Laboratory Quality Management Systems towards Accreditation in Rwanda:

A case Study of selected laboratories in Rwanda

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Laboratory Quality Management Systems towards Accreditation in Rwanda:

A case study of selected laboratories in Rwanda

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DECLARATION

I, Claver KAYOBOTSI, hereby declare that the Thesis "**Laboratory Quality Management Systems towards Accreditation in Rwanda: A case Study of selected laboratories in Rwanda**" has been written by me without any external unauthorized help, that it has been neither presented to any institution for evaluation nor previously published in its entirety or in parts. Any parts, words or ideas, of the thesis, however limited, which are quoted from or based on other sources, have been acknowledged as such without exception.

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APPROVAL

I approve that Mr. Claver KAYOBOTSI has successfully done and completed his research project in the College of Medicine and Health Science, School of Public Health, Master of Science in Epidemiology.

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Date….........../….../…2016

ABSTRACT

Introduction

The study "Laboratory Quality Management Systems towards Accreditation in Rwanda: A case Study of selected laboratories in Rwanda" was conducted under the objective to evaluate the current status of Rwanda laboratories vis-à-vis the accreditation norms and to identify possible contributing factors to sustainable laboratory quality management systems in Rwanda.

Methods

We used qualitative approach, in order to address subjects about current status of Rwanda laboratories vis-à-vis norms and standards and possible contributing factors to sustainable laboratory quality management systems in Rwanda. During data generation semi structured interview were the only qualitative data collecting tools. We used non probability sampling method. We used thematic analysis for all data from interviews, we gathered all the findings in one file, and findings were analyzed according to the objectives of this dissertation.

Results

A good number of laboratories have established Laboratory Quality Management System (LQMS) and laboratory professionals are conversant with LQMS, with positive changes over time. Since the start of implementing LQMS, the quality of Laboratory services (Patients' Waiting time, Turn Around Time and accuracy of results) has gradually improved.

There are numerous factors which were identified from the participant's opinions susceptible to drive and sustain the Laboratory Quality Management System; including the role to be played by the management of the hospital is of utmost importance with regards to success of laboratory management systems, motivating staff using different approach and mechanism such as trainings, improve the supply chain of reagents and consumables, recognitions of their academic levels, etc.

On the other hand, we identified a number of challenges that could hinder implantation, smooth implementation and sustainability of Laboratory Quality Management system; including among others; limited training, lack of representation of laboratory professional at the Ministry of

Health, staff working in poorly equipped facilities and delayed procurement process of specialized and critical Laboratory reagents and hiring maintenance companies .

Conclusion

From findings highlighted in this study, there is an established Laboratory Quality Management System which is very successful in some laboratories and the impacts it has on strengthening the laboratory services. However, the procurement system still needs to be fast-tracked for more impact. An evaluative study on purchasing and inventory systems to assess the challenges and implications to implementation of laboratory quality management system national wide is highly recommended.

Key words: Laboratory, Quality Management system, Accreditation, Rwanda

RESUME

Introduction

L'étude, « Systèmes de gestion de la qualité des laboratoires en matière d'accréditation au Rwanda : une étude de cas de laboratoires sélectionnés au Rwanda » a été menée dans le but d'évaluer l'état actuel des laboratoires du Rwanda vis-à-vis des normes d'accréditation et d'identifier les facteurs qui contribuent à la viabilité du système de gestion de la qualité des laboratoires au Rwanda.

Méthodes

Nous avons utilisé une approche qualitative pour aborder les sujets concernant l'état actuel des laboratoires du Rwanda vis-à-vis des normes et des normes et facteurs qui contribuent aux systèmes durables de gestion de la qualité des laboratoires au Rwanda.

La collecte des données Au cours de la génération de données, a été réalisée par les interviews semi-structurées qui étaient les seuls outils de collecte de données qualitatives. Nous avons utilisé une méthode d'échantillonnage non probabiliste. Nous avons utilisé l'analyse thématique pour toutes les données des entretiens, nous avons rassemblé tous les résultats dans un fichier et les résultats ont été analysés en fonction des objectifs de cette thèse.

Résultats

Un bon nombre de laboratoires ont établi le Système de gestion de la qualité du laboratoire (LQMS) et les professionnels de laboratoire connaissent LQMS, avec des changements positifs dans le temps. Depuis le début de la mise en œuvre de LQMS, la qualité des services de laboratoire (temps d'attente des patients et précision des résultats) s'est progressivement améliorée.

Il existe de nombreux facteurs qui ont été identifiés à partir des opinions des participants, lesquels sont susceptibles de conduire et de soutenir le Système de gestion de la qualité du laboratoire ;

Le rôle joué par la direction de l'hôpital qui est d'une importance capitale en ce qui concerne le succès des systèmes de gestion de laboratoire.

En outre la motivation du personnel par différentes approches, comme les formations, l'amélioration de la chaîne d'approvisionnement des réactifs et des consommables, les reconnaissances de leurs niveaux académiques, etc.

D'autre part, nous avons identifié un certain nombre de défis qui pourraient entraver l'implantation, la mise en œuvre harmonieuse et la durabilité du système de gestion de la qualité des laboratoires ; y compris entre autres ; La formation limitée, le manque de représentation des professionnels de laboratoire au ministère de la Santé, le personnel travaillant dans des

infrastructures moins équipées et un long processus de passation des marches de réactifs de laboratoire.

Conclusion

D'après les constatations soulignées dans cette étude, il existe un système de gestion de la qualité de laboratoire établi qui a beaucoup de succès dans certains laboratoires et ses impacts sur le renforcement des services de laboratoire. Cependant, le système d'approvisionnement doit encore être rapidement contrôlé pour plus d'impact. Une étude évaluative sur les systèmes d'achat et d'inventaire pour évaluer les défis et les implications pour la mise en œuvre du système de gestion de la qualité du laboratoire à l'échelle nationale est fortement recommandée.

Mots clés : Laboratoire, Système de gestion de la qualité, Accréditation, Rwanda

DEDICATION

To my family members and relatives

To my friends and colleagues

This work is dedicated.

ACKNOWLEDGEMENTS

LIST OF SYMBOLS AND ACRONYMS

ICT: Information communication technology

IQMS: Implementation of quality management system

ISO: International organization for standardization

LQMS: Laboratory quality management system

MBO: Management by Objectives

QC: Quality control

QMS: Quality management system

SLIPTA: Stepwise laboratory improvement process towards accreditation

SLMTA: Strengthening laboratory management towards Accreditation

SPIU/RBC: Single Project Implementation Unit/Rwanda Biomedical center

TAT: Turnaround time

TB: Tuberculosis

WHO: World health organization

WHO-AFRO: World health Organization-African Regional Office

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CHAPTER ONE: GENERAL INTRODUCTION

1.1.   Introduction.

According to Mbah et al.[26] Laboratories have historically been under supported in developing country health systems resulting in poor quality diagnosis and inadequate disease surveillance. Argued with the WHO[35] the labor market for laboratory workers in many developing countries is typically characterized by constrained supply (especially amongst well qualified staff), sluggish public sector demand, and relatively low wages. This leads to a high turnover of staff with highly skilled staff finding work in the private sector. Laboratory professionals are predominantly male with relatively limited female labor participation, with potential gender based barriers to advancement[31]. The focus on communicable diseases has meant that funding for broader public health laboratory services has been relatively neglected.

Therefore, not only in Sub Saharan Africa[35] but also in developing countries Laboratory professionals figure prominently among neglected cadres in health systems. There are often insufficient numbers, a skewed distribution, low level of qualifications, and limited career opportunities. Laboratory personnel often work in facilities which are poorly equipped, and do not systematically respect safety and infection control standards. These factors adversely affect the performance of laboratory professionals, who are the backbone of quality diagnostics. As a result, clinicians lose confidence in laboratory services, and often resort to presumptive diagnoses rather than laboratory confirmation[35].

Not only personnel but also Laboratory services are critical for conducting clinical diagnosis, guiding treatment, and responding to disease outbreaks. Even though accurate and reliable laboratory services contribute to the quality of clinical care and to core public health functions; historically, laboratories have been one of the weakest aspects of health systems in Africa with serious deficiencies in infrastructure, inadequate human resources, and absence of quality systems[35]. Most recently, there has been a growing recognition of the importance of laboratories and several important initiatives have been launched, including an accreditation process.

