ISO 15189 ACCREDITATION PROJECTS AND PERFORMANCE OF MEDICAL LABORATORIES IN NAIROBI CITY COUNTY, KENYA

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International Academic Journal of Information Sciences and Project Management (IAJISPM) | ISSN 2519-7711

Received: 20th June 2019

Accepted: 28th June 2019

Full Length Research

Available Online at:

http://www.iajournals.org/articles/iajispm_v3_i3_235_258.pdf

Citation: Ngeno, K. L. & Kinoti, F. (2019). ISO 15189 accreditation projects and performance of medical laboratories in Nairobi City County, Kenya. *International Academic Journal of Information Sciences and Project Management, 3*(3), 235-258

ABSTRACT

Many medical laboratories have successfully completed ISO 15189 accreditation projects and achieved accreditation recognition certificate according to Kenya National Accreditation service department in the ministry of industrialization in-charge of accreditation in Kenya. Ministry of Health in the year 2010 begun process of accreditation of national and county referral public laboratories to ISO 15189 standard with donor support while private firms channel their resources following Ministry of health recommendations. Both sectors implemented ISO 15189 accreditation three key projects. These projects are quality Management System, Process control, and resource management system. However, not all laboratories who initiated the projects have attained ISO 15189 accreditation by December 2015 according to KENAS. Thus the need for research to be done to analyze the effects of accreditation projects on the performance of medical laboratories within Nairobi City County, Kenya so as to inform a new approach to accreditation projects for laboratories that have not completed the projects in the entire country. The purpose of the study was to assess the effects of accreditation projects specifically on the performance of accredited medical laboratories in relation to Productivity, Quality of service delivery and Cost of services. The organizational theory advanced by Berle and Means in 1932 and scientific management Theory by Taylor of 1909 guided this study. Descriptive research design was used in the study with focus on all levels of management in the laboratories as respondents; Stratified sampling techniques was utilized to group different laboratory management levels (Top Management, Middle level, Operations Level and Technical personnel) and simple random sampling was used from each stratum so as to obtained varied perception views from all levels of management. The target population was seven accredited medical laboratories in Nairobi City County with measurement unit of 225 laboratory personnel with a target sample size of 141 respondents; primary data was collected using structure questionnaire. The study found out that quality management system project (β=0.312, p=0.000<0.05) has a positive and significant effect on performance of medical laboratories. Process control project (β=0.243, p=0.002<0.05) has a positive and significant effect on performance of medical laboratories. Resource management system project (β=0.318, p=0.000<0.05) has a positive and significant effect on performance of medical laboratories. The study concludes that ISO 15189 accreditation projects have a positive effect on performance of medical laboratories. The study recommends that the management of all medical laboratories in Kenya should increase the implementation and adoption of quality management system project in order to positively influence performance of their organizations. The management of all medical laboratories in Kenya need to improve on the process control projects in order to positively influence performance of their organizations. All medical laboratories should improve on their resource

management system projects for positive improvement in performance.

Key Words: *ISO 15189, accreditation projects, performance, medical laboratories, Nairobi City County, Kenya*

INTRODUCTION

Organizations worldwide have defined various ways of ensuring performance is enhanced so as to meet customer expectation of quality and safety of service or products provided. To achieve improved performance many have adopted ISO standards for either certification or accreditation to foster confidence in performance. This ISO accreditation or certification process is a project management venture performed to create an exceptional service, product, or outcome. The short-term states of projects designate a definite beginning and completion (Horine, 2005) which is award of accreditation certificate. This requires Project management knowledge because it focuses on controlling the introduction of the desired change.

Project management is the systematic application of current tools and techniques in planning, implementation, financing, controlling and coordination of activities in order to achieve desired outcome according to the project objectives within the constraints of time and cost. Project management is therefore about managing the processes of a project from defining stage to planning, execution, control to the closure of the project. A project has four main resources which need to be managed in order to ensure that the projects are successful. These resources are people, time, money, and scope. A program on the other hand, unlike a project, is an ongoing process and it could include managing a series of several projects. Projects vary in their size, simplicity, and complexity (Hamilton 1996).

Health providers across the world are establishing new performance requirements to protect cliental from poor services as well as inferior and faulty products and ever more sophisticated counterfeits like pharmaceuticals as well as medical devices which are also of concerns. Health providers, especially in the developed world, are embracing quality standardization so as to provide quality services to patients through the accreditation process.

Accreditation

Hospitals accreditation began in United States with the establishment of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 1951. In 1960 to 1970s the model moved through Canada and Australia and later adopted in Europe in the 1980s. It was in 1990s when the entire world adopted accreditation programs. Accreditation Literature review by Shaw DC (2003) bring fourth World Health Organization documentation of 36 nationwide healthcare accreditation programs in 2000; asserting corroborated by Greenfield (2009), that accreditation is an indispensable part of healthcare systems in not less than 70 countries, granted after a thorough assessment or audit by an external and independent body.

However, in the African context, in spite of the mounting appeals and significance of ISO certification and accreditation in many health organizations, its' realization in African institutions; particularly the healthcare sector has remained low. In extension, its adoption amid patients and users has not delivered tangible outcomes in the manner organizational performance endeared to patients' service satisfaction. (Zeithaml, 2000).

