ASSESSMENT OF THE QUALITY OF MEDICAL LABORATORY SERVICE PROVISION IN KENYA

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University or any other award.

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DEDICATION

I dedicate this work to my late father Mr. Mariga Thoithi Wang'ombe, mother Abishag Wambui, brothers and sisters Baru, Thoithi, Wanjugu and Wanjiku, husband Steve Njoroge Gachie and my great pillars of strength my children Melissa Wanjiku Muindi, Alvin John Gachie and Isaac Mariga Wang'ombe.

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LIST OF ACRONYMS AND ABBREVIATIONS

ANOVA	Analysis of Variance
GOK	Government of Kenya
KNBS	Kenya National Bureau of Statistics
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
MLS	Medical Laboratory Science
MOH	Ministry of Health
MOLG	Ministry of Local Government
NGO	Non Governmental Organization
NPHLS	National Public Health Laboratory Services
SOP	Standard Operating Procedure
SPSS	Statistical Package for Social Science
TQM	Total Quality Management
WHO	World Health Organization

ABSTRACT

There has been increasing interest to improve the quality of laboratory services world-wide including in many resource poor countries. In tandem with this need, the Kenya government recognizes the delivery of quality laboratory services as an integral part of the national health care strategy. Towards this goal the surveillance system for quality medical laboratory services in Kenya was instituted by the Kenya Medical Laboratory Technicians and Technologist Board. However, Kenya still has very little concrete and reliable information on the actual standard adaptation, and implementation, or the impact policy guidelines have had on laboratory services delivery. The objective of this study was to address these gaps by carrying out a situational analysis to assess the quality of medical laboratory services delivery in Kenya. The specific objectives of this research were to assess the laboratory practitioner's competence; to determine the level of compliance to practice standards; to investigate the management of quality systems; and to analyze the extent to which the patient's needs for quality laboratory services were met. As a representation of each of the regions in Kenya the study areas were situated in Nairobi, Mombasa, Kisumu and Nyeri counties. The study was both an observational and descriptive study using a cross sectional design. Purposeful sampling was used to select the laboratories while as random sampling was used for the laboratory practitioners and patients. The data was analyzed by the measures of central tendency mode, median and mean plus measures of variability, range, standard deviation and variance. Data was analyzed using least squares regression model, t-tests and one way analysis of variance (ANOVA) using Excel spreadsheets and SPSS version 19. The overall assessment was that the quality of medical laboratory services delivery in Kenya was good. The highest level of quality management systems were maintained by private high class laboratories $p > 0.052$, $p > 0.05$, $\alpha = 0.05$ which also had the highest rating of compliance to practice quality $p < 0.022$, $p < 0.05$, $\alpha = 0.05$. Faith based laboratories had the highest rating in competency of practitioners $p < 0.027$, $p < 0.05$, $\alpha = 0.05$. Analysis of patients perception of quality service provided $p < 0.039$, $\alpha = 0.05$ indicated that the private low class laboratories fared the best $p < 0.030$, $\alpha = 0.05$. Findings of this research were that the laboratory practitioners were competent, the practice characteristics were of good standard and patients perceived the services to be of good quality. The study failed to reject the null hypothesis ($p > 0.05$) pertaining to the quality management systems in place $p < 0.057$, $\alpha = 0.05$. No laboratory had adequate quality management systems in place. The recommendation of this study is there is a need for adequate internal and external quality assurance schemes to be in place to constantly monitor the quality of assay results.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Quality medical laboratory service provision is important in order to enhance diagnostic value and save lives. This is because recognition of disease is the foundation of disease control and prevention (Saliki, 2000). Unfortunately, the implementation of quality laboratory service in many resource poor countries has been unsystematic and is still questionable (Ishengoma *et al.,* 2009; Kenya *et al.,* 2012). Resultantly there are variations in terms of laboratory services delivery from one country to another. In response to this challenge, in 1979, the World Health Assembly requested the World Health Organization (WHO) to develop a program for diagnosis in primary health care facilities in developing countries (MOH/AMREF, 1996). Following this, research was conducted in 2011 to provide stakeholders in Kenya with empirical data about diagnostic capacity in Nairobi (Kenya *et al.,* 2012). This preceded a report on a research to assess the capacity of research and diagnostic laboratories in Nairobi (Kenya *et al.*, 2012). These efforts have been in tandem with recognition of the importance of medical laboratory services by the Ministry of Health (MOH) and other health service provision stakeholders (Kenya *et al.,* 2012; MOH/AMREF, 1996; MOH, 2001; 2002; MOH/KMLTTB, 2005).

In developing countries all over the world, poverty and poor infrastructure are major contributing factors leading to inefficient provision of health services (Ishengoma *et al.,* 2009). In Sub-Saharan Africa for example, the overall health indicators were documented to be the poorest of any region in the world (WHO, 2003). Health was one of the ambitious development goals for Kenya at independence. Since then, the Kenya government spent an immense amount of money,

on medical programs. Kenya has not yet fully realized its health objectives, even though the government is committed to achieving better health for all people and recognizes delivery of quality laboratory services as an integral part of this goal in the national health care strategy (MOH, 2001; MOH/KMLTTB, 2005). Against this background the National Public Health Laboratory Service (NPHLS) had drawn the attention to the need for improving the laboratory working environment and laboratory standards and bringing them up to WHO standards of quality (MOH, 2001). Towards this goal the surveillance system for quality medical laboratory services in Kenya was instituted by the Kenya Medical Laboratory Technicians and Technologist Board (KMLTTB) whose main emphasis was ensuring the requirements for accreditation were met and enabling application for and issuance of licenses by the government (MOH, 1999; MOH/KMLTTB, 2005). The Board's standards were applicable to private laboratories and government hospital laboratories operating in Kenya.

A medical laboratory at primary health care level augments both clinical diagnostic and public health activities. The use of simple laboratory tests significantly alters diagnosis and treatment. Although medical laboratory service provision is a well developed science, observations indicate that many laboratories turn out dangerously inferior work resulting in inaccurate determinations and failure to identify the causative agents in samples (Ishengoma *et al.*, 2009). According to the MOH study, the public provision of health had generally failed (MOH/AMREF, 1996).

1.2 Statement of the Problem

The quality of the laboratory services is important in achieving the national goal of improved health care. Service quality is influenced by the competence of the laboratory service providers

who are the practitioners as well as the availability of the recommended working conditions as set by the KMLTTB. There are a set of standards for quality laboratory services developed by the KMLTTB based on WHO standards (MOH/AMREF, 1996; MOH/KMLTTB, 2002), but Kenya has still very little concrete and reliable information on the actual levels of standard adaptation, and implementation, and the impact these guidelines have had on the health sector service delivery (Kenya *et al.,* 2012). The quality of service remains a growing concern even as medical diagnostic laboratories are undergoing the process of accreditation for quality services in line with WHO standards. No other studies have been made to investigate whether there has been improvement in the area of compliance to the MOH standards. Neither have studies been made to investigate the actual level of management of quality systems. Furthermore, none of the studies made have had a customer focus. The objective of this study was to address the gaps in knowledge pertaining to the laboratory practitioners' competence, the level of compliance to practice standards, the quality assurance process and the patients' perceptions of the quality of service, by carrying out a situational analysis.

1.3 Justification of the study

Laboratory services are an integral part of health care services worldwide (Saliki, 2000). In tropical countries laboratory services are particularly useful at the primary health care level because of the nature of the commonly presenting diseases and conditions, most of which may be diagnosed using simple laboratory tests. The findings of this study provide empirical evidence of the quality of medical laboratory services. The study provides a good basis to assess the practitioner characteristics of competence, and management function, and investigate the compliance pertaining to practice structure in terms of space and basic amenities. The findings

provide a comprehensive understanding about the patient's needs in order for them to deem the service to be of quality.

1.4 Research questions

The following were the research questions:

i. How competent are the practitioners manning Kenyan medical laboratories?
ii. What is the level of compliance to the laboratory practice characteristics based on MOH standards?
iii. What processes assure quality management systems are in place?
iv. What factors do the patients consider in order to perceive quality laboratory service?

1.5 Null Hypotheses

Ho Medical laboratory service delivery in Kenya is of low quality.

1.6 Objectives

1.6.1 General objective

To determine the quality of medical laboratory service delivery in Kenya.

1.6.2 Specific objectives

i. To assess the laboratory practitioner's competence;
ii. To determine the level of compliance to practice standards;
iii. To investigate the process of quality assurance of the management systems;
iv. To analyze the patient's perception of quality laboratory service.

1.7 Scope and limitations

This study was conducted in laboratories where the practitioners gave their informed consent. It was purposively limited to four counties. Each time the laboratory was visited only one manager and one service provider was selected in order to provide information. It was recognized that other practitioners within the same facility may have held varied opinions as to the quality standards implementation. It was not possible to interview all practitioners or patient attended to in the selected laboratories. Each facility was visited on three separate occasions and different service providers questioned in order to minimize the potential variation in responses. The use of multiple study methodologies improved the information received and reduced errors. Further, in order to increase reliability data was collected by the researcher.

1.8 Conceptual framework

The conceptual framework is the structural equation model or path diagram explaining the network of concepts called variables and exhibiting the flow and direction of their relationships (Chandran, 2004). This study used a conceptual framework adapted from the Parasuraman *et al.*'s quality dimensions, Eggli and Halfon's conceptual framework for hospital quality management, and Price's three dimensions of quality (Eggli and Halfon, 2003; Parasuraman, *et al.*, 1985; Price, 2005). Figure 1.1 graphically depicts the conceptual framework.

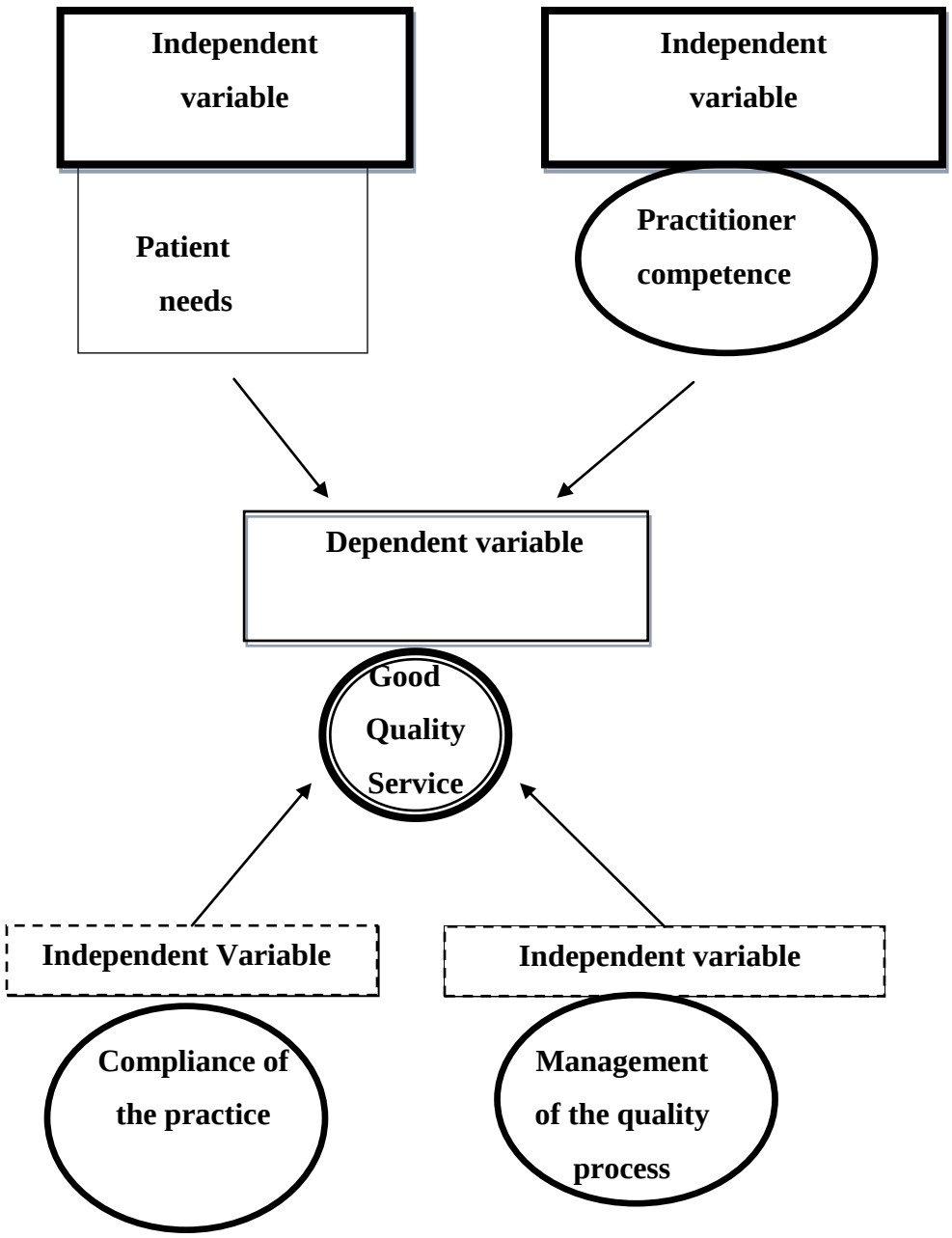

Figure 1.1: The conceptual framework

Adapted from a three domain quality model (Eggli and Halfon, 2003; Parasuraman, *et al.*, 1985; Price, 2005)

The dependent variable was good quality service (Ishengoma *et al.*, 2009). The independent variables in this study were four, namely the practitioner's competence, compliance to practice standards, quality management systems and meeting the consumer needs. The indicators in the conceptual framework were therefore grouped into the four variable domains. Three were adopted from Price's quality model, namely those pertaining to the practitioner, the practice and the process (Price, 2005). The other domain was the patient's needs (Feeny and Zairi, 1994; Parasuraman, *et al.*, 1985).

The first independent variable was the practitioner's competence. According to theory, workers who gave the best chance for implementing quality are competent (Eggli and Halfon, 2003; Tandon, 1987; Timmons and Spinelli, 2003; Kantis *et al.*, 2002). Competency was developed by education and training. In a study elsewhere, it was found that competent laboratory staff require a high degree of motivation (Bates and Maitland, 2006).

The second independent variable was the practice quality. This variable was proposed to be the level of compliance to benchmarking standards set by accreditation bodies using practice variables. These include the size of laboratory and the presence of basic amenities (MOH/AMREF, 1996; MOH/KMLTTB, 2005) which are criteria considered important by regulatory bodies in the provision of quality service.

The third independent variable was the management of the quality systems. This was conceptualized to use process variables as indicated by pre-analytical factors like safety, planning (Temtime, 2003) and cleanliness; analytical factors like the availability of standard

operating procedures (SOPs) and post-analytical factors like documentation, standardization and disposal (MOH/AMREF, 1996). Good management of the quality systems was proposed by theory to lead to good service quality.

The fourth independent variable was the patient's needs. The major consumer of laboratory service was considered in this study to be the patient and the physician. Based on literature, (KEBS, 2007; Price, 2005; Rhaman, 2001) good quality is not determined by the producer but by the consumer of the product or services. That rationale was the justification why the last independent variable was conceptualized as the patient's needs.

Based on a report on the assessment of quality of the clinical laboratory department in a specialized hospital in Alexandria, Egypt which used several of the indicators adopted in this conceptual framework, (Elhoseeny and Mohammad, 2013) indicators conceptualized as pertinent were grouped and subdivided. In this research the conceptual framework variables were further sub-divided into variable groupings based on, and using several of the indicators conceptualized in the essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996). The variables and their indicators are shown in Table 1.1. The laboratory practitioner variables were categorized as; demographics, competence and leadership. The laboratory practice variables were divided as physical facilities and basic amenities. The process of QA of the management system was categorized as pre-analytical, analytical and post-analytical process. The customer's needs variable was undivided as the only consumer investigated in this study was the patient.

Table 1.1: The Independent variables and their indicators

Variables (V)	Variable groupings (V,G)		Indicators (I)
V1 Practitioner	Demographics	(V1,G1)	Age Gender Tribe/Race Marital status Religion
	Competence	(V1,G2)	Education Training Work experience
	Leadership	(V1, G3)	Personal traits Courtesy Motivation Ethical standards
V2 Practice compliance	Physical facilities	(V2,G1)	Specifications of workroom Accessory rooms Level of security
	Basic amenities	(V2, G2)	Water Power Drainage
V3 Process of QA of Management systems	Pre- analytical	(V3, G1)	Planning documentation Cleanliness SOPs Use of controls /standards Documentation of assay
	Analytical	(V3,G2)	Process: request forms Labeling of samples Safety measures First aid measurers Disposal methods Error reporting
	Post-analytical	(V3, G3)	Documentation (post-analytical)
V4 Customer focus	Patient	(V4,G1)	Patients perception of quality service

Adapted from conceptual framework indicators in a model for healthcare service quality (Elhoseeny and Mohammad, 2013).

1.9 Operational definition of terms

Competence Ability of a person to do the job well, indicated by education, training and work experience.

Faith based Used for Christian and Muslim faiths only.

Laboratory practitioner Part of the human resource consisting of the managers/owners and service providers who are employees.

Medical laboratory Clinical facility for the microbiological, serological, chemical, hematological, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health.

Practitioner A person actively engaged in an art, discipline, or profession, especially medicine; (*technical*) a person who works in a profession, especially medicine or law; (*formal*) a person who regularly does a particular activity, especially one that requires skill.

Quality control Laboratory self inspection using planning, statistics, and process performance data.

Quality assurance	Quality systems developed that include non-operational functions involving statistical process control.
Total quality management	Has a customer focus, employee involvement and team work; performance measurement involves all laboratory functions.
Standard quality	Prescribes systematic control of activities to ensure that the needs and expectations of clients are met.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Global expectations of quality laboratory services

Globally, international differences exist in the guidelines on good quality laboratory services. The quality of service provision and the challenges laboratory practitioners face are different in developed versus developing countries (Saliki, 2000). In the developed world, the challenge is the selection of appropriate testing techniques. Quality assurance schemes in the developed countries are incorporated in the laboratory operations policies; there are established standards and enforced regulations. In developing countries the challenge is the lack of diagnostic tests. Developing countries are resource poor so the challenges are resource based, like human resource and financial resource based. Resultantly, there are considerable differences between countries in the implementation of quality laboratory services, in particular between highly developed countries and less developed countries (Kamau, 2013; Kovacs, 2004).

Globally, quality laboratory service is benchmarked by accreditation bodies. Accreditation of medical laboratories in several first world countries like Japan, USA, and Canada is regulated by provincial health authorities. In Canada, five out of ten provinces have provincial accreditation bodies. The other provinces have developed their own standards using the Canadian Council on Health Services Accreditation (Hui and Adeli, 2009). Total Quality Management (TQM) is an example of a system used to implement quality service. TQM has been adopted by laboratories in China, USA, and other first world countries (Neel *et al.,* 1998). In several less developed countries in Asia, like Bhutan, Bangladesh, Korea, Maldives, Nepal, and Sri Lanka there is no

formal accreditation (WHO, 2003), while in India accreditation is on a voluntary basis largely in private laboratories (WHO, 2003).

Quality implementation measures involve quality management systems (Basu, 2004). TQM is based on the participation of all the laboratory members and aims at long-term success through customer centeredness and satisfaction (Gentile *et al.,* 2007; KEBS, 2007; Rodez *et al.,* 2009). Quality assurance relates to activities needed to provide adequate confidence in assay results and involves inspection in order to ensure accuracy, precision and resultantly valid results (Saad and Siha, 2000). Diagnostic laboratories in places like Germany (Conraths and Schares, 2006), England (Furrows and Ridgway, 2001) and the US (Saliki, 2000) operate according to standard quality management procedures. Quality is maintained in the laboratory using internal quality assurance and locally using external quality assurance programs (Furrows and Ridgway, 2001). Laboratories in Europe, (Gouget, 2009; Kovacs, 2004) USA and Canada (Hui and Adeli, 2009) have networks of private external quality assurance schemes.

2.2 Regional expectations of quality medical laboratory services

Most African countries are barely able to sustain the basic requirements for technology and most medical laboratories in the third world are struggling to bring in line cost effective technologies (Eleuch, 2011; Glencross *et al.,* 2008; Ishengoma *et al.,* 2009; Kamau, 2013). Health care in Africa is under the same capricious rule as all other services. Investment in laboratories is poor and most patients have no access to medical laboratories (Petti *et.al.,* 2006). Where laboratories are present there is often lack of diagnostic tests in the available laboratories (Gray and Carter, 1997; Saliki, 2000). In sub-Saharan Africa laboratory services are limited by inadequate human

resources, infrastructure and supplies (Mallapaty, 1999; Cohen, 2007; Kenya *et al.*, 2012). In many of these countries, laboratory services are grossly neglected and under-utilized with the test results that are produced frequently ignored by clinicians, who often treat patients according to their empirical clinical judgment leading to the misuse of drugs and other resources (Kamau, 2013; Pornsilapatip *et al.*, 1990).

