthcare workers, agrees that the performance of healthcare organizations are linked to employee attitudes and behaviours. It further recommends that, the essential human factors need to be addressed in order to achieve positive attitude which leads to positive behaviours among healthcare workers (Edem, Akpan and Pepple 2017).

Fuller and Farrington (1999) disagrees with the above mentioned theory, that employee behaviours determines the performance of the organization. They believe the interrelated processes that make up the system of the organization should work together to fulfil the organization's objectives (Fuller and Farrington 1999). Equity

theory proposes that behaviours does not drive performance but it is the employees motivation to achieve the set goals and targets that determines the performance (Redmond 2016). Other researches confirms that manager's ability to motivate employees directly affect the performance of the organization irrespective of the behaviours of the employees (Freedom Learning Group 2017).

2.5.7 Effect of Employee Motivation on Performance

Motivation is defined as the power that pushes and energizes individuals to achieve personal and organizational goals (Kelechi and Ndugbu 2014). Other authors describe it as the attitude a person portrays towards a particular subject or task, it is a way a person choses to acts in a particular way (Lumen Learning 2007). Bergström and Martínez (2016), defines motivation as intrinsic force that govern the individual's behaviour. It is a person's effort and resilience in the face of obstacles (Kelechi and Ndugbu 2014). Others define motivation as the driver or inducer of a person to perform in a particular way (Kachitsa 2020). Motivation influences the level of work performance, the efficiency achieved and time spent on activity. The definitions reveal that there is a clear link and relation between employee's motivation and their productivity. It is a role of management to manage employee motivation effectively toward achieving organizational goals.

A study conducted by Gallup, in the United States of America in 2018, indicated that 66% of American workforce were disengaged which resulted in demotivation. Demotivated employees in various organizations lead to decreased productivity and decreased profitability (Gullup Inc. 2018). Another study done in developing countries which included four literature databases, investigated motivation factors among healthcare workers. The results revealed that healthcare workers are generally motivated by human factors such as financial incentives and career development. Recognition is highly influential in healthcare worker motivation and that adequate resources significantly increase morale (Willis-Shattuck *et al.* 2008). In 2018 data from systematic review, which included United Kingdom (UK), Europe, Africa and Asia was collected and analysed. The review aimed to investigate the organisational factors which affect healthcare employee motivation. The results indicated that the core factors that affect employee motivation of healthcare workers included financial incentives,

career development. Fundamental factors that drives healthcare workers and have proven to boost their morale include: financial incentives, career development, conducive working environment and management and leadership approaches (Abimbola, Senaka and Tony 2018). From different studies on motivation, it can be concluded that financial incentive is not a driving force that stimulate healthcare workers. and Acknowledgement and being recognized seemed to be the main and important stimulant in healthcare employee motivation. In rural settings, where healthcare workers are expected to multi-task and work long hours' appreciation for the work they do is what motivates them. Knowing that their job plays a crucial role in improving the quality of lives of people in poor communities encourages them to give their best against all odds.

Literature review and the above mentioned studies agrees that, there are two types of motivation influences, namely: intrinsic and extrinsic motivation. Both of these influences may impact healthcare workers positively or negatively, which will be displayed in their performance (Legault, 2016). It is believed that intrinsic influences are responsible for making a person work towards the achievement of personal goals. While extrinsic influences drive a person towards reaching organizational goals (Kelechi 2013). Carol (2013) defines intrinsic motivation as the desire and satisfaction that an individual obtain from a particular goal. Being intrinsically motivated does not mean a person is not expecting a remuneration, rather it means that remuneration alone, is not enough to keep a person committed to the goal (Dweck 2013). The literature further state that, there has to be a purpose or driving force that will enable a person to remain focused and committed (Paul and Dale 2013).

Other authors describe intrinsic motivation as a reason to participate in an activity. They further state that intrinsically motivated individuals engage in tasks that they enjoy. (Schunk and Pintrich 2008). According to Richard and Deci (2017) intrinsic motivation is defined as inspiration that is provoked by the meaning of the mission rather than the reward of the particular deed. Intrinsic motivation rewards include but are not limited to: personal satisfaction to the individual performing a task, recognition, information gained and a sense of achievement.

Extrinsic motivation is described as external stimuli that triggers one to act. Extrinsic factors are tangible and include remunerations, bonuses, salary increments and benefits. It is extrinsic because they are external to the task and the control of the size, type and whether or not they are granted is dependent on somebody else not on the individual performing the task (Kelechi and Ndugbu 2014). According to literature, extrinsic motivation remains significant for workers. Salary still remain one of the deciding factors for most individuals when accepting a new job offer.

It is believed that employees perform better in positions where organizational goals are clearly defined and attainable (World Health Organization 2011a). Leadership is expected to give clear guidance and support to employees, to ensure that organization goals are achieved. This means that leadership and management support has a direct impact on the level of motivation. Poor communication, Ambiguous targets and undefined goals may result in low motivation and eventually lead to poor performance. Literature suggests that organisation values and ethos has an effect on the employee's level of pride in themselves and their jobs. It further states that organizational values, which speak to employee dignity, enforces positive attitude and morale help alter perception about the job and enhances motivation of employees (Odukah 2016).

A survey that was conducted in the US Army revealed that appropriate assigning of tasks was a significant factor for efficiency and motivation of soldiers. The study further revealed that employees performed better in the tasks they asked or volunteered to perform. Such tasks resulted to employees feeling more satisfied with their jobs and improved motivation to perform better in their duties (Odukah 2016). This study suggests that job satisfaction and motivation on the job is not only possible but guaranteed when staff are engaged and consulted on the tasks they are expected to perform.

2.6 Stages of Change using a Transtheoretical Model

The Stages of Change (SOC) Theoretical Model or Transtheoretical Model (TTM) was used to address the research problem and guide the research to formulate strategies for improvement and recommendations (LaMorte 2016). The model's principle is that behavioural change is a process, not an event. As a person endeavours to change a behaviour, he or she moves through five stages: pre-contemplation, contemplation,

preparation, action, and maintenance. People at different stages have different informational needs, and benefit from interventions designed for their stage.

The TTM emphasis is on the decision-making of the individual and is a model of intentional change. It works on the hypothesis that people do not change behaviours hastily and conclusively. Rather, change in behaviour, occurs continuously through a cyclic process.

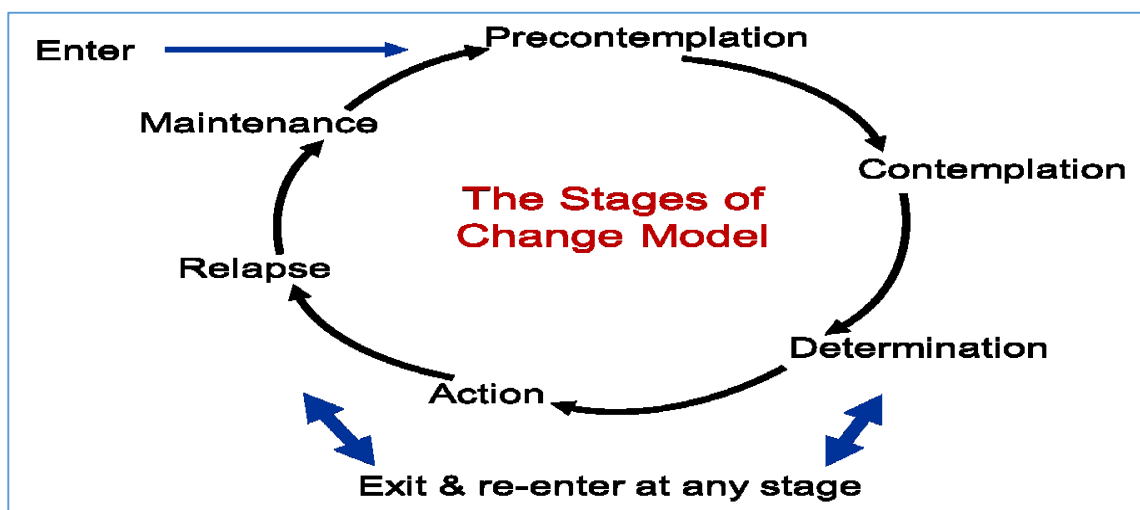


Figure 2.1 Transtheoretical Model

(Source: [sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChange Theories/html](http://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChange%20Theories/html))

Pre-contemplation - In this stage, people have no intention of taking action and are often ignorant to their problematic behaviours. Individuals in this phase are not aware of the value of changing behaviour and they focus mainly on the negative aspects of changing behaviour.

Contemplation - In this stage, people have an intent of taking to action and a plan to do so in the near future. People recognize that their behaviour may be problematic and are willing to change their behaviour with equal emphasis on both pros and cons. Even with this recognition, individuals often feel hesitant toward changing their behaviour.

Preparation (Determination) - In this stage, people have the intention to take action and some steps have been taken toward the change in behaviour. Individuals believe altering their behaviour will lead to more productivity/ efficiency or healthier lifestyle.

Action - In this stage, people have transformed their behaviour for a shorter period of time and intend to stay committed to the behavioural change. Individuals may exhibit

this change by correcting their problematic behaviour or acquiring new positive behaviours.

Maintenance - In this stage, people's behaviour has been changed and continues to be maintained for the long-term. Individuals have decided to maintain the behaviour change going forward. People in this stage work to prevent relapse to earlier stages.

It is important for management to understand that during the behaviour change process some people will experience relapse. Relapses may assist the person to become stronger in their decision to change or be a trigger for giving up in the quest for change. The key to recovering from a relapse is to review and find the root-cause of quitting. It is important to identify personal strengths and weaknesses, and develop a plan to resolve those weaknesses to solve similar problems that may reoccur in future.

2.7 Conclusion

Chapter two provided an in-depth review of the literature on different human factors and the effects they have on employee performance, productivity and motivation. The human factors discussed are also directly related to human behaviour and attitude, which need to be positive across the organization employees in order for organizations to achieve desired goals and enhance productivity. To address the attitude and behaviour of employees within the NHLS, TTM is a model of choice for this study. The stages of change model (TTM) were also discussed and explained in this chapter.

There are currently no published studies that have investigated the effects of human factors on staff performance, productivity and staff motivation in medical laboratories. There is also paucity of studies on the human factors that affects laboratory accreditation. Based on the reviewed literature, it is clear that human factors have a direct relation with individual's performance, productivity and motivation, and should be considered by organizations when strategies are developed to achieve the set targets (in this case the achievement of SANAS accreditation). This study sought to close the gap in knowledge by determining the effects of human factors on implementation of accreditation in the medical laboratories of KZN. Chapter three will describe the methodology used for this study.

Chapter 3: Methodology

3.1 Introduction

This chapter focuses on the research processes which were undertaken in the execution of this study. This includes the research approach, study area, study design, study population, sampling strategy, recruitment process, method used for data collection and data analysis. Ethical considerations as well as inclusion and exclusion criteria are also discussed in this chapter.