Presently, the laboratory infrastructure and test quality for all types of clinical laboratories remain in its nascent stages in most countries in Africa. In Rwanda, very little is known while the accreditation process was just recently initiated. Therefore, the research under this study aims at evaluating factors contributing to Laboratory quality management systems, towards accreditation in Rwanda with the case study of selected laboratories in Rwanda.

1.2.   Problem Statement

In many developing countries laboratories have historically suffered from inadequate infrastructure, limited funding, and lack of skilled personnel. Lack of access to accurate laboratory services results in misdiagnosis, which in turn leads to compromised patient care, higher costs, and continual transmission of communicable diseases. The inability to provide etiological confirmations during disease outbreaks can lead to delays in responding efficiently to outbreaks and difficulties in controlling or eradicating endemic diseases, elevating risk of disease transmission, and fueling economic costs. Rwanda was not left apart due to the horrible period of carnage and 1994 genocide perpetrated against the Tutsi which left the country in the ruin.

Despite the atrocious, according to the Ministry of Health[27] (p47) Rwanda has made good progress over the last two decades since the enormous challenges faced in the aftermath of the 1994 genocide perpetrated against the Tutsi that destroyed the entire political, and environmental, social and economic, health and education fabrics of this country. Rwandans have benefited from rapid economic growth, reduced poverty, more equality and increased access to services including health, education and technology among others. This has been possible only through the hard work and dedication of millions of Rwandans supported by friends of Rwanda. Rwanda progress strengthens the belief that its development ambitions towards the Vision 2020 can be achieved with its concerted efforts[27]. Thus the health and laboratory systems have improved at the tremendous level towards laboratory quality management accreditation set by ISO 15189 among other development paradigms. Though laboratory accreditation is instrumental to successfully drive of laboratory systems in patient care and treatment, it's solely contribution, may not be sufficient to build sustainable laboratory quality management systems, it is of utmost importance to identify other contributing factors to sustain laboratory quality management systems and controlling communicable diseases in the region given the role of laboratories in controlling communicable diseases as long as top 10

causes of deaths in EAC member states. Therefore, the research evaluated the status of laboratories vis a vis norms and standards and factors contributing to laboratory quality management towards accreditation in Rwanda.

1.3. Research objective

This study aimed at achieving following objectives:

1.3.1. General objective

The general objective of this study was to evaluate the status of Rwanda laboratories and identify possible contributing factors to sustainable laboratory quality management systems.

1.3.2. Specific objectives

This research explored through the following specific objectives:

1. To evaluate the current status of Rwanda laboratories vis-à-vis the accreditation norms and standards.

2. To identify factors which are susceptible to contribute to success of laboratories and stumble on challenges that hinder the achievement of laboratory quality management system in Rwanda.

1.4. Research questions

This study aims at answering following questions:

1. What is the current situation of Rwandan laboratories with regards to the accreditation norms and standards?
2. What are factors which are susceptible to contribute to success and sustainability of quality laboratories management in Rwanda?

1.5. Significance of the research

View the fact that on one hand laboratories are critical to effective national health systems, accurate and reliable laboratory services are essential for supporting clinical diagnosis, guiding treatment, and managing the spread of drug resistance. On the other hand, the lack of access to accurate laboratory services can result in misdiagnosis, which in turn leads to compromised

patient care, higher costs, and continual transmission of communicable diseases. The inability to provide etiological confirmations during disease outbreaks can lead to delays in responding efficiently to outbreaks and difficulties in controlling or eradicating endemic diseases, elevating risk of disease transmission, and fueling economic costs among others. Therefore, this study will inform policy makers on possible contributing factors reform towards strengthening Rwanda laboratory systems and transforming it into a real laboratory medicine. Suggestions and recommendations will help improve laboratory quality management systems in Rwanda and help manage gaps that are currently hindering the proper and quality performance of laboratories in Rwanda.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

2.1.1. Medical laboratory

Kanagasabapathy et al [24] [(p37)] argued that medical laboratory is one part of the laboratory that is equipped with various biomedical instruments, equipment, materials and reagents (chemicals) for performing different laboratory investigative activities by using biological specimens (whole blood, serum, plasma, urine, stool, etc) (Kanagasabapathy, A.S. & Pragna, R., 2005).

2.1.2. Laboratory quality

Laboratory quality can be defined as accuracy, reliability, and timeliness of the reported test results Turnaround Time (TAT). The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting[36].

2.1.3. Laboratory management

The first step in a systematic approach to the management and organization of a health laboratory begins with the establishment of general goals and specific objectives by the laboratory staff. The use of such objectives for purposes of management is known as management by objectives (MBO).

In order to achieve these objectives, the laboratory must have adequate facilities, equipment & supplies, and an adequate number of qualified personnel. As used here, goals are those general and qualitative statements of overall philosophy of the organization[36].

2.1.4. Role of Laboratory in Health Care and Training of Laboratory Personnel

As discussed by Abimiku[1] the laboratory is an integral part of a nation's health service. It gives the service a scientific foundation by providing accurate information to clinicians and to other responsible bodies for:

- Treating patients

- Deciding health priorities and allocating resources.

- Monitoring the development and spread of infections pathogens as well as status of non-infectious acute or chronic diseases or their markers; tumor markers, hormones, cancer cells, etc.

- Investigating preventable premature loss of life.

- Deciding effective control measures against major prevalent diseases.

Without reliable laboratory support:

- Patients are less likely to receive the best possible care.

- Resistance to essential drugs will continue to spread.

- The sources of disease may not be identified correctly.

- Epidemics and the spread of major communicable diseases will not be checked reliably.

- Valuable financial and human resources may be diverted to ineffective control measures[1].

2.1.5. Quality Assurance

Quality assurance is more than a set of routine procedures. It is also a state of mind and intellectual commitment to meet, and a determined desire to exceed a specified set of performance criteria.

> **Definition and Purpose of Quality Assurance**

Quality assurance has been defined by WHO[34] as the total process whereby the quality of laboratory reports can be guaranteed. It is a set of activities followed starting from specimen collection up to issuing of test results to ensure test results are as accurate and precise as possible. It is the sum of all the activities in which the laboratory is involved to ensure that test results are of good quality. The purpose of quality assurance (QA) in laboratory practice is to provide test results that are relevant, reliable, timely, interpreted correctly[34].

> **Components of Quality Assurance**

Effective quality assurance detects errors at an early stage before they lead to incorrect test results. Laboratory personnel need to be aware of the errors that can occur when collecting specimens (pre-analytical stage), testing specimens (analytical stage), reporting and interpreting test results[34] (post analytical stage).

2.1.6. Quality Control

Abimiku[1] described that the term quality control covers that part of quality assurance, which primarily concerns the control of errors in the performance of tests and verification of test results. QC must be practical, achievable, affordable, and above all continuous.

It refers to operational procedures and the activities needed to maintain the quality of results. Quality control involves the use of a variety of methods or techniques to reduce variance in analytical procedures.

Quality control system ensures that results fall within certain limits[1]. Use of either of the limits is dependent on:

- Lab facility- instrument, infrastructure
- Training /experience of lab personnel
- Quality of reagents and other materials

2.1.7. Quality management

Devoted by the ISO 9001 [21] [(57)] Quality management is the coordinated activities to direct and control an organization with respect to quality.

In the period between 1920 and 1950, quality management focused on inspecting of the products. The main objective of the inspections was to satisfy the customers[21]. Quality management is a process for ensuring that all the activities necessary to design, develop, and deliver a product or service are conducted effectively and efficiently. It typically involves one or more of the following elements: quality planning, quality control, quality assurance and quality improvement[26].

Thus, it focuses not only on product and service quality, but also on the means to achieve it. By utilizing quality assurance and control of functions as well as of products, it is possible to achieve more consistent quality. Although quality control and quality assurance have long been familiar tools within Laboratory Quality Management System for ensuring data accuracy and consistency, the broader concept of a Quality Management System (QMS), which also

incorporates quality planning and quality improvement, may be less familiar and less widely utilized[36].