In realization of high HIV burden in Kenya early 2003, the Ministry of Health opened the National HIV Reference Laboratory and in 2008 added National Microbiology Reference Laboratory with aim of having them as centre of quality excellence, through provision of proficiency testing schemes and mentorship/Assessor on HIV/TB care and treatment in the country. But lack of QMS in the two National reference laboratories then could not allow them to benchmark with international organizational standards, due to lack of validation of its analytical testing processes thus restraining its capacity and influence to play roll of center of excellence (Gichuki 2014). However, the two National reference laboratories joined Strengthening Laboratory Management Towards Accreditation (SLMTA) program early 2010 and among first Kenya's cohort of twelve other laboratories, with the ambition of achieving ISO 15189 accreditation, which they succeeded in achieved within a period of three years in March 2013.

Private sectors have not been left behind in the need to have accreditation of their laboratories; using institutional designed approaches unlike Public health laboratories that used SLMTA program, within the same period up to 12 private laboratories attained accreditation in the country according to KENAS newsletter 2015. Five of these laboratories are located within Nairobi City County which formed part of the target population facilities during this study.

ISO 15189 Accreditation Process Projects

International Organization for Standardization is a global confederation of state standards bodies (ISO member bodies) charged with the responsibility of developing and review International Standards through ISO technical committees following the petition by any involved member body in a subject matter for which a technical committee has been time-honored to undertake. Key stakeholder's either International institute, governmental or non-governmental, in association with ISO, also take part in the process in collaboration with the International Electro-Technical Commission (IEC) on all aspects of electrotechnical standardization. Fulfilling ISO 15189 requirements by Medical laboratories confirm that the laboratory has met requirements for technical competence as well as management system necessary for reliable delivery of technical and quality results. ISO 15189 – 2012 Clause 4 provide for the standard to be documented in a language applicable to a medical laboratory's operations and meets the principles of ISO 9001:2008 on Quality management systems requirements which are significant requirements by Joint IAF-ILAC-ISO Communiqué issue of (2009).

The first version of ISO 15189 was published in 2003, with first revision done in 2007 and the third edition of the standard was published in 2012. These standards support global improvement and harmonization of clinical practices across healthcare departments by ensuring health and safety of patients, healthcare providers and protection of data for improvement in the overall quality of care. The standard is used by laboratory customers, regulatory authorities and accreditation bodies as a measure of medical laboratory competence. In 2012, revision of the standard was done to incorporate mandatory assessment against measurement uncertainty and traceability making it latest version ISO 15189-2012 standard (ISO standards newsletter 2012).

ISO 15189 on medical laboratory requirements for quality and competency standard provide a guideline on three main accreditation processes projects which many laboratories have taken as main organizational projects so as to achieve accreditation certification:

First ISO 15189 accreditation project is development and implementation of quality management (QMS) which is a project management function of planning through development of a set of policies, processes and standard operating procedures (SOP) by all stakeholder from top management to technical level through Quality improvement committee functions; made of Laboratory Manager, Quality manager, technical representatives from six major laboratory departments and buy in institutions top management representative because they are involved in planning and oversee implementation in the central of an organization. This QMS process project team define the development of required Manuals, Policies and procedures with all having purpose, responsibilities, document control/revision, training and review of training through competency testing before, during and after implementation; (ISO 15189 – 2012 Standard)

The committee comes up with a budget for procurement of computers, printers, stationeries, internet service lines for proper coordination of documents development, review and approval is forwarded to procurement office for purchase, installation, and training of users.

Developed QMS documents are then used for training as well as providing guidance to laboratories on adherence to ISO 15189 standard requirements through its vision statement which provide clear focus for laboratory system development, improved coordination and synergies across all levels of management; because QMS process project envisage standard way of doing things with aim of improving efficient service delivery measured by increased productivity through increase in number of tests, workload which can translate to higher revenue and smooth processes as expected to lead to overall customer satisfaction.

Secondly ISO 15189 process control project employs project management knowledge of Monitoring and evaluation as well as controlling through development and implementation of process control project which is made of both internal and external controls processes done to oversee project implementation to enhance timely detection of potential errors for corrective and preventive action to be taken. The ISO 15189 provides for the development of measuring

performance through annual appraisal of Quality management systems and personnel through competency testing which agrees with Kaplan and Norton (1996) who suggested performance measurement of systems employed in an organization using Balance Scorecard, which provides an overall organizational performance measure, which provide managers quick and complete measure of the organization aerial view. The key benefit is that ISO accreditation process control project performance is progressively observed and measured against standard for any deviation from the project management plan. ISO 15189 standard uses process control through entire QMS so as to identify errors/non-conformance in a pre-analytical stage; where the laboratory establishes control programs on personnel proper maintenance of equipment, accurate patients' identification and handling, specimen collection process. Analytical process control programs include internal quality system checks, operation of laboratory information system, equipment troubleshooting techniques and interpretation of results. Post-analytical stage involves results review and posting, Amendment of results, recalling and re-issue of results, the measure of TAT and customer feedback with aim of providing quality and reliable results with minimal errors. The key measure of overall quality performance across all the three stages is the Proficiency testing, where laboratory participate in peer comparison exercise uses blinded specimens from an accredited international provider. These key areas form the ISO accreditation independent Variables sub-units of interest for the basis for evaluating laboratory performance. Another measure of process control is incident reports of non-conformance, corrective actions as well as preventative measures put in place to avoid recurrence; which include bio-security or safety hazards and delay beyond prescribed timeliness to provide required results (ISO 2012).