3.2 Study design

This was a descriptive cross sectional quantitative study using prospective and retrospective methods of data collection. The prospective method utilized a pre-tested questionnaire to assess the degree of knowledge, attitudes and behavioural factors affecting employee motivation and management support that might result in the slow process of accreditation of laboratories. Two performance quality indicators namely, the turnaround time (TAT) for test results, and the closure of non-conformities (NCs) audit findings were correlated with the level of staff motivation and this was the retrospective aspect of the study.

3.3 Study area

The study was conducted using selected accredited and non-accredited NHLS laboratories in KZN. Employees from accredited and non-accredited laboratories constituted the study sample. All staff members were divided into accredited and non-accredited strata. Next, the systematic sampling strategy was used but first the individuals within each stratum were ordered or listed alphabetically, by name. From the employees that were randomly selected, the laboratory that they came from automatically became the participating laboratories.

The NHLS has a total of 64 laboratories in KZN of which thirty-three (51.6%) are based in rural areas, twenty-three (35.9%) in urban and eight (12.5%) in peri-urban areas.

Currently, only 21 (32.8%) of these laboratories are accredited, two (2) of which are rural, seventeen urban (17) and two are (2) peri-urban.

Fifty (50) laboratories were selected that were made up of twenty-four out of thirty-three (24/33) rural laboratories, eight out of eight (8/ 8) peri-rural laboratories and eleven out of twenty-three (11/23) urban laboratories.

Table 3.1 Study area – Number of laboratories represented in the study

Laboratory Demographics	Rural	Peri-rural	Urban	Total
Number of NHLS Laboratories in KZN (n)	33 (51.6%)	8 (12.5%)	23 (35.9%)	64 (100%)
Number of labs included in this study	24/33	8/8	11/23	50/64
Accredited Laboratory in each category	2 (3.1%)	2 (3.1%)	17 (27%)	21/64(32.8%)

3.4 Study population and sampling strategy

The study population consisted of all the employees of the NHLS laboratories in KwaZulu-Natal. The sample was drawn from the list of all the employees after stratification of the laboratories by accreditation status. Participants included all NHLS employees that impact in laboratory accreditation including laboratory managers, laboratory technologists, laboratory technicians, laboratory clerks, pathologists, quality assurance coordinators and house-keepers. The sample size was determined using the Raosoft sample calculator (Raosoft.Inc), which is available online. With a population size of 1,317 employees, and setting the confidence interval at 95% with an anticipated response rate of 50%, the final sample size was determined as 298.

The study utilized a combination of stratified and systematic sampling strategies. Using the former method of sampling, all the employees was divided into accredited and non-accredited laboratories. This resulted in 876 and 441 individuals within the accredited and non-accredited stratum, respectively. The names of these individuals was then ordered alphabetically before applying the systematic sampling strategy. Selection intervals (n) for each stratum was determined by dividing the population size by the sample sizes. With sample sizes of 876 for accredited and 441 non-accredited employees, the n values were 2.0 and 3.0 respectively. This resulted in 441 and 148 individuals within each stratum. From the 441 individuals, one hundred and forty-eight individuals were randomly selected resulting in final sample size of 296.

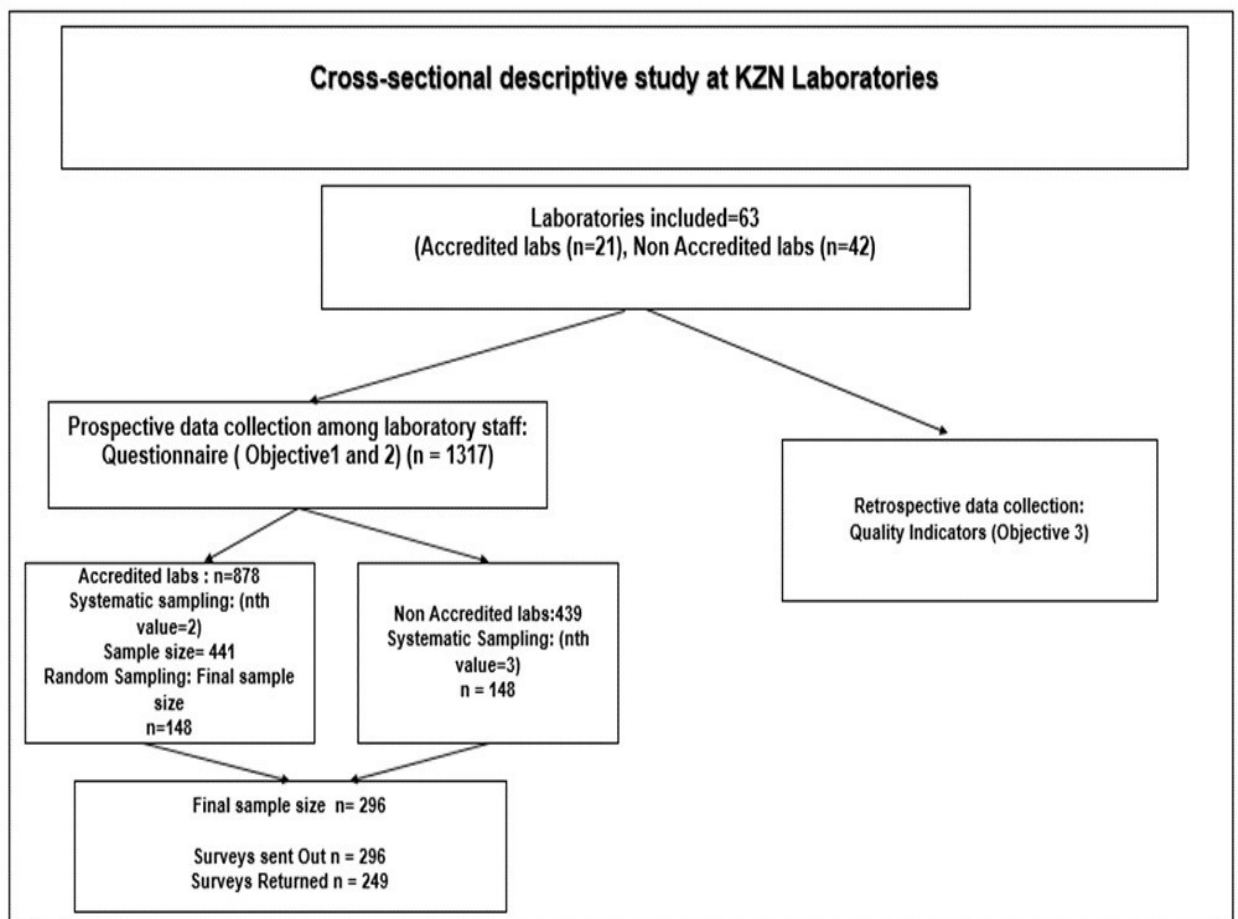


Figure 3.2 Study design and sampling strategy

3.4 Recruitment of participants

Permission was obtained from NHLS to conduct the study (Appendix 2). All selected employees were notified telephonically and appointments set up to provide them with the information letter (Appendix 3). They were provided with information letters and the

informed consent forms inviting them to participate in the study and all those who gave consent were provided with the questionnaire (Appendix 4) to complete.

3.4.1 Inclusion and exclusion criteria

Among the employees that were selected, all those that had less than one year of working experience in the current laboratory were excluded from the study. Laboratory employees that were part of the pilot were also excluded.

3.5 Ethical considerations

Permission to conduct the study was sought from the NHLS Academic Affairs Research and Quality Assurance (AARQA) department, (Appendix 1 and Appendix 2) and Ethics clearance (Appendix 3) was obtained from the DUT ethics committee. For confidentiality and anonymity, the study collected only the age, gender and staff categories as demographic information and not the participant names.

The questionnaires were given unique identification codes and were self-administered.

3.6 Data collection

The study utilized a modified employee motivation and management support assessment questionnaire (Appendix 5) adapted from (Odukah 2016). These were distributed to the selected NHLS employees by the principal investigator (PI). The questionnaire was made up of twenty-one closed ended and one open ended questions. Participants chose from a scale of agreement with the following options: Strongly Agree (SA), Agree (A), Neither Agree nor Disagree (N), Disagree (D) and Strongly Disagree (SD).

3.6.1 Pilot study

For relevance, question variations, respondent interest and attention among employees, the questionnaire (Appendix 4) was piloted among ten employees, five from each of the two laboratories, namely, the Public Health and Kwa-Mashu laboratories.

The data was captured onto an Excel file, with each participant entered into a row with columns of the corresponding question numbers. The Likert type data was coded by

assigning ordinal values to the categories of participant responses, namely, SD=1, D=2, N=3, A=4 and SA=5. All the questions were phrased to identify ideal states to avoid reverse coding. Other data included participant demographic information, the number of years working at the laboratory and staff category. Laboratory data included business/ district unit and the geographic location (urban, rural or peri-urban setting).

3.7 Data analysis

For analysis the data were divided into three Likert scales, attitudes and behaviour (questions 1 to 6), practices and line management support (questions 7 to 14) and knowledge and leadership (questions 15-20). Cumulative scores were computed for each participant and then transformed into cumulative percentages.

For objective 1: The attributes-attitudes and behaviour and practices were assessed by grading the cumulative percentages of attitudes and behaviours as excellent, good and poor.

For objective 2: Cumulative percentages of the leadership index questions were used to assess the level of support provided by laboratory management. These were graded as excellent (80%-100%), acceptable (51%-79%) and poor (0%-50%).

The benchmark ranges of scores for each scale were decided depending on the nature of the questions and variations across demographics.

For objective 3: Recognition (question 10 of section B) and good career opportunities (question 5 of section A) were used as proxy for motivation, as these are some of the factors that were identified as such by one study as motivation factors (Nabi et. Al 2017) and these were used as exposure variables. Closure of non-conformance (NCs) obtained by the laboratory within a specified time frame and the Turnaround times (TAT) of routine tests were assigned ordinal values and were used as outcome variables and compared across strata. For this objective, the data was collected retrospectively from the laboratory statistics provided from each of the participating laboratories. The annual data for 2018 was used.

Descriptive analysis was conducted and the mean and the standard deviation (SD) were used for continuous variables while percentages and proportions were used for categorical data. For inferential statistics, the data was checked for completeness and consistency of variables before importing to SPSS version 20. The chi square test and

odds ratios (ORs) were used to compare categorical data between the strata. Any associations that had a p value less 0.05 and a confidence interval that includes the null value of 1 were concluded as statistically significant. For continuous variables, the two sample test was used to determine the mean differences and the corresponding p value was used for statistical significance.

3.7.1 Methodology used for data analysis:

3.7.1.1 Statistic descriptor

The T-test: is a type of inferential statistic used to determine if there is a significant difference between the means of two groups, which may be related in certain features. It is mostly used when the data sets would follow a normal distribution and may have unknown variances.