2.1.8. Laboratory Quality Management System

Laboratory quality management system is a set of all aspects of the laboratory operation, including the organizational structure, processes and procedures that need to be addressed to assure quality[10]. There are many procedures and processes that are performed in the laboratory and each of these must be carried out correctly in order to assure accuracy and reliability of testing.
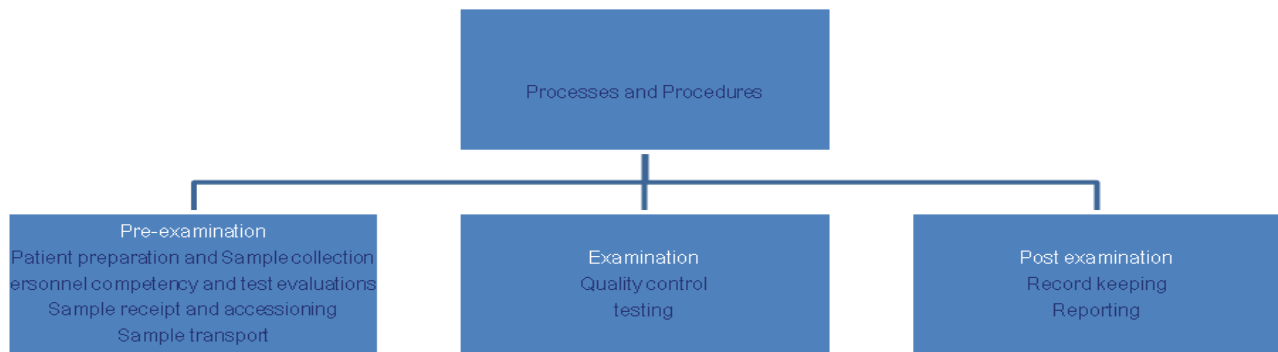
Figure 1. The cycle Laboratory Quality Management System

Source: Researcher compilation (2016).

An error in any part of the presented cycle above can produce a poor laboratory result. A method of detecting errors at each phase of testing is needed if quality is to be assured[14]. ISO standards group laboratory processes into pre-examination, examination and post-examination categories. Comparable terms in current laboratory use include: pre-analytic, analytic and post-analytic processes; or pre-test, test and post-test processes[14]. The entire set of operations that occur in testing is called the path of workflow. The path of workflow begins with the patient and ends in

reporting and results interpretation. The concept of the path of workflow is a key to the quality model or the quality management system, and must be considered when developing quality practices[14].

2.1.9 The laboratory quality management system model

When all of the laboratory procedures and processes are organized into an understandable and workable structure, the opportunity to ensure that all are appropriately managed is increased. The quality model used here organizes all of the laboratory activities into 12 quality system essentials[24]. These quality system essentials are a set of coordinated activities that serve as building blocks for quality management. Each must be addressed if overall laboratory quality improvement is to be achieved.
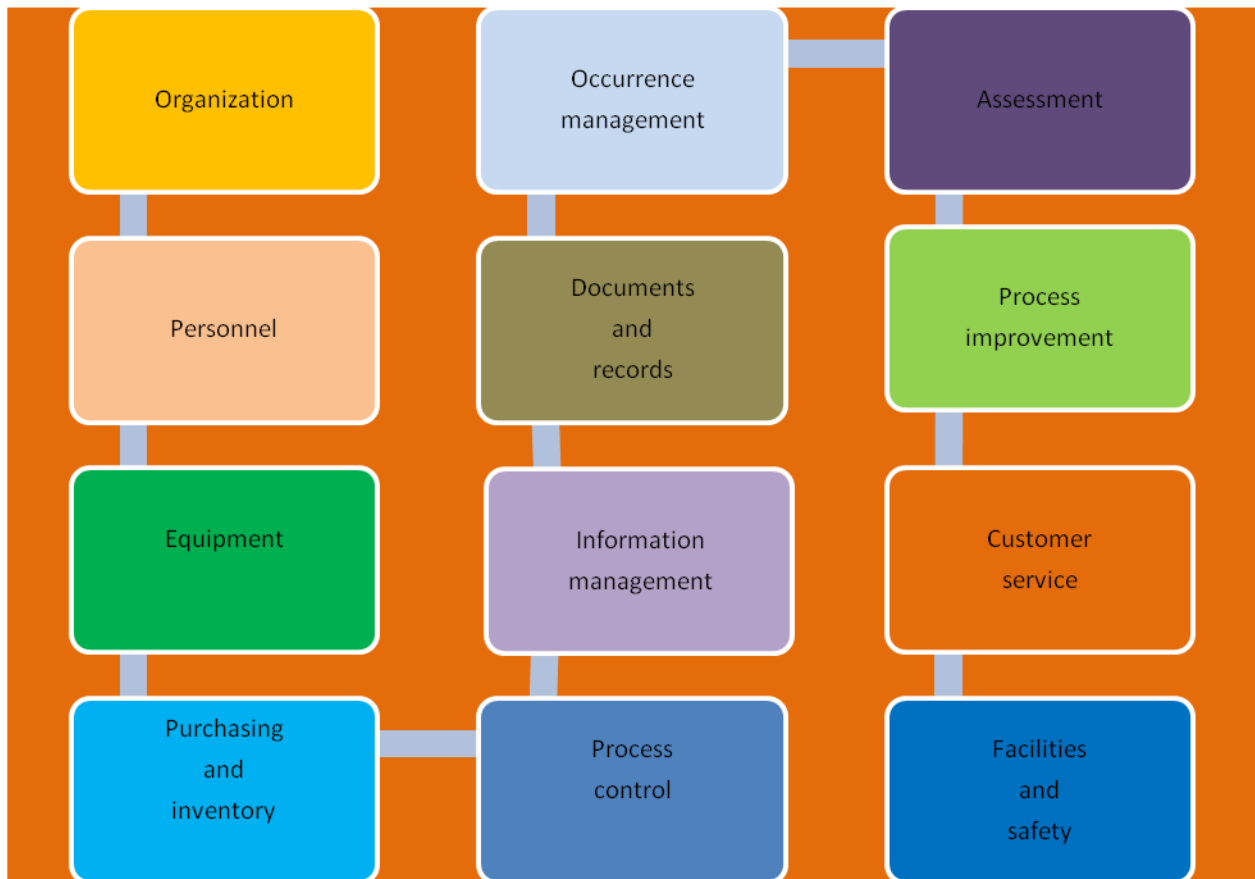
Figure 2. The laboratory quality management system model

This quality management system model was developed by CLSI, 1 and is fully compatible with ISO standards[15].

Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the quality essentials. The quality model used here organizes all of the laboratory activities into twelve quality system essentials[15].

2.1.10 Accreditation

Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Laboratory accreditation is the formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do[24]. It provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence[24]. The concept of laboratory accreditation was developed to provide third-party certification that a laboratory is competent to perform the specific test or type of tests. Laboratory accreditation is a means to improve customer confidence in the test reports issued by the laboratory so that the clinicians and through them the patients shall accept the reports with confidence[25].

Therefore, assessment is the means of determining the effectiveness of a laboratory's quality management system. Standards, as well as other normative documents that provide guidelines, form the basis for assessment. An important way for a laboratory to be recognized as delivering accurate and reproducible results is to go through evaluation or assessment processes conducted by a credible, qualified organization. Successful completion of this process gives the laboratory recognition that it is in compliance with the quality standards and norms used for the assessment. Hence, Kanagasabapathy[24] (p79) mentioned that the fulfillment of laboratory quality management system results in respecting norms or standards of accreditation.

2.1.11. Standard

World Health Organization WHO[35] discussed that a standard is an authoritative document setting forth criteria for performance and characteristics. Standards may be issued by national, regional,

or international standards bodies. The most widely accepted international standards are issued by the International Organization for Standardization (ISO), a federation of national standards bodies from more than 140 countries. ISO standards are formulated by technical committees. In the case of medical laboratories, the most applicable standard is ISO 15189[15(p78)], "Medical Laboratories—Particular requirements for quality and competence," for use by medical laboratories in developing their quality management systems (QMSs) and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories. Accreditation audit based on ISO 15189 evaluates a laboratory's QMS; technical competence; and ability to provide reliable and accurate test results[35].

2.1.12. Quality System: Systematic Approach to Ensure Quality

The importance of quality in the functioning of health care laboratories in developing countries has been universally recognized. Laboratories practicing the principles of quality assurance generate relevant, reliable and cost-effective results.