In several African countries, like Nigeria, Ghana, Burkina Faso, Malawi, Zambia, Uganda, Tanzania and Kenya, the laboratory assays to identify infections are routinely unavailable, and investigators frequently neglect the importance of diagnostic testing (Bates and Maitland, 2006). However, studies in Nigeria on client satisfaction reported that in spite of the level of services provided most of the clients were satisfied with the laboratory services (Ige and Nwachukwu, 2010). Still, for many common infections in sub-Saharan Africa, clinical diagnosis is not adequately sensitive or specific (Bates and Maitland, 2006).

2.3 The concept of quality

Quality is an interdisciplinary concept that is a dynamic process not a static goal (Saad and Siha, 2000). In health service delivery quality it is of paramount importance. However, quality still means different things to different stakeholders. The stakeholders of laboratory services are patients who require the tests, clinicians and/or medical officers and health management teams (Shahangian and Snyder, 2009).

If stakeholders of the laboratory are to perceive quality service, the determinants include availability, and equipment (Ishengoma *et al.,* 2009), competence and credibility of the staff

(KEBS, 2007; Parasuraman *et al.,* 2004) and proper leadership where the head of the laboratory is adequately trained and not a laboratory attendant or other person not authorized to carry out laboratory procedures (Ishengoma *et al.,* 2009). KEBS (2007) determinants of quality include process indicators like documentation, planning, cleanliness and are based mainly on parameters developed by WHO.

Without the medical laboratory assay results, the physicians base diagnosis on signs and symptoms involving human senses (Ishengoma *et al.,* 2009). This is a strategy that includes the patient's description of the condition, assumes the physician and the patient's senses are highly developed and assumes effective articulation of the problem by the patient. Laboratory methods have the potential to be highly precise and give highly suggestive findings because laboratories use instruments and exact methods (Kovacs, 2004). There are many illnesses where variable signs and symptoms manifest in different individuals and it is in these cases that the laboratory plays an important role (Saliki, 2006).

2.4 Evaluating quality laboratory service

Measuring service can be considered under three factors namely the practitioner competence, the compliance to practice design and the management of the assay process (Price, 2005). The first factor, the practitioner competence, is often considered the most important resource of any organization (Armstrong, 1999). The human resource's individual competence, influenced by the personal traits, has a bearing on how the enterprise is established and run, and the delivery of service (Armstrong, 1999; Price, 2005). The practitioners serving the health sector have been documented to be mismanaged, with multiple authorities competing for their control (MOH,

1994). Competence is achieved by gaining knowledge through education and training (Chandrasekar, 2011)

The second factor is compliance to practice characteristics which ranges from access (Kenya *et al.,* 2012), to tangibles which include physical facilities and equipment (Parasuraman *et al.,* 2004). The essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF 1996) concluded that many laboratories were built without designated laboratory rooms and had no access to electrical power or running water. The study investigated public laboratories, leaving a gap in the investigation of the laboratories that are faith based and those that are private. The research did not categorize by socioeconomic status and study laboratories with limited financial resources while in reality Kenyans have access to both public and private laboratories (Kenya *et al.,* 2012). This was a study that viewed quality from a dimension of quality inspection based on the application of quality standards and was not oriented to the more advanced (Yusof and Aspinwall, 2000; KEBS, 2007) quality concept of meeting the customer's needs.

The third quality factor was management of the assay process (Badri, Attia and Ustadi, 2009). According to the MOH/AMREF (1996) and Kamau (2013), laboratory techniques were poorly standardized, outdated techniques were still in use and quality assurance activities were not routinely carried out to ensure reliability of the assay results. According to the MOH, the public provision of health in Kenya had generally failed (MOH, 1994; MOH/AMREF, 1996).

2.5 The human resource

2.5.1 The laboratory practitioner competence

The human resource factors that affect service provision have been widely researched (Armstrong, 1999; Timmons and Spinelli, 2003; Rao, 2004). Many personal factors are subjective and semantic differences exist among the dimensions, for example terms like leadership, confidence and creativity have many connotations. Commitment and determination were considered to be important success factors by several researchers. The UK Rennes SME survey (1995-1997) and Tandon's studies inference was that owners who were committed to their firms were no more successful than those showing less involvement (Hankinson *et al.,* 1997; Tandon, 1987). According to Bird (1989), the paramount personal competencies required were an internal focus of control and leadership skills. Leadership was considered key in the concept of hospital quality service (Eggli and Halfon, 2003). Empirical studies by Tandon (1987) did not suggest leadership to have any bearing on venture performance.

Laboratory workers need constant training in order to establish, maintain and demonstrate the accuracy of diagnostic tests, a major challenge for most laboratories in sub-Saharan Africa. The Ministry of Education (MOE) Sessional Paper No. 6 states that training should include skills acquisition at a level commensurate with the resources available (MOE, 1998). The process of laboratory diagnosis requires that after practitioners have learned to perform assays they learn though experience and by attending workshops and seminars how to improve and offer better quality of service (Saliki, 2000)

Traditional attempts to describe competency were conceptualized to have been in terms of knowledge, skills and attitudes (Shahmandi, 2011) while current attempts tend to focus instead on the specific success, traits, and motivation (Shih, 2001). Motivation, particularly achievement motivation (n-Ach) and personality, was identified as most predisposing to successful activity (Manimala, 1999). Motivation may result from push or pull factors. Pull factors include having successful parents or positive role models. Push factors include being retrenched, retired or dissatisfied with prior employment. Studies have indicated that motivation correlates with success (Shih, 2001). People who were devoted wanted to utilize their skills, wanted to follow the example of a person admired, and were concerned about their own status were more likely to succeed. Findings in Kenya indicated that family background, education, training, and knowledge of the enterprise were key performance success factors (Kibas and K'Aol, 2004).

2.5.2 Demographics

Studies have demonstrated that socio-demographic variables are significantly important in determining healthcare quality, patient satisfaction, and patient trust (Alrubaiee and Alkaa'ida, 2001). Based on theory, the practitioner's credibility is influenced by the age, gender, the number of years of experience, the marital status, race or tribe, and training in the related industry (Alrubaiee and Alkaa'ida, 2001; Kantis *et al.*, 2002; MoE, 1998; Timmons and Spinelli, 2003). Competencies like religious affiliation, ethical or moral standards have been considered important by researchers (Puchalski, 2009). In the developed world, more than 75 percent of medical schools teach topics related to spirituality and health, and hospitals are beginning to develop spirituality programs to increase the delivery of compassionate care (Puchalski, 2009).

Researchers have also found significance of patient's demographic variables in moderating their satisfaction (Alrubaiee and Alkaa'ida, 2001).

2.6 Compliance with practice quality

The tangible clues to compliance with practice quality include the laboratory design and layout, physical facilities, equipment, reagents, SOPs and basic amenities (Parasuraman *et al.,* 2004; Price, 2005). The essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996) gives a detailed account of the specific requirements of a clinical laboratory. Recommendations are that laboratories should be well planned and supplied with all essential facilities plus recommended equipment to enable staff perform essential tests and offer quality service (MOH/AMREF, 1996; MOH/KMLTTB, 2005).

2.7 Quality assurance management systems for the assay process

According to the KEBS Quality Management Systems Requirements (KEBS, 2007), the analytical process is an activity that uses resources to enable the transformation of inputs into outputs. Laboratory work may be divided into three stages; pre-analytical, analytical and post-analytical (Price, 2005). Quality is affected by the stage of the process. Pre-analytical quality involves planning (Feeny and Zairi, 1994; Price, 2005), ensuring that equipment is working properly and tests being affordable (Price, 2005). Basic features of analytical quality include the reliability of methods, and observance of safety procedures (MOH/AMREF, 1996). Reliability involves keeping of records correctly and performing the service at the designated time (Parasuraman *et al.,* 2004). Post-analytical considerations include documentation, disposal of waste, and the standardization of the assay (Price, 2005).

In health service delivery, quality is of paramount importance. If stakeholders of the laboratory are to perceive quality service, the determinants include good accessibility, qualified and competent staff (KEBS, 2007; Parasuraman *et al.,* 2004), and affordability (Ishengoma *et al.,* 2009).

According to KEBS (2007), quality determinants include process indicators like documentation, planning, cleanliness and are based mainly on parameters developed by Parasuraman *et al.* (1985). Service quality evaluation, therefore, not only involves the technical quality (outcome) but also the functional quality or process (KEBS, 2007; Parasuraman *et al.,* 1985; Price, 2005). An advantage of laboratory service is that information obtained establishes a permanent record and justifies the subsequent treatment.

2.8 Customer focus

The increase in number of service quality patient satisfaction studies over the past few years indicates that the concept of quality improvement has become more important year by year in the service industry and stresses the importance of patients' views as an essential tool in the processes of monitoring and improving quality of healthcare services (Alrubaiee and Alkaa'ida, 2011). Quality is increasingly perceived to be judged not by the producer but by the receiver (KEBS, 2007). Based on those researchers, a true measure of acceptable quality is customer satisfaction, which takes into account both the objective and subjective interpretations of the needs and expectations of the customer and stakeholders (Gentile *et al.,* 2007; KEBS, 2007; Price, 2005; Rhaman, 2001).

2.9 Policy affecting the medical services

Quality laboratory testing is crucial to confirm clinical diagnoses, and direct public health care policy (Petti *et. el.,* 2006). In its government policies, Kenya is committed to achieving better health for all its citizens and recognizes delivery of basic health packages as a national primary strategy (MOH, 2001). The strategy focuses upon key issues, like quality assurance, service coverage (WHO, 2012), practitioner management and training, and infrastructural capacity (MOH, 2001). This strategy is stipulated in the laws of Kenya including the KMLTTB Act No. 10 of 1999, the Public Health Act Cap. 242, the Clinical Officers (Training, Registration and Licensing) Act Cap. 260, and the Malaria Prevention Act Cap. 246.

In Kenya, medical laboratory services spread across a broad range of providers including private or individual practitioners, Non Governmental Organizations (NGOs), Community Based Organizations (CBOs), faith-based and public health facilities. The government adopts a collaborative inter-ministerial approach to the co-ordination and improvement of health services. As a result, the Kenyan health sector comprises of NGOs, missions, private and public health facilities. In Kenya, health services are delivered through a network of registered health facilities, with the public health system accounting for 51% of the total number of facilities (MOH, 1999). Medical laboratories are grouped into various categories (MOH/ KMLTTB, 2002; Kenya *et al.*, 2013) based on administrative structure devolving from the national and county levels. This excludes other criteria such as assays performed, work load and work capacity, staffing norm, and types of patients served. The general quality standards include employment of qualified technical laboratory staff, application of safety procedures, recording and maintenance of laboratory generated data, disposal of waste products, preparation of the patient and

incorporation of internal and external quality assurance schemes (Shahangian and Snyder, 2009). According to the classification by the KMLTTB, medical laboratories fall into categories based on capacity and the level of affiliated hospital housing the laboratory. The categorization is level 1: dispensary, level 2: health centre, level 3: former sub-district, level 4: former district, level 5: former provincial and level 6: national or referral. The Board classification tends to focus the government operations. A Tanzania model in the study of health laboratories in the Tanga region covered both the private and government practice but it also lacked socioeconomic perspectives (Ishengoma *et al.*, 2009).

The mandate of health services in Kenya is primarily vested with the MOH under the Public Health Act Cap. 242 of the Laws of Kenya, and under various subsidiary legislations dealing with specific areas of health services provision (MOH, 2001). These include the Pharmacy and Poisons Act Cap. 244, which deals with many of the reagents used in the laboratory. It also includes the Science and Technology Act Cap. 250. This Act deals with all matters relating to scientific and technological activities, including manpower. Of paramount importance is the Medical Laboratory Technicians and Technologists Act, No. 10 of 1999. According to this Act, medical laboratory technologist means a person holding a diploma, higher diploma or a degree in medical laboratory technology. The MOH, Ministry of Health Services and the Ministry of Local Government are the main collaborators in the implementation of laboratory services in partnership with CBOs and religious organizations. The MOH has the responsibility to formulate policies, establish and enforce standards and mobilize resources for health development. The former provincial and district levels of the MOH have the role of implementing health programs and delivering health services.

CHAPTER THREE

3.0 METHODOLOGY

3.1 The study area

The study areas were Nairobi, Mombasa, Kisumu and Nyeri counties. Based on the old constitution, prior 2010, Kenya was divided into 8 provinces, namely Central, Coast, Eastern, Nairobi, North Eastern, Nyanza, Rift Valley and Western. Four former provinces were purposefully selected for this study. Currently, as of the 2013, Kenya is divided into 47 counties (Kenya National Bureau of Statistics, 2012).

The major towns and cities of the eight former provinces and their respective populations prior of 2013 were as follows: Nairobi province, Nairobi city approximate population of 2,143,254 people; Mombasa province, Mombasa city: 665,018; Nyanza province, Kisumu city: 322,734; Central province, Nyeri town: 98,908; Eastern province, Embu town: 42,092; North Eastern province, Garisa town: 50,955; Rift Valley province, Nakuru town: 219366; and Western province, Kakamega town having a population of approximately 73,706 people (Central Bureau of Statistics, 2006). Statistics showed that about 75% of the Kenyan population was concentrated in the agricultural belt northwest from Nairobi to the Uganda boarder. Most of the remaining area was either arid or semi arid and is sparsely populated. The four former provinces having the cities or towns with the highest population were purposefully selected as study areas. The approximate population was 3,000,000 in the selected areas. These study areas are shown in Figure 3.1.

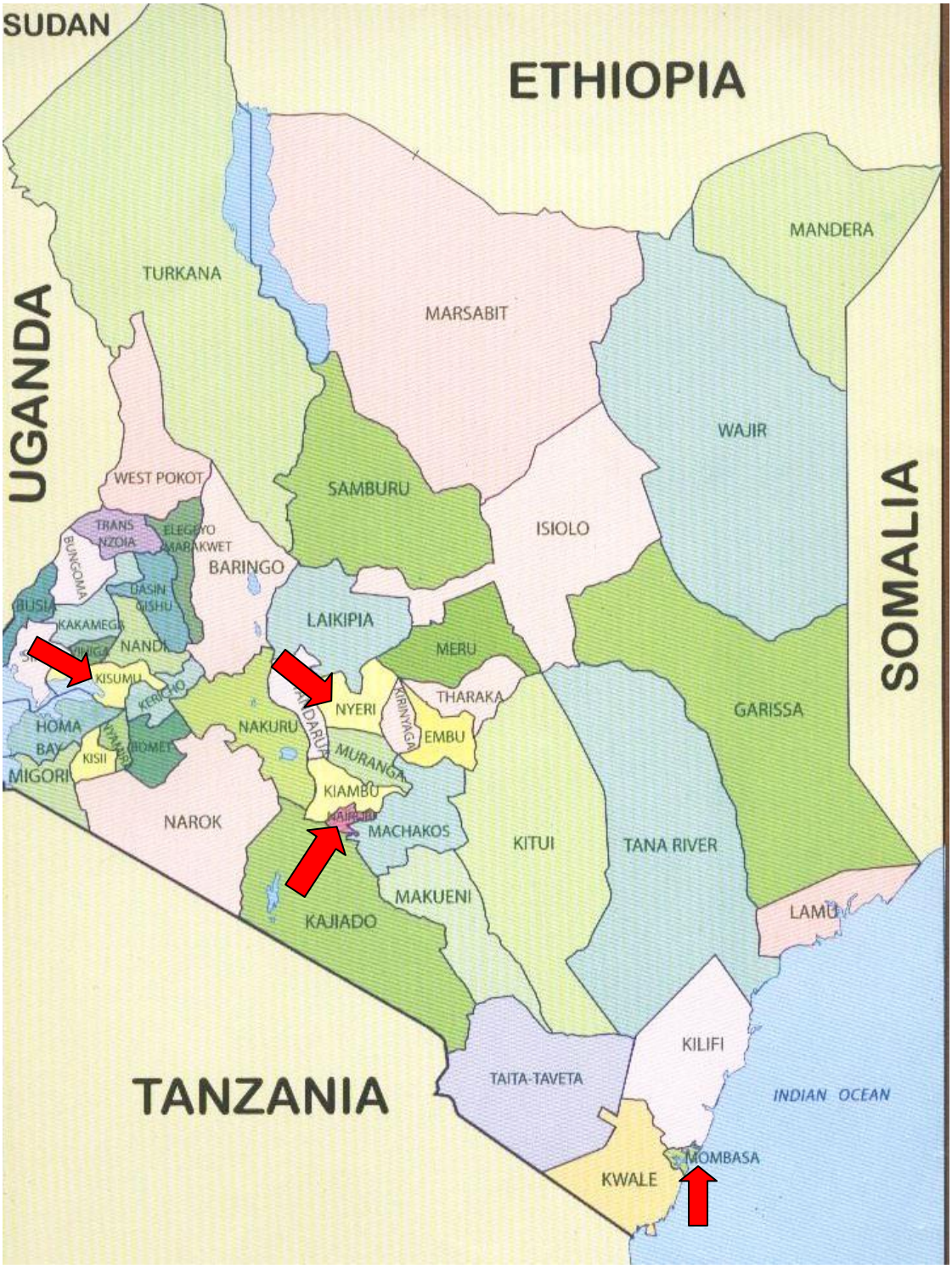

Figure 3.1: Map of Kenya showing the study areas

3.2 The research design

This study was both an observational and descriptive study using a cross sectional design.

3.3 Variables

As described in the conceptual framework, the independent variables for this study were the competence of the laboratory practitioners**,** the compliance of laboratory practice to standard quality, the management of the quality systems for the assay process and the patient's perception of quality laboratory service.

3.4 Study population

3.4.1 Target population

The population for this study constituted the practitioners in the functional medical diagnostic laboratories in the selected four counties. Using the former (prior 2012) provincial boundaries system, the selected Kenyan counties used in this study were Nairobi, Mombasa, Nyeri and Kisumu while as using the current (after 2012) system the counties used were Nairobi, Mombasa, Nyeri and Kisumu.

The medical laboratories were grouped based on categorization in the study of health laboratories in Tanzania (Ishengoma *et al.,* 2009) and the KMLTTB classification (MOH/KMLTTB, 2002). To ensure comprehensive categorization, this research adopted a three-tier criteria which merged the Kenya government categories (which mainly focused on government practice), the Tanzania model (which included government and private practice) and drew a socio-economic category to produce the classification tabulated in Table 3.1**.** The

laboratories in each of the four study counties were grouped into seven strata according to ownership (private, faith based or government) before facilities were randomly selected from each stratum.

Table 3.1: Laboratory groupings

Ownership	Stratum category	Current classification (post 2012)
Government	Provincial	Level 5 and 6
	District	Level 3 and 4
	Regional/ divisional	Level 1 and 2
Faith based	Christian	
Private	High class	
	Middle class, medium level	
	Low class, low socio-economic level	

Source: Ishengoma *et al.,* (2009)/ MOH/AMREF, (1999).

3.4.2 Inclusion criteria

The research included autonomous laboratories, laboratories affiliated to a specific health worker mainly, nurses, clinical officers, laboratories run by community based organizations, NGOs and those run by mission or religious based organizations. Laboratories affiliated to public or government health centers were also included in this study.

The practitioners included in this study were those managers who were willing to participate and allow the researcher to investigate the laboratory and service providers who were employees having worked in the facility for more than three months. Patients included in this study were those of eighteen years and above.

3.4.3 Exclusion criteria

Excluded were all other categories of medical diagnostic laboratories other than clinical laboratories. Any practitioner who was not willing to participate in this study was excluded. Any patient who was under eighteen years of age was also excluded from this study.

3.5 Sampling techniques

3.5.1 Sampling of the laboratories

Laboratories in the four study counties were selected using purposive sampling based on the feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996). In this study, laboratories were selected in Nairobi, Mombasa Kisumu and Nyeri. The sampling technique was based on the study of health laboratories in the Tanga region of Tanzania (Ishengoma *et al.*, 2009).

In this sampling framework, insight into the study issues was based on prior information-rich cases from which a great deal was learned about issues of central importance to the purpose of the research, thus the term purposeful sampling. Based on this criterion, the common and useful denominators for the former provinces chosen were provided. The first criterion used was the population densities of the main towns and cities in the former provinces. The second factor was that in all the former provinces chosen, all the categories of the classification and groupings of the types of laboratory were available. There was in the selected regions at least one provincial, one district and one dispensary laboratory all in the same vicinity. Also, in the same vicinity a faith-based laboratory and a laboratory serving resource poor settings, a laboratory serving the middle class and a laboratory found in a region of affluence. The last criterion used in the

purposive sampling was that those former provinces covered a wide range of the Kenyan population and variations.