The Chi-squared test: evaluates if two categorical variables are related in any way. Cumulative percentage of employees with a score of 4 and 5.

The Mann-Witney U test: is a nonparametric test of the null hypothesis that it is equally likely that a randomly selected value from one population will be less than or greater than a randomly selected value from a second population. In this instance, we will test if employees from accredited labs rank higher than those from non-accredited labs.

3.7.1.2 Word cloud

Word cloud is a visual representation of text data, typically used to depict keyword from text. The more frequent the response, the bold its text. In this study it depicts answers to the open question 21 under Section C.

3.7.1.3 Concordant and discordant pairs:

- A pair of observations is concordant if the subject that is higher on one variable is also higher on the other.
- A pair of observations is discordant if the subject that is higher on one variable is lower on the other. If a pair of observations is in the same category of a variable, then it is neither concordant nor discordant and is said to be tied on that variable.
- A positive and a negative value of gamma indicates positive and negative associations, respectively.

3.8 Recruitment process

Permission was obtained from NHLS to conduct the study (Appendix 2). All selected employees were notified telephonically and appointments set up to provide them with the information letter (Appendix 4). They were provided with information letters and the informed consent forms inviting them to participate in the study and all those who gave consent were provided with the questionnaire (Appendix 5) to complete.

Conclusion:

This presented and thoroughly explained the method used for research approach, it described the study design and sampling strategy that was used. The recruitment process, for data collection and data analysis was also explained in detail. The next chapter will focus on the results obtained from this study and interpretation of results will also be included in chapter 4.

Chapter 4: Results

4.1 Introduction

The purpose of this chapter is to present the findings of this study. In this chapter, data is organized systematically according to the study objectives.

4.2 Descriptive data analysis:

4.2.1 Participant demographics and laboratory information

Table 4.1 Demographic information of participants stratified by accreditation status

Characteristic		Accredited Laboratories(n=21) n (%)	Not accredited Laboratories(n=43) n (%)
Age	Mean (SD)		
Age	39.0 (9.16)	39.3(8.9)	38.6 (9.4)
Years of service	12.1 (8.1)	12.9 (8.4)	11.3 (7.8)
	Frequency (%)		
Age group			
<30	28 (11.4)	14 (50)	14 (50)
30-40	140 (56)	72 (51)	68 (49)
41-50	47 (19.2)	28 (59.6)	19 (40.4)
>50	34 (13.9)	16 (47.1)	18 (52.9)
Total	249 (100)		

Years of service		Accredited Laboratories(n=21) n (%)	Not accredited Laboratories(n=43) n (%)
1-5	42 (17)	16 (43.2)	21 (56.8)
6-10	78 (31.3)	43 (57.3)	32 (42.7)
11-15	80 (32.1)	36 (47.4)	40 (52.6)
16-20	20 (8)	9 (47.4)	10 (52.6)
21+	29 (11.6)	17 (60.7)	11 (39.3)
Total	249 (100)		
Gender			
Female	165 (66.3)	87 (52.7)	78 (47.3)
Male	84 (33.7)	42 (50.6)	41 (49.4)
Total	249 (100)		
Job category			
Laboratory manager	25 (10)	5 (20)	20 (80)
Laboratory technologist	78 (31.3)	53 (68)	25 (32)
Laboratory technician	67 (27)	30 (44.8)	37 (55.2)
Laboratory clerk	53 (21.3)	27 (51)	26 (49)
Other	26 (10.4)	14 (53.8)	12 (46.2)
Total	249 (100)		

Table 4.2 Laboratory information on geographic setting and facility type stratified by laboratory

Characteristic	Frequency (%)	Accredited n (%)	Not accredited n (%)
Facility Type			
CHC	68 (27.3)	14 (20.6)	54 (79.4)
District	33 (13.3)	6 (18.2)	27 (81.8)
Regional	89 (35.7)	48 (53.9)	41 (46.1)
Tertiary	59 (23.7)	59 (100)	0 (0)
Total	249 (100)	127	122
Geographical setting			
Urban	100 (40.2)	98 (98)	2 (2)
Rural	105 (42.2)	13 (12.4)	92 (87.6)
Peri-rural	44 (17.6)	16 (36.4)	28 (63.6)
Total	249 (100)	127	122

4.3 Result interpretation for the descriptive analysis:

Out of the 296 participants that were enrolled to participate, two hundred and forty-nine (249/296) responded, resulting in a response rate of 84%. Of the 249 (99%) that had recorded gender, one hundred and sixty-five (66.3%) were female of which 87 (52.7%) were from accredited laboratories. The mean age of the participants was 39 years (SD=9.0) with slightly more than half ((136/249) 55%) of the participants in the

30-40-year age category, and these were equally distributed between the accredited and non- accredited laboratories, both 50%. Most of the participants (78/249) 31.3% were laboratory technologists, of which 53/76 (68%) were from the accredited laboratories. This group was followed by the laboratory technicians with (67/249) 27% participants. The laboratory managers were the job category that had the least number of participants, 25/249 (10%) of which 20/25 (80%) were from non-accredited laboratories. [Table 4.1]. The mean years of service was 12.1 years (SD= 8.1) with many of participants (80/249) 32.1% having between 11 and 15 years of service. Slightly above half of these, (40) 52.6% were from non- accredited laboratories. [Table 4.1].

Sixty-eight (27.3%) of the 249 participants were from the CHC laboratories, of which 54 (79.4%) were from the non-accredited laboratories. These were followed by (89/249) 35.7% participants from the regional laboratories, of which 48 (53.9%) were from accredited laboratories. Most of the participants (105/249) 42.2% were from laboratories in a rural setting, of which only (13/105) 12.4% were from accredited laboratories compared to (98/100) 98% participants who were from accredited laboratories in an urban setting, [Table 4.2].

Table 4.3 Sociodemographic determinants of laboratory accreditation

Variable	OR (95% CI)	P-value
(Intercept)	0.03 (0.001 - 0.578)	0.032
Age Group		
30 to 40	0.81 (0.068 - 11.899)	0.866
41 to 50	2.71 (0.176 - 52.126)	0.48
> 50	2.8 (0.131 - 67.322)	0.507
Sex		
Female	ref	
Male	1.15 (0.363 - 3.922)	0.81
Job category		
Laboratory technologist	1.79 (0.426 - 8.027)	0.43
Laboratory technician	0.82 (0.214 - 3.244)	0.772
Laboratory manager	0.18 (0.009 - 1.551)	0.165
Other	0.6 (0.051 - 5.074)	0.653

Years of service		
6 to 10	40.14 (3.41 - 1255.066)	0.01
11 to 15	8.85 (0.631 - 300.8)	0.144
16 to 20	9.24 (0.231 - 514.105)	0.233
> 20	6.01 (0.257 - 286.401)	0.297
Facility type		
District	1.13 (0.272 - 4.495)	0.863
Regional	0.38 (0.08 - 1.502)	0.19
Tertiary	0 (0 - inf)	0.99
Geographical setting		
Rural	0.16 (0.039 - 0.535)	0.005
Urban	265.2 (24.73 - inf)	0
Attitude and behaviour index		
Acceptable	0.74 (0.138 - 3.419)	0.704
Poor	1.27 (0.364 - 4.312)	0.705
Knowledge and practices index		
Acceptable	0.04 (0 - 1.526)	0.175
Poor	0.74 (0.023 - 13.986)	0.847

Leadership and management support index		
Acceptable	0 (0 - inf)	0.993
Poor	3.13 (0.177 - 113.773)	0.471

Table 4.3 displays the logistic regression analysis between laboratory accreditation status as the outcome variable and the socio-demographic characteristics as the explanatory variables. It can be noted from this table that having 6-10 years of service had a statistically significant positive association with the accreditation status of a laboratory (OR=40.14; p value=0.01). Being in a laboratory in a rural setting had a statistically significant negative association with the accreditation status of a laboratory (OR=0.16; p value=0.005).

4.4 Participant's responses cumulative and grading scores:

Table 4.4 Participant responses stratified by laboratory accreditation status

Participant responses	Leadership and management support		Knowledge practices and		Attitude and behaviour	
	Accredited (%)	Non-accredited (%)	Accredited (%)	Non-accredited (%)	Accredited (%)	Non-accredited (%)
Strongly agree	14.0	10.0	14.0	13.0	21.6	21.2
Agree	33.0	40.0	24.0	25.0	48.1	53.1
Neither agree nor disagree	20.0	18.0	22.0	19.0	18.5	15.9
Disagree	14.0	13.0	14.0	12.0	5.7	5.1
Strongly disagree	19.0	19.0	27.0	31.0	6.1	4.7

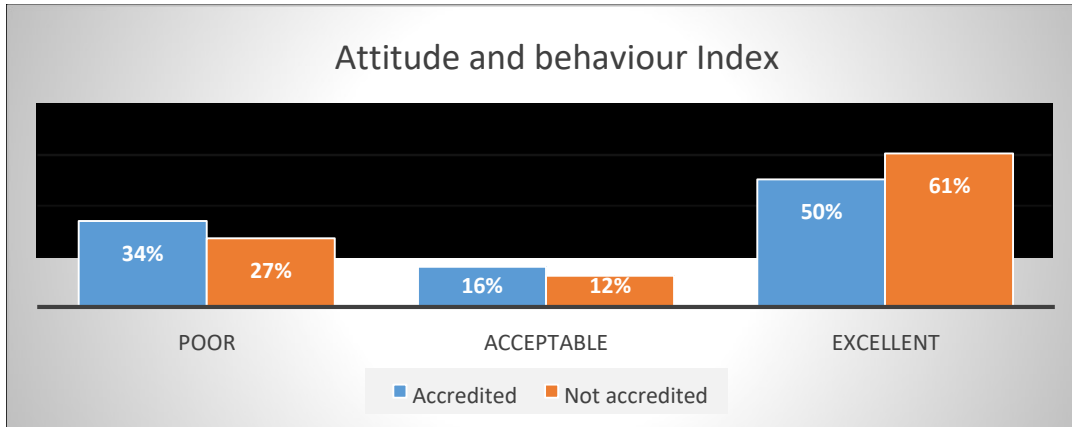


Figure 4.1 Cumulative and grading scores for the attitude and behaviour index stratified by laboratory accreditation status