Quality means meeting the standards[18]. The standards are predetermined requirements for a particular substance or service[19]. Quality is of paramount importance in health laboratories. Reliable results produced by a laboratory improve the decision making capacity of the clinicians as well as public health physicians. The consequences of poor quality could be serious. It could lead to inappropriate action or inaction leading to over treatment, over investigation or mistreatment, lack of treatment or inadequate investigations. Delayed or suboptimal responses as a result of poor quality of laboratory services could adversely affect the credibility of the laboratory and may also invite legal action[20].

Quality is ensured through a well-defined quality system which is a part of overall quality management aimed at ensuring consistency, reproducibility, traceability and efficacy of the products or services. Accordingly, a quality system is defined as the organizational structure and resources needed to implement quality requirements[20].

The International Organization for Standardization (ISO)[17] defines a quality system as the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. A quality system has the following five key elements: Organizational

management and structure, documentation, monitoring & Evaluation, training and quality standards.

2.1.13. Organizational Management and Structure

The overall responsibility for the design, implementation, maintenance and improvements in quality system rests with the laboratory management. Quality is the responsibility of all the staff members of the organization[20].

> **Documentation**

A document is a record whether in printed or electronic version, of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures etc[19].

> **Monitoring and Evaluation**

The laboratory management develops and implements quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management should take appropriate steps to address them. Error management should be vigorously mplemented[20].

Assessment of quality through audits (internal or external) and participation in external quality assessment schemes are other tools, the results of which should guide the management in further improving quality.

> **Training**

The quality system is only as good as the staffs who actually work for it. No matter how good the quality system is on paper, if it cannot be translated into practice, quality cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency based and must be followed by post-training courses to provide a continuous support[21].

> **Quality Standards**

The quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. These need to be followed strictly to meet the regulatory requirements as well as to monitor the functioning of the laboratory. Both management and technical standards need to be followed to ensure quality. These must also conform to the local aws[21].

2.2. Empirical literature

Empirical literature addresses the understanding of research literature on the laboratory quality management system of the past studies and researches experiences

2.2.1. International laboratory standards

Guy-Michel[13] [(p63)] argued that a part of quality management is assessment, measuring performance against a standard or benchmark. The concept of quality management requires that standards be set, and again industry has been in the lead. Using a set of standards established by the United States of America military for the manufacture and production of equipment, the ISO established standards for industrial manufacturing; we know these standards as ISO standards[13].

➢ **International Standards Organization (ISO)**

The ISO 9000 documents provide guidance for quality in manufacturing and service industries, and can be broadly applied to many other kinds of organizations. ISO 9001[14] addresses general quality management system requirements and applies to laboratories.

➢ **Clinical and Laboratory Standards Institute (CLSI)**

Another important international standards organization for laboratories is the Clinical and Laboratory Standards Institute (CLSI), formerly known as the National Committee for Clinical Laboratory Standards (NCCLS). CLSI uses a consensus process involving many stakeholders for developing standards. CLSI developed the quality management system model. This model is based on 12 quality system essentials, and is fully compatible with ISO laboratory standards[10].

2.2.2. Laboratory Quality Management System in Europe

Laboratory accreditation can help laboratories to produce consistent results by means of implementing the framework of a documented quality system[3]. The Canadian Standards

Associations[4] presented the current status of accreditation of hair testing laboratories based in Europe. They found 48 percent of the laboratories accredited and 31 percent of the laboratories accredited to ISO 17025. Alemnji[2] found approximately 67 percent of government or police laboratories were not accredited. World Health Organisation[37(p 77)] claimed there was ambiguity of perceptions about the meaning, purpose, and principles of quality assurance and accreditation among European forensic science laboratories. The personnel of some laboratories did not know the fact that a laboratory without having a quality management system cannot get accredited. This problem is attributed to "lack of awareness syndrome." World Health Organisation[37] claims the improper use of quality management tools in the laboratory has a negative effect on laboratory activity especially on continuous improvement implementation.

2.2.3. Laboratory Quality Management System in developed countries

World Health Organisation[35 (p432)] made an analysis of the causes of discrepant results in proficiency tests in a testing laboratory and investigated the reasons of erroneous laboratory results in the years of 2003 and 2007. World Health Organisation[35] investigated accreditation process and standardization of Pathology Laboratories in Pakistan. They claimed physical conditions and limited qualified workforce were the reasons of current insufficient accreditation status in Pakistan[35].

WHO[32] explained quality regulations and accreditation standards for clinical chemistry in Turkey. He mentioned insufficient accreditation status in clinic laboratories and emphasized the importance of having a necessary infrastructure and directions in the health care in Turkey. On the other hand, there are successful implementations of accreditation reported in the literature.

WHO[32] showed accreditation process of the Quality System by ISO 17025 standards in a national reference laboratory of Argentina. They found the implementation improved systematic recording and control of the tasks, robustness of the traceability chain and external recognition of quality of the laboratory.

WHO[35 (p21)] found accredited laboratories had more satisfactory and less suspicious and unsatisfactory laboratory performances than non-accredited laboratories. Thus, they claimed accredited laboratories were more successful than non-accredited laboratories. Peter[30] have

explained implementations of ISO 17025 accreditation of a laboratory within racing chemistry in Britain. They reported successful results in spite of difficulties of implementation of accreditation.

Peter[30] presented implementation and maintenance of the ISO 17025 quality assurance system in the General Chemical State Laboratory of Greece. The laboratory could prove the reliability of the test results and technical competence to clients and regulators. They experienced that accreditation and international quality standard of the laboratory improved its competitiveness.

2.2.4. Laboratory Quality Management System in Africa

Public health systems in sub-Saharan Africa have long remained fragile due to fundamental limitations and lack of prioritization of human, financial and training resources; laboratory infrastructure; and resource and management capacity[35]. Of the 340 accredited laboratories in Africa, only 28 (8.2%) are in sub-Saharan Africa; the other 312 primarily private laboratories are located in South Africa. Sub-Saharan Africa has a population of more than 800 million, the majority of whom rely on government services for health care. The increasing burden of priority diseases such as HIV, tuberculosis and malaria in the Region continues to challenge the weak existing systems. Public health programs have encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care[35].

Due to such challenges, according to the World Health Organisation[37(p101)] argued that the joint conference on laboratory quality management systems (LQMSs) convened in Lyon, France in April 2008 by WHO and the US Centers for Disease Control and Prevention (CDC) issued a statement in support of a stepwise, standards-based process towards internationally-recognized accreditation: "It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189."

Therefore, The WHO Guidelines for the Stepwise Laboratory Improvement Process Towards Accreditation in the Africa Region (SLIPTA) provides a framework for countries in their efforts to strengthen national laboratory services through fulfillment of the requirements in the ISO

15189 standard[34]. The SLIPTA guidelines are in accordance with WHO core functions to set standards and norms and to support countries to implement them. This process is intended to encourage, support and recognize the implementation of quality management systems (QMSs) in medical laboratories in the African Region so that laboratories provide safe, timely and accurate results for patient care and public health purposes[34].

2.2.5. Laboratory Quality Management System in Nigeria

Achieving accreditation in laboratories is a challenge in Nigeria like in most African countries. Nigeria adopted the World Health Organization Regional Office for Africa Stepwise Laboratory (Quality) Improvement Process towards Accreditation (WHO/AFRO– SLIPTA) in 2010[3].

In Nigeria, clinical laboratories are grossly inadequate with poor infrastructure[3] and Quality Management Systems (QMS) are uncommon[3]. Family Health International 360 (FHI360), with funding from the President's Emergency Plan for AIDS Relief (PEPFAR) through United States Agency for International Development (USAID) and Global Fund to fight AIDS Tuberculosis and Malaria (GFATM) supported the Government of Nigeria to scale up Antiretroviral therapy (ART) services to 134 health care facilities across 36 states and the Federal Capital Territory (FCT) from 2005 to 2012. Scaling-up ART service includes laboratory strengthening and support aimed at providing quality services to HIV/ AIDS patients[3].

Access to services with the highest standards remains the major focus in FHI360 ART program implementation. Although this intervention led to improve laboratory service, over time it became apparent that this level of capacity did not translate to quality laboratory services as defined by some international standards for clinical laboratories, including ISO 15189[2]. Thus, beside investment in the expansion of diagnostic access, concurrent improvements and more attention in the quality of laboratory testing are needed to ensure clinician and patient confidence in test results[2]. Accreditation is emerging as a preferred framework for building quality medical laboratory systems in resource-limited settings[35].