When each laboratory was sampled, four different research tools were used: one used for the managers, one for the service provider, one for the practice characteristics and finally a tool for the consumers of the product, that is, the patient. Therefore, the total number of research tools used was a minimum of eighty-two. This figure was arrived at by multiplying (4×7×4= 82). The laboratories were investigated on three separate occasions to ensure reproducibility bringing the figure to a minimum of 246 research tools.

3.5.2 Sampling of the patients

The patients given the instruments were selected randomly (Chandran, 2004) up to a total of 15 based on the study of customer needs (Feeny and Zairi, 1994). The graphic representation Figure 3.2 illustrates the sampling framework used in this research.

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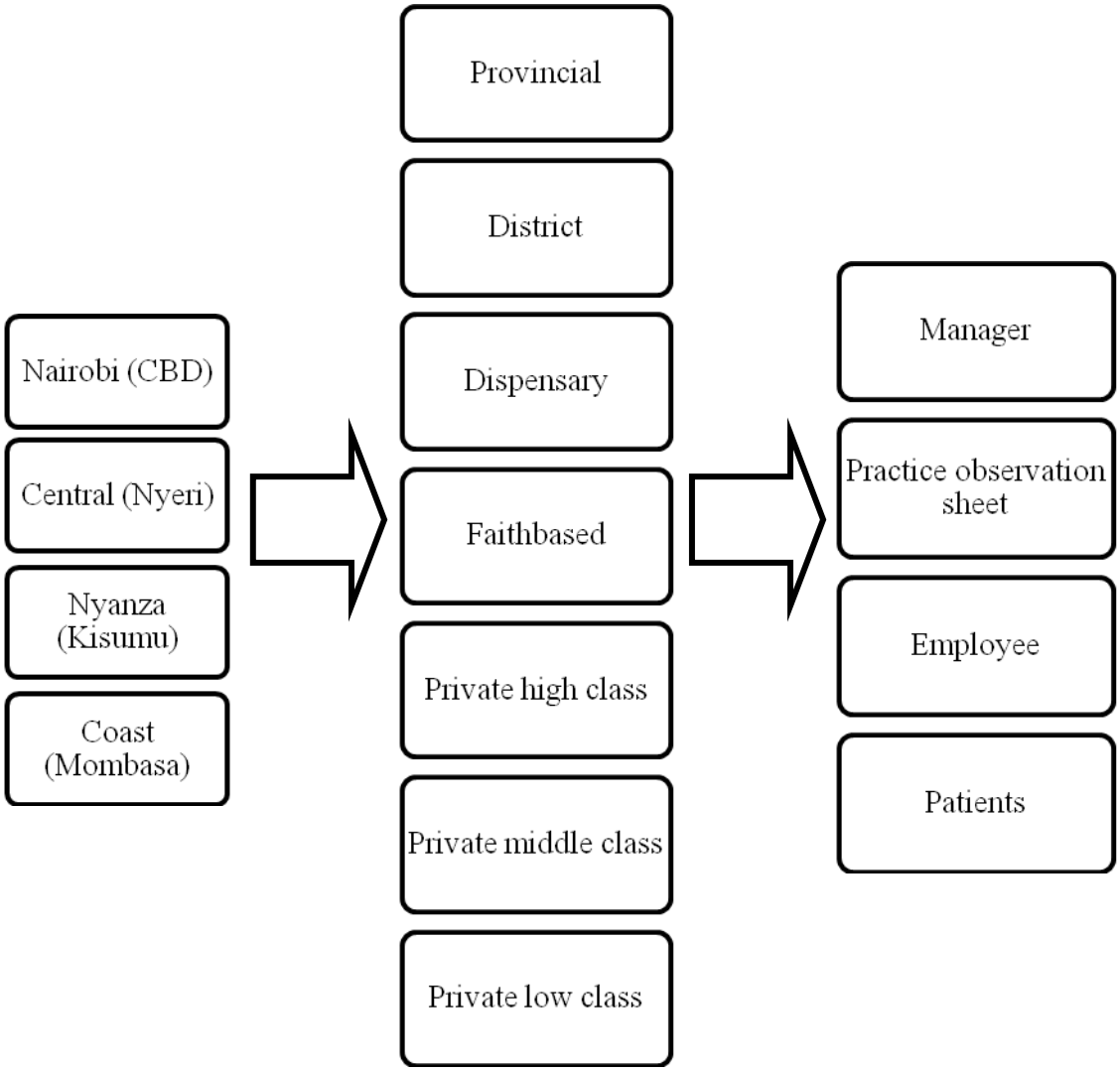

Figure 3.2: The sample collecting mode

Adopted from Ishengoma *et al.* (2009)

3.5.3 Sample size determination

The patient's sample size determination was made considering the population of 3,000,000 in the selected study area. For a margin of error of 5% and a confidence level of 95% the recommended sample size was 385√ (Kirkwood, 2010). In this study n was = 416.

The sample size n and margin of error E are given by

$$x = Z(^{c}/_{100})^{2} r(100-r)$$

$$n = {}^{Nx}/_{((N-1)E^{2} + x)}$$

$$E = \sqrt{\left[{}^{(N-n)x}/_{n(N-1)}\right]}$$

Where N is the population size, r is the fraction of responses that you are interested in, and $Z(c/100)$ is the critical value for the confidence level c. (Kirkwood, 2010).

3.6 Construction of research instruments

Three semi-structured standard questionnaires were used as research instruments (Appendix 1). The questions were adapted from an instrument used in the essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996). The questionnaires were used to determine a number of aspects including; demographics, competencies based on knowledge, skills and motivation, ethics, compliance of practice standards, the quality assurance systems and other themes related to the working environment. Interviews with the health laboratory staff were used to provide information on levels of motivation and attitudes towards work. The interviews were also used to correlate information given by the managers with the information given by the employees or service providers.

3.6.1 Validity

Validity of the research instruments was tested through a pilot study. The questionnaires were pilot tested using randomly selected laboratories in Nakuru county, to refine the instruments to ensure they collect the required data. The respondents who participated in the pilot-testing of the questionnaires did not form part of the main sample frame of the study in order to avoid bias.

Creswell (2003) and Mugenda and Mugenda (1999) advise that validity can be achieved through organization of questions around the central themes of the research and by triangulation. The authors state that other steps used in validation include using member checking, and using discrepant information. Towards this goal, triangulation of different data sources was used as the service providers and managers were interviewed and the observation checklist used fostered this triangulation. Other steps taken to ensure validity were that the questionnaires were taken back to the participants during three subsequent visits and the questions were organized around the four major themes of the research.

3.7 Data collection techniques

The instruments were aligned according to the specific objectives as described. Questionnaires administered ‘on site’ by the researcher were used to establish the type of diagnostic services provided by the study health facilities, the tests performed by the laboratories, the methods used for each test, the availability of SOPs and investigate patient’s views on the factors they consider important in the implementation of quality service. The questionnaires were administered to assess the qualifications of the staff of each health laboratory, training, professional registration, or licensing and other matters related to the working environment.

Interviews with health laboratory staff and direct observations were used to gather information on the cleanliness, specifications of the workroom, availability of basic facilities, methods of disposal and documentation.

3.7.1 Data collection to investigate the effect of the practitioner

The methods of collecting primary data pertaining to the competence of the practitioners were structured interviews using semi-structured standard questionnaires and structured primary observation (Appendix 1). Structured face-to-face interviews minimize weaknesses such as low questionnaire return rates, misinterpretation of questions and other limitations inherent in mailed survey questionnaires (Saunders, 2003).

The motivation scenarios were accompanied by a Likert's scale for participants to provide a rating from 1 (very important) to 4 (not applicable). Leadership was assessed by a Likert's scale for participants to provide a rating from 1 (nil) to 4 (strong).

3.7.2 Data collection to investigate the practice

An observation checklist adapted and modified using parameters developed by the essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996), was used to investigate the practice characteristics using the structured primary observation data collection method. The specific features that were used in this research were the specifications of the main working room and the accessory rooms, the level of security and safety, essential facilities like water, power, drainage disposal and toilets, and the type of equipment used.

3.7.3 The analytical process quality

Analytical quality was investigated by structured primary observation (Cozby, 2004; Creswell, 2003), the questionnaires and a checklist.

3.8 Data analysis

The data was double-entered, cleaned and subsequently analyzed. Data analysis was done mainly using quantitative statistical methods for parametric analysis.

3.8.1 Rating the practitioner

The data on all the workers is presented in tables that list their clinical laboratories, their quality of service ranking and their scores on the individual factors of demographics, competence and leadership traits. The median which is the central value when all the scores are arranged in order or the 50th percentile has been used. The frequency distribution was computed using the Statistical Package for Social Sciences (SPSS) version 19.

3.8.2 Investigating the practice

Descriptive statistics using the mode, median and mean which are a measure of central tendency were used to analyze the effect of the practice. The data in this case was analyzed using Excel spreadsheets and SPSS version 19.

3.8.3 Analyzing the quality management systems involved in the assay process

Measurement of the quality management systems in place was classified into 3 phases: pre-analytical; analytical; and post-analytical. Planning and documentation was analyzed by measures of central tendency mean, median and mode as well as measures of variability (Mugenda and Mugenda, 1999). The assay process was analyzed by the measures of central tendency plus measures of variability. Variability was measured using the range, standard

deviation (SD) and variance. Data was analyzed using least squares regression model and t-tests, contingency table tests (chi) and one way analysis of variance (ANOVA).

Compliance to practice benchmarking standards was investigated using an observation checklist adapted and modified using parameters developed by the essential laboratory feasibility study for primary health care laboratories in Kenya (MOH/AMREF, 1996). The specific features that were investigated in this research were the specifications of the main working room and the accessory rooms, the level of security and safety, basic facilities like water, power, drainage disposal and toilets.

Management of the quality assurance of the analytical process was investigated by structured primary observation (Cozby, 2004; Creswell, 2003), the questionnaires and a checklist. The patient's needs were investigated using a structured questionnaire administered by face-to face interviews in order to elicit patient views on the type of service they deem as good quality.

3.9 Ethical considerations

Kenyatta University Ethics Committee gave ethical clearance for the study with assurance that the results will be used only for study purposes. This was presented to each head of the laboratory and/or service employee worker to increase the chances of participation. Only laboratories where the owner/manager and/or service provider willingly cooperated and agreed that the patients be interviewed were used in this study.

CHAPTER FOUR

4.0 RESULTS

4.1 Assessment of laboratory practitioner's competence

Two categories of practitioners were assessed in order to carry out this research. Those categories are the owner/managers (or bosses) and service providers who were employees. Table 4.1 shows the practitioners who were respondents in this study during the first visit. For subsequent visits only one practitioner was interviewed per visit (n = 56×2 = 112).

Table 4.1: Practitioner respondents on first visit

County	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middles class**	**Private low class**	Total
Nairobi (M)	1	1	1	1	1	1	1	7
Nairobi (E)	2	2	1	3	1	1	2	12
Mombasa (M)	1	1	2	1	1	1	1	8
Mombasa (E)	1	2	3	1	1	1	1	10
Kisumu (M)	1	1	2	1	1	1	1	8
Kisumu (E)	1	2	1	1	2	1	1	9
Nyeri (M)	1	1	1	1	1	1	1	7
Nyeri (E)	2	2	1	1	1	1	1	9
Total	10	12	12	10	9	8	9	

Key

M Manager
E Employee

4.1.1 The practitioner respondents demographic profiles

The demographic characteristics of the practitioners manning the laboratories were reported. Even though the interviewees were randomly selected, far more men than women working in the laboratories were interviewed. Only a third of the laboratory managers who participated in this study were female. In Mombasa county the male female ratio of the respondents was approximately 1:1, in Nairobi approximately 1:1 but in Nyeri and Kisumu counties the ratios were approximately 8:2 and 9:1 respectively. The workforce gender proportions in the selected laboratories were roughly even. The mean male to female ratios of the technical workforce, excluding the auxiliary and support staff, in the laboratories sampled were approximately 49% female and 51% male. The male female ratio of the laboratory practitioners was approximately 1:1. Table 4.2 shows the practitioner demographic profiles categorizing laboratory workers per county and distinguishing between the managers and employees for each demographic parameter.

The largest percentage of the managers that were interviewed were in the 35-44 years age bracket while the biggest percentage of employees interviewed were between 25 and 34 years old as shown in Table 4.2. Employees that participated in this study were of a younger age grouping than their bosses. Majority (55% - 86%) of the laboratory practitioners who participated in this study were married.

Table 4.2: The practitioner's demographic profiles

		Laboratory workers (%) per category		Workers (%) per county			
		Managers	**Employees**	**Mombasa**	**Nairobi**	**Nyeri**	**Kisumu**
Gender	Male	71^{a}±1.2	59^{a}±1.1	50^{a}±0.8	47^{a}±1.3	80^{a}±2.4	90^{a}±1.2
	Female	29^{b}±0.8	41^{b}±0.8	50^{a}±0.6	53^{a}±0.7	20^{b}±1.6	10^{b}±0.8
Age	18-24	0^{b}	6^{c}±1.1	7^{b}±0.6	0^{c}	0^{c}	10^{b}±0.2
	25-34	47^{a}±0.6	53^{a}±0.7	50^{a}±2.4	60^{a}±1.2	40^{a}±0.4	50^{a}±0.8
	35-44	53^{a}±0.8	37^{b}±1.2	43^{a}±0.8	40^{b}±0.8	50^{a}±1.4	40^{a}±1.1
	45-54	0^{b}	3^{c}±0.1	0^{c}	0^{c}	10^{b}±0.6	0^{c}
Marital status	Single	14^{b}±1.2	22^{b}±1.6	29^{b}±0.9	21^{b}±1.3	10^{b}±0.8	10^{b}±0.6
	Married	75^{a}±2.6	74^{a}±3.4	55^{a}±0.8	72^{a}±2.0	79^{a}±1.8	86^{a}±3.4
	Separated	7^{c}±0.4	2^{c}±0.2	14^{c}±0.7	4^{c}±0.2	5^{c}±0.3	1^{c}±0.0
	Divorced	2^{c}±0.1	1^{c}±0.1	1^{d}±0.2	2^{c}±0.3	3^{c}±0.1	1^{c}±0.1
	Widowed	2^{c}±0.2	1^{c}±01	1^{d}±0.2	1^{c}±0.1	3^{c}±0.4	2^{c}±0.2
Religion	Catholic	23^{b}±1.2	26^{b}±1.4	9^{c}±0.8	26^{b}±1.6	51^{a}±2.4	12^{b}±0.5
	Protestant	55^{a}±2.1	53^{a}±1.0	33^{b}±0.5	61^{a}±2.5	38^{b}±1.5	74^{a}±3.2
	Muslim	12^{c}±1.2	9^{c}±0.8	52^{a}±1.5	1^{c}±1.0	0^{d}	2^{c}±0.1
	Indigenous	6^{d}±0.5	6^{c}±0.4	3^{c}±0.2	4^{c}±0.7	8^{c}±0.4	9^{b}±0.4
	Atheist	2^{d}±0.2	3^{d}±0.1	1^{c}±0.1	5^{c}±0.4	2^{c}±0.1	2^{c}±0.2
	other	2^{d}±0.4	3^{d}±0.4	2^{c}±0.7	3^{c}±0.4	3^{c}±0.5	2^{c}±0.1

Values are given as means of triplicates ± SD. Means within the column with different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$)

The majority of managers interviewed were Protestant Christians. There was a significant difference ($p < 0.05$) between the Catholics manning faith based laboratories (57%) and those manning all other categories of laboratories (means ranging from 4% - 10%). A majority (57%) of the Christian faith based laboratories sampled were manned by practitioners predominantly of the Catholic faith.

4.1.2 Assessment of laboratory practitioner's education and training

The laboratories sampled were manned by well educated and trained staff as shown in Table 4.3. Only a minority of the support staff were reported to have no formal training.

Table 4.3: The practitioner's level of education and training

	Laboratory categories							
Education/ Training (%)	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**	**Mean**
Support staff	24.4	17.1	2.4	26.8	14.6	9.8	4.9	14.3
O Dip MLS	41.7	24.1	2.5	10.5	13	7.4	0.9	14.3
H ND MLS	20	6	4	16	24	22	8	14.3
Managers: (%)								
Form four	100	100	100	100	100	100	100	100
Form six	6	4	2	7	9	5	9	6
University Degree	4	2	0	5	10	6	0	3.9
Employees: (%)								
Form four	100	100	100	100	100	100	100	100
Form six	2	1	0	5	6	3	3	2.9
University Degree	1	0	0	2	2	1	0	0.9

Key
Support staff Support staff with no formal training
O Dip MLS Ordinary diploma in medical laboratory science
H ND MLS Higher national diploma in medical laboratory science
Form four Form 4 education prior laboratory training
Form six Form 6 education prior laboratory training

All the laboratories were manned by staff with a basic minimum of ordinary level, Kenyan form four level of education. Very few practitioners were university graduates.

Figure 4.1 shows practitioners' responses on the motive they viewed as important in service provision. The ratings were different for the various laboratory categories. The practitioners in government laboratories placed no emphasis on making money as shown in Figure 4.1.

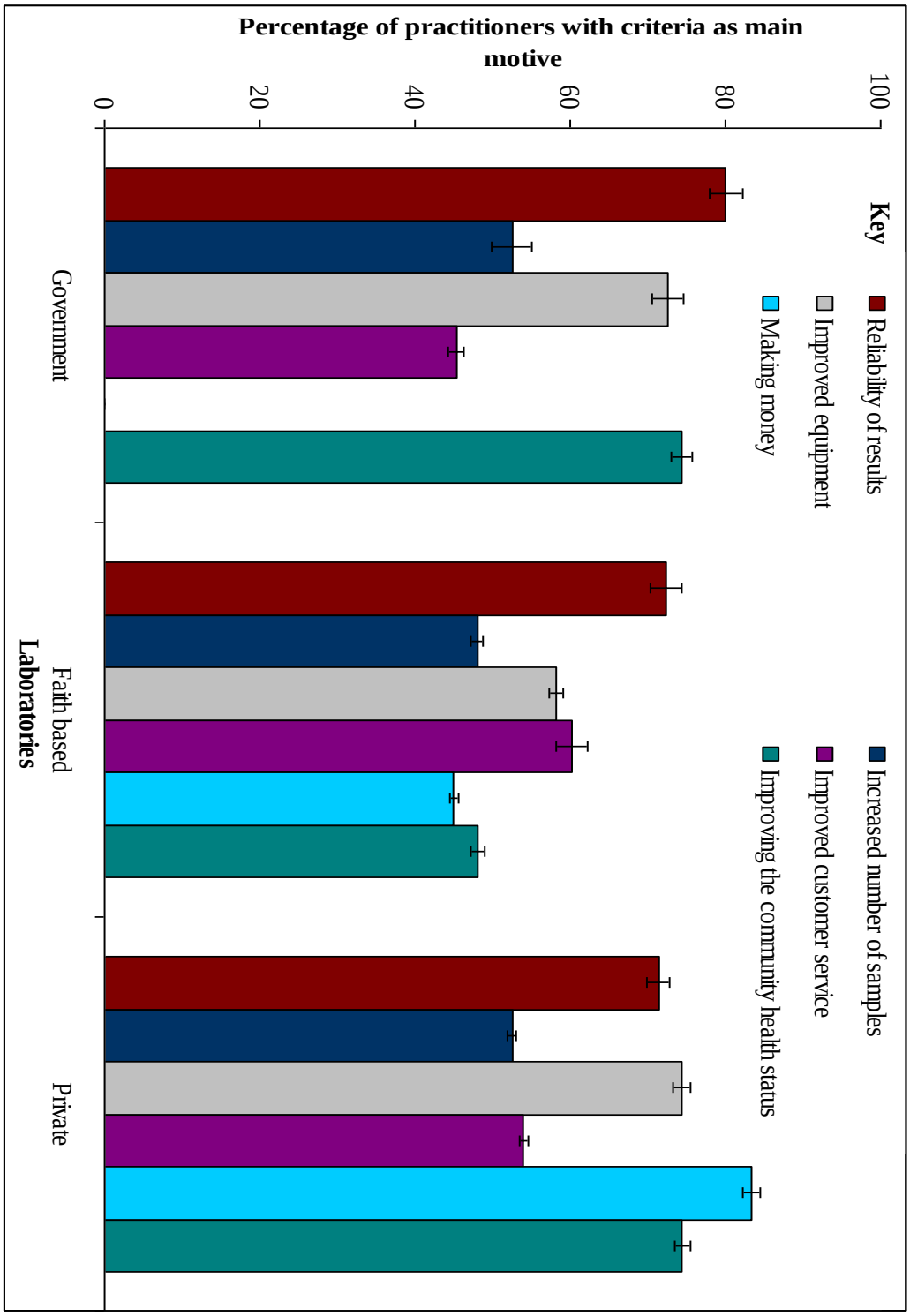

Figure 4.1: Practitioners' motive for service provision

As motivation for working in the current laboratory, practitioners of government owned laboratories rated reliability of results higher than any other motivation factor. Government laboratory practitioners placed the greatest emphasis on reliability of results when compared with faith based and private laboratory practitioners. According to practitioners

of government laboratories, the next most important criteria was improving the health status of the community, improved equipment and lastly the factor they considered important in the implementation of quality service was improving customer service. Faith based laboratory practitioners rated ensuring reliability of results as the most important motivator. Equally and highly rated were improving customer service and improving equipment. Least in rating was making money. Private laboratory practitioners rated making money as their primary motivator. They rated making money as very important in 85% of the cases which was greater than their emphasis on reliability of results, improved equipment and improving the health status of the community. Ensuring reliability of results was rated lowest by the private laboratories in comparison with government and faith based laboratory practitioners.