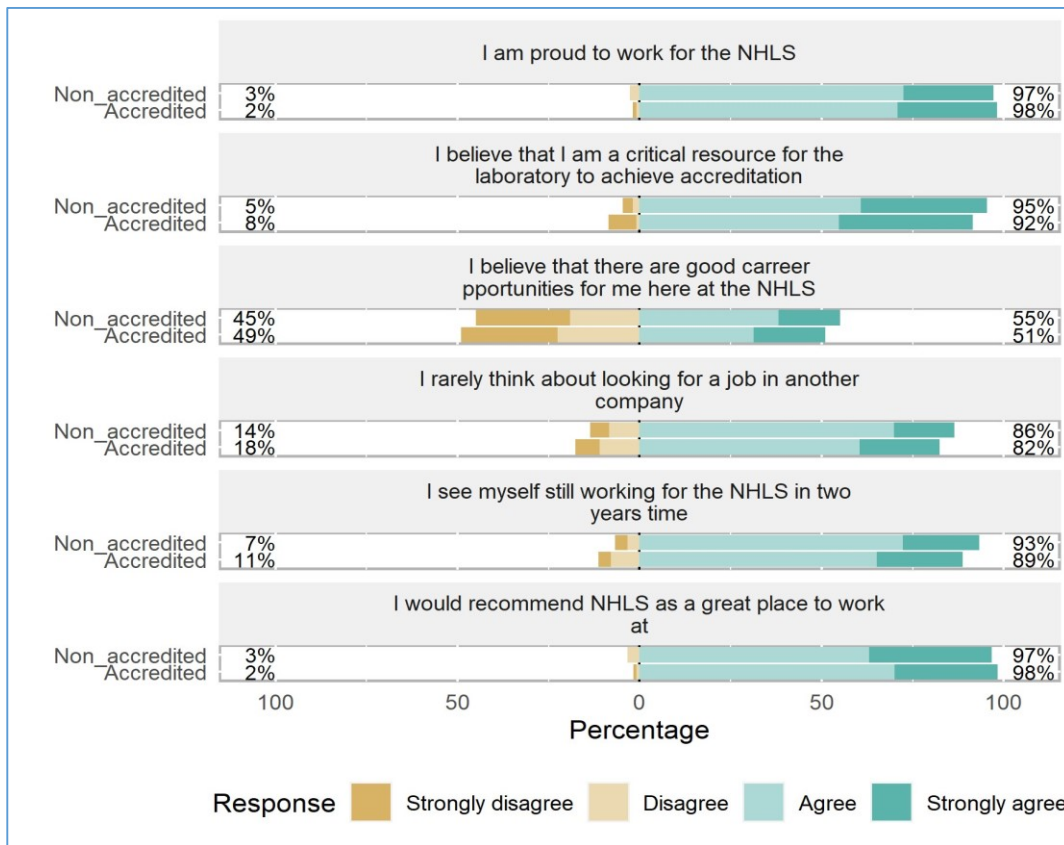


Figure 4.2 Responses to the attitude and behaviour questions stratified by laboratory accreditation status

4.5 Result interpretation for the cumulative and grading scores analysis: Attitude and behaviour index

Figures: 4.1 and 4.2 display the cumulative and grading scores as well as the responses to questions relating to attitudes and behaviour. It can be noted that the majority of participants (50% and 61%) from the accredited and non-accredited laboratories respectively, had excellent scores. Whilst most of the participants from both the accredited and the non-accredited laboratories agreed that: (1) they are proud to work for the NHLS; (2) they believe they are a critical resource for the organization; (3) they rarely think about looking for a job in another organization; (4) they see themselves still working for the NHLS in two years' time and (5) they can recommend NHLS as a great place to work at. Almost half of the participants did not believe that they have good career opportunities at the NHLS, with 49% from accredited laboratories and 45% from non-accredited laboratories.

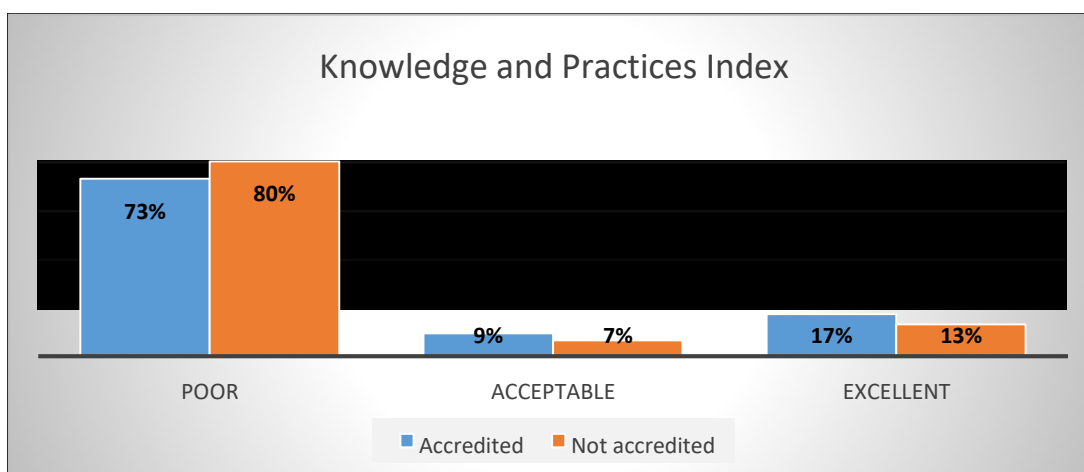


Figure 4.3 Cumulative and grading scores for the knowledge and practices index stratified by laboratory accreditation status

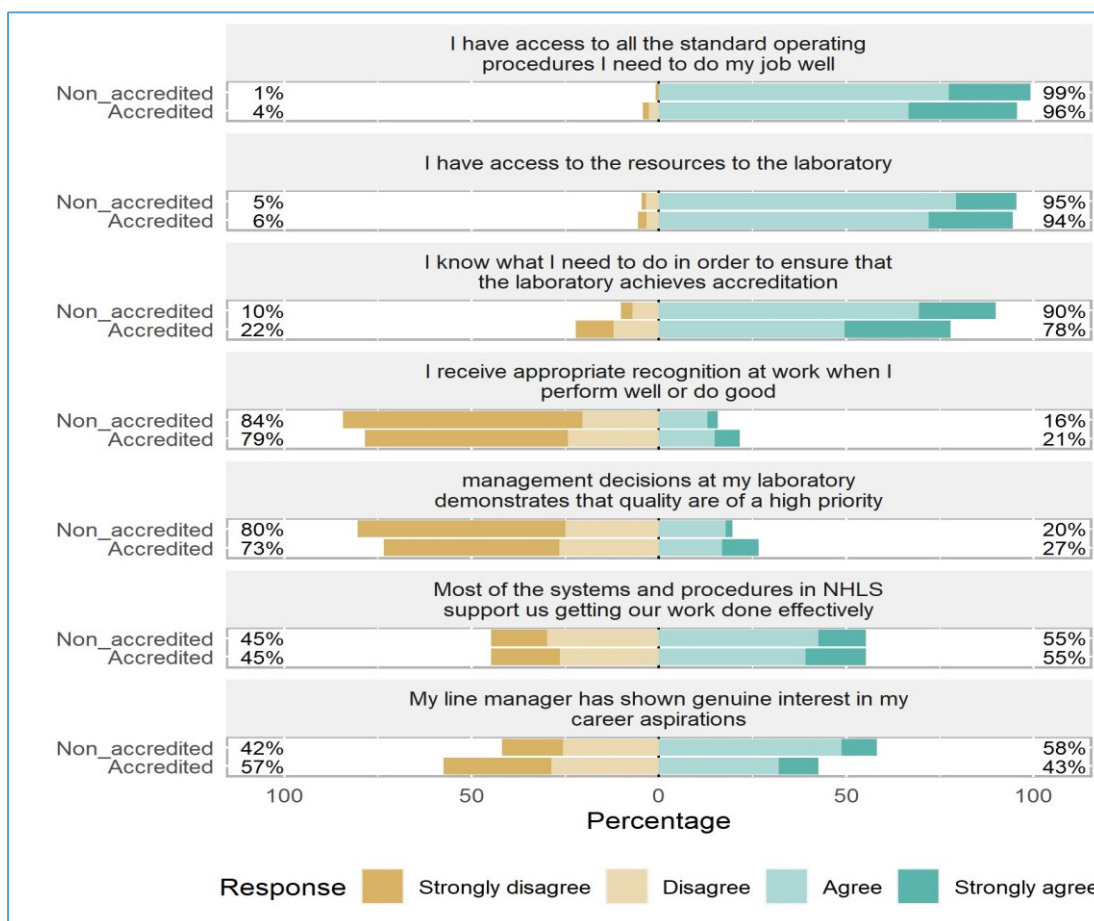


Figure 4.4 Cumulative and grading scores for the knowledge and practices index stratified by laboratory accreditation status

4.6 Result Interpretation for the Cumulative and Grading Scores Analysis: Knowledge and Practices Index

The cumulative and grading scores, and the responses to questions pertaining to knowledge and practices are displayed in figures 4.3 and 4.4 from where it can be noted that only 14% and 13% of the participants from accredited and non-accredited laboratories respectively, had excellent scores. Almost all the participants from both the accredited and non-accredited laboratories, agreed that they have access to the Standard Operating Procedures (SOPs) and other resources and that they know what they need to do to ensure that their laboratories get accredited. However, most (79% and 84% from accredited and non-accredited laboratories respectively) disagreed about receiving appropriate recognition at work when they perform well and about management decisions at their laboratories demonstrating high quality, 73% and 80% from accredited and non-accredited laboratories, respectively.

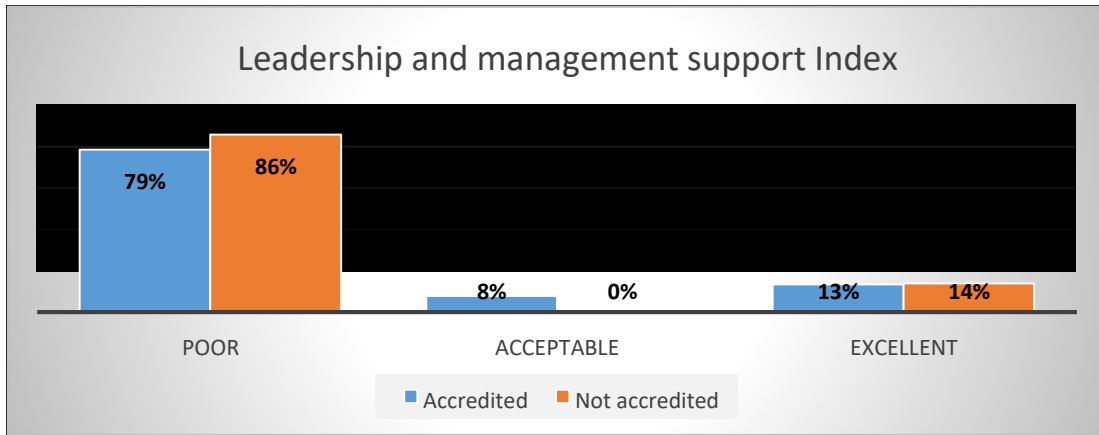


Figure 4.5 Cumulative and Grading scores for leadership and management support index stratified by accreditation status