2.2.6. Laboratory Quality Management System in Rwanda

Argued by the Ministry of Health[27(67)] Rwanda has set ambitious targets for growth and poverty reduction in its vision 2020. Within this framework, the Rwanda's Health Sector Policy translates

the Government's overall vision of development in the health sector, as set out in Vision 2020 and the Economic Development and Poverty Reduction Strategy (EDPRS II 2013-2018). Since the adoption of the previous Health Sector Policy in 2005, much has changed in terms of national socio-economic development and more specifically in the health sector[27]. The Health Sector Policy gives general orientations for the sector which are further developed in the various sub-sector policies guiding key health programs and departments.

In Kigali, Rwanda, July 2009, the WHO Regional Office for Africa, in collaboration with CDC, the Clinton Health Access Initiative (CHAI), the American Society for Clinical Pathology (ASCP) and other partners, launched SLIPTA in the presence of government health officials from 13 African countries[27]. The Strengthening Laboratory Management Towards Accreditation (SLMTA) training program was also introduced in Kigali as a preparatory initiative to ready laboratories for SLIPTA. From late 2009 through 2010 SLMTA has been active in nine countries in sub-Saharan Africa. At the Fifty-eighth session of the WHO Regional Committee for Africa (held in Yaounde, Cameroon, September 2008) and the fifty-ninth session (held in Kigali, Rwanda, September 2009) Member States adopted Resolutions AFR/RC58/R2 and AFR/RC59/R4, respectively, calling for capacity strengthening of public health laboratories and centers of excellence to improve disease prevention and control[27].

2.3. Analysis model

An analysis model in this research was used to outline possible courses of action and present a preferred approach to an idea and thought that lead this study. Analysis model clarified concepts and proposes relationship among the concepts in a study. This sub-chapter named the analysis model for this study depicts and tackles different concepts that made the reader aware of their meanings and their interconnectivity. This was done in order to highlight useful and key concepts used in the research.
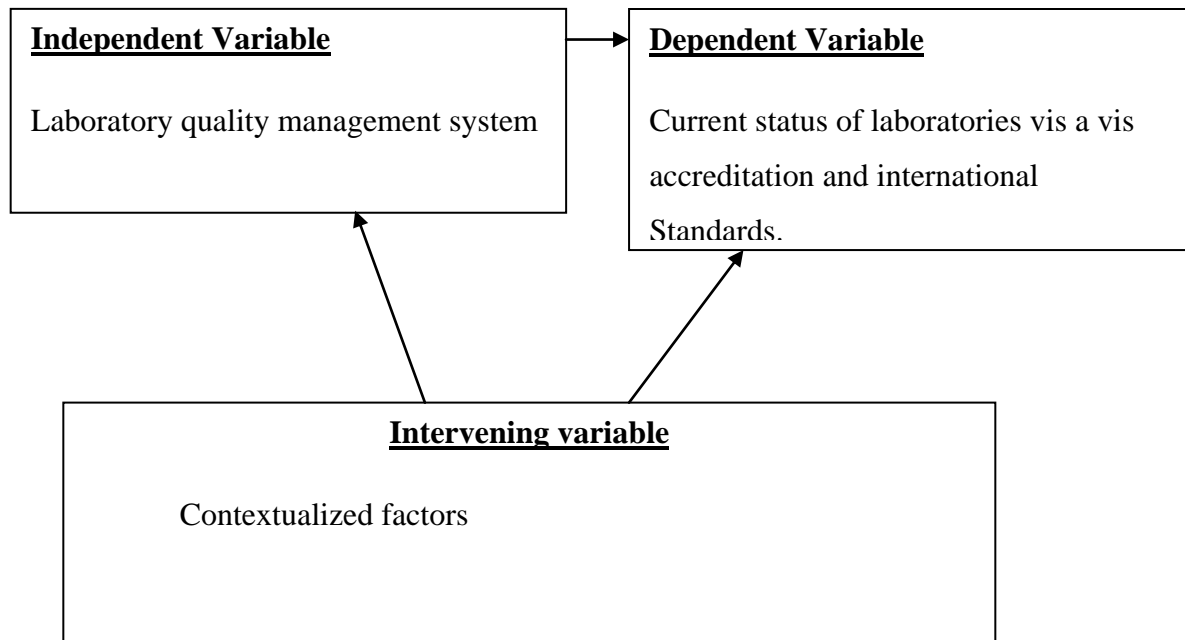
Figure 3. Analysis model

Source: Researcher compilation (2015)

The conceptual framework reflects the interrelationship between the two variables in the study and intervening variables which could have effects on both independent and dependent variables. Independent variable in this study is Laboratory quality management system; this was assessed by checking the Stepwise laboratory improvement process towards accreditation (SLIPTA) check list components such as Customer satisfaction, lab professional satisfaction and confidence, lab technicians' participation in Hospital management decisions, the level of academic trainings. On job trainings among others, Documents and Records, Management Reviews, Organization and Personnel, Client Management and Customer Service, Equipment,

Purchasing and Inventory, Process Control and Internal and External Quality Assessment, Information Management, Facilities and Safety among others[31].

Dependent variable is the current status of our laboratories vis a vis accreditation and international standards such as management requirement ,organization and management, quality management system, document control, preventive action, quality and technical records, management review. Technical requirements such as personnel, accommodation and environmental conditions and laboratory equipment[32]. This was assessed by viewing the related literature. Intervening variables was the contextualized factors contributing to laboratory quality management system which are assessed through data collection procedures such as staff competency, conditions of work, laboratory management system, financial management and moral values.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. Research Design

We adopted an exploratory research design in order to address subjects about current status of Rwanda laboratories vis-à-vis norms and standards and possible contributing factors to sustainable laboratory quality management systems in Rwanda. Data collection was done using a semi structured interview. We used a qualitative approach to collect data from the field through a use of semi structured interview.

The interview questionnaire was composed of open ended questions in order to give respondents time to express themselves and help the researcher obtain relevant and rich information on the currents situation of laboratory management quality system and challenges it faces which hampers its successful implementation in Rwanda.

Also documents were used to exploit related literature written by different authors who generated diverse ideas on the subject of the research study. During data generation semi structured interview, were the only qualitative data collecting tools that were utilized with Laboratory professionals, and administrative personnel from health facilities with a quite extensive experience.

The research being an exploratory study was seeking to understand current inputs and explore other possible factors that could be strengthened. Through data collection we used non probability sampling method. Thus purposive sampling was the basic sampling technique which was administered.

3.2. Description of the sample

3.2.1. Population of the study

The population of the research was composed of Laboratory professionals, and administrative personnel from the selected laboratories in Rwanda.

Thus the population of the research was selected in various institutions presented in the figure below:
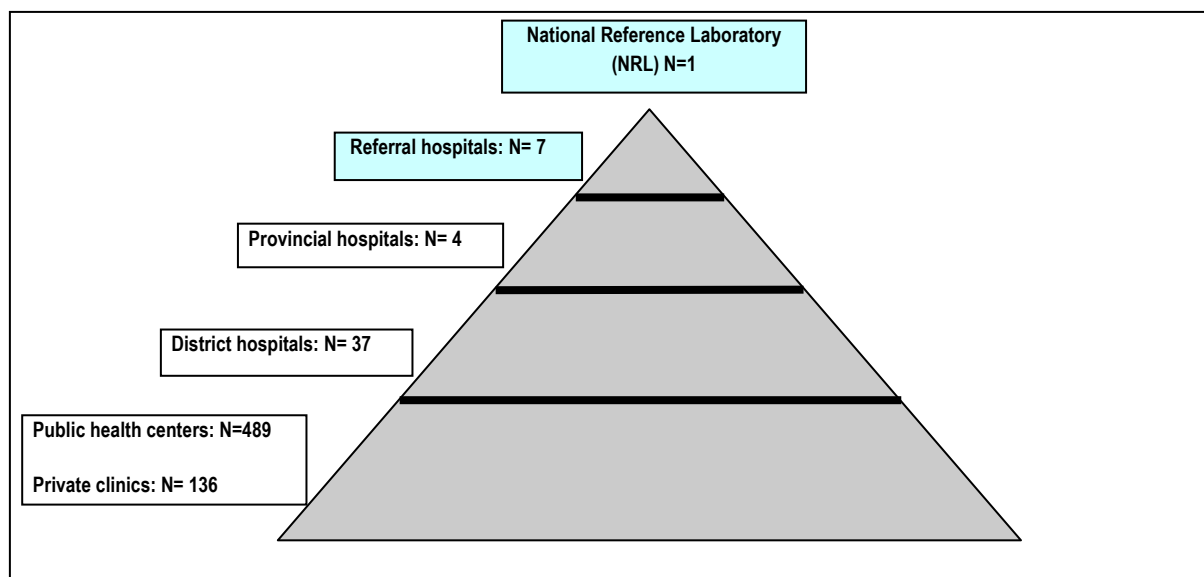
Figure 4. The general population of the research

Source: NRL/Lab Network database (2013)

3.2.2. Target population

Targeted population was composed of laboratory professionals from all the strata of laboratories shown in the figure (4) and their administrators.