Table 4.4 shows the manager's ratings of the leadership skills they considered themselves as strongly exhibiting in comparison with the employee's views of the manager's leadership ratings.

Table 4.4: The practitioners' ratings of their leadership trait

Trait	Perceptions of management skills (%)		*p* value
	Laboratory managers' response	**Employee's views of the lab managers.**	
Committed	71.3^{a}±3.7	59.2^{b}±1.8	0.045
Internal locus of control	71.9^{a}±1.9	50.1^{b}±1.9	0.042
Self confident	53.2^{a}±2.2	34^{b}±1.0	0.044
Initiative	65.7^{a}±3.7	68.8^{a}±1.2	0.057
People want to follow	59.8^{a}±1.3	64.5^{a}±0.5	0.056
Readily uses expertise	71.1^{a}±0.8	48.3^{b}±0.7	0.042
Honest	59.8^{a}±2.0	68.4^{a}±1.6	0.051
Inspires	88.6^{a}±1.1	63^{b}±2.0	0.045
Builds strong relationships	59^{a}±1.7	61.6^{a}±1.4	0.060
Empowers	62.5^{a}±2.5	39.1^{b}±1.9	0.038

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

There was a significant difference ($p < 0.05$) between the employees and managers ratings on level of commitment, need to control, initiative, readily using expertise, inspiration and empowerment. Employees did not always agree with the boss's perception of their success traits. In some cases the discrepancies were large, like in the employees' perception that the boss inspires them (variance 25.6). The highest rating they gave their bosses was for initiative and honesty. Very few felt their managers were empowering. Bosses had a higher opinion of their own leadership skills than the opinion the employees had of them. The highest factor that laboratory managers perceived themselves having was that they inspire.

Table 4.5 shows the ratings of the employee's perception of the manager's leadership skills that they considered as strongly exhibiting per laboratory category. There were significant inter group differences ($p < 0.05$) for the employee ratings of their bosses' leadership success traits.

Table 4.5: Employee's ratings of manager's leadership

	Laboratory category						
	Provincial	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Leadership ratings (% of practitioners reporting managers' skill as strong)							
Committed	46^{c}±1.1	54^{c}±0.9	50^{c}±1.7	83^{a}±2.7	46^{c}±0.8	50^{c}±0.7	67^{b}±1.3
Internal locus of control	45^{c}±1.2	51^{c}±3.3	50^{c}±0.0	21^{d}±0	65^{b}±0.5	53^{c}±0.8	100^{a}
Initiative	25^{c}±1.2	71^{b}±3.3	100^{a}	100^{a}	25^{c}±0.5	33^{c}±0.8	67^{b}±1.5
Emulatable	25^{d}±0.9	57^{c}±2.4	75^{b}±2.6	17^{d}±0.6	75^{b}±2.5	5^{e}±0.0	100^{a}
Readily uses expertise	50^{c}±1.6	57^{c}±2.0	100^{a}	83^{b}±4.1	75^{b}±2.1	67^{b}±1.3	33^{d}±2.1
Honest	75^{b}±3.5	57^{c}±1.4	50^{c}±1.3	100^{a}	33^{d}±1.3	67^{b}±1.7	33^{d}±1.0
Inspires	75^{b}±2.4	57^{c}±1.5	25^{d}±1.7	100^{a}	100^{a}	10^{e}±0.0	33^{d}±1.4
Strong relationships	25^{c}±1.2	57^{b}±0.9	25^{c}±1.2	83^{a}±3.1	33^{c}±2.0	33^{c}±0.9	67^{b}±2.2
Empowers	25^{c}±1.8	29^{c}±0.7	2^{d}±0.0	83^{b}±3.7	25^{c}±1.4	2^{d}±0.0	100^{a}

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

Table 4.5 shows that the employees who rated their bosses highly were those of faith based laboratories. The managers who were considered self confident, emulatable and empowering by their employees were those managing private low class laboratories. Those who were rated highly for taking initiative and readily used expertise were those managing dispensary laboratories.

The employees reportorial of the manager's courtesy ratings are shown in Table 4.6. In all sampled laboratories, the practitioners manning provincial, district, faith based and private laboratories were polite, friendly, showed respect to the patients and were clean and neat.

Table 4.6: Employee's ratings of manager's attitudes and certain ethical values

	Laboratory category (% of practitioners)

	Provincial	District	Dispensary	Faith based	Private high class	Private middle class	Private low class
The attitude/courtesy ratings (% of practitioners reporting managers' skill as strong)							
Politeness	100[a]	100[a]	67[b]±1.3	100[a]	100[a]	100[a]	100[a]
Respect	100[a]	100[a]	67[b]±1.7	100[a]	100[a]	100[a]	100[a]
Friendliness	100[a]	100[a]	100[a]	100[a]	100[a]	100[a]	100[a]
Clean, neat personnel	100[a]	100[a]	67[b]±1.2	100[a]	100[a]	100[a]	100[a]
Ethics (% of practitioners reporting managers' skill as strong)							
Safeguard privacy	100[a]	87[a]±1.2	67[b]±2.6	92[a]±1.7	100[a]	96[a]±1.3	94[a]±1.6
Give patient results	100[a]	100[a]	100[a]	100[a]	100[a]	100[a]	100[a]

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

The practitioners in dispensaries were friendly but not all were polite, showed respect to patients nor were clean and tidy. All the practitioners wore clean laboratory coats and were neat. A mean of 75% of the practitioners responded to safeguard patients' privacy and confidentiality. All laboratory workers responded that they only gave results either to the doctor who requested for the test, or to the affected patient. They all reported that they did not give results to the person paying for the test if that person was not the patient.

4.2 Determination of level of compliance to practice standards

Practice standards requirements were met to varying degrees. Table 4.7 shows the level of compliance of physical facilities and the accessory rooms. Table 4.7 shows only the private high class laboratories had 100% compliance with all the determinants of the physical facility indicators and accessory rooms.

Table 4.7: Level of compliance of physical facilities and the accessory rooms

	Laboratory category						
(%) Compliance	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
	Compliance pertaining to physical facilities						
Room ≥5x4m	100^{a}	83^{a}±3.1	67^{b}±1.1	100^{a}	100^{a}	75^{b}±2.4	0^{c}
Smooth floor	67^{b}±1.8	67^{b}±2.1	33^{c}±1.0	100^{a}	100^{a}	100^{a}	0^{d}
Non-slippery floor	100^{a}	100^{a}	33^{c}±1.9	100^{a}	100^{a}	75^{b}±1.8	100^{a}
Window 15% of floor area	100^{a}	83^{a}±2.0	33^{c}±0.5	60^{b}±1.1	100^{a}	83^{a}±2.4	0^{d}
Lockable cupboards	50^{c}±1.6	67^{b}±2.4	33^{d}±0.8	60^{b}±1.4	100^{a}	75^{b}±1.9	0^{e}
Two sinks	100^{a}	100^{a}	67^{b}±1.2	100^{a}	100^{a}	75^{b}±2.3	0^{d}
Lighting	100^{a}	100^{a}	33^{b}±1.4	100^{a}	100^{a}	100^{a}	33^{b}±0.9
	Compliance pertaining to accessory rooms						
Waiting bay	100^{a}	100^{a}	33^{c}±1.6	100^{a}	100^{a}	100^{a}	50^{b}±2.4
Washrooms	100^{a}	83^{a}±2.7	0^{c}	100^{a}	100^{a}	67^{b}±2.2	0^{c}
Storage room	100^{a}	100^{a}	33^{c}±1.3	100^{a}	100^{a}	100^{a}	50^{b}±1.8

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

As seen in Table 4.7, the criteria of having dimensions of 5 × 4 m of the main working room was met by most, 83%, of laboratories. All provincial laboratories, faith based and private high class laboratories had adequate room dimensions. The laboratories that had non-slippery floors were 87%. The windows occupied at least 15% of the floor area in provincial and private high class laboratories. Only private high class laboratories were found to have at least three adequate lockable cupboards with 1× 0.5 meters plus enough shelves in all cases. Provincial, dispensary, faith based, and private high class laboratories all had two sinks. Lighting was adequate in all laboratories except dispensary laboratories and private low class laboratories.

Figure 4.2 shows compliance pertaining to the availability of features for enabling laboratory safety and security. The majority of laboratories had all the features except for fire buckets.

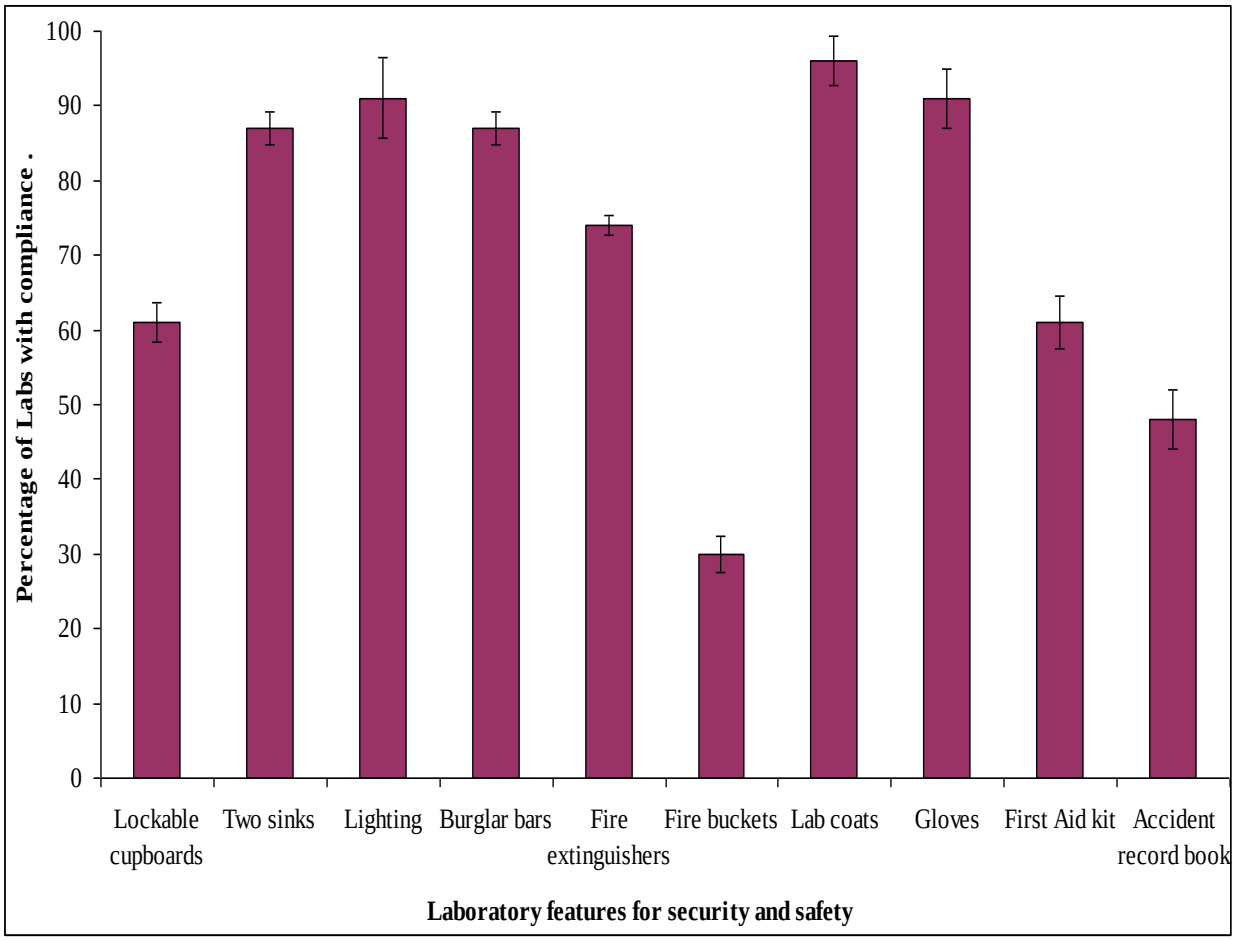

Figure 4.2: Availability of features for enabling laboratory safety and security

All the private high class laboratories had total compliance in availability of tangibles involved in maintaining security and enabling safety. All the laboratories sampled in all categories had secure lockable doors. The provincial laboratories had total compliance in every factor considered for security and safety, except having fire buckets which only 50% of the laboratories complied with. The compliance rating of the private low class was the lowest.

Table 4.8 shows the level of compliance of the basic amenities. Those were water, power and drainage. All laboratories sampled were compliant in having either running water or a container with stored water.

Table 4.8: Level of compliance of the basic amenities

	Laboratory category						
(%) Compliance	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Compliance pertaining to water as a basic amenity							
Running tap water	100^{a}	100^{a}	$33^{c}\pm1.9$	100^{a}	100^{a}	100^{a}	$50^{b}\pm1.2$
Container with tap	$50^{b}\pm2.2$	$33^{c}\pm1.6$	100^{a}	$80^{a}\pm3.4$	100^{a}	$50^{b}\pm2.0$	$50^{b}\pm1.8$
Compliance to power as a basic amenity power and drainage							
Electricity	100^{a}	100^{a}	$50^{c}\pm1.5$	100^{a}	100^{a}	100^{a}	$67^{b}\pm1.9$
Solar	$50^{a}\pm2.4$	$50^{a}\pm1.6$	$50^{a}\pm2.2$	$40^{a}\pm1.1$	$50^{a}\pm0.9$	0.0^{c}	$33^{b}\pm1.5$
Closed drainage	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}
Disposal facilities	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

Table 4.8 indicates that all the laboratories met the required criteria for electricity. All the laboratories had either a main power supply or an outside charger solar system and met the criteria in having electrical power points. Some laboratories had both systems and could use a generator in case of power shortage. Either system was considered adequate as long as there was provision of electrical power points. The laboratories had a closed drainage from the laboratory sink to a septic tank or a deep covered pit and an incinerator, or a brick constructed or metal drum with a deep covered pit for disposal of ashes.

4.3 Assurance of quality management systems of the assay process

4.3.1 Quality assurance of the pre-analytical process

Table 4.9 shows a comparison of the managers and the employees reportorial on whether they hold regular staff meetings and if they have good work plans.

Table 4.9: Practitioner's reportorial on meeting and planning

	Manager's views		Employee's views	
Laboratory category	**Hold regular meetings**	**Good work plan**	**Hold regular meetings**	**Good work plan**
Provincial	100^{a}	100^{a}	100^{a}	100^{a}
District	$50.5^{c}\pm2.1$	$70.4^{b}\pm2.1$	$37.5^{d}\pm0.9$	$62.5^{b}\pm1.7$
Dispensary	$50.2^{c}\pm3.0$	$60.7^{b}\pm1.6$	$50.6^{c}\pm1.2$	$50.5^{c}\pm3.1$
Faith based	$67.3^{b}\pm2.7$	100^{a}	$50.1^{c}\pm1.1$	$75.7^{b}\pm2.5$
Private high class	$67.5^{b}\pm1.8$	$83.5^{a}\pm3.2$	$50.9^{c}\pm2.4$	$75.5^{b}\pm3.3$
Private middle class	$80.5^{a}\pm2.9$	100^{a}	$67.5^{b}\pm2.8$	100^{a}
Private low class	100^{a}	100^{a}	100^{a}	100^{a}

Values are given as means of triplicates ± SD. The means in the same column having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

There were significant inter group differences between laboratory owners and the laboratory service providers' responses on whether they held regular staff meetings in their laboratories as seen in Table 4.9. The laboratory practitioners were asked if there had a good work plan in their laboratories and 84% of the laboratory service providers agreed that they had good work plans. The government owned laboratories that indicated they had good working plans were 75%. The respondents from government owned laboratories had the largest number of laboratories that did not have a good working plan.

The laboratories categories that reported holding regular staff meetings in all cases were the provincial and private low class. The private laboratories reported holding regular staff meetings more than the other types of laboratories while the government owned laboratories reported they held meetings in their laboratories less frequently especially for the district and the dispensary laboratories. Private high class and faith based laboratories had the lowest ratings based on the employees views on regularity of staff meetings with only fifty percent of the laboratories reporting that meeting were held on a regular basis. There were significant differences ($p < 0.05$) between the managers and the employees reportorial on holding regular meetings and having good work plans except in the cases of provincial and private low class laboratories.

Table 4.10 shows the reportorial on the existence of other pre-analytical factors like pre-analytical documentation and cleanliness. The private laboratories and faith based personnel all had clean and tidy laboratory coats, and were generally clean and tidy. The laboratories were clean and tidy, including the work benches.

Table 4.10: The pre-analytical process

	Laboratory category						
(%) Compliance	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Clean neat lab coats	$96^{a}\pm1.0$	$83^{a}\pm2.2$	$10^{c}\pm1.2$	100^{a}	100^{a}	100^{a}	100^{a}
Clean neat personnel	100^{a}	100^{a}	$67^{b}\pm1.7$	100^{a}	100^{a}	100^{a}	100^{a}
Tidy lab	$70^{b}\pm1.9$	$70.0^{b}\pm2.8$	$85^{a}\pm2.2$	100^{a}	100^{a}	100^{a}	100^{a}
Tidy bench	$80^{b}\pm1.5$	$80.0^{b}\pm2.9$	$90^{a}\pm2.3$	100^{a}	100^{a}	100^{a}	100^{a}
Well displayed SOPs	$80.3^{b}\pm2.4$	$75.6^{b}\pm1.9$	$70^{b}\pm2.2$	$89.1^{a}\pm3.1$	100^{a}	100^{a}	$75.7^{b}\pm1.2$

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

The government laboratories had significant differences ($p < 0.05$) in the percentage of clean and neat personnel wearing clean and neat laboratory coats. There were also significant differences ($p < 0.05$) among the government laboratories which were clean and tidy and maintained clean and tidy work benches. In all categories of laboratories, there were significant differences ($p < 0.05$) in the having well displayed SOPs.

4.3.2 Quality assurance of the analytical process

Table 4.11 shows the quality assurance measures in place for the analytical process. There were significant between group differences ($p < 0.05$) between the various laboratory categories quality assurance implementation. There were also significant within group differences ($p < 0.05$) between the quality assurance measures in place in each laboratory category.