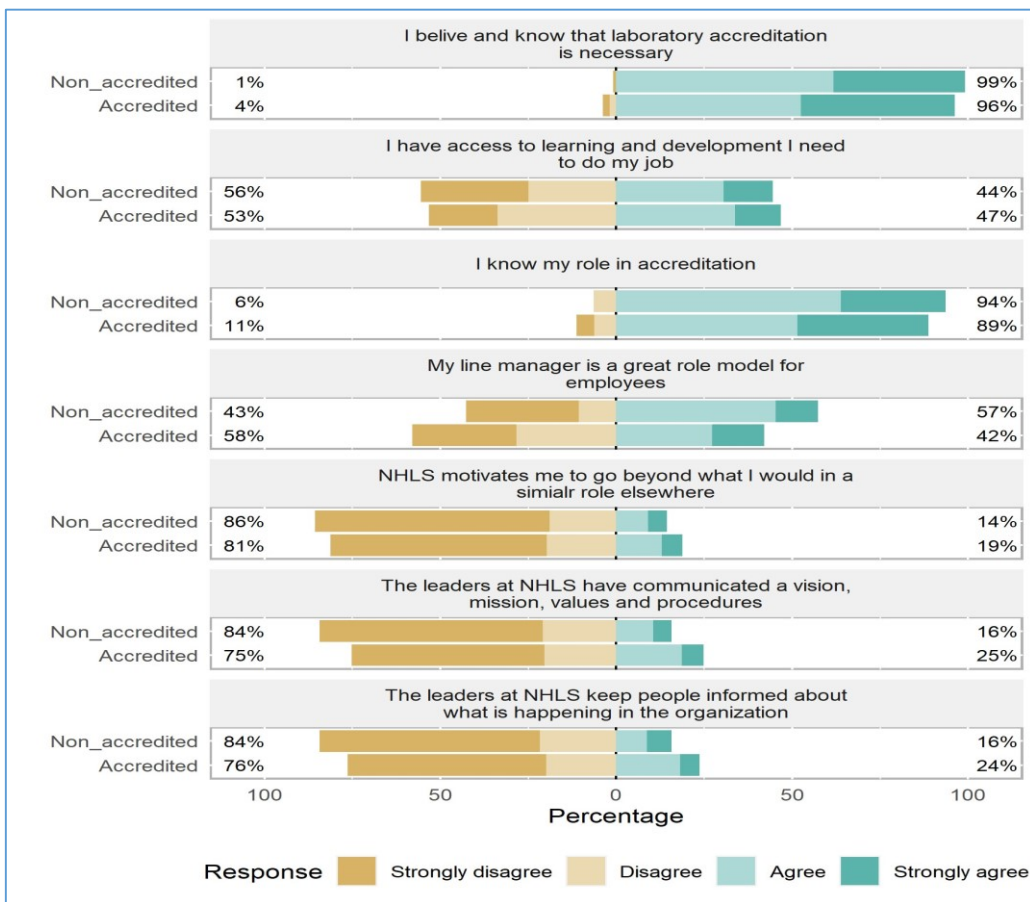


Figure 4.6 Cumulative and Grading scores for management support and leadership index stratified by accreditation status

4.9 Result Interpretation for the Word Cloud Analysis:

Figure 4.7 is a graphic depiction of the responses from 15 participants who stated responses to the open-ended question that was asking about what the participants would have liked the investigators to have asked them. It can be noted from this word cloud that the text that indicate the top five concerns of participants, as indicated by the boldness and frequency of colour of the text, were in the areas of human resources, management responsibilities, salary or compensation, competency and job satisfaction.

4.10 Inferential statistics

4.10.1 T test hypothesis

$$H_0: \text{Mean}_{\text{accredited}} = \text{Mean}_{\text{not accredited}}$$

$$H_1: \text{Mean}_{\text{accredited}} > \text{Mean}_{\text{not accredited}}$$

4.10.2 Chi-squared test results

Table 4.6 Statistical significance between the accredited and non-accredited Laboratories

Sections	Accredited	Not accredited	p-value
Attitudes and behaviour mean (SD)	69 (27.9)	73.6 (25.8)	0.91
Knowledge and practices mean(SD)	46.2 (28.4)	48.5 (24.6)	0.76
Leadership and management support mean (SD)	37.4 (30.7)	37.5 (28.2)	0.51

Table 4.6 Determining associations between human factors and accreditation status

Indices	Agree	Disagree	Total	OR	95%CI	p- value
Attitudes and behaviour						
Accredited	526	89	615	0.78	0.561.09	0.199
Not accredited	539	71	610			
Total	1065	160	1225			
Knowledge and practices						
Accredited	411	292	703	0.90	0.731.12	0.99
Not accredited	415	266	681			
Total	826	558	1384			
Leadership and management support						
Accredited	354	333	687	0.93	0.75-1.15	0.63
Not accredited	367	321	688			
Total	721	654	1375			

4.11 Result Interpretation for the Inferential Statistics Analysis

Using the odds ratios (ORs) and the accompanying confidence intervals (95% CI) from the chi square test, the null hypotheses cannot be rejected. We can, therefore, conclude that there were no associations between accreditation status and attitudes and behaviour, knowledge and practices and leadership and management support, tables 4.4 and 4.5.

The corresponding p values were 0.19; 0.99 and 0.63, all of which indicate that, although there was a notable difference in the responses of participants from accredited and non-accredited laboratories, these differences are not statistically significant.

The ORs reveal that the odds in favour of accredited laboratory participants having good attitudes and behaviour and knowledge were reduced 7% and 22% respectively, (ORs=0.93 and 0.78). The odds in favour of accredited laboratory participants agreeing with practices and management support were reduced by 0.10% (OR=0.90) compared to their non-accredited laboratory counterparts. All the 95% confidence intervals include 1 indicating that the null hypotheses cannot be rejected.

Using the Mann-Witney U test, there was also no indication of participants from the accredited laboratories rating higher than their non-accredited laboratory counterparts, p- values = 0.89, 0.49 and 0.10 for attitudes and behaviour, practices and knowledge, leadership and management support [Tables 4.7 and 4.8].

4.12 Mann-Witney U test results

Table 4.7 Determining associations between human factors and accreditation status using Mann-Witney U Test

Sections	p - value	Conclusion
Attitudes and behaviour	0.89	There is no indication that participants from the accredited laboratories rate higher than their non-accredited counterparts with regards to attitudes and behaviour.
Knowledge and Practices	0.49	There is no indication that participants from the accredited laboratories rate higher than their non-accredited counterparts with regards to knowledge and practices.
Management Support	0.10	There is no indication that participants from the accredited laboratories rate higher than their non-accredited counterparts with regards to leadership and management support.

Table 4.8 Concordant and discordant pairs

Sections	Tau value
Attitudes and behaviour index	0.17
Knowledge and Practices	-0.18
Management support	-0.21

The Mann-Whitney U test is a nonparametric test, that allows two groups or settings to be compared without making the assumption that values are normally distributed.

A t-test is a type of inferential statistic, used for the hypothesis testing. It used to determine if there is a significant difference between the two groups, which may be related.

Table 4.9 Determining the association between laboratory performance and laboratory accreditation status

Accreditation status	Target met	Target not met	OR	95% CI
Turn- around time (TAT)				
Accredited	36	3	33.5	8.86-11.96
Not accredited	24	63		
Total	60	66		
Closure of NCs				
Accredited	32	7	6.86	2.77-16.98
Not accredited	42	63		
Total	74	70		
	Average number of days taken to close NCs	% of NCs closed within expected time		
Accredited Laboratories	21.4	100		
Non Accredited Laboratories	51.7	23.3		

Table 4.9, shows the bivariate analysis between the laboratory accreditation status as the outcome variable and the TAT as the explanatory variable. Out of the 126 laboratories that had TAT data, slightly less than half (60/126) 47.6% met the target for this indicator. Of these, thirty-six (60% were accredited laboratories. Of the 66

laboratories that did not meet the target, almost all (63, 95%) were non-accredited laboratories. The odds of meeting the TAT target were 33.5 times higher among the accredited laboratories compared to the non-accredited laboratories, OR=33.5, and this difference was not statistically significant, 95% CI 8.86-11.96.

For the closure of NCs, about (74/144) 51.4% of the laboratories that had data for this indicator, met the target. Of these, forty-two (56.7 %) were the non-accredited laboratories. Of the remaining 70 laboratories that did not meet this target, the majority (63, 90%) were non-accredited laboratories. With OR = 6.89, it can be concluded that the odds of meeting the target were 6.9 times higher among the non-accredited laboratories compared to accredited laboratories, and this difference was not statistically significant with a 95% CI of 2.77-16.98.

Conclusion:

The aim of this chapter was to present the study findings and interpret the results against the objectives. The next chapter will focus on the discussion of the results presented in this chapter.

|Chapter 5: Discussion

5.1 Introduction

In the previous chapter, the research findings (results) were presented. This chapter focuses on the result interpretation, discussion of the findings and related literature. The results and policy recommendations are discussed in line with the study objectives and recommendations for policy are expressed in accordance with the SOC theoretical model.

At the time when this study was conducted, the NHLS-KZN had approximately one thousand and three hundred and seventeen (1317) employees in 63 different laboratories. The aim of this study was to explore human factors such as, employee behaviour and attitudes affecting the slow process of accreditation in the NHLS laboratories of KZN.

5.1.1 Study Objectives:

1. To determine if there is an association between attitudes and behaviours and the level of employee knowledge and practices, with laboratory accreditation.
2. To determine if there is association between the level of support provided by the laboratory management and laboratory accreditation
3. To investigate correlation between employee motivation and laboratory performance using the laboratory Turnaround Time (TAT) for test results and closure of non-conformance as quality indicators.

5.2 Participant Demographics and Laboratory Accreditation Status:

As part of descriptive analysis, it was noted that NHLS has more female employees in both accredited and non-accredited laboratories, meaning that gender equity within the organization is not balanced. There was no significant difference in the distribution of female gender between the two strata (accredited and non-accredited laboratories).

The results also indicated that the accredited laboratories had twice the number of staff (67%) when compared with the non- accredited laboratories (33%). These findings could be a factor that impacts obtaining SANAS accreditation. This agrees with the

theory that staff complement is one of the human factors which has a major influence on the organization's performance and overall productivity (Habtoor 2016). In the study conducted in Yemeni and Middle East region which involved 87 industrial companies, that investigated the influence of human factors on the quality management, (Habtoor 2016), it was concluded that having adequate staffing as a human factor, impacts positively on the improvement practices and organisational performance. Fourteen (14) other studies done in hospitals, also suggest that inadequate staffing levels were significantly associated with poor quality patient care and increased risk in patient safety.