Thirdly ISO 15189 accreditation project is the development and implementation of Resource management system project by use of project management methodology in the execution of project using allocated resources so as to achieve required results. ISO 15189 requires the development of resource management system that can guarantee efficiency in service delivery. Quality management improvement committee procures laboratory information systems which have patient management component, resource management, and personnel management. This is always achieved through implementation of purchase and inventory policies from QMS project by incorporating electronic or manual system which would enable clear identification of items required, procurement process, management and accounting for all available resources with aim of ensuring continuous service delivery at fair cost. (ISO 15189 - 2012 standard).

Prudent management of resources defines performance as a summary measure of resources utilization in relation to quantity and quality of work which is evaluated at the individual; department, or organizations level, performance may be expressed as an accomplishment into dimensions of organizations efficiency, effectiveness, and productivity (Drucker, 2004). According to Richard (2009), organizational performance encompasses outcomes: financial performance (Net profits, return on investment and return on assets); product market performance; and total shareholder economic and return value).

The laboratory using procurement policy is able to monitor the performance of vendors to ensure that procured goods or services meet stated criteria and can help improve healthcare management at a fair cost. For example, supply chain requires better inventory management through improved forecasting skills and utilization tracking systems. To agree with British Standards Institute affirmation of the resulting advantages accruing from ISO accreditation are bigger responsibility, accountability from staff and quality consciousness leading to minimization of resources wastage and translation to affordable service delivery.

Medical Laboratories

A medical laboratory or clinical laboratory is a department in hospitals system dealing with clinical specimen's collection and analysis so as to provide guidance to the clinicians on the type of disease/ condition patients are suffering from for effective treatment and disease control. Laboratory results are performed to aid clinicians in medical decisions of mode of treatment patient may require depending on laboratory outcomes, assertion confirmed by Forsman (1996) from developed countries estimation of 60% to 80% of patient care decisions depend on laboratory reports which are relatively accurate and precise than clinical decision criteria alone (Miners 2008). Nonetheless, clinical patient management and laboratory diagnostics are interdependent; where laboratory data provide confirmation for clinical decision making as suggested by clinical symptoms or the clinical treatment guidelines often warrant laboratory testing.

Laboratory improvement inclines to the health care accreditation project process, through standards organization encouragement to achieve internationally recognized criteria. Second, accrediting bodies would revise these international standards within predetermine schedule based on research updates and acceptable best clinical practices with aim of eliciting continuous quality improvement, which would lead to the provision of high-quality and safe health care services as well as improved patients' health outcomes (Braithwaite, 2010).

Adherence to ISO 15189 standards and implementation of accreditation process projects was foster improvement/efficiency in operations in customer laboratory service delivery through the elimination of laboratory errors. Though there are limited publications providing a direct linkage between accreditation and elimination of laboratory mistakes and in extension patient outcomes, several literatures have demonstrated that participation in Proficiency Testing programs (Peer comparison) a key quality indicator of ISO 15189 accreditation process control project which confirms the accuracy of laboratory test results. Ehrmeyer (2004) established that laboratory in limited resources enrolled for at least 3 cycles of an external CD4/C8 quality control program resulted in a 26% to 38% decrease in laboratory errors with CD4/C8 count amongst laboratories in United State of America following implementation of CLIA guidelines on improvement in the quality of laboratory services. Bergeron (2010) found out that when proficiency testing became

USA national standard requirement laboratories reported decrease in failures following successive participation suggesting that it was likely that patients were benefiting from improved medical decision being made due to reduced errors reported However, available literature did not explore all process control aspects but majored on proficiency testing only thus there was need for extension study on more process control determinants from perception of persons working in this accredited laboratories with assumption that all respondent had knowledge of all process control parameters.

The Bergeron finding has had pressure impact to laboratory networks in current day to innovatively improve in their proficiency testing performance to a level of minimal errors, which would translate to accuracy in treatment and in extension acquisition of market share. This has been evident with marketing flyers from most of the accredited facilities with aim of assuring the target market that the operations within their laboratories conform to recognized international standards. A study by Casadesus and Jimenez (2000) indicated that ISO 9001 certification served to improve the possibility of obtaining new contracts and accessing new markets. Organizations working to achieve its objectives would easily earn a status from its stakeholders, especially the largest service consumer, society opinion leaders, suppliers and existing and potential employees (Sroufe, and Curkovic, 2008).