Table 4.11: Quality assurance measures

Reporting measure often used (%)	Laboratory category						
	Provincial	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Repeating assays	$21.2^{c}\pm1.1$	$19.9^{c}\pm1$	$20.3^{c}\pm0.9$	$33.4^{b}\pm1.2$	$50.3^{a}\pm1.8$	$20.4^{c}\pm1$	$25.6^{c}\pm1.4$
Triplicate assays	$12.4^{c}\pm0.2$	$12.2^{c}\pm0.9$	$11.7^{c}\pm0.2$	$22.8^{b}\pm1$	$33.5^{a}\pm1.5$	0^{d}	$26.1^{b}\pm1.2$
Standardized kits	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	$75.4^{b}\pm1.9$
Control samples	$79.7^{a}\pm1.8$	$60.3^{b}\pm1.2$	$21.4^{c}\pm0.8$	$89.4^{a}\pm2.1$	$67.1^{b}\pm1.7$	$61.6^{b}\pm0.9$	$50.0^{c}\pm1.7$
Inter lab trials	$41.6^{a}\pm1.3$	$21.3^{b}\pm0.8$	$19.9^{b}\pm0.5$	$44.8^{a}\pm1.6$	$40.0^{a}\pm1.1$	$19.8^{b}\pm0.8$	$25.6^{b}\pm0.9$
Automation	$62.8^{b}\pm1.1$	$50.9^{c}\pm1.2$	$40.5^{d}\pm1.5$	$33.2^{d}\pm0.5$	$81.2^{a}\pm2.2$	$81.6^{a}\pm2.4$	$52.3^{c}\pm1.3$
Refresher courses: Managers	$95.7^{b}\pm0.9$	$91.5^{b}\pm1.4$	$51.3^{c}\pm1.6$	100^{a}	100^{a}	100^{a}	$51.1^{c}\pm1.6$
Refresher courses: Employee	$87.7^{b}\pm0.9$	$80.5^{b}\pm1.4$	$11.3^{c}\pm1.6$	100^{a}	100^{a}	$95.4^{a}\pm2.1$	$11.1^{c}\pm1.6$

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

As seen in Table 4.11, routinely repeating sample assays was reported as rare and in most laboratories never done. Private high class laboratories fared the best, with 50% reporting to frequently repeat sample assays. None of the laboratories routinely performed triplicate assays. Standardized kits were reported to be frequently used by 81% of the respondents. All government laboratories, faith based, private high and middle class laboratories reported the use of standardized kits. Seventy five percent of private low class laboratories reported the use of standardized kits. Control samples were used regularly except in dispensaries. In all categories of laboratories, inter laboratory trials were rare. All managers of faith based, and private high and

middle class laboratories attended refresher courses regularly. More managers attended refresher courses frequently than employees.

Table 4.12 shows the reportorial of analytical process documentation, requisitioning and safety measures. As shown, all provincial, faith based, private high and middle class laboratories constantly compared request forms with sample details. No laboratory categories reported never having requisitioning difficulties. All laboratories, except private low class reported constantly labeling all samples. All laboratories, however, reported there were cases of labeling errors. All laboratories reported there were incidences of specimens lacking integrity. In no category of laboratory were all practitioners aware of how to use fire extinguishers. In no case did all practitioners report knowing where fire buckets were. Only faith based and private high class laboratories reported that practitioners always wore laboratory coats. No laboratory reported wearing of gloves constantly. All practitioners reported knowledge of first aid. All provincial and private high class laboratories had accidents records book.

Table 4.12: Reportorial of documentation, requisitioning and safety measures

	Laboratory category						
% Reporting measure often used	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Reportorial of analytical process documentation and requisitioning (%)							
Request forms c/w sample details	100^{a}	$75^{b}\pm1.1$	$76^{b}\pm2.0$	100^{a}	100^{a}	100^{a}	$83^{a}\pm0.9$
Requisitioning difficulties Constantly	$75^{a}\pm2.2$	$51^{b}\pm1.3$	$25^{c}\pm0.4$	$10^{e}\pm1.2$	$12.5^{d}\pm0.6$	$33^{c}\pm1.0$	$10^{e}\pm1.4$
Sample labeling and integrity (%)							
Samples labeled	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	$67^{b}\pm1.2$
Labeling error	5^{b}	5^{b}	1^{b}	1^{b}	1^{b}	1^{b}	$67^{a}\pm0.9$
Specimen Lacking integrity	30^{a}	$25^{a}\pm0.8$	$25^{a}\pm0.2$	27^{a}	$25^{a}\pm1.1$	23^{a}	25^{a}
Implementation of safety measures (%)							
Knowledge of use of fire extinguishers	$79^{a}\pm1.1$	$57^{b}\pm1.3$	$23^{c}\pm0.1$	$80^{a}\pm0.9$	$90^{a}\pm1.4$	$57^{b}\pm1.1$	$50^{b}\pm0.2$
Knowledge where fire buckets are	$51^{b}\pm1.5$	$10^{c}\pm0.9$	$10^{c}\pm0.4$	$21.2^{c}\pm1.1$	$91.1^{a}\pm2.3$	$11^{c}\pm0.3$	0^{d}
Wearing of lab coats	$89^{a}\pm1.3$	$90^{a}\pm2.0$	$67^{b}\pm0.9$	100^{a}	100^{a}	$90^{a}\pm0.8$	$90^{a}\pm1.1$
Wearing of gloves	$80^{a}\pm1.2$	$83^{a}\pm2.1$	$67^{b}\pm1.0$	$90^{a}\pm1.4$	$91^{a}\pm0.8$	$90^{a}\pm3.1$	$90^{a}\pm0.9$
First aid measures per laboratory category							
Knowledge of first aid	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}	100^{a}
Accidents record	100^{a}	$51^{c}\pm1.2$	0^{d}	$41^{c}\pm0.6$	100^{a}	$67^{b}\pm0.9$	0^{d}

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

4.3.3 Quality assurance of the post-analytical process

All provincial, district, faith based, private high class and private middle class laboratories had adequate disposal facilities. Only 50% of the sampled private low class laboratories and 33% of

the sampled dispensaries had adequate disposal facilities consisting of either an incinerator, a metal drum or a deep covered pit.

Table 4.13 shows the practitioners' reportorial on the level of implementation of strategies to minimize errors. There was no category of laboratory that was rated good.

Table 4.13: Practitioners' reportorial on strategies to minimize errors

	Laboratory category						
	Provincial	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Work checked (%)							
Daily	$25^{c}\pm2.1$	$13^{c}\pm0.4$	$75^{a}\pm2.5$	$83^{a}\pm2.9$	$27^{c}\pm1.1$	$67^{b}\pm2.1$	$67^{b}\pm1.4$
Weekly	$25^{b}\pm1$	$25^{b}\pm2.1$	$25^{b}\pm1.5$	$17^{c}\pm1.1$	$50^{a}\pm2.0$	$33^{b}\pm1.0$	0^{d}
Monthly	$50^{a}\pm2.3$	$62^{a}\pm1.2$	0^{c}	0^{c}	0^{c}	0^{c}	$33^{b}\pm0.6$
Never	0^{b}	0^{b}	0^{b}	0^{b}	$23^{a}\pm0.6$	0^{b}	0^{b}
Results integrity problems (%)							
Constantly	0^{b}	$26^{a}\pm1.7$	$24^{a}\pm1.0$	0^{b}	0^{b}	0^{b}	$33^{a}\pm1.2$
Rarely	$24^{a}\pm1.1$	$10^{b}\pm2.3$	$6^{c}\pm2.1$	$13^{b}\pm0.4$	$13^{b}\pm0.4$	$13^{b}\pm0.4$	$33^{a}\pm1.1$
Never	$76^{b}\pm1.9$	$64^{b}\pm2.3$	$70^{b}\pm2.3$	$87^{a}\pm1.3$	$87^{a}\pm1.3$	$87^{a}\pm1.3$	$33^{c}\pm1.3$
Calculation of means (%)							
Daily	$26^{b}\pm1.4$	$12^{c}\pm1.0$	0^{d}	$17^{c}\pm0.6$	$77^{a}\pm2.1$	$32^{b}\pm0.3$	0^{d}
Weekly	0^{b}	0^{b}	$25^{a}\pm1.7$	$34^{a}\pm1.0$	$23^{a}\pm1$	0^{b}	0^{b}
Monthly	$51^{a}\pm1.1$	$24^{b}\pm1.1$	$24^{b}\pm1.2$	$49^{a}\pm2.1$	0^{c}	$35^{b}\pm1.1$	0^{c}
Rarely	$23^{a}\pm0.4$	$13^{b}\pm0.4$	0^{c}	0^{c}	0^{c}	0^{c}	$33^{a}\pm0.9$
Never	0^{c}	$51^{a}\pm1.3$	$51^{a}\pm2.1$	0^{c}	0^{c}	$33^{b}\pm0.3$	$67^{a}\pm2.1$
Requesting retesting sample (%)							
Constantly	$24^{a}\pm1.1$	$13^{b}\pm0.4$	0^{c}	0^{c}	0^{c}	$33^{a}\pm0.2$	0^{c}
Rarely	$66^{b}\pm1.9$	$87^{a}\pm1.3$	$51^{b}\pm2.1$	$91^{a}\pm1$	$91^{a}\pm1$	$33^{c}\pm0.4$	$50^{b}\pm2.1$
Never	$10^{b}\pm2.3$	$11^{b}\pm1.3$	$49^{a}\pm1.1$	$9^{b}\pm2.3$	$9^{b}\pm2.3$	$33^{a}\pm0.5$	$40^{a}\pm1.1$

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

In no instance was work reported to be checked daily. Some private high class respondents reported that their work was never checked. No class of laboratory had 100% rating in daily calculation of mean values. Most laboratories reported requests for retesting of assays as rare.

Table 4.14 shows the reportorial of the documentation process. There were significant within group and between group differences ($p < 0.05$) in the reportorial of the documentation process.

Table 4.14: The documentation process

	Laboratory category						
(%) Compliance	**Provincial**	**District**	**Dispensary**	**Faith based**	**Private high class**	**Private middle class**	**Private low class**
Patients suggestion/ Complaints.	$20^{c}\pm0.2$	$20^{c}\pm1.2$	$10^{c}\pm1.2$	$89^{a}\pm0.9$	$40^{b}\pm1.2$	$33^{b}\pm0.5$	$20^{c}\pm1.1$
Registration of all assays.	$81^{b}\pm1.2$	$80^{b}\pm0.9$	$70^{b}\pm1.6$	100^{a}	100^{a}	100^{a}	100^{a}
Filling of sample tally sheet daily.	$40^{c}\pm1.6$	$30^{c}\pm0.6$	$30^{c}\pm0.5$	100^{a}	100^{a}	$61^{b}\pm1.2$	$50^{b}\pm0.8$
Filling of OP daily samples register.	$80^{b}\pm2.0$	$81^{b}\pm1.8$	$80^{b}\pm1.6$	$68^{c}\pm0.7$	$83^{b}\pm1.5$	$80^{b}\pm1.6$	100^{a}
OP monthly reports.	100^{a}	$61^{c}\pm1.1$	$81^{b}\pm1.2$	$57^{c}\pm1.8$	100^{a}	100^{a}	100^{a}

Values are given as means of triplicates ± SD. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

As shown in Table 4.14, no category of laboratory had complaints/ suggestion boxes in all cases. The laboratory category with the highest rating was the faith based laboratories. No government laboratory category had total compliance in reporting to register all assays. The dispensaries had

the poorest rating, where 70% reported to register all assays. Only faith based and private high class laboratories had total compliance in reporting to daily fill the sample tally sheet. Only private low class laboratories had total compliance in reporting to fill the out-patient daily samples register. Very few district laboratories and dispensaries reported to daily fill the sample tally sheet. All private laboratories reported to fill out patients monthly reports.

4.4 Assessment of the patient's perception of quality service

The consumers who participated in this study were a total of n= 416: Nairobi n = 116, Mombasa n=87, Kisumu n=106 and Nyeri n=107.

Table 4.15 shows the demographic profiles of the patients in this survey. The consumer male female ratio was roughly 1:1.

Table 4.15: The patient's demographic profiles

	Consumers	**% Prevalence**
Gender	Male	52±1.5
	Female	48±1.2
Age	18-24	11±0.5
	25-34	46±0.9
	35-44	22±1.7
	45-54	21±1.2
Marital status	Single	44±1.5
	Married	49±1.6
	Separated	3±0.1
	Divorced	1±0.2
	Widowed	3±0.2
Religious affiliation	Catholic	25±0.9
	Protestant	54±1.5
	Muslim	11±0.7
	Indigenous	6±0.3
	Atheist	3±0.1
	Other	3±0.3
Values are given as means of triplicates ± SD		

The majority of consumers interviewed were between 25-34 years of age, most were of middle class 65% and there was a slight majority of married 46% over single 44% patients. The majority of patients interviewed were protestant Christians. The majority indicated they were of middle class. Figure 4.3 shows the relationship between the social origin of the consumer respondents in the study and the laboratory categories they attended.

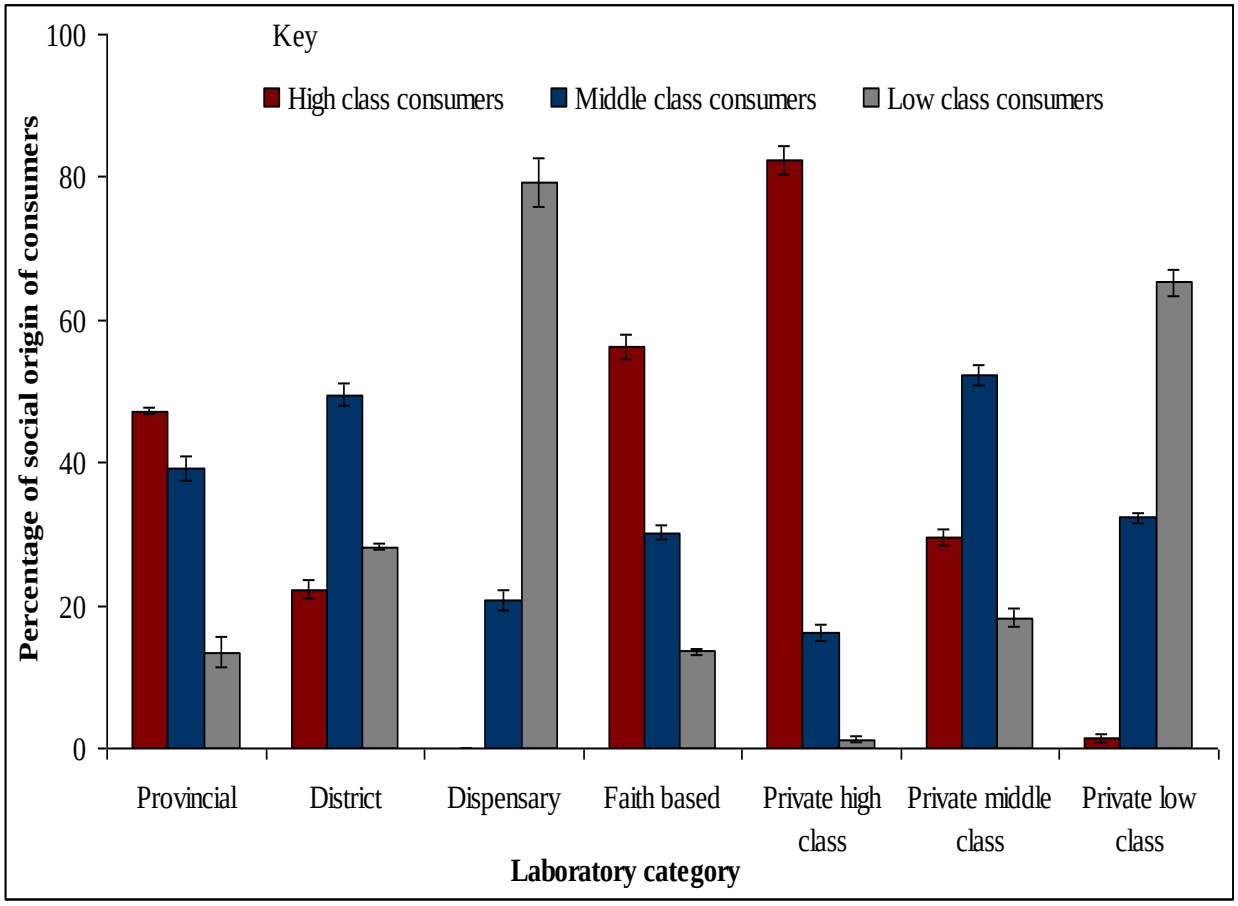

Figure 4.3: Patient's social origin per laboratory category

The majority of consumers who responded to be of high social class attended private high class hospitals and faith based hospital laboratories. Patients of middle class attended all the categories

of laboratory facility but particularly the private middle class hospitals and the district hospitals. Those patients who indicated that they were of low social class mainly attended the private low class laboratories and also mostly attended government hospitals especially the dispensaries.

Table 4.16 shows the consumer level of education and training. Very few patients with no formal education answered the questionnaire.

Table 4.16: The Consumers level of education

Education /Training	Provincial	District	Dispensary	Faith based	Private high class	Private middle class	Private low class
Consumers: (%)							
No formal education	4	7	10	5	3	5	7
Primary	80	40	3	50	69	45	20
Form four	27	15	3	36	42	27	16
Form six	1	2	0	2	3	2	0
University Degree	8	2	1	15	18	10	6

Most consumer respondents in this study had attained primary and secondary level of education.

Figure 4.4 below shows the consumers' perceptions of practitioners' demographic characteristics they considered important in the implementation of quality service. Results indicated that Mombasa county consumers placed the greatest emphasis on demographics.

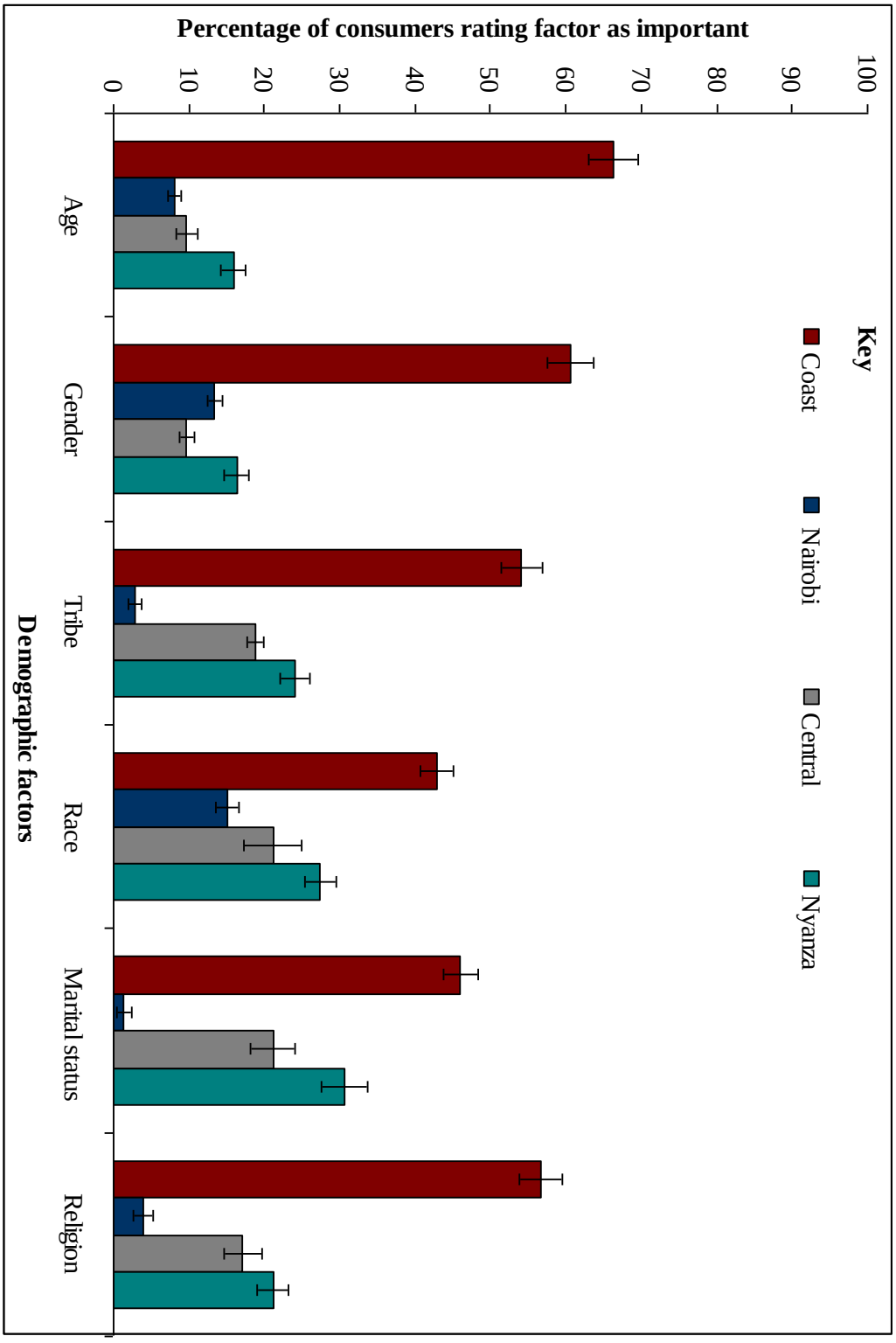

Figure 4.4: Demographic characteristics important to patients

The patients in Nyeri, Kisumu and Nairobi counties did not perceive practitioner's age, gender, tribe, marital status, or religion as important demographics in the implementation of quality service as shown in Figure 4.4. Mombasa county consumers valued

the practitioner's age, gender, tribe, race, marital status, religion, and respect for cultural values more than other consumers.

Patients from different parts of the country placed different emphasis on the factors they considered important in order for them to perceive the laboratory practitioner as competent. Figure 4.5 shows some competence factors the patients considered most important.