Other studies suggest that staffing levels are associated with the workload and complexity of the tasks. They suggest that when more multi-tasking is required of employees, the more complicated the tasks become, which may lead to increased workload (Holden *et al.* 2012). In the laboratory environment, rural laboratories have less employees when compared to laboratories in the urban setting, thus staff are required to multi-task and perform various tasks throughout the laboratory. This creates complexity and increased workload for employees in carrying out their duties. In the urban laboratories, specific tasks are assigned to specific categories of staff and as a result there is not much multi-tasking meaning the work for each staff is less complicated. For example, in rural laboratories, laboratory managers are often expected to fulfil the tasks of laboratory technologists, clerical staff and inventory clerks while still fulfilling the laboratory manager's duties. In most of accredited urban laboratories, laboratory managers are expected to perform managerial duties, but have the support of clerical staff who perform the data capturing duties, specific procurement clerical staff to perform inventory management duties and technical staff responsible for processing of samples. Considering these factual differences, it is possible that, accreditation is not a top priority in rural laboratories.

The descriptive results further revealed that NHLS does not have a problem of high staff turnover, both in accredited and non-accredited laboratories as most participants had an average of 12 years' experience within the organization. A study conducted by the Hay Group in different companies that provide services, stated that the employee retention is increased by 54% when employees are proud to work for the organization (Goffee and Jones, 2013). This is in keeping with results obtained from the attitude and behaviour index.

Although NHLS did not have a problem of high staff turnover, the study revealed that most (68%) laboratory technologists that work in the rural laboratories are junior technologists that are recently qualified and are deployed to these laboratories as part of their compulsory community service. In general, medical technologists are not as willing to work in rural laboratories as compared to urban laboratories. Urban and peri-urban laboratories always attract the more experienced staff, ensuring that the technical staff are more experienced when compared with the technical staff in rural laboratories. It is possible that one of the human factors contributing towards slowness of accreditation in the rural areas could be the lack of competent and experienced technologists, since the SANAS accreditation process assess the technical competency of the laboratory.

5.3 Participant Attitudes and Behaviour in Relation to Laboratory Accreditation Status

The first objective was to explore employee behaviour & attitudes; knowledge and practices and leadership and management support affecting the slow process of accreditation in the NHLS laboratories services in KZN. Figures 4.1 and 4.2 display the cumulative and grading scores as well as the responses to questions relating to attitudes and behaviour. Approximately half of participants (50%) from the accredited and 61% from non-accredited laboratories respectively, displayed positive attitudes and behaviour towards the organization.

Whilst most of the participants from both the accredited and the non-accredited laboratories agreed that they are proud to work for the NHLS; they believe they are a critical resource for the organization; they rarely think about looking for a job in another organization; see themselves still working for the NHLS in two years' time and they can recommend NHLS as a great place to work at. It was found that almost half of the participants did not believe that they have good career opportunities at the NHLS with 49% from accredited laboratories and 45% from non-accredited laboratories. According to Fink (2014), the healthcare organization that has little or no opportunities for professional growth often lead to low employee morale. For NHLS where half of the staff in both the accredited and non-accredited laboratory facilities feel like there are limited opportunities for growth, this should pose as a risk for the organization. These

findings should alert the NHLS leadership and management to focus on addressing low morale issues which might be present throughout the organization.

In a study that was conducted in India, which was designed to assess the level of employee engagement in a company, empowerment and growth were critical predictors of employee engagement in the organization (Nadu 2011). If staff do not feel like they have good career opportunities within the organization, though they are happy to be there, they might end up with low morale which have a negative impact on the organisations operations, in this case it could be accreditation of laboratories.

While most of the employees regard the NHLS as an employer of choice, 31% of participants had poor attitude and behaviour towards the organization operations. Only 56% of employees, indicated positive attitude and behaviour. Literature states that attitudes and behaviours of employees have a direct effect on the overall performance, it further suggests that negative attitudes lead to behaviours such as, laziness, negligence, rudeness and carelessness, ultimately results in a low employee morale/ motivation (Wood 2019). In the context of the medical laboratory, behaviours such as laziness, negligence and carelessness would be detrimental to achieving quality standards and may have a critical impact on the laboratory outputs especially since the NHLS provides a service to about 80% of the South African population. Another study concurs with the theory that poor attitude and negative behaviour has a negative impact on the overall productivity of the organization (Suleiman 2013). According to Mack (2019), poor attitude in the workplace leads to negative behaviour, decreased productivity and decreased performance. In the present study about half of the employees were found to have poor attitude and negative behaviour towards NHLS operational processes, thus this is likely to be another human factor that could contribute towards the slowness of laboratory accreditation in the NHLS.

5.4 Participant Knowledge and Practices in Relation to Laboratory Accreditation Status

The first objective further determines the level of knowledge and practices and assesses it, in association with the implementation of accreditation. The cumulative and grading scores, and the responses to questions pertaining to knowledge and practices are displayed in figures 4.3 and 4.6 from where it can be noted that 73% and 80% of the participants from accredited and non-accredited laboratories, respectively,

had poor scores for knowledge and practices. Almost all the participants from both strata, agreed that they have access to the Standard Operating Procedures (SOPs) and other resources and that they know what is needed to ensure that their laboratories get accredited. However, most (79% and 84% from accredited and non-accredited laboratories respectively) disagreed about receiving appropriate support and recognition at work when they performed well. The participants (73% and 80%) from accredited and non-accredited laboratories, respectively, also stated that management decisions did not demonstrate that quality is of a high priority.

The literature agrees that inadequately trained employees result in poor job performance, negligence and increased work-related stress (Martinelli, 2018). In the present study, it was found that 77% of employees of the NHLS felt that they lack knowledge on what was expected in their roles and that they were not adequately trained to perform their jobs efficiently to achieve SANAS accreditation. The findings also suggested that 83% of NHLS employees are not motivated to go beyond what is expected from them (question 17). A study conducted in Nigeria, among healthcare professionals, also supports this theory, that lack of knowledge and poor practice not only leads to poor performance and wrong diagnoses but it also leads to a lack of motivation for staff to perform their core duties (Aluko *et al.* 2016).

5.5 Participant Perceptions on Management Support and Leadership in Relation to Laboratory Accreditation Status

The second objective of this study was to determine if there is an association between the level of support provided by the laboratory management and laboratory accreditation. Figures 4.5 and 4.6 display the cumulative and grading scores as well as the responses to questions on management support and leadership. It can be noted that majority of participants rated management and leadership support as poor. The majority (96% from accredited and 99% from non-accredited laboratories) agreed that they believe and know that laboratory accreditation is necessary and 89% and 94% from accredited and non-accredited laboratories, agreed that they know their role in accreditation. However, most participants from both laboratory types strongly disagreed about the NHLS motivating them to go beyond what they would in a similar role elsewhere that the organization leaders communicated the vision, mission, values

and procedures to them and about leaders keeping people informed about what is happening in the organization. Only a few participants, (42%) from the accredited laboratories agreed about their line manager being a great role model for the employees compared to 57% of participants from the non-accredited laboratories.

The results of this study suggests that one of the human factors that is affecting the implementation of laboratories in the NHLS is management support and leadership. Cumulative and grading scores indicated that about 83% of participants stated that there is a lack of employee engagement which speaks to a lack of management support and mentorship. This was indicated by the responses in question 17 to 20 and also from the open-ended question (question 21). According to LaMarco (2019), when leadership lacks the ability to provide direction, coaching and motivation for staff, organisational culture and morale often suffer. He further stated that poor leadership is the root cause of loss of productivity in the organization (LaMarco 2019).

The main issues that were raised in an open ended question, were: staff complement (inadequate human resource), management support, competency of staff and compensation (salary). These issues are core responsibilities and accountabilities of leadership and management. These findings also agree with the results obtained from questions that assessed leadership and management support, where most of the employees did feel that the NHLS is failing when it comes to management support. This was also reflected in question 10 where most of the staff stated that the management does not recognize the employees who are performing well (84% from non-accredited and 79% from accredited laboratories). Also from question 11, where 80% of employees from non-accredited and 73% from accredited laboratories felt that management decisions do not support quality service delivery. More than half of employees in the NHLS did not believe that the line managers have genuine interests in their career aspirations, this was expressed in the scores from question 13, which might correlate to the scores of question 4 where more than half of employees stated they do not have opportunities for professional growth. All these results suggest that a weakest link in the NHLS is the leadership and management support. It is highly possible that this gap has resulted in low employee morale which maybe the cause of

slowness of implementation of accreditation. It is also important to note that these issues seem to be existing in both the accredited and non-accredited laboratories.

According to the different literature, managers and directors of the organizations are necessary and essential for good healthcare service delivery (Ayeleke *et al.* 2018). Ayeleke (2018) continues to state that healthcare sector requires effective leadership to lead and drive changes throughout the health system to achieve desired goals of the continuous reforms in healthcare organisations. It has also been suggested that, healthcare employee morale is dependent on the relationship between line managers and staff, it states that a high employee morale or lack of it is always initiated from top management down (Fink 2014).

The WHO operational manual stated that managers shall strive to be good leaders to ensure efficient and quality service (WHO 2011). According to literature lack of leadership and poor management support results in demotivation of staff, decreases productivity and increases the risk of health and safety hazards in the organization (Foster 2017). According to literature, when leaders in healthcare organizations don't know how to bring out the best in their employees and fail to address low morale issues or lack of motivation, this results in decreased productivity, increased patient complaints, dissatisfied consumers of care and compromised patient care service (Fink 2014). (Shriar 2017) concurred with the theory that poor leadership is the main cause of low morale in the workplace.

5.6 Correlation between Employee Motivation and Selected Quality Indicators

The third objective was to investigate the correlation between employee motivation and laboratory performance using the two quality indicators, namely: laboratory Turnaround Time (TAT) for test results and closure of non-conformances. Table 4.9, shows the bivariate analysis between the laboratory accreditation status as the outcome variable and the TAT as the explanatory variable. The results from quality indicators suggested that accredited laboratory achieves TAT, which is expected since they have more number of staff when compared to the non-accredited laboratories. It must also be emphasized that the results also proved that most laboratories that are accredited are in urban settings where the staff are more senior with more years of experience. There is also various of expertise such as pathologists, scientists that are always present on

sites. Accredited laboratories all have designated laboratory supervisors and laboratory managers whose main role is to ensure that, laboratory operations including achieving TAT run smooth. The same resources are not available in rural and peri-rural laboratories where most of the non-accredited laboratories are. These could be the contributing factors that favours accredited laboratories over non-accredited laboratories. As mentioned in the previous discussion that staff complement plays a critical role in the laboratory productivity. The odds of meeting the TAT target were 33.5 times higher among the accredited laboratories compared to the non- accredited laboratories, OR=33.5, and although this is an obvious and marked difference it was not statistically significant, 95% CI 8.86-11.96. It can be concluded that there is an association between TAT and accreditation.

