Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories in the WHO Sub Saharan Africa region. A cross-national analysis of three countries

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A thesis submitted in partial fulfilment of the requirement for the degree of Master’s in international health

By
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Declaration:

Where other people’s work has been used (either from a printed source, internet or any other source), this has been carefully acknowledged and referenced in accordance with departmental requirements. The thesis “Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories in the WHO Sub Saharan Africa region. A cross-national analysis of three countries.” is my own work.

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List of Abbreviations

AFRO	Africa Region
CLSI	Clinical and Laboratory Standards Institute
DST	Drug Sensitivity Testing
HIV	Human Immunodeficiency Virus syndrome
HOD	Head of Department
IDI	In-depth Interviews
LIMS	Laboratory Information Management System
MOH	Ministry of Health
NTRLs	National Tuberculosis Reference Laboratories
PI	Principal Investigator
QO	Quality Officer
QMS	Quality Management System
QSEs	Quality System Essentials
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SOPs	Standard Operating Procedures
SRLs	Supranational Reference laboratories
SSA	Sub Saharan Africa
TB	Tuberculosis
WHO	World Health Organization

Definition and explanation of Relevant Concepts

Tuberculosis (TB): TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extrapulmonary TB). The disease is spread when people who are sick with pulmonary TB expel bacteria into the air, for example by coughing (1).

TB incidence: the number of new and relapse cases of TB arising in a given time period, usually 1 year (1).

TB mortality: the number of deaths caused by TB in a given time period, usually 1 year excluding deaths among HIV positive TB cases (1).

End TB strategy: Global strategy and targets for tuberculosis prevention, care and control after 2015 developed by World Health organisation (1).

Laboratory accreditation: Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Laboratory accreditation is a process that employs independent external assessment to determine conformity with recognized standards for quality management systems (QMSs) and competent laboratory practice. Accreditation is a validation process established to ensure that medical laboratories deliver high quality services that meet the needs and requirements of their clients (2).

Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) is a checklist which provides a framework for countries to strengthen their national laboratories through fulfilment of the requirements in the ISO 15189 standard by awarding stars from no star to 5 stars (2). It is intended to improve performance and reliability of laboratories to eventually meet the standards required for application towards accreditation (2).

Quality Management Systems: “coordinated activities to direct and control an organization with regard to quality. All aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality.” This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI) (3).

DATOS is an organisation based in the Netherlands focusing on laboratory strengthening worldwide, with a primary focus on low and middle-income countries.

National TB Reference laboratory (NTRL) Manager: responsible for coordinating and running of day to day laboratory activities in all departments and compilation of overall NTRL reports sent to higher management.

Head of Department(HOD): responsible for coordinating and running of day to day activities in a department conducting specific tests or activities in the NTRL and compilation of report sent to NTRL Manager.

Acknowledgement

I would not have managed to reach this moment without the amazing direct and indirect input from many people.

Firstly, my utmost gratitude goes to the NTRL laboratory managers, Head of Departments, Quality Officers and the SRL representative who participated in this study despite their busy work schedules.

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My studies and this research project would not have been a success without support from the KIT Scholarship Fund.

I am greatly indebted, foremost to my husband who allowed me to be away from him for 1 year to pursue my studies, to my family and friends for their prayers and unmitigated emotional support.

Finally, I am grateful to God for being my stand by, counsellor and amazing source of strength and comfort throughout the project. Glory to His Name forever.

Abstract

Background

Highest Tuberculosis (TB) disease morbidity and mortality is pervasive across the Sub Saharan Africa region. Efficient laboratory services are pivotal at all stages of the tuberculosis care cascade, from diagnosis and drug resistance testing to monitoring of treatment response. Laboratories implementing quality management systems (QMS) have improved test quality and general quality of services which in turn has a good impact on patient care. However, National TB Reference Laboratories (NTRLs) in most Sub Saharan Africa (SSA) countries are not accredited and face various challenges in QMS implementation. In line with the End TB strategy and to have better health for the people, it is therefore imperative that factors influencing QMS implementation in these laboratories be explored, and strategies be proposed to overcome them with urgency.

Method

A mixed method quantitative and qualitative explorative research was conducted in the NTRLs of top five TB Burden (2016),English speaking countries in the World Health Organization Sub Saharan Africa region between June 2018- July 2018. Five questionnaires were sent to NTRL managers and eight in-depth interviews were conducted with Head of Departments (HOD) in NTRLs, Quality officers (QO) and a Supranational Reference Laboratory (SRL) representative. Results are from three countries out of five that were invited to participate in the study (response rate: 60%).