The patients in Kisumu county placed the greatest value on practitioner competence whereas patients in Mombasa county did not rate practitioner competence as an important need.

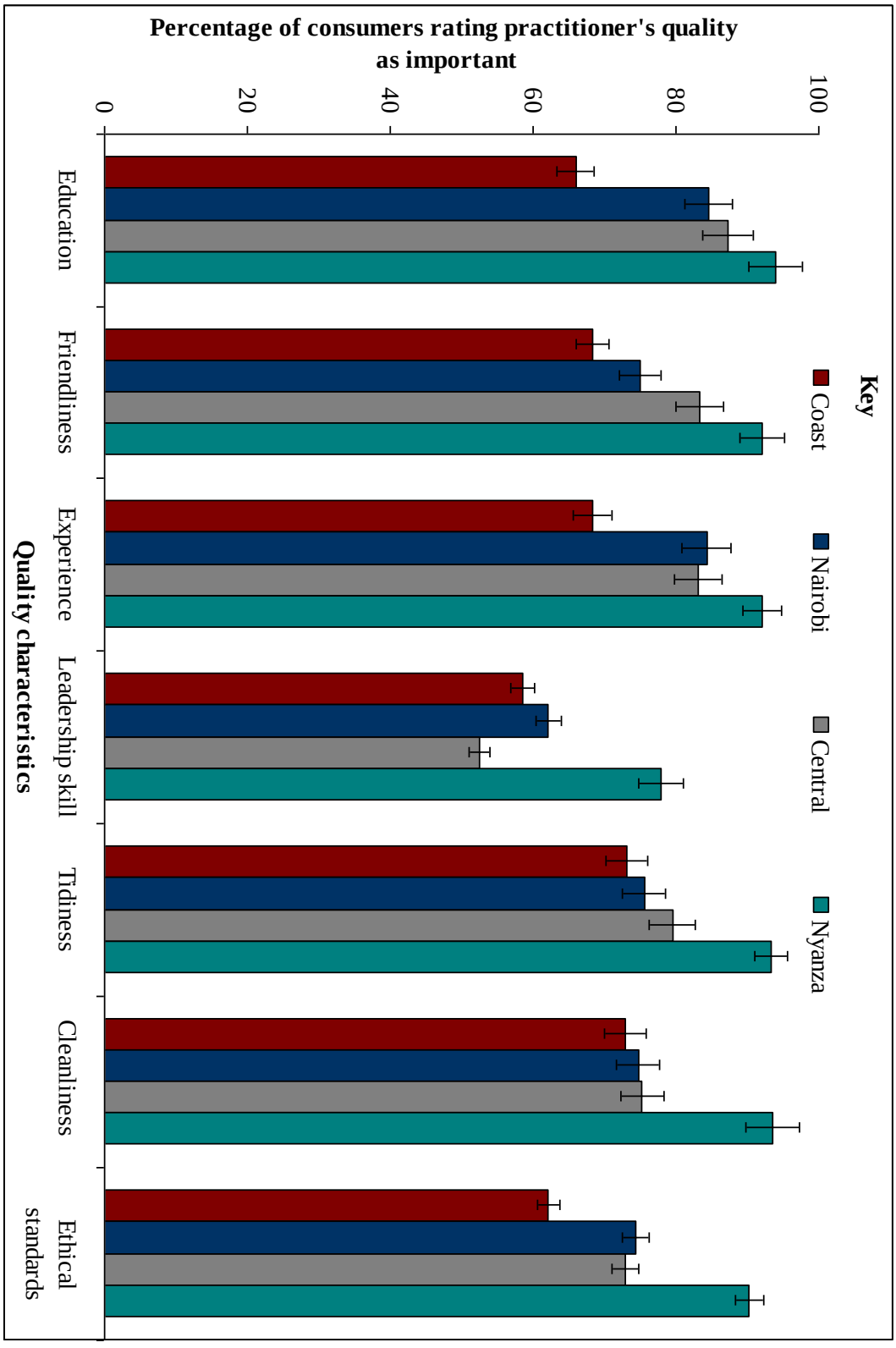

Figure 4.5: The manager's competence factors considered important by patients

Table 4.17 shows the rating of importance of practitioner competence to consumers. There were significant between group and within group differences ($p < 0.05$) per laboratory category.

Table 4.17: The practitioner competency factors important to consumers

	Important personal factors				
	Leadership	**Tidiness**	**Cleanliness**	**Ethics**	**Confidentiality**
Mombasa county					
Provincial	$45.2^{b}\pm1.3$	$60.2^{b}\pm3.4$	$58.3^{c}\pm1.3$	$50.6^{c}\pm3.1$	$63.2^{b}\pm1.3$
District	$42.1^{b}\pm3.4$	$54.7^{c}\pm2.5$	$52.1^{c}\pm2.3$	$47.5^{c}\pm2.3$	$61.4^{b}\pm2.3$
Dispensary	$30.7^{c}\pm2.2$	$41.8^{c}\pm3.9$	$30.5^{d}\pm0.8$	$35.9^{d}\pm1.3$	$59.5^{c}\pm1.7$
Faith based	$69.3^{a}\pm1.9$	$69^{b}\pm1.6$	$67.1^{b}\pm1.8$	$62.0^{b}\pm4$	$77.3^{a}\pm2.2$
Private high class	$65.1^{a}\pm2.9$	$70.5^{a}\pm2.1$	$70^{a}\pm0.9$	$64.3^{b}\pm2.8$	$73.6^{a}\pm2.5$
Private middle class	$54.7^{a}\pm2.1$	$55.3^{c}\pm2.2$	$59.5^{c}\pm2.3$	$61.b^{a}\pm1.4$	$70.7^{a}\pm1.3$
Private low class	$32.2^{c}\pm1.8$	$36.5^{d}\pm1.7$	$36.8^{d}\pm1.6$	$54.3^{c}\pm0.9$	$57.3^{c}\pm1.8$
Nairobi county					
Provincial	$45.2^{b}\pm1.6$	$74.3^{a}\pm2.4$	$76.2^{a}\pm1.8$	$66.4^{b}\pm1.5$	$93^{a}\pm2.1$
District	$43.4^{b}\pm1.4$	$62.3^{b}\pm1.9$	$69.4^{b}\pm2.4$	$71.3^{a}\pm2.3$	$94^{a}\pm2.0$
Dispensary	$32.3^{c}\pm3.2$	$37.5^{d}\pm1.6$	$35.9^{d}\pm2.5$	$69.6^{b}\pm1.7$	$89.2^{a}\pm2.4$
Faith based	$69^{a}\pm2.4$	$70.4^{b}\pm1.9$	$70^{b}\pm1.6$	$79.5^{a}\pm1.9$	$94.3^{a}\pm1.8$
Private high class	$66^{a}\pm2.9$	100^{a}	$97^{a}\pm2.9$	$71.2^{a}\pm1.1$	100^{a}
Private middle class	$55.3^{a}\pm2.2$	$92.3^{a}\pm2.7$	$90.6^{a}\pm3.2$	$70.6^{a}\pm2$	100^{a}
Private low class	$33.6^{c}\pm1.7$	$34.6^{d}\pm1.2$	$39.6^{d}\pm0.8$	$67.4^{a}\pm1.1$	$80.6^{b}\pm2.7$
Nyeri county					
Provincial	$36.5^{b}\pm3.2$	$76^{a}\pm1.9$	$79.4^{b}\pm1.3$	$67.4^{a}\pm1.4$	100^{a}
District	$25.7^{c}\pm1.5$	$67.5^{b}\pm1.7$	$68.6^{b}\pm1.4$	$65.2^{a}\pm2.5$	100^{a}
Dispensary	$16.5^{d}\pm2.8$	$67.0^{b}\pm1.6$	$58.3^{c}\pm2.5$	$62.8^{a}\pm1.9$	$94.7^{a}\pm2.1$
Faith based	$58.6^{a}\pm1.9$	$73.2^{a}\pm1.5$	$70.7^{a}\pm1.8$	$78.3^{a}\pm2.1$	100^{a}
Private high class	$63.1^{a}\pm2$	$92.6^{a}\pm3.5$	$99.6^{a}\pm3.9$	$80.5^{a}\pm0.9$	100^{a}
Private middle class	$45.3^{b}\pm2.9$	$69.0^{b}\pm2.1$	$72^{a}\pm2.7$	$71.4^{a}\pm1.8$	100^{a}
Private low class	$15.5^{d}\pm1.8$	$32.1^{d}\pm1.1$	$31.9^{d}\pm2.1$	$50.6^{a}\pm2.1$	$96.3^{a}\pm1.4$
Kisumu county					
Provincial	$79^{a}\pm4.1$	$99.2^{a}\pm2.4$	$95^{a}\pm2.1$	$92.5^{a}\pm3.9$	$97.3^{b}\pm2.5$
District	$73^{a}\pm1.2$	$92.3^{a}\pm2.2$	$99.6^{a}\pm1.4$	$88.4^{a}\pm2.6$	$97^{b}\pm2.6$
Dispensary	$57^{a}\pm2.3$	$88.4^{a}\pm1.8$	$85.0^{a}\pm1.9$	$87.6^{a}\pm1.5$	$90.4^{b}\pm1.5$
Faith based	$93.5^{a}\pm2.6$	100^{a}	100^{a}	$95.4^{a}\pm2.1$	100^{b}
Private high class	$82^{a}\pm2.9$	100^{a}	100^{a}	$92.7^{a}\pm2.8$	100^{a}
Private middle class	$72.1^{a}\pm0.9$	$95.7^{a}\pm1.3$	$87.3^{a}\pm2.2$	$87.5^{a}\pm1.4$	$98.0^{a}\pm2.3$
Private low class	$55.4^{a}\pm1.6$	$81.6^{a}\pm1.7$	$82.5^{a}\pm1.8$	$83.5^{a}\pm1.9$	$85.2^{b}\pm1.8$

Values are given as means of triplicates ± SD. The means in the same column per county having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

The ability to maintain confidentiality was considered the most important need patients had in order to perceive the practitioner to be delivering good quality service.

Figure 4.6 shows a comparison of the importance of positive attitude, education and experience to consumers of the different laboratory categories.

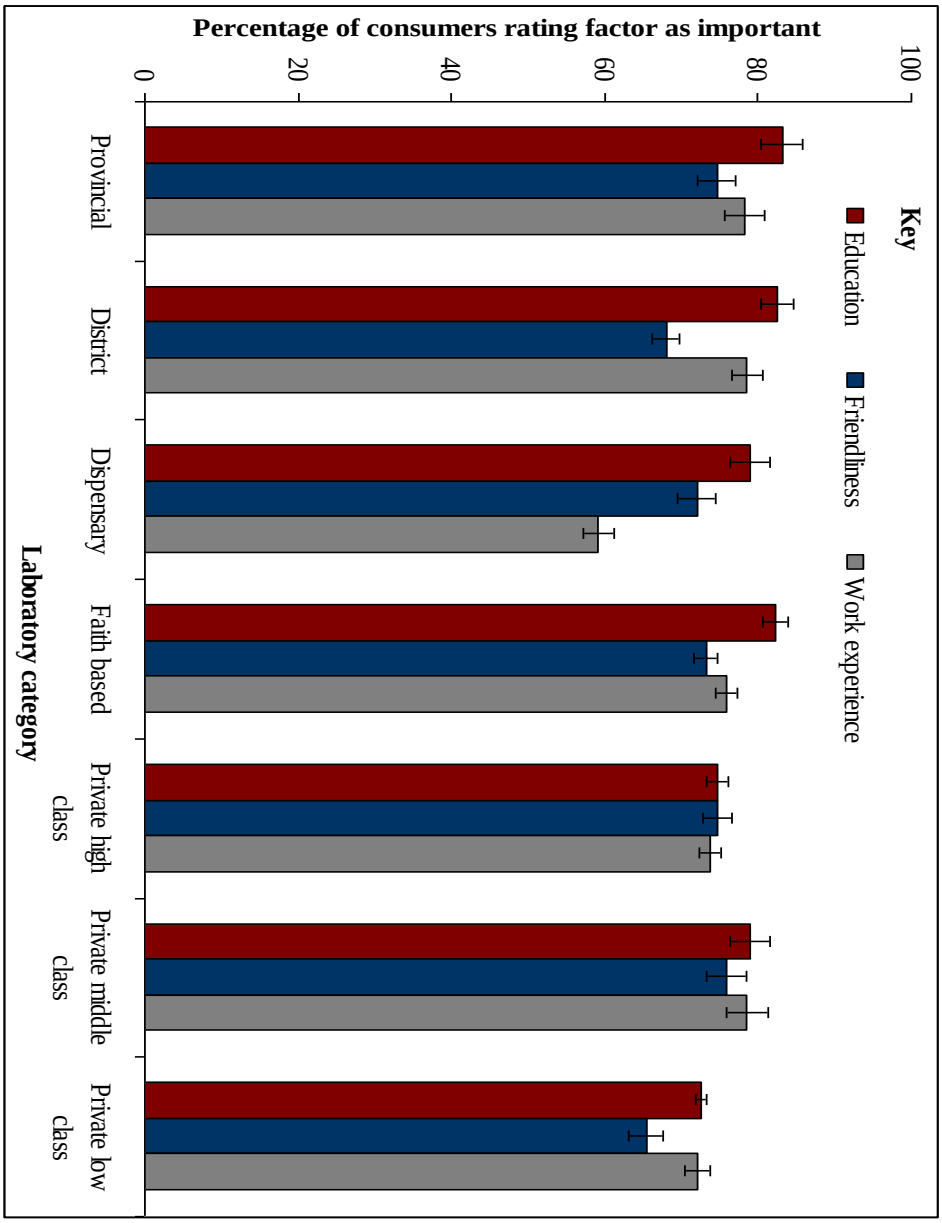

Figure 4.6: A comparison of competence factors important to consumers

The patients stated that they valued the practitioner's education and training, almost giving the same weighting as the positive attitude indicated by the friendliness of the laboratory worker.

Table 4.18 shows the patient's views on practice quality. Most consumer respondents deemed the cleanliness of the laboratory as their most important need. The next in rating was the ease of access, then the adequate size of the laboratory.

Table 4.18: Patient's perceptions of important practice characteristics

	New/ modern	Established	Adequate size	Cleanliness	Easy access
Mombasa county					
Provincial	77^{a}±1.8	84.5^{a}±3.4	100^{a}	100^{a}	92^{a}±2.6
District	86^{a}±2.9	71.5^{b}±2.2	100^{a}	100^{a}	100^{a}
Dispensary	55^{c}±1.1	65^{b}±0.4	85^{b}±3.4	90^{a}±3.1	70^{b}±1.8
Faith based	69^{b}±1.2	69^{b}±1.8	77^{b}±1.6	92^{a}±1.8	92^{a}±1.9
Private high class	65^{b}±09	70^{b}±1.5	80^{b}±0.9	100^{a}	95^{a}±3.5
Private mid-class	54.5^{c}±2	54.5^{c}±1.9	82^{b}±1.5	91^{a}±0.8	91^{a}±2.6
Private low class	33^{d}±1.1	66.5^{b}±0.8	66.5^{c}±1.6	100^{a}	67^{b}±1.5
Nairobi county					
Provincial	25^{c}±1.4	89^{a}±1.8	86^{a}±3.1	96.5^{a}±1.8	93^{a}±1.2
District	81^{a}±2.1	94^{a}±3.6	100^{a}	100^{a}	94^{a}±2.6
Dispensary	42^{b}±2	96^{a}±1.5	67^{b}±2.1	100^{a}	71^{b}±1.5
Faith based	50^{b}±1.9	60^{b}±1.4	70^{b}±1.1	100^{a}	90^{b}±1.6
Private high class	77^{a}±2.7	69^{b}±1.6	77^{b}±1.4	100^{a}	100^{a}
Private mid-class	71.5^{a}±2.3	73.5^{b}±2.2	80^{a}±0.7	100^{a}	80^{a}±2.7
Private low class	70^{a}±1.6	70^{b}±1.8	90^{a}±3.3	80^{a}±1.0	80^{a}±1.4
Nyeri county					
Provincial	36.5^{b}±2.1	74^{a}±1.4	91^{a}±4.1	96^{a}±1.8	93.5^{a}±0.9
District	65^{a}±0.9	70.5^{a}±3.4	76.5^{b}±1.9	94^{a}±2.7	96.5^{a}±0.4
Dispensary	16.5^{c}±0.5	67^{a}±2.4	67^{b}±1.6	83^{a}±1.6	100^{a}
Faith based	42^{b}±1.2	83^{a}±3.3	100^{a}	100^{a}	95.5^{a}±0.2
Private high class	33^{b}±1.1	33^{b}±0.8	50^{c}±0.7	91.5^{a}±2.5	83.5^{a}±2.7
Private mid-class	23.5^{c}±0.6	44.5^{b}±1.4	72^{b}±1.6	83.5^{a}±2	97.5^{a}±0.2
Private low class	15.5^{c}±0.7	69^{a}±2	92.5^{a}±3	92^{a}±3.1	100^{a}
Kisumu county					
Provincial	100^{a}	95^{a}±3.1	95^{a}±2.9	100^{a}	95^{a}±2.9
District	100^{a}	58^{b}±1.5	67^{b}±0.6	100^{a}	67^{b}±1.6
Dispensary	26^{e}±0.6	37.5^{d}±2	75^{b}±1.9	100^{a}	100^{a}
Faith based	45^{d}±1.9	65^{b}±2.9	70^{b}±0.7	100^{a}	90^{a}±1.3
Private high class	72^{c}±1.6	72^{b}±1.8	78^{b}±2.1	100^{a}	89^{a}±0.8
Private mid-class	100^{a}	95^{a}±1.4	100^{a}	100^{a}	81^{a}±2
Private low class	62.5^{c}±1.5	62.5^{b}±0.9	62.5^{b}±1.5	100^{a}	100^{a}
Mean	56.9±1.9	69.9±2.4	80.6±2.8	96.1±1.9	89.4±1.8

Values are given as means of triplicates ± SD. The means in the same column per county having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

Table 4.19 shows the patient's views on the assay process quality. Most of the consumers' responses indicated that cleanliness and tidiness of the laboratory was most important.

Table 4.19: The Patient's perception of assay process quality

	Laboratory category						
Compliance (%)	**Provincial**	**District**	**Dispensary**	**Faith**	**Private high class**	**Private middle class**	**Private low class**
Lab smells good	94.1^{a}±2.2	92.4^{a}±1.1	81.3^{a}±1.5	80.1^{a}±1.2	90.5^{a}±0.1	84.4^{a}±1.9	87.2^{a}±1.8
Good sample collection	87.5^{a}±1.4	86.5^{a}±2.1	89.4^{a}±0.9	87.5^{a}±0.9	82.5^{a}±0.9	86.3^{a}±1.7	89.3^{a}±2.4
Respect of cultural values	38.2^{b}±1.0	23.1^{c}±0.8	29.6^{c}±1.1	37.5^{b}±0.5	35.2^{b}±0.3	51.2^{a}±0.8	38.3^{b}±0.9
Reliable results	93.4^{a}±1.3	90.0^{a}±1.4	91.3^{a}±1.8	93.0^{a}±1.8	92.4^{a}±2.5	85.1^{a}±1.8	93.1^{a}±2.1
Timeliness	72.3^{a}±0.9	73.1^{a}±0.6	47.2^{b}±0.7	57.1^{b}±1.4	67.0^{a}±0.8	69.5^{a}±0.9	51.5^{b}±0.5
Affordable service	94.7^{a}±1.2	90.3^{a}±1.8	89.4^{a}±1.3	87.5^{a}±0.6	84.6^{a}±1.5	86.5^{a}±1.5	87.4^{a}±1.6
Information provided	90.1^{a}±0.8	88.5^{a}±2.5	86.1^{a}±2.3	89.3^{a}±1.5	90.5^{a}±0.8	80.2^{a}±1.4	84.5^{a}±1.2

Values are given as means of triplicates ± standard deviation. The means in the same row having different superscript letters are significantly different from each other at 5% confidence interval ($p < 0.05$).

As seen on Table 4.19, when considering the ratings as per laboratory category, patients of provincial and district laboratories considered that the most important process quality criteria was that the laboratory smells good and the service was affordable. For patients in provincial and district laboratories, the highest process rating was that the laboratory smells good. Cumulatively, 87% of the respondents thought that the laboratories' good smell was an important factor in the implementation of quality service. Most consumers in this study indicated that the reliability of results in the laboratories was very important in achieving good quality services.

All patients valued good sample collection and Kisumu patients rated that criterion almost as important as timeliness and information provided. Mombasa county valued respect for cultural values almost as highly as reliability of results. All patients valued being provided with information. Nairobi patients valued that criterion almost only slightly lower than reliability of results and affordability of services. Affordable services rated the most important criterion in Nyeri county, even higher than reliability of results.