Remembering the primary purpose of laboratory ISO 15189 accreditation assures consumers of laboratory service of reliable, consistent and guarantee quality patient outcomes as sign of improved performance at its core and it was against this background that the study assessed the laboratory accreditation to ISO 15189 standard using three main process projects and performance of medical laboratories in relation to four key performance indicators productivity, Quality of service, Cost of service delivery and assessed their feeling on their social laboratory reputation as Casadesus (2000) define reputation as spontaneous, ubiquitous, and efficient method of social control in natural environmental setting. ISO Accreditation spurs confidence on laboratories and reliance amongst authorities, clinicians and patients on kind of accurate and precise results produced. These may lead to successful achieving laboratory to justify the need for more resources required to maintain the quality of service. Adequate resourcing improves laboratory ability and performance.

STATEMENT OF THE PROBLEM

Medical laboratory have been channelling huge resources to ISO 15189 accreditation projects as metric benchmark for improvement in performance, however absence of published performance change from implementation of the three key ISO 15189 accreditation projects which include quality management system, process control and resource management which could be lowering productivity because it involves intense documentation process, Increase cost of service delivery from amount of resources allocated, poor quality of service which could damage reputation of

the laboratory. Perked question whether private or government institutions should continue pushing for implementation of these accreditation projects through resources support or first reflect on performance effects of an already accredited institution so as to channel resource to projects guided by each positive project effects on medical laboratory performance; was the basis and interest to undertake this study. Literature review by Greenfield (2008) findings from Dutch, North America and European Union demonstrated indeterminate conclusion on effects of accreditation projects on performance but suggested that accreditation foster change on service, organizational perspective change and professional growth; which is equivocal to Braithwaite; (2010) question on whether accreditation projects can lead to improved quality of patients care and outcomes, Shaw; (2010) study on the effect of certification in hospitals suggested that individual hospital's higher levels of adherence to quality management standards are more associated with ISO accreditation projects than with ISO certification; with a recommendation for further studies to establish relationship between the accreditation high levels compliance and organizational performance on all the accreditation key projects which this study tried to establish. Greenfield and Braithwaite (2008) extensive literature review of health sector accreditation study would discover evidence for the capacity of ISO accreditation to transforms and enhance professional growth in healthcare delivery and study suggested for establishing the relationship between professional development and the organizational performance. Braithwaite (2010) presumption that cultural and leadership behaviour of healthcare institution rather than clinical performance, positive consumer participation nor organizational climate is as a results of accreditation in Australia, may not be the case in developing countries with diverse cultural and leadership styles due to resource limitation. Due to limited empirical literature on direct effects of ISO accreditation processes development and implementation on laboratory performance; therefore there are controversies which needed to be addressed hence a need for extension research to determine extent of all ISO accreditation processes projects using specific performance indicators in developing country among 7 laboratories that had attained ISO 15189 accreditation in Nairobi City County using key ISO accreditation processes projects with an aim to demonstrate each of the three key projects effects on performance indicator and would form future evaluation reference when implementing ISO 15189 accreditation projects in Kenya .

GENERAL OBJECTIVE

The main objective of the study was to assess the effects of ISO 15189 accreditation projects on the performance of medical laboratory in Nairobi City County.

SPECIFIC OBJECTIVES

1. To analyse the effects of quality management system projects on the performance of medical laboratories.

2. To establish the effect of process control project on the performance of medical laboratories.
3. To measure the effects of resource management systems project on the performance of medical laboratories.

THEORETICAL REVIEW

Theories are formulated to predict, explain and understand phenomenon or challenge and extend existing knowledge within the limits of critical bounding assumptions with the reason of explaining the connotation, nature, and challenges related with an observable fact, often experienced but not explained in the world, so that the knowledge and understanding gained can act in more informed and effective ways Abend (2008).

Organizational Theory

This theory was American creation by Berle and Means in 1932 and Modified by G. Burrel in 1966. Theory state that process with structures including norms, rules, and routines, established as authoritative guiding principle, Scott (2004) asserts that institution are social formation that have attained a high degree of pliability, they are composed of cultural cognitive, normative and regulative element that, together with related activities and resources, provides stability defining social life. The dimension of decoupling implies that for organization to be seen to be adopting definite institutional practices was even introducing formal processes intended to be implemented. This theory support ISO 15189 Accreditation standard establishment of Quality Management system projects which provide for developing of organization policies, Manuals and standard operating procedures, which guides in maintenances of the standard's requirements and its effect, is performance of medical laboratory in relation to productivity. These Quality policies provide rules/norms involving intense documentation processes which can increase workload. Quality Manual is reference template which provides guidance on requirements for fulfillment of project with aim of increasing revenue through increase in testing scope of the laboratory. The technical SOP guide on procedures to follow so as to meet customer needs.

Deming's Theory of Profound Knowledge

The theory of profound knowledge is a culmination of Dr. W. Edwards Deming's lifelong work management philosophy grounded in systems theory he developed in 1966. He viewed organization as a system form as a network of interrelated components linking processes and people. Deming (1966) define success of an organization to be depended on how best the managers are capable of handling the subtle balance of the components for optimum output of the system. In relation to ISO 15189 standards requirements expectation is based on process

control project which link pre-analytical, analytical and post-analytical process to ensure quality in service delivery.