For the closure of NCs, all accredited laboratories met the target. The average days taken for accredited laboratories to close the NCs was 21 working days compared to 52 working days taken by non-accredited laboratories. It must be noted that SANAS accredited laboratories are compelled by SANAS to close all the NCs within 25 working days, failure to do so, might lead to laboratory accreditation to be suspended. This could be the reason there seem to be compliance in the SANAS accredited laboratories when compared to the non-accredited laboratories. The staff complement and number of experts in the accredited laboratories also plays a vital role in ensuring that NCs are closed timeously.

5.7 Limitations of the study

Using the odds ratios (ORs) and the accompanying confidence intervals (95%CI) from the chi square test, the null hypotheses cannot be rejected. We can therefore conclude that there were no associations between accreditation status and attitudes and behaviour, practices and management support, and knowledge. The corresponding p values were 0.19,

0.99 and 0.63, all of which indicate that, although there was a notable difference in the responses of participants from accredited and non-accredited laboratories, these differences are not statistically significant this could be due to the sample size.

The odds of meeting the TAT target were 33.5 times higher among the accredited laboratories compared to the non- accredited laboratories, OR=33.5, and this difference was not statistically significant, 95% CI 8.86-11.96. This could also be because of sample size.

5.8 Application of the Study Findings to the Theoretical Model (TTM)

The findings of this study suggest that human factors have an effect on the implementation of accreditation in medical laboratories of KwaZulu- Natal. Based on the present study results, the main areas of concern in the NHLS that are likely to be the cause of the slowness in implementation of accreditation are:

- Inadequate management support and leadership
- poor staff morale/ lack motivation among NHLS employees

According to the TTM model wherein this study was framed, the behaviour change that is desirable to change the accreditation situation of the KZN laboratories was suboptimal. It would appear that the necessary motivation and the appreciation of the importance of the laboratories to undergo the accreditation process, and the necessary precursor processes were not clearly understood by the laboratory personnel. Such cognitive appreciation of the accreditation processes and poor motivation was displayed by all categories of staff, from technicians to technologists in rural laboratories and the management personnel.

As indicated by the TTM, a person attempts to change a behaviour, he or she moves through five stages: pre-contemplation, contemplation, preparation, action, and maintenance. People at different points along this continuum have different informational needs, and benefit from interventions designed for their stage. This study shows that most of the laboratories were stuck on the pre-contemplation, contemplation, and at best the preparation stages (particularly in urban laboratories). The inadequate preparation and action components were influenced directly by the low

motivation / morale of the laboratory staff and the poor management support displayed for the accreditation preparedness by senior management.

Theoretically the accredited laboratories would be expected to perform better than the non-accredited laboratories. This is mainly due to the fact that the accredited laboratories would have been certified to possess adequate staffing levels, have shown efficiencies in the performance to tests and according to required standards and have adequate infrastructure and management processes to perform better. However, based on the results of the proxy indicators of lab performance, namely, the closure of non-conformances within the stipulated timeframes and the turnaround times for the laboratory results, there were no significant difference in the performance (p value) between these laboratories. This suggests that although employees in accredited laboratories had taken appropriate action to ensure the accreditation of their laboratories, the maintenance of such actions was inadequate. Such as situations pose risks and raises questions about the sustainability and maintenance of the accreditation status of the laboratories. The accreditation is a renewable process done on an annual basis by SANAS; hence there is a need to address the maintenance stages at the accredited laboratories to prevent relapses into old habits and regression in terms of employee motivation as such a scenario will reverse the accreditation gains made (change in behaviour, occurs continuously through a cyclical process). The key to recovering from a relapse is to review the quit attempt up to that point, identify personal strengths and weaknesses, and develop a plan to resolve those weaknesses to solve similar problems the next time they occur.

Conclusions and Recommendations

6.1 Conclusions of the Study

From the study it can be concluded that human factors do affect the implementation of laboratory accreditation throughout the NHLS. The main human factors are leadership and management support and knowledge and practices among the employees of the NHLS. This agrees with literature and different studies that have been conducted globally that support that human factors do affect performance of the healthcare employees and laboratory staff are part of the healthcare workforce. WHO have also acknowledged and endorsed the facts that human factors have a direct effect on the performance of healthcare workforce (WHO 2011). It is thus the reason that NHLS should look into the human factors in order to ensure that the laboratory accreditation is not only achieved but also sustained in all already accredited laboratories.

6.2 Recommendations based on TTM:

Based on the TTM, it is recommended that ongoing training and sensitisation programmes for employees in all the laboratories focusing on the importance of accreditation and the need of maintenance thereof. It is also recommended that there is strengthened capacitation of the laboratory management personnel with regards to accreditation requirements and the benefits thereof, so that they are able to provide improved leadership and support to their employees regarding the accreditation process. It is also advised that the NHLS, embrace the fact that they have high levels of staff loyalty, either due to limited career opportunities or given the fact that they have super-specialised fields of work, however in order to maintain this, the NHLS needs to create career paths for all laboratory personnel to improve their morale / motivation. The NHLS should also consider providing incentives for accredited laboratories to ensure the maintenance of accreditation. The possible incentives may be financial and/or non-financial; and should comprise positive and punitive measures where indicated.

6.3 General Recommendations from study findings

It is recommended that further studies are done on leadership and Management support in the NHLS so that the root-causes are identified and challenges in this regard are resolved in order for the overall organization performance to be improved.

It is also recommended that, since human factors affect the healthcare workforce, the accrediting bodies such as SANAS include a tool for assessing the human factors and how they affect the reliability of results produced by the accredited laboratories in their checklists.

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Appendix 1: Request to conduct Research in NHLS

Ms Mbalenhle A. Ngubo - Mdletshe
EThekwini Quality Assurance Co-ordinator
EThekwini Business Unit-KZN
Fax: (086 520 3188)/ Phone: (031 327 6700/80)

**For attention:
NHLS AARQA
KZN REGIONAL OFFICE**

REQUEST FOR PERMISSION TO CONDUCT RESEARCH IN NHLS LABORATORIES IN KWAZULU NATAL REGION

Dear: Mr S. Bandezi

My name is Mbalenhle Audrey Ngubo- Mdletshe (Payroll number: 10946-2) and I am currently studying toward my Master's Degree in Medical Laboratory Science- Faculty of Health at The Durban University of Technology - ML Sultan Campus, (Student Number: 19951796). The research I wish to conduct for my Master's dissertation; involves conducting surveys in different laboratories in KwaZulu Natal that will be randomly selected. The title of my dissertation is:” **Determining factors contributing to non-SANAS accreditation among NHLS laboratories in KwaZulu- Natal**”

This project will be conducted under supervision of Dr Rogerio Phili (PhD- Public Health, UKZN), who is currently a director in his Practice (NEW START). Dr Phili has worked in NHLS as EThekwini Business Unit manager, before leaving for Aurum as the director of Public Health Department. Ms Lindiwe Cele (Master's Degree in Public Health- UP) is currently working as a research scientist for CAPRISA, she was previously working in NHLS- KZN as an epidemiologist. Dr Pavitra Pillay (PhD- Public Health, UKZN) is my DUT supervisor (Primary supervisor) she is currently working at DUT as one of the senior lectures in the Department of Biomedical and Clinical Technology.

I am hereby seeking your consent to, approach a number of laboratories in KwaZulu Natal, where surveys will be distributed to staff to complete. I have provided you with a copy of my proposal and a Data collection tool to be used for this project. I am currently awaiting approval and Ethics clearance from DUT Ethics committee.

Upon completion of my study, I, together with two of my supervisors (Dr R. Phili and Ms L. Cele) intend to submit this for publication. I undertake to provide the organization- NHLS with a copy of the full research report, should this be required.

If you require any further information, please do not hesitate to contact me on: 082 612 6211/ 031 327 67 00/80 (contact number) and mbalenhle.ngubo@nhls.ac.za (email address). Thank you for your time and consideration in this matter.

Yours sincerely,
Mbalenhle Audrey Ngubo- Mdletshe
EThekwini Quality Assurance Co-ordinator

2: NHLS Approval letter to Conduct Research



Academic Affairs and Research
Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 386 6142
Fax: +27 (0)11 386 6296
Email: babatyi.kgokong@nhls.ac.za
Web: www.nhls.ac.za

18 June 2019

Applicant: Ms Mbalenhle Ngubo-Mdletshe
Institution: National Health Laboratory Service
Department: Ethekwini Quality Assurance
Email: mbalenhle.ngubo@nhls.ac.za
Tel: 031 327 6700/80
Cell: 082 612 6211

CC: Mr Sibulele Bandezi

Re: Provisional Approval to conduct a study at the National Health Laboratory Service (NHLS) – KwaZulu-Natal Region

Your application to undertake a research project titled "**Determining factors contributing to non-SANAS accreditation among NHLS laboratories in KwaZulu- Natal**" has been reviewed. This letter serves to advise that the application to conduct the proposed research in the NHLS premises has been provisionally approved.

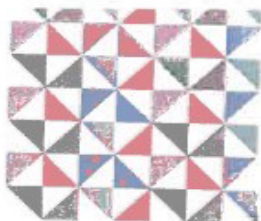
As mentioned on the protocol – the study will involve 64 laboratories and the anonymity of the participants together with the organisation is guaranteed.

Please note that final approval will be granted on your compliance with the NHLS conditions of service and that the study can only be undertaken provided that the following conditions have been met.

- Ethics approval is obtained from a recognised SA Health Research Ethics Committee.
- Participation is at the prerogative of the approached Laboratory Manager as indicated in the Research Study Information Letter.
- Confidentiality is maintained at participant and institutional level and there is no disclosure of personal information or confidential information as described by the NHLS policy.
- A final report of the research study and any published paper resulting from this study are submitted and addressed to the NHLS Academic Affairs and Research office and the NHLS has been acknowledged appropriately.

~~Dr Babatyi Malope Kgokong~~
National Manager, Academic Affairs and Research

Appendix 3: Ethical Clearance



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

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2375

Email: irahad@dut.ac.za

http://www.dut.ac.za/research/institutions/research_ethics

www.dut.ac.za

30 October 2019

Ms M A Ngubo
05 Duddon
42 Ferguson Road
Glenwood
Durban
4001

Dear Ms Ngubo

The effect of human factors on the implementation of accreditation in Medical Laboratories in KwaZulu-Natal
Ethical Clearance number IREC 144/19

The Institutional Research Ethics Committee 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 4: Participant Information Letter with Consent



LETTER OF INFORMATION



LETTER OF INFORMATION

Title of the Research Study:

The effect of human factors on the implementation of accreditation in Medical Laboratories in KwaZulu-Natal

Principal Investigator/s/researcher:

Mbalenhle Audrey Ngubo; Master of Health Sciences: Medical Laboratory Science

Co-Investigator/s/supervisor/s:

Dr P Pillay (PhD: Public Health), Dr Rogerio Phili (PhD: Public Health) and Ms Lindiwe Cele (MPH)

Dear Participant

You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please do not hesitate to ask me, the researcher (Principal investigator) if there is anything that is not clear or if you need more information.