3.2.3. Sampling method

The information was collected from Laboratory professionals, administrators working closely with laboratories. Thus we collected data through a non-probability sampling method with a purposive sampling technique. We used a purposive sampling strategy (participants selected according to pre-selected criteria) to select participant from the selected laboratories. Participants who fulfilled below the preset criteria were selected.

- ❖ Be a laboratory professional;
- ❖ Be a laboratory an administrator working closely with the laboratory;
- ❖ Be available and willing to provide with information

Table 1. *Target population of the study*

Sector	District	Province	Institution
Ngoma	Huye	Southern	Kabutare DH
Ngoma	Huye	Southern	Polyclinic La Medical
Busasamana	Nyanza	Southern	Nyanza HC
Kibirizi	Gisagara	Southern	Kibilizi DH
Bweramana	Ruhango	Southern	Gitwe DH
Remera Rukoma	Kamonyi	Southern	Rukoma DH
Ngoma	Rulindo	Northern	Rutongo DH
Muhoza	Musanze	Northern	Ruhengeri RH
Byumba	Gicumbi	Northern	Byumba DH
Kibungo	Ngoma	Eastern	Kibungo DH
Kiziguro	Gatsibo	Eastern	Kiziguro DH
Nyagatare	Nyagatare	Eastern	Nyagatare DH
Nyagatare	Nyagatare	Eastern	Nyagatare HC
Nyarugenge	Nyarugenge	Kigali City	NRL
Kamembe	Rusizi	Western	Gihundwe DH
Rubengera	Rubengera	Western	Rubengera HC

Source: Researcher compilation (December, 2015)

3.3. Data collection process

Semi-structured interview questionnaire was prepared and responses were documented in English. Questionnaire and semi-structured interview data were collected including demographic characteristics of participants. Extraction and addition of main points interview sessions were done in English. Data quality was maintained starting from interview preparation up to data collection and analysis.

3.3.1. Non-participatory observation

The researcher took notes on how participants understood structured questions, what they did not understand easily and what they misunderstood in order to observe how are they conversant with laboratory quality management systems. (e.g. I don't understand the question, this question can be better answered by my colleague in charge of quality…).

3.4. Data collection instruments

The primary data were obtained using face to face interview from the targeted populations.

3.4.1. Semi-structured interview

The semi-structured interview permitted face-to-face contact with respondents, provided opportunity to explore topics in depth and allowed the interviewer to explain or help clarify questions, increasing the likelihood of useful responses on factors contributing to laboratory quality management and possible contributing factors. Interviews were recorded by respect of ethics and other information was noted down in order to ensure originality of respondents' statements.

3.5. Ethical Considerations

Considering the ethical issues is an important aspect of doing this research. The researcher has a significant amount of power in the research process, which should be considered. Ethical standards required the researchers to not put participants in a situation where they might be at risk of harm as a result of their participation or information given. It was prudent to protect the identity of respondents and the people involved. However, the respondents and informants were anonymous covered where the researcher and respondents consented. The researcher did present their names but other relevant information was recorded and analyzed. Finally, guided by the need for confidentiality and respect for ethical principles, all interview records and data collected were kept safely.

- **Risks management**

The researcher did not foresee any significant risk related to this study, either by nature of the research topic or presented by the design of the study. This study did not record any personal

identifiers of the participants in the field notes and instead used other numerical identifiers. Data from the field was transcribed without any personal identifiers.

- **Respect for Persons**

Further, to protect participants, they were required to read and sign Informed Consent forms so as to ensure they were well aware about the overall purpose and objectives of the study and its intended end goal. Also, this study sought ethical clearance from the institution's ethical review board; so as to abide with research standards and regulations.

- **Beneficence**

As individuals, participants were not expected to benefit directly from the study. However, the results of this study were intended to be published and shared with these study participants noting they were literate individuals to enrich their knowledge.

3.6. Data Analysis and Management

Before doing the analysis, the entire data was cross checked for reliability and completeness on the collected hard copy data and soft copy of the entered data. We used thematic analysis for all data from interviews, we gathered all the findings in one file, and findings were analyzed according to the objectives of this dissertation. We organized findings in such way that were under four different themes below:

- Status of laboratories vis a vis international Norms and Standards:

- Contributing factors to LQMS

- Challenges and

- Suggestions and others factors which can drive the implementation of successful and sustainable Laboratory Quality Management System.

We proceeded with the analysis of findings putting the various opinions in connection with each other and presented them under corresponding themes, which were identified to support analysis and discussion of findings in order to arrive at relevant thematic conclusions and recommendations.

The first analysis was to evaluate the current status of Rwanda laboratories vis-à-vis the adherence to norms and standards and possible contributing factors.

The second analysis was to explore factors which are susceptible to contribute to success of laboratories but also identifying possible challenges that hinder the achievement of laboratory quality management system in Rwanda.

The third analysis was to explore our own observations; these were framed in a more generalized way so that they could also be useful for informing researchers interested in this research area. Data were stored in password protected computer and backup were saved by flash and CDs.

CHAPTER FOUR: RESULTS

4.1. Demographic characteristics of respondents

Socio-demographic characteristic of respondents is presented in table 2 below.

Table 2. *Demographic characteristics of participants*

Description		Laboratory technicians
Total number	All categories	88
Sex	Male	56
	Female	32
Age	Between 21 and 30	34
	Between 31 and 40	37
	Between 41 and 50	17
	Beyond 51	-
Education level	No formal education	-
	Primary level	-
	Secondary level	25
	Diploma level A1	14
	Bachelor's level	47
	Master's level	2
	PhD level	-
Work and service experience	Between 3 and 5 years	4
	Between 6 and 8 years	14
	Between 9 and 12 years	29
	Between 12 and 15 years	37
	Beyond 15 years	4

Source: Primary data (October 2016).

4.2. Observation

During analysis we categorized findings from observations, semi structured interview. We observed that an important number of participants were enough conversant with LQMS while there is a room for improvement for a small number of participants.

4.2.1. Enough conversant with the Laboratory quality management system

An important number of participants were conversant with Laboratory Quality Management System in general and the twelve laboratory quality essentials in particular; translated by below quotations from participants.

"Training of laboratory professionals on all the 12 Laboratory quality essentials is paramount" (Polyclinic la Medicale)

"there are factors susceptible to contribute to LQMS, like SLMATA trainings that improve knowledge and skills but also opportunities for Quality Assurance and Quality Control activities" (Laboratory Specialist at the National Reference Laboratory)

"LQMS is good but intangible product not easily recognized benefits to staff working environment and quality of services" (Laboratory Specialist at the National Reference Laboratory).

There is a sound need of straightening management review for effective laboratory operations and supply chain system" (Laboratory technician at Nyagatare DH).

4.2.2. Room for improvement on the Laboratory Quality Management system

Though a good number of respondents were enough conversant with laboratory quality management system; however, a small number of respondents need to improve their knowledge vis a vis LQMS, the interview captured a number of responses which were not appropriate to the questions; some of these are mentioned below:

"*Affordable results and good laboratory working" & "Lack of connection in the service"*

Additionally, demotivation was also observed in some of the laboratories, where translated by typical responses below:

"Laboratory staff is not motivated, and this impact on service interruption" & "Due to the fact that laboratory staff are not paid according to their academic level it is surely demotivating"

4.3. Current Status of laboratories vis-à-vis norms and standards towards the accreditation

A good number of laboratories have established Laboratory Quality Management System (LQMS) and laboratory professionals are conversant with LQMS, with positive changes over time. They testified that since they have started implementing LQMS using the SLIPTA WHO/AFRO approach, the quality of Laboratory services (Patients' Waiting time, Turn Around Time and accuracy of results) has gradually improved. Below are the corresponding quotations from participants.