Figure 4.7 shows Kisumu county patients' perception of process quality. The highest need for consumers in Kisumu county was that it was affordable. Timeliness also ranked high and was just as important as affordable service for most patients. Good laboratory smell was rated highly in Kisumu county. For dispensary and private middle class laboratory patients, that criterion ranked similar to reliable results.

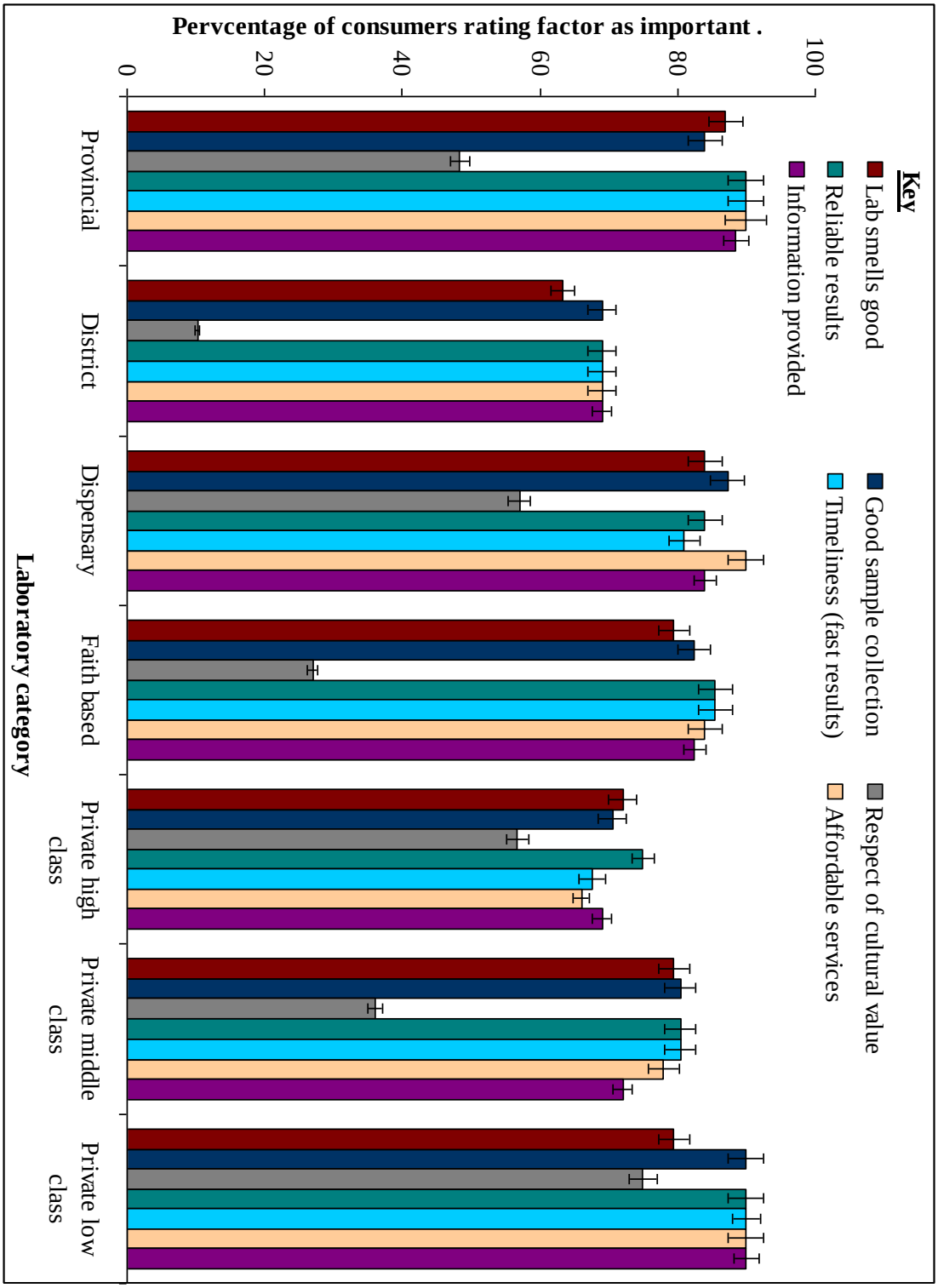

Figure 4.7: Kisumu county patients' perception of process quality

Some Kisumu county patients valued respect for cultural values; particularly private low class and dispensary patients. Kisumu county patients valued reliability of results first, then next timeliness of the service. The laboratory smelling good was rated most highly by Kisumu county patients, who also valued good sample collection.

Figure 4.8 shows Nyeri county patients' perception of process quality. Nyeri county patients valued affordable services the most important quality factor. For provincial and dispensary patients, affordable service was more important than reliable results. Nyeri county private middle class laboratory consumers viewed timeliness to be just as important as reliable results. Timeliness was an important quality criterion for all consumers in Nyeri county. Patients in private middle class in Nyeri county perceived timeliness and reliability of results to be of equal and highest rating. Reliable results ranked highest only for faith based and private low class Nyeri county laboratory consumers.

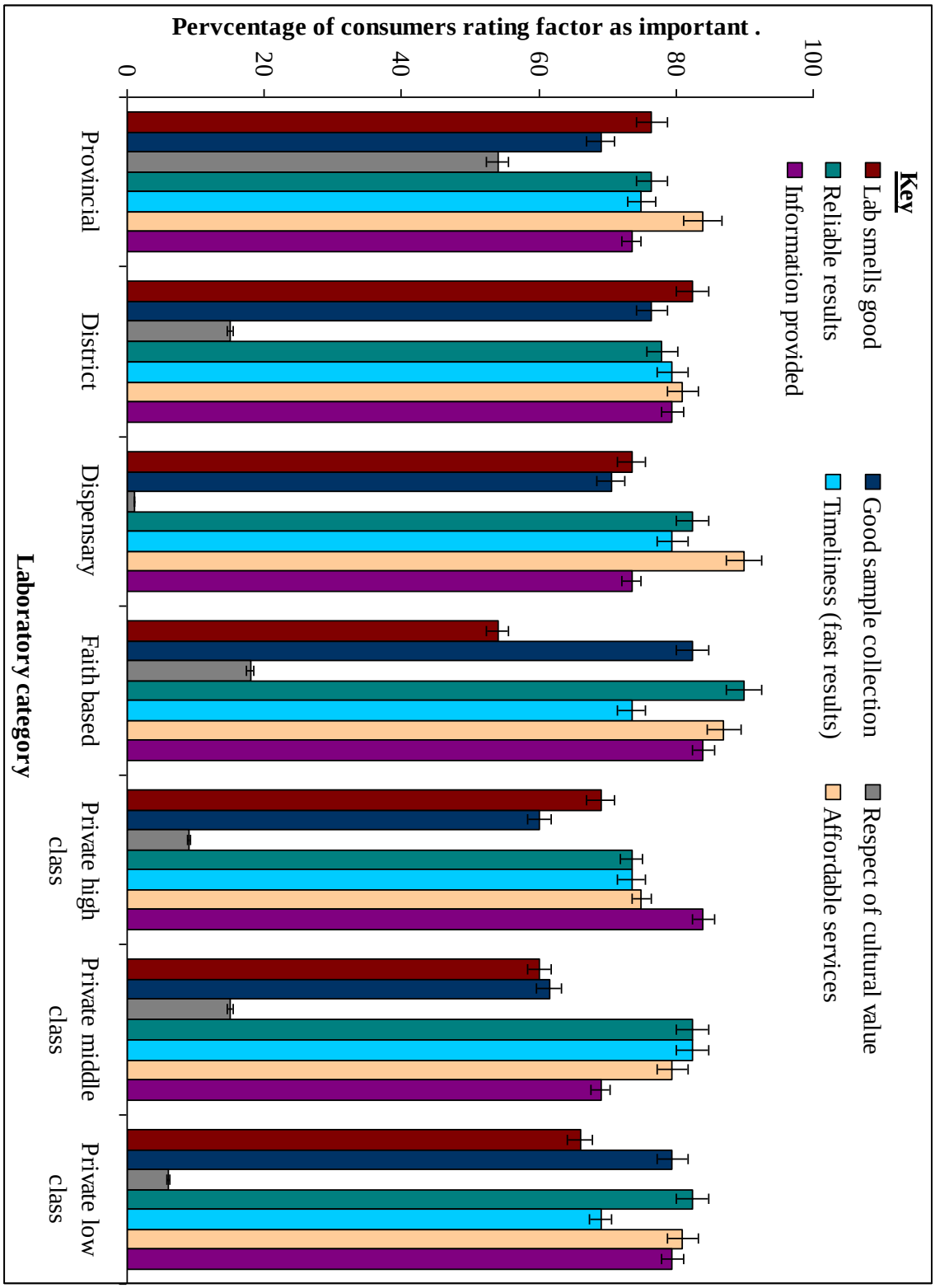

Figure 4.8: Mombasa county patients' perception of process quality

Figure 4.9 shows Nairobi county patients' perception of process quality. Nairobi county patients valued most reliability of results, next information provided and affordability of service.

Information provided, as well as affordable services were important needs in Nairobi county patients. Reliable results ranked highest as a need for Nairobi county consumers of dispensaries, faith based, and private laboratories.

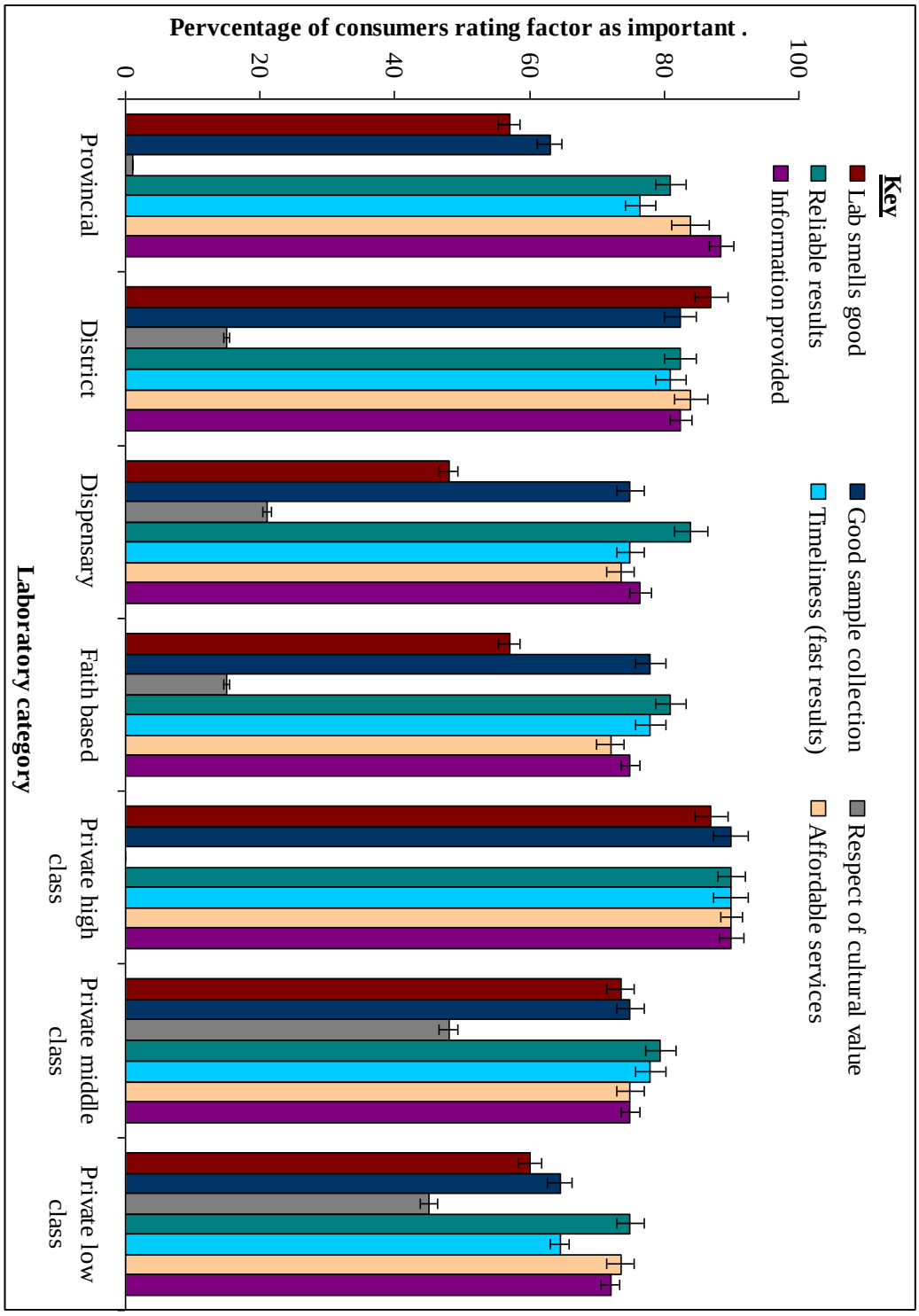

Figure 4.9: Nairobi county patients' perception of process quality

Figure 4.10 shows Mombasa county patients' perception of process quality. Patients in Mombasa county valued respect for culture by the practitioner. They also placed value on the laboratory smelling good.

The laboratory smell was the most important quality characteristic for Mombasa county patients in provincial, district, and private high class laboratories. Respect for cultural values was a main quality value for all Mombasa county consumers. It was the highest ranking quality need for Mombasa county district, dispensary, and faith based laboratory consumers.

Mombasa county patients of middle class laboratories valued good sample collection most. Reliable results as a quality need ranked second, together with respect for cultural values for provincial laboratory patients. For Mombasa county patients in district laboratories, reliable results ranked fifth after the laboratory smelling good, good sample collection, respect for cultural values, and information provided. In Mombasa county reliable results ranked highest as a need for private high class patients.

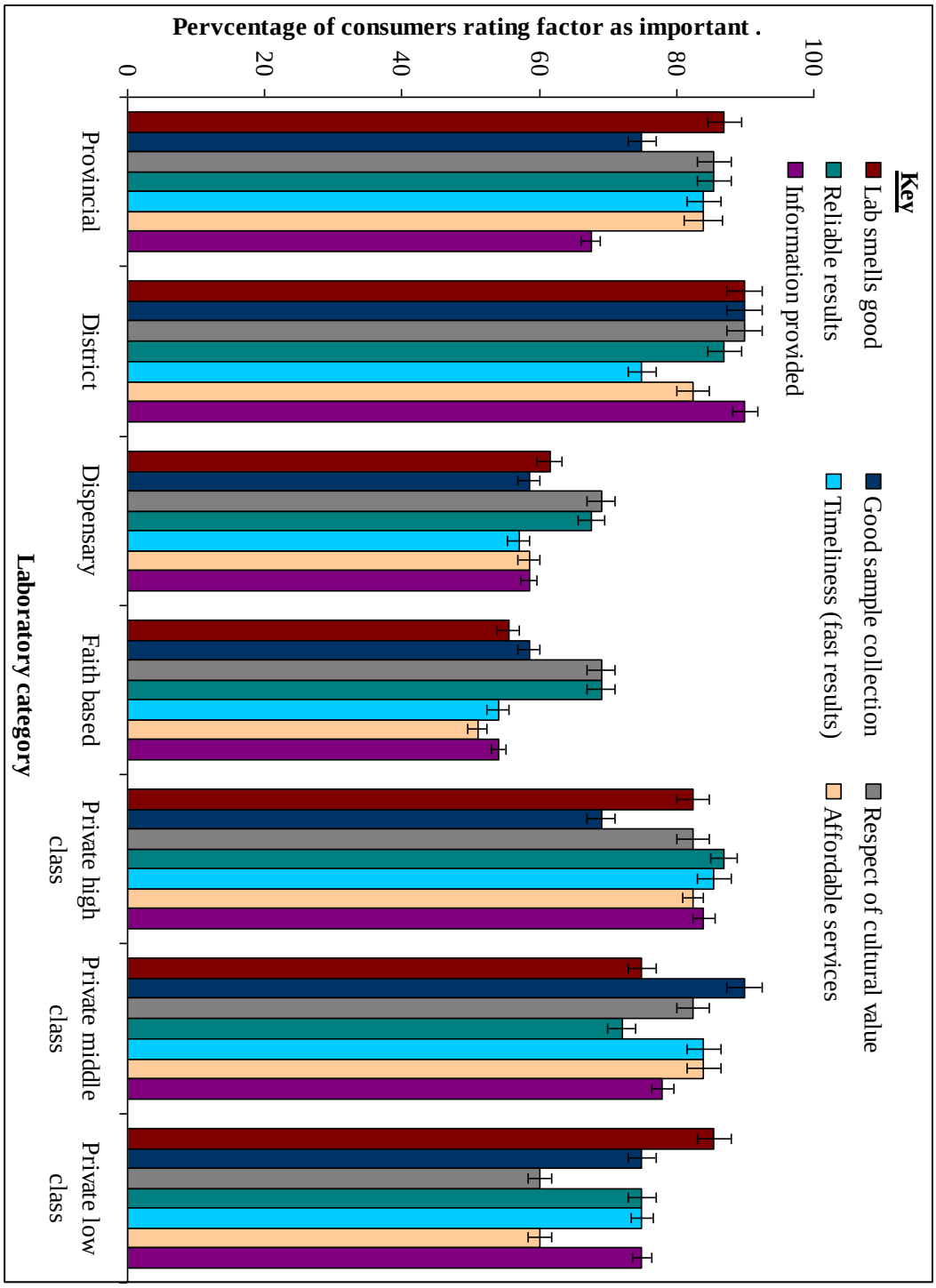

Figure 4.10: Mombasa county patients' perception of process quality

In conclusion, as shown on Table 4.20, the highest level of quality management systems were maintained by private high class laboratories $p > 0.052$, $p > 0.05$, $\alpha = 0.05$ which also had the highest rating of compliance to practice quality $p < 0.022$, $p < 0.05$, α

= 0.05. Faith based laboratories had the highest rating in competency of practitioners $p < 0.027$, $p < 0.05$, $\alpha = 0.05$.

Table 4.20: Test of hypothesis

P values (α = 0.05)	Practitioner's Competence	Compliance of quality practice characteristics	Quality management systems	Consumer quality needs
Provincial	0.048	0.027	0.059	0.042
District	0.032	0.036	0.065	0.045
Dispensary	0.042	0.041	0.069	0.042
Faith based	0.027	0.033	0.063	0.038
Private high class	0.045	0.015	0.052	0.039
Private middle class	0.038	0.039	0.053	0.036
Private low class	0.030	0.045	0.061	0.030
General *p* value	**0.047**	**0.043**	**0.059**	**0.039**

The null hypothesis is rejected if the *p* value is less than α. The lower the *p* value the stronger the rejection hence the better the quality. Therefore the null hypothesis was not rejected ($p > 0.05$) pertaining to the quality management systems in place. The null hypothesis was rejected ($p < 0.05$) concerning patient's needs, practice compliance and practitioner competence. The overall assessment was that the quality of medical laboratory service delivery in Kenya was good.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Practitioner competence

Laboratory service quality may be conceived as composed of not only the technical task but like all other health care service there is an interpersonal exchange at a practitioner patient inter-phase, hence the relevance of investigating the practitioner's delivery of service. The foundation

of the assessment of results pertaining to the practitioner was based on pioneering work by Parasuraman *et al.,* which proposed that regardless of the type of service, consumers used basically similar criteria or determinants in evaluating service quality (Parasuraman *et al.,* 1985).

The majority of practitioner respondents were of the protestant denomination, Christian faith. Based on this study, and in tandem with Max Weber's theory, the private high class laboratories sampled were owned by mainly protestant Christians. Pioneering work concerning the protestant work ethics by Max Weber in the 1930s proposed the theory that Protestants trained their followers the value of hard work, thrift and a desire for material advancement as opposed to Catholics who placed a lower emphasis on material advancement of their flock (Manimala, 1999). Based on Max Weber's protestant work theory, the successful private enterprises were most likely to be run by protestants while as other non-profit making faith based laboratories run by Catholics.

All workers except a few manning dispensaries were found to be polite, friendly, showed respect and were clean and neat in appearance. Research indicates that health workers interaction involving empathy and responsiveness, and courtesy have a significant effect on health care service quality (Elhoseeny and Mohammad, 2013).

Based on this study the laboratory practitioners manning Kenyan laboratories were all competent. They were well educated with a minimum qualification of ordinary level, also well trained with a minimum qualification of ordinary diploma in Medical Laboratory science plus

were all registered with the KMLTTB. The study showed that the managers tended to be better educated and trained than the employees.