The current methods that are used for quality management systems (QMS) in the NHLS have been ineffective, particularly in the rural laboratories (KZN Quality Assurance Focus committee 2019:8). The quality of laboratory service in SA is dependent on technical skills, quality management systems and the motivation of human resources, as is the case in sub-Saharan Africa (Simundic et. al 2011).

Most laboratories in KwaZulu-Natal (KZN) province of SA are located in rural and peri-urban areas and rely on high usage of manual systems and human labour compared to urban laboratories where state of the art machinery and technology are available. The starting point in establishing the factors influencing the slow uptake of SANAS accreditation for the KZN laboratories should begin with an understanding of the motivators and disincentives of human capital working at these laboratories (Allam 2017:118). To our knowledge, no such studies have been undertaken in KZN.

In addressing the research problem, the Stages of Change (SOC) Theoretical Model will be used to guide the research, document findings and to formulate strategies for improvement and recommendations, as it provides suitable framework for such. The model's basic premise

is that behaviour change is a process, not an event. As a person attempts to change a behavior, he or she moves through five stages: pre-contemplation, contemplation, preparation, action, and maintenance. People at different points along this continuum have different informational needs, and benefit from interventions designed for their stage.

The purpose of this study is to determine the extent to which employee motivation influences the accreditation status of a laboratory. The objectives of this study are:

4. To determine if there is an association between the level of knowledge, staff attitudes and behaviours with laboratory accreditation.
5. To determine if there is association between the level of support provided by the laboratory management and laboratory accreditation

Employee motivation in this study is defined as the sum of processes that influence the arousal, direction and maintenance of behaviours relevant to work settings (Nguyen 2017:10 -11).

In this study you will be required to complete a survey questionnaire. You will be required to complete a qualitative survey questionnaire with twenty closed- ended and one open ended questions. To complete the survey questions will take approximately 5 minutes of your time.

There are no risks involved as the NHLS management is aware that the survey is conducted and anonymity will be maintained. The principal investigator (PI) will be the only one, who knows, who has participated in the survey. Your information will be kept confidential. You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

There will not be any direct benefit to you as the participant but the organization will get information based on the answers you provide and this will benefit all medical laboratories in South Africa (SA). The principle investigator will obtain a Masters' degree and the researchers will also publish the results of this study.

Your responses to this survey will be anonymous. Please do not write any identifying information on your survey questionnaire that you be completing. Every effort will be made by the principal investigator to preserve your confidentiality including the following:

- Assigning codes for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the principal investigator

- Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and victimization risk.
- The survey questionnaire will be directly emailed or hand delivered by the principal investigator to the participant (The participant will decide the method of receipt of questionnaire, time and place). All completed surveys will be placed in temper proof envelopes or directly email to the principal investigator. To those participants that will be sending it through temper-proof envelopes, they will be a locked box/pigeon hole that these envelopes will be placed in and only the principal investigator will have the key for these boxes. The principle investigator will collect all the completed survey questionnaires from the participating laboratories. Please note that there will be no compensation for this study.

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher.

If you withdraw from the study before data collection is completed, your data will be destroyed.

If you have questions at any time about this study, or you experience any challenges as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Principal Investigator, please contact my Durban University of Technology (DUT) supervisor: Dr Pavitra Pillay (Senior Lecturer); Department of Biomedical Technology and Clinical Technology; Faculty of Health Sciences; Tel: 031-3735423/ 031 3735411; Fax: 031-3735295; email pillayp@dut.ac.za. Complaints can be reported to the Director: Research and Postgraduate Support, Prof S Moyo on 031 373

Thank you for participating



INFORMED CONSENT

Statement of Agreement to Participate in the Research Study:

I hereby confirm that I have been informed by the researcher, about the nature, conduct, benefits and risks of this study - Research Ethics Clearance

Number: _____,

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

_____ **Name of Participant** **Date** **Time** _____ **Signature/Thumbprint**

(name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____ **Full Name of Researcher** _____ **Date** _____ **Signature**
_____ **Full Name of Witness (If applicable)** _____ **Date** _____ **Signature**

_____ **Full Name of Legal Guardian (If applicable)** _____ **Date** _____ **Signature**

Appendix 5: Data Collection Tool

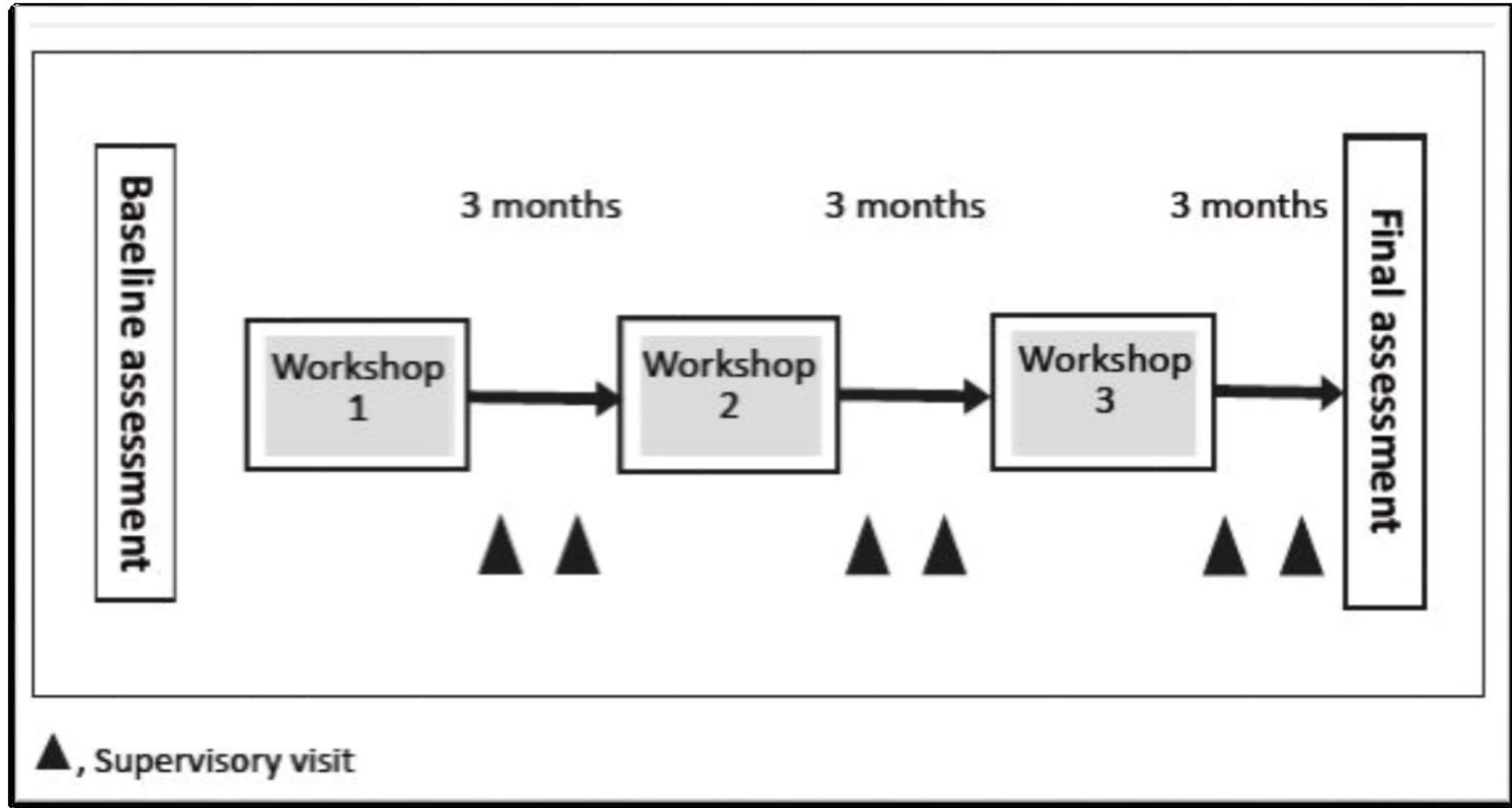
Laboratory name: -----Facility type: CHC Tertiary District Geographical Setting: Urban Rural Peri-Rural

Section A: Age (in yrs.) -----Sex: Male Female Years of service as an NHLS Employee

Job Category: Laboratory Manger Medical Technologist Medical Technician Laboratory Clerk Other

Section B: Attitudes and Behaviour	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1.I am proud to work for NHLS					
2.I would recommend NHLS as a great place to work in					
3.I rarely think about looking for a job in another company					
4.I see myself still working for the NHLS in two years' time					
5. I believe that there are good career opportunities for me here at the NHLS					
6. I believe that I am a critical resource for the laboratory to achieve accreditation?					
Section C: Practices					
7. I have access to the resources and things I need to do my job well and achieve accreditation.					
8.I have access to all the standard operating procedures (SOPs), learning and development I need to do my job well in order for the organization to achieve accreditation					
9..Most of the systems and processes in NHLS support us getting our work done effectively towards achieving accreditation					
10.I receive appropriate recognition at work when I perform well or do good					
11.Day- to –Day decision making by management at my laboratory demonstrate that quality and improvements are of a high priority (i.e. Decisions taken by management aim to achieve accreditation)					
12.My line manager (or someone in management) has shown genuine interest in my career aspirations					
12.I know what I need to do in my role in order to be successful and efficient, to ensure that the laboratory achieves accreditation					
Section D: Knowledge					
13. Is accreditation necessary?					
14. I know my role in accreditation?					
15.NHLS motivates me to go beyond what I would in a similar role elsewhere					
16.The leaders at NHLS keep people informed about what is happening in the organization, including policies and procedures necessary to achieve accreditation					
17.My line manager is a great role model for employees					
18.The leaders at NHLS have communicated a vision, mission, values and procedures that assist me to achieve accreditation.					
19.Is there something that you think we should have asked you in this survey? Please tell me. You can use the back of the survey to write what I should have asked you.					

Appendix 6: SCHEMATIC DIAGRAM OF HOW SLMTA PROGRAM IMPLEMENTATION



Appendix 7: SLIPTA CHECKLIST



REGIONAL OFFICE FOR **Africa**

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015

For Clinical and Public Health Laboratories



TABLE 4a: Summary of WHO AFRO SLIPTA checklist that covers the 12 Quality System Essentials and the weighted marks of each section out of the 250 total points.

Section	Total points	Assessed score [†]
1. Documents and records	25	
2. Management reviews	12	
3. Organisation and personnel	20	
4. Client management and customer service	8	
5. Equipment	30	
6. Internal audit	10	
7. Purchasing and inventory	30	
8. Information management	14	
9. Process control and internal and external quality assessment	43	
10. Corrective action	8	
11. Occurrence/incident management and process improvement	10	
12. Facilities and safety	40	
Total score	250	

[†], The assessed score for each section would be placed in this column.

Appendix 8: SLIPTA STEPWISE PROCESS TOWARDS ACCREDITATION