Deming also observed that understanding of systems made up of interrelated units and to achieve quality from optimized component in reference to the goal, depend on prevailing management style employed and in order to achieve quality, each component is needed to strengthen and not compete with one another. ISO 15189 accreditation process control project is deemed achieved when peer comparison informs of proficiency testing checking all the three stages score >80% to peers. During analytical stage incidents reported determine the quality of service and is linked to staff competency as competent staff make allowable errors. The third stage of post-analytical process is the time taken for service to be delivered thus providing fidelity of purpose of the system according to Deming, without goal, there is no system uniqueness. Then, identify the apparatus with processes and the interrelationships of the components within the relationships.

Scientific Management Theory

The Scientific management theory advanced by Taylor in 1909 aimed at growing productivity and making work easier by scientifically studying work methods and setting standards through his four principles of determining efficient way of working which support process control project classification of process flow from Pre analytic to post analytic, second principle of matching workers to areas of training through competency review of laboratory personnel to determine areas of training and strength, thirdly monitoring performance which support peer comparison with other laboratories in addition to monitoring performance incidents in regards to safety and fourth principle is sharing of responsibilities support need to obtain views from all levels of management due to their variation in responsibly (Schermerhorn, 2005). Laboratory accreditation as outlined by KENAS is based on two main approaches.

The first approach was used by the two National reference laboratories referred to SLMTA program and the world health organization SLIPTA checklist for identifying conformance and non-conforming areas to determine accreditation preparedness using the 12 listed quality system essentials (QSEs). The checklist provides progress report using star rating depicting level of conformance to ISO 15189 standard requirements: zero to five-star grading percentage of (0 – 54%), (55 – 64%), (65 – 74%), (75 – 84%), (85– 94%), and (≥ 95%) consecutively and laboratory is deemed to be ready for accreditation assessment by accrediting body after attaining >95% score. The second approach was direct accreditation body guided process used by private sector.

Situational Theory

Situational theory was developed by Paul Hersey and Ken Blanchard in 1970s. They viewed effective leadership as being task-relevant and define successful leaders to be persons who adapt

their leadership style through their ability and willingness to lead or influence. They also noted that effective leadership varies depending on the person or group that is being lead and always influenced by the job to be accomplished, Introduction of SLMTA in Kenya which aimed at training of laboratory leaders of all management levels to understand the ISO 15189 standard requirements in order to prepare them for its implementation which fulfill Situational Theory statement that staff at work differ in readiness level.

Laboratory technical managers would be referred as staff with low tasks and readiness because of their little ability based on training would require a different management approach than staff who are high in readiness and ability, confidence, skills, and willingness to work matching top-level managers because they are policymakers. The Theory asserts that top-level manager's responsibility is to enhance their subordinates' motivation to achieve organizational goals: in this case laboratory accreditation to ISO 15189. This study tried to establish relation of this theory in regards to response from different levels of staff working in Nairobi City County accredited laboratories through administration of similar questionnaire to all levels of management. This theory support process control system projects independent variable, where measurement was through the effects on the quality of service when varied readiness of different levels of personnel are put together to achieve organizational goals.

Expectancy Theory

The expectancy disconfirmation theory was developed by Victor H. Vroom in 1964 who suggested that consumers of products/services form contentment judgments by evaluating actual product/service provided. This theory can be cemented with Consistency theories with suggestion that when consumer expectations and the actual product/service presentation do not match makes the consumer feel some scale of tension and in order to reduce this tension the consumer would make adjustments in either their expectations or perceptions of the product's/service actual presentation.

Most of private laboratories accreditation process projects begun when there was realization that public health facilities couldn't meet the quality of service expected by customers due to reported service interruption resulting from poor resource management and inadequacy of supply chain management system which was changed to Kenya Medical Supply Agency in 2014 (KEMSA). ISO 15189 standard demands for non-interruption of service due to stock-outs caused by poor resources management. The standard provides guidance on development of efficiency in forecasting, procurement and inventory control through resource management system implementation. This theory supports resource management system project independent variables with aim of explaining how process improvement on resource management was used to meet customer expectations of cost effective service and continuous service delivery devoid of interruption due to stock outs

EMPIRICAL REVIEW

Studies done in the United States and Europe demonstrate occurrence of medical laboratories errors from pre-analytical stage processes which include specimen collection, labeling, and shipment; analytical stage which is actual testing in the laboratory); and post-analytical stage which involve data management and reporting results, showed a 46%–68% of errors occurring in the pre-analytical while 18%–47% are occurring in post-analytical stages of the laboratory process. Findings supported by Plebani (2009) who explain recognition of accredited Laboratories in offering higher test reliability, process flow performance, excellent quality management system, and brilliant staff competence. However, the study findings can be attributed to developed countries with robust testing systems which may not reflect developing country set-up with limited infrastructural capacity, cultural diversity and leadership styles.

According to Trevor (2010) he asserted that a working national laboratory accreditation program in a country can only be achieved through clear laboratory standard operating procedures that promote accreditation as requirement for all laboratories, Ministry designate quality standards whereby a country laboratories can be audited and define both local or international accrediting bodies authorized to audit laboratories and provide accreditation certificates on their performance against the ministry designated quality standards. Many a times it is understood that Medical laboratory process strengthening programs are essential to accrediting public-sector laboratories would result in tangible improvements in the quality of service delivery and there is likelihood for patients to benefit from improved care and treatment decision resulting from a reduction in test errors and thus fair cost.