Research has showed that experience and motivation are a necessity for quality execution of the production process (Chandrasekar, 2011). The main motive the laboratory workers had in government laboratories in order to provide service was not to make money whereas the private laboratory owners rated making money as their most important motivating factor. For several laboratories making money was rated more important than providing reliable results. In low socio-economic environments where a vast majority of Kenyans live, as Eleuch (2011) noted, in resource poor areas, there is a need for health care providers to satisfy patients, provide quality service and maximize profit under limited resources in a competitive environment.

Managers in this study were rated very well pertaining to their leadership traits. The results of this study indicated that 56% of the employees gave their managers a strong leadership rating and 62% regarded their manager as one who builds strong relationships. Those values are higher than but still in tandem with Chandrasekar (2011), whose results were that 49.4% of the respondents maintained a strong relationship with their superior at the work place.

Based on McClelland's achievement motivation theory some people, with certain characteristics have a great need to achieve irrespective of the surrounding. They assume responsibility and have internal locus of control. All people differ on that personality variable referred to as locus of control. The private low class laboratory manager's rated well and were all considered to have internal locus of control. The private low class managers were rated best by their employees as

pertaining to their commitment, being emulatable, and empowering. The employees who rated their bosses most highly as having the best leadership quality were those of faith based laboratories. They felt their bosses were, polite, showed respect, were clean and neat, friendly and honest. Ultimately faith based laboratories had the highest rating in competency of practitioners $p < 0.027$, $p < 0.05$, $\alpha = 0.05$. This research indicated that the highest quality practitioner were of faith based laboratories followed by those of private low class laboratories.

5.2 Investigating the level of compliance to practice characteristics

This research indicated that private high class laboratories serving the resource rich in Kenya met the total practice standards requirements $p < 0.022$, $p < 0.05$, $\alpha = 0.05$. For all other categories of laboratories the characteristics of the laboratory practice were not strictly adhered to with varied levels of compliance.

Studies have indicated that because private hospitals have to stay in business, they have to try to provide a good service to the customers (France and Francis 2005). The poor services indicated by results of this study by the private low class laboratories may be due to the postulation (France and Francis 2005) that the regulatory bodies are using cross-laboratory benchmarking that measures the wrong outcomes based on observation that private sector laboratories do not have the luxury of running into deficits, they get their costs identified accurately based on consumer demands.

According to Chandrasekar (2011) it is the quality of the employee's workplace environment that most impacts on their level of motivation and subsequent performance. All government

laboratories were specifically built for their purpose. Chandrasekar (2011) noted that the actual physical layout of an office is extremely important when it comes to maximizing productivity and his study inference was that the majority of the employees felt they are given the required space and facilities to do their job. The inference of this inquiry was that only private high class laboratories had total compliance to laboratory physical facilities. Dispensaries rated poorly pertaining to the practice quality characteristics. This was despite the fact that they are specifically built by the government or using Community Development Funds. Only 67% had adequate room dimensions, 67% had inadequate lighting. Half of the private low class laboratories visited had no waiting bay. Patients in these facilities often waited inside the laboratory prior being served and while waiting for results. In the present study fire extinguishers, sand buckets and accident books were not present in the majority of laboratories sampled.

5.3 The analysis of quality management systems for the assay process

Studies (Badri *et al.*, 2009) delineated several facets of quality and underlay the importance of process quality which was defined as how the service is delivered. Planning and meeting was one aspect where private low class laboratories faired very well in comparison with private high class laboratories based on reports from the employees and managers. Meetings are very important in the management of the quality service because studies on nonverbal communication found that 7% of any message is conveyed through words, 38% through certain vocal elements, and 55% through nonverbal elements like facial expressions, gestures and posture, (Mehrabian,1972). These results have led to the conclusion that the body language, level of politeness, enthusiasm

and the degree of employee participation in staff meetings often illustrate how profitable enterprises are.

All the staff manning private and faith based laboratories in this study were found to wear clean laboratory coats and were clean and neat. Those findings were consistent with findings that 33.9% of the patients agreed that employees at the hospital investigated in Egypt appeared to be neat (Elhoseeny and Mohammad, 2013).

As for maintaining quality assurance, what the laboratory staff referred to as inter-laboratory trials were really result confirmation with a reference laboratory. It is a requirement of the accrediting bodies in other parts of the world that laboratories take part in national quality control schemes (Feeny and Zairi, 1994). In Kenya, no laboratory visited repeated samples frequently, fewer did triplicate assays and no laboratory was found to perform inter-laboratory trials. Neither did any laboratory use automated equipment frequently. Standardized kits were frequently used except in 25% private low class laboratories.

Laboratories reported problems with requisitioning. A problem quoted was: "Clinicians sometimes write so badly." Practitioners also reported there were problems with sample labeling and samples lacking integrity.

One of the key elements of TQM is that achieving quality requires constant learning for everyone in an organization, and that learning needs to be part of the organizational culture (Basu, 2004). Not only should staff members be learning from others in the organization, but

they should also be encouraged to take courses, to attend organization-sponsored trainings and workshops, to visit other organizations, etc., to continually learn more about their work, and to get new ideas. In this study managers reported to attended refresher courses more frequently than the employees. In this study other than practitioners manning private low class laboratories and dispensary laboratories, practitioners reported to attend refresher courses regularly..

The cumulative ratings of the process determinants indicated that the process in the laboratory was inadequate for providing quality service. The lowest *p* value was for private high class laboratories $p = 0.52$, $p > 0.05$, $\alpha = 0.05$.

5.4 The patients perception of service quality

Pioneering contribution in the area of managing quality includes Cozby's idea on the definition of quality as meeting the customer's requirements (Cozby, 2004). In order to facilitate being sensitive to the consumer's needs one method is using the complaints/suggestion box in order to monitor patient's views. In this study it was found that no category of laboratory took this mode of customer care seriously yet according to Kenya Standards Quality management systems (KEBS, 2007) monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the requirements are met.

Studies indicate that quality service has been considered to be the degree of fit between the customer's expectations and his perceptions of the service (Feeny and Zairi, 1994, Parasuraman et.al (1985). In tandem with research in Egypt on hospital service quality, this study used patients whose demographics of sex, age, marital status social economic grouping and religious

affiliation where noted so that they were representative of population of interest (Elhoseeny and Mohammad, 2013). In Kenya the majority of the population is contained of the youth which includes the age categories of 15 up to 34 years which made up of 55% of the persons visiting the laboratories cumulatively (KNBS, 2014). This concurred with the fact that the age ratio of the youth was larger in this study implying that many patients were likely to be patients from the age group of 15-34 years.

The state of consumer demographics have been found to have a significant effect on their perceived perception of hospital service quality (Elhoseeny and Mohammad, 2013). The characteristics investigated in the Egypt study included education and socioeconomic variables like income levels. The results of this research were in agreement with findings of this research that the practitioner, practice and practice quality needs varied with the differences in laboratory category visited by the patient.

Researchers have noted that patients find difficulty in the evaluation of healthcare services and they rarely know on which feature of the health service to base their judgments on or how best to evaluate those feature they chose to evaluate especially when patients try to evaluate the more technical features of the healthcare service such as the qualifications of the medical staff (Elhoseeny and Mohammad, 2013). Patient's in the Egypt study were found to base quality of service on the hospitality of the staff, attentiveness, responsiveness, the rooms being visually appealing and clean plus the information provided. Most patients in this study valued

information provided. Patients in this study valued non-tangible practice characteristics like the laboratory smell, accessibility and affordability.

Studies in Egypt have shown that hygiene and cleanliness ranked as the top most important issues in the hospital (Elhoseeny and Mohammad, 2013). The patients interviewed for this research had varied analytical process requirements depending on their geographical locations. Kisumu patients valued most highly the laboratory smelling good, cleanliness and good sample collection technique. Nyeri county patients considered the affordability more important than reliable results. Nairobi patients valued reliable results first then next important was rated information provided. The Mombasa people placed the greatest importance on respect for cultural values.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

In conclusion, findings of this research were that the laboratory practitioners were competent, and the practice characteristics were of good standard plus the patient's needs were adequately met by the quality of service. The null hypothesis was rejected ($p < 0.05$) concerning practitioner not being competent $p < 0.047$, $\alpha = 0.05$. Faith based laboratories fared the best $p < 0.027$, $\alpha = 0.05$. The null hypothesis was also rejected ($p < 0.05$) concerning lack of compliance of practice characteristics $p < 0.043$, $\alpha = 0.05$. The private high class laboratories had the highest practice ratings $p < 0.015$, $\alpha = 0.05$. The null hypothesis was also rejected ($p < 0.05$) pertaining to patients needs not met by the quality of service provided $p < 0.039$, $\alpha = 0.05$. The private low

class laboratories fared the best $p < 0.030$, $\alpha = 0.05$. The null hypothesis was not rejected ($p > 0.05$) pertaining to the quality management systems in place $p > 0.057$, $\alpha = 0.05$. No laboratory had adequate quality management systems in place.

6.2 Recommendations

6.2.1 Recommendations from the study

Hospital management needs to consider the human resource as the most important resource in all laboratories and continuously find ways to motivate workers. Based on this study not all workers felt they were adequately motivated.

The practice standards set by the MOH/KMLTTB should be set based on needs assessment considering all stakeholders including owner/manager and patient needs so that the cost of setting up a laboratory considers the cost of patient service requirements. There needs to be a relationship between quality, clinical laboratory service effectiveness and evidence - based quality indicators. Meaning the KMLTTB standards should have a customer focus.

There is a need for adequate internal and external quality assurance schemes to be in place by the MOH for the constant monitoring of the quality of assay results.

6.2.2 Recommendations for further work

i) Analysis is needed on human resource management of clinical laboratories; staff motivation and continuous training incentives.

ii) Investigations are needed on: the level of awareness and practice of health and safety issues by the workers; laboratory safety measures in place; safety tangibles present; their routine use; fire and disaster preparedness.

iii) Longitudinal studies are recommended so quality indicator data is collected over time to

iv) Develop a model of laboratory services tailor made for consumers of all income levels including low income earning Kenyans.

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Appendix 1: Introductory Letter

Dear Sir/Madam,

I am conducting a study to assess the quality of medical laboratory service provision in Kenya. Your laboratory falls in the category I would like to assess. I would be grateful if you would give of your time and knowledge. If you do not wish to answer any question please say so and proceed to the nest question. This is an academic excersise and the information obtained will remain confidential.

Thank you

Wachuka Njoroge
Ph D student
Medical laboratory science department
Kenyatta University

Appendix 2: Questionnaires

PRACTITIONER AND PRACTICE INDICATORS OBSERVATION SHEET

Structure/feature	**Specification**	**Compliance**
Main working room	Room dimensions 5 x 4m Floor smooth Floor non slippery Ventilation window floor are 15% Lockable cupboards 3 of 1 x 0.5 meters Shelves Two sinks: one for staining One for hand washing Lighting	
Security and safety	Metal bars on windows and vents Secure lockable door Fire extinguishers Fire buckets Laboratory coats Gloves First aid kit Accidents record book	
Essential facilities Water	Running water Or aspirator bottle, Container with tap rainwater collection	
Power	Mains power of 12 volt Batteries recharged or solar system Electrical power points	
Drainage	Closed drainage from laboratory sinks to a septic tank or deep covered pit	
Disposal	Incinerator, brick constructed or metal drum with deep covered pit for disposal of ashes	
Toilets	Flush toilets Latrines Separate toilet facilities for patients and staff	

PRACTITIONER AND PRACTICE INDICATORS OBSERVATION SHEET

Structure/Feature	**Specification**	**Level of compliance**
Accessory rooms	Waiting bay Wash room Store	
Credibility and courtesy	Clean and neat premise Clean and neat personnel Politeness Respect Friendliness	

What constraints/problems have you encountered in the implementation of quality services?

_____

_____

_____

_____

_____

_____

Once again thank you for your time and participation

Administrative information

Questionnaire number	
Start time	
End time	
Date	

QUESTIONNAIRE FOR LAB OWNER/MANAGER

SECTION A

This section has questions pertaining to the practice

A1 Year of starting the lab [ ]

A2 **Staff qualifications (indicate the number of each category)**

	No formal training	**Ordinary diploma**	**Higher national diploma**	**University degree**	**Other form of training**
Number of technical staff					
Number of support staff					

A3 Which factors do you consider important in the implementation and maintenance of quality services of your laboratory? Number in order of importance from 1-7 if a factor is not important please number it zero-0

Factor	**Importance**
Retention on high quality staff ……	[ ]
Reliability of results …….	[ ]
Increased number of samples assayed …….	[ ]
Improved equipment ……	[ ]
Improved customer services ……..	[ ]
Making money …….	[ ]
Improving the community health status ..	[ ]

SECTION B

This section has question pertaining to the Assay Process

B1 Planning (*Please tick the correct answer Yes or No*)

I have a comprehensive business plan Yes [ ] No [ ]

I wrote the business plan myself Yes [ ] No [ ]

We hold regular staff meetings Yes [ ] No [ ]

I have a good lab work plan Yes [ ] No [ ]

B2 Documentation

The lab has well displayed SOPS Yes [ ] No [ ]

Lab requests patients suggestions/complaints Yes [ ] No [ ]

B3 Documentation *Tick the correct answer (Yes or No)*

The lab registers all assays Yes [ ] No [ ]

Samples Tally sheet is filled daily Yes [ ] No [ ]

Outpatients Daily Sample Register Book is always filled Yes [ ] No [ ]

Outpatients monthly activity reports are kept Yes [ ] No [ ]

B4 Give details of any other important documentation method you are using

_____

_____

B5 Indicate the QUALITY ASSURANCE measures you have put in place (Tick in the correct box)

	Frequently	Rarely	Never
Validation of routine tests with the reference test			
Repeating sample assays			
Triplicate assays (doing each sample 3 times)			
Using standardized kits			
Randomly checking using a control sample			
Inter-lab trials (at random checking your results with other labs)			
Using automated equipment			

Taking staff for refresher courses			

SECTION C

This section has question pertaining to the practitioner (human resource)

C1 Gender Male ☐ Female ☐

C2 Age ☐ Years old

C3 Marital status Single ☐ Married ☐ Separated ☐ Divorced ☐

C4 Motivation

What made you **choose** to work in a laboratory?

C5 Social origin I am born in a …… class family (tick correct answer)

Wealth upper ☐ Middle ☐ Low/poor ☐

C6 Education highest level of education

Primary School	Form 4	Form 6	University

C7 Training (please indicate name of training institution)

JLT	Ordinary Diploma	Higher National Diploma	University Degree

C8 Religious affiliation

Catholic	Protestant Denomination	Muslim	Local Indigenous	Atheist	other

C9 Work experience (*please tick the category that applied to you*)

	Name of facility	For how long were you there	Why did you leave
Was an employee in a medical lab similar to the present laboratory			
Was employed in a large health facility like a hospital			

C10 To whom would you disclose patient information the: (please tick all the correct choices)

Doctor ☐ person paying ☐ the closer relative ☐ spouse ☐ employer ☐ patient ☐ for the test

C11 Motivation: To what extent did the following factors affect your choice to work in the lab

1- very important 2-important 3-not important 4-not applicable

Tick the correct box indicating level of importance

	1	2	3	4
To gain social reputation				
To be your boss				
Because you were unemployed having lost your previous job				
Because you had failed to secure other formal employment				
Because you were in a state of transition				
Your parents were health workers				
To be like a person you admired				
To improve the health status of those in the community				
Other reason please state				

C15 Leadership traits: What do you consider are your leadership success traits?

Please tick the correct characteristics level

	Nil	Weak	Moderate	Strong
Commitment: Are you totally dedicated to the lab				
Do you work constantly towards lab goals				
Leadership: Are you a person people want to follow?				
Self confidence: do you believe in yourself and have an internal locus of control				
Initiative: for you put yourself in positions where you are personally responsible for success or failure				
Do you have a need to control				
Do you readily use expertise and relevant help?				
Are your honest in your lab dealings?				
Do you inspire those who work with you?				
Have you built strong relationships with those who work for you				
Do you empower others who work for you				
Ethical standards: Do you safeguard the privacy and confidentiality of patients				
Creativity: You do things differently from other labs				
Creativity: As a person are you imaginative				
Creativity: You have found something that already exists (not yet perceived) that improves your lab				

Thank you very much for giving of your time

QUESTIONNAIRE FOR LAB SERVICES PROVIDER

SECTION A

This section has questions pertaining to the practice

A1 Year of starting the lab ☐

A2 **Profit** ☐

Samples assayed per day

A3 Which factors do you consider important in the implementation and maintenance of quality services of your laboratory? Number in order of importance from 1-7 if a factor is not important please number it zero-0

Factor	**Importance**
Reliability of results …….	[ ]
Increased number of samples assayed …….	[ ]
Improved equipment ……	[ ]
Improved customer service ……..	[ ]
Making money …….	[ ]
Improving the community health status …	[ ]

A4 **Error reporting**

	Constantly	Every day	Every week	Every month	Rarely	Never
You is work checked						
You have incidences of labeling error						
Samples are labeled						
Requisition difficulties (reading what is on the request form)						
Request forms compared with sample details						
Cases of specimen lacking integrity						
Results integrity problems						
Checking previous reports with current result						
Calculation of mean values						
Doctors request for retesting of samples						

SECTION B

This section has question pertaining to the assay process

B1 **Planning** *Please tick the correct answer (Yes or No)*

We hold regular staff meetings	Yes [ ]	No [ ]
I have a good work plan	Yes [ ]	No [ ]

B2 **Documentation**

The lab has well displayed SOPS	Yes [ ]	No [ ]
Lab requests patients suggestions/complaints	Yes [ ]	No [ ]

B3 **Documentation** *Please tick the correct answer (Yes or No)*

The lab registers all assays	Yes [ ]	No [ ]
Samples tally sheet is filled daily	Yes [ ]	No [ ]
Outpatients daily sample register book is always filled	Yes [ ]	No [ ]
Outpatients monthly activity reports are kept	Yes [ ]	No [ ]

B4 Give details of any other important documentation method you are using

_____

_____

_____

_____

_____

B5 Indicate the QUALITY ASSURANCE measures you use (tick in the correct box)

	Frequently	Rarely	Never
Validation of routine tests with the reference test			
Repeating sample assays			
Triplicate assays (doing each sample 3 times)			
Using standardized kits			
Randomly checking using a control sample			
Inter-lab trials (at random checking your results with other labs)			
Using automated equipment			
Attending refresher courses			

SECTION C

This section has question pertaining to the practitioner (human resource)

C1 Gender Male ☐ Female ☐

C2 Age ☐ Years Old

C3 Marital Status Single ☐ Married ☐ Separated ☐ Divorced ☐

C4 Motivation:

What made you **choose** to work in this laboratory?

C5 Social Origin I was born in a …… class family (tick correct answer)

Wealth upper ☐ Middle ☐ Low/poor ☐

C6 Education highest level of education

Primary School	Form 4	Form 6	University

C7 Training *(please indicate name of training institution)*

JLT	Ordinary diploma	Higher National diploma	University degree

C8 Religious Affiliation

Catholic	Protestant denomination	Muslim	Local indigenous	Atheist	other

C9 To whom would you disclose patient information the: (please tick all the correct choices)

Doctor ☐ person paying ☐ the closer relative ☐ spouse ☐ employer ☐
Patient for the test ☐

C10 Motivation: to what extent did the following factors affect your choice to work in this laboratory

1- very important 2-important 3-not important 4-not applicable

Tick the correct box indicating level of importance

	1	2	3	4
To gain social reputation				
To be your boss				
Because you were unemployed having lost your previous job				
Because you had failed to secure other formal employment				
Because you were in a state of transition				
Your parents were health workers				
To be like a person you admired				
To improve the health status of those in the community				
Other reason please state				

C11 Leadership traits: What do you consider are your Boss's leadership success characteristics?

Please tick the correct characteristics level

	Nil	Weak	Moderate	Strong
Commitment: He/ She is totally dedicated to the Lab				
Works constantly towards Lab goals				
Leadership: A person people you want to follow?				
He/she has self confidence has an internal locus of control				
Initiative: puts him/herself in positions where personally responsible for success or failure				
Has a need to control				
Readily use expertise and relevant help?				
He/she is honest in your lab dealings?				
Inspire those who work with you?				
Has built strong relationships with those who work for you				
Empower others who work for you				
Ethical standards: Safeguards the privacy and confidentiality of patients				
Creativity: Does things differently from other labs				
Creativity: He/she is imaginative				
Creativity: Has found something that already exists (not yet perceived) that improves your lab				
Other important success characteristics of your boss?				

Thank you very much for giving of your time

Start time ☐ **Finish time** ☐ **Questionnaire No** ☐