"There is a great improvement in compliance with LQMS compared to last past 3 years and this can be seen through Increased number of staff and skills as well as infrastructures and equipment which has enormously contributed to this process". (lab technician at KIBUNGO District Hospital)

"The improvement in implanting LQMS is remarkable, however there is a need to keep increasing human resources for health in numbers (man power and skills)". (lab technician at KIBUNGO District Hospital)

On-site Trainings& Mentorship as well as Continuous Professional Development (CPD) that Laboratory workforce has benefited has been an important catalyst input and enabled them implementing laboratory quality management systems. Below are quotations from participants

"Most of lab staff received SLMTA training and participate in implementation of LQMS; additionally, NRL has established a Quality assurance and Quality Control Unit which coordinate and supervise all activities related with LQMS."

On the other hands, participants testified that the LQMS is fluctuating; over time due to context at individual settings in particular when there are changes happening within the system itself whether in personnel, stock out of important reagents…, but also implementing successfully

LQMS increase the visibility of the laboratory and subsequently increase of patients and workload.

"The status of LQMS changes overtimes due to a number of factors including staff turnover, stock out, and some norms not respected as it should be, however the situation has drastically positively changed since last 4 years (Nyagatare)".

"Respect of norms and standards is subsequent to augmentation of clients coming for consultation and testing therefore need increase of manpower" (Kibilizi). He added *"We cannot say something on time because we, who work at the district levels, receive many samples from our patients here and health centers that we need to treat with the small number of technicians. It is a serious problem."*
"we have few staff with an important workload due to the population we serve and to some extent we don't have sufficient time to adhere to norms and standards".

At some extent, participants were optimistic to see changes happening with the implementation of Laboratory Quality Management System, below is a corresponding quotation from an administrator at Kibungo District laboratory.

" Patient waiting time reduced from more than 4 hours to below 2 hours; and long waiting time was associated with loss of results, paper work recording results." (added a laboratory technician at Kibungo district Hospital).

"In addition, we noted a sound respect of protocol and policies, electronic record and this has impacted on reducing Turn Around Time and subsequently, patient hospitalization time reduced due to the fact that lab results are timely released to patients."

The LQMS need to be sustained, and the sustainability is an everyday work and oversight, the management need to put forward the sustainability plans to contain factors susceptible to hinder a sustainable implantation of LQMS, participants mentioned among other factors; laboratory infrastructures, continuity of laboratory services delivery, Human Resources for Health, Capacity building and supply chain. below are quotations from participants.

"There is a number of factors that often cause service interruption limitation in financial resources, default of lab materials without even spares." (Kabutare).

"Insufficient infrastructures, human resources but also a low level of academic training, is hindering the implementation of LQMS, to my understanding, it is important to have a comprehensive plan for lab professional training to be supported by the government under the human resources for health scheme." (Kibilizi).

There is a need to establish a sustainable mechanism laboratory equipment maintenance and supply chain management at National (local) capacity for preventive maintenance, to be planned and budgeted for to reduce the equipment "down time" and hence improve quality of laboratory services as well as sustain the expensive investments for these equipment.

"It is important to draw a clear roadmap of on job trainings and formal academic trainings(Nyanza), increase visit and maintenance of equipment, the GOR provide high level institution in lab area and revise the current curriculum to accommodate bio engineering concepts.

"There is a sound need to provide trainings based on needs without necessarily sticking on biomedical sciences only, think to expand in specialization (eg: hematology, biochemistry, cytology...)" (Nyanza)

"Explore the feasibility to improve supply chain of lab reagents and consumables and revisit the staffing norms at all laboratory levels." (kibilizi).

4.4. Factors which are susceptible to contribute to success of laboratories.

The role to be played by the management of the hospital is of utmost importance with regards to success of laboratory management systems,

"Here we see a potentiality of active involvement of hospital management, excellent leadership of hospital management and team work as catalyst of implementing LQMS; in addition, team work constitute integral part of the orientation process of new hired staff."

Motivation of staff using different approach and mechanism is a way of maintaining sustainable LQMS. Below are quotations of participants

"Motivation, raise the functionality and quality of laboratory operations, workshops meaning also allowances is another kind of motivation." (Byumba)

"Continual training on laboratory QMS, SLMTA training, renovation of laboratory infrastructure, specific budget for lab accreditation, motivation of laboratory staff (example of satellite labs: they have improved the QMS due to support from partners".

"Modern equipment and infrastructures are key element that contribute to the implementation of LQMS." (lab technician at Nyagatare District Hospital)

"LQMS is a process, the government needs to continue support mentorship and help continue to improve the knowledge in accreditation and comply with standards on lab and make available equipments to help service of good quality"

"It is important to invest in laboratories in terms of training and financial resources but also to adhere to recommendations from supervision visits." (Policlinic la medical).

"I can see a good number of actions towards implementing successfully the LQMS, I can mention; reinforcement of capacities of laboratories with regards to infrastructures and staffing, align the cost of testing with the actual tariff to enable hospitals to sustain provision of reagents and subsequently, resolve the recurrent problem of stock out."

The LQMS cannot be differentiated with uninterrupted delivery service, which is not always the case in some health facility settings.

"Fine tune the supply chain mechanism and engage the local private sector in equipment maintenance would march contribute to LQMS as long term solution." added a laboratory technician at Kibungo District Hospital.

"Leave the management of laboratory commodities and reagents solely to the laboratory and separate them from other medical commodities" (pharmaceuticals, medical...)

"Quite number of remedial measures could be suggested including; Structure of laboratory systems in health sector, including levels, number of lab professionals per level, channel of reporting".

4.4. Challenges to Laboratory Quality Management Systems

The combination of limited training, lack of representation of laboratory at the Ministry of Health and staff working in poorly equipped facilities results in a vicious cycle of demotivation and underperformance. Below are quotations of participants.

"Demotivation of lab personnel due remuneration not aligned with their education level may hinder the implementation of LQMS (Nyanza) laboratory A2 don't exist at the labor market then we pay A2 while we pay A2 while they are A0 level of education; MOH do not recognize their level of education, this situation has an implication of staff turnover." (added Nya0nza hospital lab manager).

Poor Infrastructures and poor service of equipment constitute a challenge for Laboratory services delivery and hence LQMS affected at all levels. Below are quotations of participants

"Poor infrastructure, maintenance of equipments, lower level of staff in lab department, inventory and supply chain management which are not sufficient."

Interviewees reported though training is needed for all staffs, training given for the laboratory personnel is very minimal and the utilization is also not in the proper way to cope with the requirements in the implementation of LQMS.

"Insufficient infrastructures, human resources but also a low level of academic training, is hindering the implementation of LQMS, to my understanding, it is important to have a comprehensive plan for lab professional training to be supported by the government."

"Lack of representation of laboratory at the level of MOH is one of the factors susceptible to hinder accelerating the implementation of LQMS."

"Lack of accrediting bodies, as they are the main pillars of accreditation process, they need to be strengthened and lead to accreditation by certified bodies (ASLM, SANAS, KENAS, etc)." (NRL)

"Default of laboratory equipment and Lack of bio engineers but also demotivated staff who are not paid according to their level." (Senior laboratory specialist at Byumba District Hospital).

The challenges are not only related to resources but also to behaviors in the extent that staff may not adhere to norms, standards and procedures not necessarily due to lack of resources. Below quotation of a senior lab specialist at the National Reference laboratory.

"Some lab staff do not apply and respect QLMS policy and guidelines and I think this may be due to only behaviors. Revealed a senior laboratory Specialist at the National Reference Laboratory" (NRL)

Delayed procurement process of specialized and critical Laboratory equipment and hiring maintenance companies and low skills in forecasting of reagents and consumables are among factors hindering the implantation and sustainability of LQMS. Below is the quote of laboratory technician at CHUK.
"Long Procurement process and lack of skills in quantification and forecasting of lab reagents and commodities hinder a good implantation of LQMS".

Participants also reported to not external preventive and curative maintenance agreement and schedule, therefore lacking of equipment maintenance that can serve in case of emergency, considering this of major challenge.