However, there was limited literature that was seeking to use performance as indicator for accreditation projects in developing world public sector laboratories. Existing efforts had largely focused on overall accreditation's performance and its overall impact (Greenfiel 2008). According to Ebrahim (2011) publication on healthcare accreditation system which was seeking to provide valuable insights in direct relationship between performance and accreditation, provided indicators that could make possible the challenging task of auditing accreditation projects performance based on Australia study where some of the indicators were used in pushing for decisions by policymakers and authorities to measure the success of accreditation projects within a specified time period. Secondly, the study reflected the expressions of professionals and academicians, which had been overlooked by previous studies. This study was seeking perception of professionals working in the target facilities so as to provide insight view of accreditation projects and performance to reduce bias which may have been reported by policy makers; thus need to stratified various levels of management for reasonable view on accreditation projects effects on medical laboratory performance.

According to Greenfield (2008) literature review study on healthcare accreditation projects and the organizational performance he concluded that there were mixed and inconsistent results because various studies did not demonstrate either confirmation or neutral evidence regarding the effects of accreditation projects on the healthcare organization. However, he concluded that these programs could promote behavioral change and professional development among personnel in healthcare organizations. According to Braithwaite (2006) he demonstrated limitation of accreditation to only supporting its effectiveness, due to their subjective nature or limited coverage, which left out key accreditation processes project approach as a measure against the performance thus there was need for more research to study accreditation projects effectiveness and performance of medical laboratories which informed the objective of this study using ISO Accredited laboratories within Nairobi City County to provide directional effects on policy formulation for future planning and implementation of accreditation projects in Kenya's laboratories.

According to Braithwaite (2006), he argued that a multiple level research design would provide conclusive evidence on the performance and effects of accreditation process project. This study was considering recommendation by Scrivens'(1997) of use of perception to provide a critical indicator valuable glance and determining meaning of the latest trends in evaluating accreditation process projects with initial approach requiring multiple groups, involved/Participated in accreditation process projects providing detailed perception of the process and their outcomes. Approach supported by Hurst (1997) through public health sector study where he confirmed that perceptions of healthcare stakeholders' and accreditation assessors collected during the performance of their undertaking of accreditation projects according to accreditation standards would provide a non-biased response on accreditation processes projects and performance because all parts participate in various levels of the projects. This study informs the approach in obtaining data of laboratories accreditation by involving staff from all levels of management and their response outcomes would guide in determining a more effective approach to accreditation processes projects in relation to laboratory performance.

Greenfield (2008) found out in his literature review study that the value of accreditation projects was indeterminate from Dutch, North America, and European Union study on accreditation predictor; he did acknowledge the cultural and economic status could be affected organization performance perception of accreditation. Even though a number of studies have suggested that accreditation projects promote service, organizational, professional change and development, but no equivocal link to improvement on quality of care or patient outcomes attributable to accreditation process projects implementation. The objective of the study was to determine effects between ISO accreditation process projects based on quality indicators of performance require identification and development of tangible measures of achievement of accredited healthcare laboratories. It provided for qualitative investigation and the positive effects to be qualified to the effective implementation and performance of the accreditation processes

projects. However, Wasiams (2004) recommended for further studies that would provide information on the association between accreditation projects and patient outcomes indicators or doctor's satisfaction and the changes resulting from these process projects in subject organizations.

However, Gustafson (2002) criticize Scrivens (1997) perception approach for being superficial and judgmental and he pointed out procedural challenges in measuring healthcare outcomes in regards to accreditation projects implementation based on the perception of stakeholders as there interest limit open interrogation. Shaw (2003) articulated concerns on the challenges of defining 'endpoints' of ISO accreditation projects and impact change based on the expectations of users and observers because it always have component of continuous improvement whenever target is not met rendering invalid measurement of accreditation projects' performance in regard to outlined challenges: Nonetheless Menon (2001 noted that due to the complexity nature of the healthcare sector; which is the earlier challenges in itself, it is worth considering the perception approach which could be safer, despite its deficiency as it provides insight of immediate implementers of the projects and their views would reflect the expected outcomes. Weighing the perception safety informed the approach this study was take by gathering personnel perception of accreditation effects/relationship on laboratory performance.

In Kenya, Patients and Health Service Stakeholders are becoming increasingly more sophisticated, better informed and a lot of weight has been put on ISO 9001 on Quality Management System requirements, while medical laboratories have embraced ISO 15189 standards that provides the specific requirements for quality and technical competence.

Ministry of health on the realization of the absence of accredited public health laboratory embarked in the adoption of WHO Maputo resolution AFR/RC58/R2 (2008) in 2009, which called for a strengthening of public health laboratories in the African Region. The Maputo Declaration focused on integrated laboratory support for major diseases and urged Member states to develop and implement national laboratory policies and strategic plans. The declaration also motivated countries, partners, and donors to develop a laboratory network with integrated systems for efficiency in support for multiple diseases investigation at various levels of a laboratory network. The hierarchical laboratory network with the national reference laboratory at the apex; regional referral, specialize laboratories (Cancer/oncology labs), County laboratories and lower health center laboratories to understand the need of providing accurate laboratory testing service for patient care/treatment, disease prevention, and control.