"Default of laboratory equipment and Lack of bio engineers but also demotivated staff who are not paid according to their level." (Byumba)

"Major hindering factors to LQMS include; Lack of norms and standards (comprehensive structure), Understaffing VS laboratory workload, Lack of laboratory representation in decision making forums, Law level confidence of laboratory professionals due to historical background, underestimated for long time." (Nyagatare)

Shortage of laboratory department manpower, others were working but having degrees that were not recognized, was being faced and reported influence the motivation of work and implementation of LQMS.

"One of demotivating factor that should be considered not recognizing degrees of lab professionals in terms of salaries and other incentives. Having a representation of laboratories, the ministry level would increase advocacy and level of confidence". (participant from Nyagatare).

Most of institution did not have smooth purchasing and inventory system and financial resources and particular budget for laboratory department that was the major obstacles faced in the implementation of LQMS.

"*You know, quality is always expensive and yet the financial resources allocated to the laboratory are quite limited". (KIZIGURO)*

"We cannot say something on time because we, who work at the district levels, receive many samples from our patients here and health centers that we need to treat with the small number of technicians. It is a serious problem, testified (Head of Lab department, at Gihundwe District Hospital).

In addition, the participants declared that, salaries and incentives which are not in line with academic level is not a good catalyst to accelerate the implementation of Laboratory Quality Management Systems. This is shown in the below quote from the interview at Kibilizi District Hospital;

"I would like to mention a demotivating factor, due to salary scheme not aligned with academic level for example when someone is A0 but currently being paid as A1"

Another participant emphasized through statement in the quotation below:

"Demotivation of lab personnel due remuneration not aligned with their education level may hinder the implementation of LQMS"

Another participant at Nyanza laboratory added;

"Laboratory level of A2 don't exist at the labor market then we pay our technician as A2 level while they are A0 level of education; MOH do not recognize their level of education, this situation has an implication of staff turnover going to private health facility settings where they will be well paid".

CHAPTER FIVE: DISCUSSION

5.1. DISCUSSION

Laboratory Quality Management System in is very nascent in Rwanda, and it is of utmost importance to understand its current situational status and factors susceptible to drive its success and sustainability and identify challenges which could hinder it smooth implementation and sustainability.

5.1.1. Current Status of laboratories vis-à-vis norms and standards towards accreditation

Regarding the current status of laboratories vis-à-vis norms and standards towards accreditation, laboratories have established Laboratory Quality Management System (LQMS) and laboratory professionals are conversant with LQMS, with positive changes over time. Since they have started implementing LQMS using the SLIPTA WHO/AFRO approach, the quality of Laboratory services (Patients' Waiting time, Turn Around Time and accuracy of results) has gradually improved. In some laboratories, the implementation of LQMS increased scores in SLIPTA and helped the institutions to improve the level of visibility and service delivery.

In a study "Experience in implementing a quality management system in a tuberculosis laboratory," which was conducted in Kisumu, Kenya an implementation of LQMS, showed a sustained reduction in culture contamination rates for solid (from 15.4% to 5.3%) and liquid media (from 15.2% to 9.3%), hence improving good laboratory practice and operation[40] ;there were have regular follow up on LQMS implementation activities in the laboratory, make good communication with laboratory staff, having financial Support, facilitation of training program and hire additional staff had an impact on having good progress on SLMTA implementation.

In Rwanda, there are several reasons involved; on-site Trainings & Mentorship as well as Continuous Professional Development (CPD) that Laboratory workforce has benefited. LQMS need to be sustained, and the sustainability is an everyday work and oversight, the management need to put forward the sustainability plans to contain factors susceptible to hinder a sustainable implantation of LQMS, participants mentioned among other factors; laboratory infrastructures, continuity of laboratory services delivery, Human Resources for Health, Capacity building and

supply chain. As a result, of LQMS clinicians can be confident of laboratory services, and abandon presumptive diagnoses rather than laboratory confirmation.

In a cross-sectional health facility-based descriptive study which was conducted between February 2013 and March 2013 in Addis Ababa, using structured questionnaire as well as observation to elicit information on quality management system of laboratories in intermediate referral facilities. Findings showed that the quality management system of laboratories performing CD4 count and AFB microscopy in Addis Ababa was established, but does not yet meet the international Standards and therefore, more intensive effort were still needed to address quality[39].

5.1.2. Factors which are susceptible to contribute to success of laboratories.

The management of the hospital has to play a big role with regards to success of laboratory management systems, by providing incentives and internal motivation as well as oversight. Motivation of staff using different approach and mechanism is a way of maintaining sustainable LQMS.

Factors are not only seen as incentives in term of funding but also training opportunities for laboratory workers, upgrading of laboratory infrastructures and an introduction of new technologies which are less time consuming can contribute to improved working environments.

5.1.3. Challenges to Laboratory Quality Management Systems

The combination of limited training, lack of representation of laboratory at the Ministry of Health and staff working in poorly equipped facilities results in a vicious cycle of demotivation and underperformance.

Given the fact that laboratory platforms and equipment is not yet at high level of automation, it absolutely requires a good number of man power to enable a quick service delivery and maintain LQMS.

The challenges are not only related to resources but also to behaviors in the extent that staff may not adhere to norms, standards and procedures not necessarily due to lack of resources. Below quotation of a senior lab specialist at the National Reference laboratory.

Delayed procurement process of specialized and critical Laboratory equipment and hiring maintenance companies and low skills in forecasting of reagents and consumables are among factors hindering the implantation and sustainability of LQMS.

Unmet Needs for Laboratory Professionals may hinder smooth implementation of LQMS and need to be addressed

In a study conducted to evaluate challenges faced by National Laboratory Services, findings showed major challenges which include a shortage of skilled and trained personnel, an inadequate infrastructure, a lack of equipment, inadequate supply-chain management for consumables and reagents, poor equipment maintenance, lack of clear policies, and insufficient leadership. Consequently, clinicians lack confidence in laboratory results and often rely on clinical diagnosis and empirical treatment instead of laboratory-confirmed diagnosis.

5.2. Conclusion

From findings highlighted in this study, there is an established Laboratory Quality Management System which is very successful in some laboratories and the impacts it has on strengthening the laboratory services. However, the procurement system still needs to be fast-tracked for more impact.

On the other hand, there are major challenges to the implantation of LQMS, which need to be addressed; Hospital management support to the laboratory is very minimal because it is not reserved a particular budget, finance, purchasing and budget were the major challenge for successful implementation of LQMS. Strong inventory system should be implemented to overcome test interruption. Purchasing system of equipment, consumable and reagents in laboratory department was not satisfactory. Some laboratories dated from the colonial period require the new or renewal of infrastructures to cope with modern laboratory equipment and quality management imperatives.

5.3. Recommendations

Laboratory quality management system constitutes the foundation for strengthening health care systems. Therefore, it is of imperative to recommend various stakeholders for successful implementation of LQMS towards sustainable health system in Rwanda:

- Continue sustaining LQMS is labor-intensive hence requires more staff and funding than current establishments.
- It is paramount to increase the level of involvement of the Hospital management in laboratory operations and dedicate a particular budget to support acquisition of critical equipment, reagents and consumables.
- Continue investing in laboratory infrastructures, equipment maintenance and Human resources at all levels of the National laboratory network pyramid.
- Supply chain of laboratory items is better to be handled on time in order to prevent any interruption of laboratory testing.

5.4. Limitation and implications for future research

5.4.1. Research limitations

An important challenge is the language of some respondents because some were using French while the language of publication is English. Therefore, we had to translate and interpret interviews, questionnaires and responses to the extent we believe that the information translated included in this document is close to the information provided by respondents.

Some respondents, may have refused to answer questions to embellish their profile, believing that the research is an administrative investigation rather than pure academic research purpose. However, we took time to explain to the respondents extensively the purpose of research and ensure to bring recommendation to authorities to gain the trust of respondents. Also in order to minimize the reluctance to offer information the researcher had to introduce himself carefully and courteously to potential respondents and explained the rationale behind the research.

5.4.2. Perspectives for future research.

It would be inappropriate to conclude this study without making reference to the research further perspectives. There is a need to conduct evaluative study on purchasing and inventory systems to assess the challenges and implications to implementation of laboratory quality management system national wide.

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APPENDICES

    A. Recommendation letter

    B.   Ethical approval

    C. Consent Form

    D.   Data collection tools

    E. Observation Form