RESEARCH METHODOLOGY

Research Design

This is a plan for collecting and utilizing data so that desired information can be obtained with sufficient accuracy (Huberman, 2004). The study was adopting descriptive research design. Schindler (2003) explained descriptive research design as a study that concerns with discovering who, what, when, and how of the relevant phenomenon. The study was depending on how the personnel working in the accredited laboratories perceive their organizational performance now that the laboratory is ISO 15189 accredited.

Target Population and Sample Size

The target population is a group about which desired information for the study is derived from a general population. The target population were 7 ISO 15189 accredited laboratories in Nairobi City County (KENAS Newsletter of 2015) with personnel from top-level management, Middle level, Operation level and technical personnel making up a unit of measure documented as 225 (Institution records as at December 2015). According to Kothari (2006), the technique produces estimates of overall population parameters with greater precision and ensures a more representative sample is derived from a relatively homogeneous population. The sample size of the study was derived from the formula below as recommended by Mugenda (2003):

$$nf = \frac{n}{1 + \frac{n}{N}}$$

= 384/ (1+384/225) = 141

Where: nf = Sample size (when the population is less than 10,000); n = Sample size (a constant when the population is more than 10,000); N = Estimate of the population size; 225 (According to institutions records Dec 2015)

Stratified sampling was employed to group different management levels as (Top Management, Middle-level Management, Operation level and Technical Personnel). Where simple random sampling technique was used to obtained sample size from the stratus.

Data Collection Instrument

The data collection instrument was structured questionnaire with sub-units of the dependent variable and an open-ended question which provide respondent chances to express own opinion outside structured sub-units questions. The structuring of the questionnaire was guided by the time available, the nature of data to be collected and objectives of the study so as to minimize variation in response to study variables.

Data Collection Procedure

A questionnaire is a research tool that collects data over a population sample (Kombo 2006). The study used structured questionnaires as the primary data collection tool which administered to the respondents from top-level managers, middle managers, operation managers and technical personnel. With the questionnaire, the findings remain confidential and saved time because the questions had been distributed to cover key areas of the how variables could be measured. The questionnaire was dropped in the institution with help of laboratory manager and collected after every week for a period of 1 month. The questionnaires utilized a five-point Likert's scale namely Strongly Agree (5), Agree (4), Not Sure (3), Disagree (2) and Strongly Disagree (1).

Data Analysis and Presentation

Descriptive statistical data analysis was used as described by Mann (1995) as statistics that quantitatively describe or summarize features of a collection of information. The Likert's scales scores were analyzed in excel to determine the Mean, percentage and standard deviations. The study also determined regression coefficient so as to establish the relationship between the independent and the dependent variables with help of SPSS and obtained information were presented using frequencies tables.

$$\mathbf{Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \varepsilon}$$

Where: **Y** is= Performance; $\mathbf{X_1}$ = Quality Management System Project; $\mathbf{X_2}$ = Process Control Project; $\mathbf{X_3}$ Resource Management System Project; β_0 = Constant; β_1, β_2 and β_3 are Coefficients and $\boldsymbol{\varepsilon}$ = Error Term

RESEARCH RESULTS

The main objective of the study was to determine the effects of ISO 15189 accreditation projects on the performance of medical laboratory in Nairobi City County. The specific objectives of the study were; to analyse the effects of quality management system projects on the performance of medical laboratories; to establish the effect of process control project on the performance of medical laboratories and to measure the effects of resource management systems project on the performance of medical laboratories.

Quality Management System Projects and Performance of Medical Laboratories

The study found out that quality management system project has a positive and significant effect on performance of medical laboratories. The implementation of quality policies has improved efficiency and that the use of technical SOP has improved patients waiting time (TAT). The study further revealed that implementation of quality policies has increased laboratory workload

and that the use of technical SOP has increased tests menu scope. However, respondents were not sure whether adherence to quality manual has increased laboratory revenue.

Process Control Project and Performance of Medical Laboratories

The study revealed that process control project has a positive and significant effect on performance of medical laboratories. Analytical controls have reduced incorrect results reports errors. Summative implementation of process control project has improved customer satisfaction rating based on quality of laboratory service offered. Process control projects have improved proficiency testing scores. Pre-analytic controls have reduced specimens' rejections and post-analytical controls process checks have improved personnel competency levels. Pre-analytical controls have reduced personnel incidents and accidents.

Resource Management Systems Project and the Performance of Medical Laboratories

It was established that resource management system project has a positive and significant effect on performance of medical laboratories. Stock management system has seen a reduction in stock loss due to expiry of stocks. Stock management system has seen reduction interruption of Laboratory service due to stock outs. Proper identification of laboratory needs have reduced cost in service delivery. Structured prequalification of suppliers have led to transparent partnership with suppliers. Implementation of electronic procurement process has reduced on stock orders lead time.

REGRESSION ANALYSIS

In order to determine the effect of ISO 15189 accreditation projects on the performance of medical laboratory in Nairobi City County, regression analysis was used. The model summary is used to report the values of the coefficient of correlation R and the coefficient of determination R square as shown in Table 1.

Table 1: Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.888[a]	.789	.784	1.39103

a. Predictors: (Constant), Resource Management System Project, Quality Management System Project, Process Control Project

Table 1 shows R square as 0.789, this shows that 78.9% change in performance of medical laboratories is explained by their ISO 15189 accreditation projects. Therefore, there are other factors that explain the remaining 21.1% change in performance of these institutions which future studies should focus on.

The researcher conducted ANOVA at 5% level of significance. The findings are as reported in Table 2.

Table 2: Analysis of Variance

	Sum of Squares	df	Mean Square	F	Sig.
Regression	919.862	3	306.621	158.462	.000[b]
Residual	245.741	127	1.935		
Total	1165.603	130			

a. Dependent Variable: Performance

b. Predictors: (Constant), Resource Management System Project, Quality Management System Project, Process Control Project

Table 2 shows that the value of $F_{calculated}$ is 158.462 while that of $F_{critical}$ is 2.676. Thus, $F_{calculated} > F_{critical}$ and this can be interpreted to mean that the overall regression model was significant.

The findings on the beta coefficients with respective p values of the variables showing their significance to the study are indicated in Table 3 below.

Table 3: Regression Coefficients

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	2.943	.788		3.734	.000
Quality Management System Project	.312	.074	.453	4.222	.000
Process Control Project	.243	.068	.061	3.567	.002
Resource Management System Project	.318	.062	.413	5.107	.000

a. Dependent Variable: Performance

Therefore, the following regression model is established from Table 3;

$$\mathbf{Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \varepsilon}$$

Where: **Y** is= Performance; $\mathbf{X_1}$ = Quality Management System Project; $\mathbf{X_2}$ = Process Control Project; $\mathbf{X_3}$ Resource Management System Project; β_0 = Constant; β_1, β_2 and β_3 are Coefficients and $\boldsymbol{\varepsilon}$ = Error Term

Therefore, at 5% level of significance, quality management system project (β=0.312, p=0.000<0.05) has a positive and significant effect on performance of medical laboratories.

Therefore, as an organization strives to improve on quality management system projects, their performance also increases. The finding is consistent with Donabedian (1998) who established that QMS projects lead to rising in confidence in the quality of care provided by the laboratory resulting in high levels of predictability on procedures, structures, and outcomes of care, following the classic distinction.

Process control project (β=0.243, p=0.002<0.05) has a positive and significant effect on performance of medical laboratories. This shows that any effort to improve on process control project would see an increase in performance. The finding is in line with Which Roth (2007) who alludes that stakeholders are always concerned about non-functioning and unintended cost of quality improvement initiatives from implementation of process control projects.

Resource management system project (β=0.318, p=0.000<0.05) has a positive and significant effect on performance of medical laboratories. Therefore, an improvement in resource management system project would lead to an increase in performance. Yeung (2002) establishes that the key benefits the organizations derive from ISO 15189 accreditation resource management system project in health process particularly in respect to organizational performance is measured success and efficiency on their operations supported by process controls projects efforts; which was certainly influence significantly overall performance of the laboratory in relation to cost of production which can directly translate to cost on service delivered.

CONCLUSION

Quality Management System Projects and Performance of Medical Laboratories

Quality management system project has a positive and significant effect on performance of medical laboratories. The implementation of quality policies has improved efficiency and that the use of technical SOP has improved patients waiting time (TAT). The implementation of quality policies has increased laboratory workload and that the use of technical SOP has increased tests menu scope.

Process Control Project and Performance of Medical Laboratories

Process control project has a positive and significant effect on performance of medical laboratories. Analytical controls have reduced incorrect results reports errors. Summative implementation of process control project has improved customer satisfaction rating based on quality of laboratory service offered. Process control projects have improved proficiency testing scores.

Resource Management Systems Project and the Performance of Medical Laboratories

Resource management system project has a positive and significant effect on performance of medical laboratories. Stock management system has seen a reduction in stock loss due to expiry of stocks. Stock management system has seen reduction interruption of Laboratory service due to stock outs. Proper identification of laboratory needs have reduced cost in service delivery.

RECOMMENDATIONS

The study recommends that the management of all medical laboratories in Kenya should increase the implementation and adoption of quality management system project in order to positively influence performance of their organizations. In order to increase in efficiency and patient waiting time, this study recommends that the senior management team of medical laboratories in Kenya need to consider implementation of quality management system projects.

The study further recommends that the management of all medical laboratories in Kenya need to improve on the process control projects in order to positively influence performance of their organizations. In order for all the medical laboratories in Kenya to record an improvement in proficiency testing scores, the study recommends an increased adoption and implementation of process control projects.

The study also recommends that all medical laboratories should improve on their resource management system projects for positive improvement in performance. The stock management systems among medical laboratories should strive to reduce stock loss due to expiry of stocks and interruption of laboratory service due to stock outs.

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