Results

It is important to note that every laboratory included is at a different stage of QMS implementation and their strengths and challenges vary. Knowledge and awareness on various tools, practises and requirements on QMS implementation is present. Audits have been a source of improvement and strengthened QMS practices in NTRLs. Mentors did not offer the same and standardized help in different laboratories. International NTRLs networking platforms have been a strength to implementing QMS. NTRLs also experienced problems external to their span of control, yet these affected their QMS implementation process. Examples are:

- Poor/absent sample transport system.
- QMS not being part of pre-service training curriculum.
- Poor management/support from institutions the NTRLs are part of.

Conclusion

More strengths than challenges were found related to implementation of process and improvement management aspects of Quality Systems Essentials (QES). The major challenges found were related to implementation of QMS requirements for resource management with the QSE ‘organization’ being the most challenging element of the QMS implementation process. The main ways in which challenges related to ‘organization’ were overcome were lobbying and engagement of management team and partners. Availability of an earmarked budget for projects and equipment management should be provided by the national TB program or international partners to ensure longevity and adequate maintenance of equipment and success of QMS implementation and maintenance.

Key words

Tuberculosis- laboratories-Accreditation- Laboratory Quality- ISO 15189-Sub Saharan Africa

Word Count: 11 012

Introduction

Working as a government medical officer at a hospital close to Zimbabwe-Botswana border, seeing large numbers of patients with TB disease and an increasing number of those with multi drug resistant TB raised so many questions in my inquisitive mind. Most of the patients I saw were locals who had gone to work in either Botswana or South Africa. I was intrigued by the growing trend of drug resistant TB cases in my region, which consequently got me more interested in seeking ways of improving our TB care. I started attending TB care trainings and updated myself with the current management of TB patients. My obvious zeal in TB care was quickly recognised by the provincial TB coordinator and the higher management who appointed me Trainer of trainers in TB Care where I would be involved with a team of health care workers going around the country training other health care workers on TB.

Shortly after I started being a trainer of trainers in TB Care I came to KIT for my Master program. During the NTC course we were taught about many diseases affecting low and middle-income countries and TB came up again further fuelling my passion to better TB Care in these settings. Empowered with the research skills and intercultural communication skills which I was taught in the MIH program and an opportunity that had arose from DATOS organization for conducting research for TB laboratory strengthening, I decided to work on a mixed quantitative- qualitative study to explore factors influencing QMS in NTRLs in SSA.

I see TB as a disease without borders and being able to diagnose it quickly and more efficiently may lead to reducing its burden globally. Since I had been working in TB care in my country, I knew some challenges we were facing and issues that led to them in our NTRL and therefore I wanted to learn from other neighbouring countries what they were facing and what issues were behind these challenges. The countries selected in this study were the top five TB burden English speaking countries in WHO 2016 Report.

I have personally learned a lot through my study and will help initiate some of the recommendations that came out through the study in our TB laboratories starting at district level. I am also making plans to publish it on a peer reviewed journal for all others to learn and strengthen their laboratories. My motto from this study is *"If TB has no borders let our bid to strengthen NTRLs be without borders."*

Chapter 1

Background

The existence of TB is backdated to many centuries ago. Published evidence of the disease is seen in the skeleton of remnants of the human kind around the 1600s (5). Its scourge on the human kind earned it the epithet “Captain of Death” (4). Modern Strains of *Mycobacterium tuberculosis* appear to have originated in Africa about 20,000 years ago (human prehistory) (5). Thomas McKeown’s analysis of the decline in TB mortality in Wales around 1800s suggests that the decline can be mainly contributed to improved social and economic conditions prior to the advent of drugs which were effective in treating the disease (6). This optimistic scenario was overpowered around the 1990s when not only a rise in TB cases was noted, but also the emergence of drug resistant TB (4). In 1991 the World health Assembly declared TB a “global public health problem” (7).

The disease is spread by someone infected with open pulmonary TB via coughing or sneezing aerosols that contain bacteria. TB is associated with poverty and poor housing conditions that facilitate the spread of the bacteria. Apart from the pulmonary system, TB can affect any part or system in the human body (Extra pulmonary: TB meningitis, TB lymphadenopathy, TB abdomen, TB of the bone etc.) (8)(9).

The global burden of TB remains high. Worldwide, 10.4 million new cases and 1.3 million deaths among HIV negative TB patients were recorded in 2016 (1). The highest global estimated total TB incidence rate of 254 per 100 000 population is in the World Health Organisation (WHO) Africa Region (AFRO) (1). The top 5 English speaking sub-Saharan African (SSA) countries in the 30 high TB burden countries according to estimated incidence are South Africa (781 per 100 000), Lesotho (724 per 100 000), Namibia (446 per 100 000), Zambia (376 per 100 000) and Kenya (348 per 100 000) (1). The highest estimated TB mortality rate of 41 per 100,000 population year (excluding TB deaths among people living with HIV) is found in Sub Saharan nations (1).

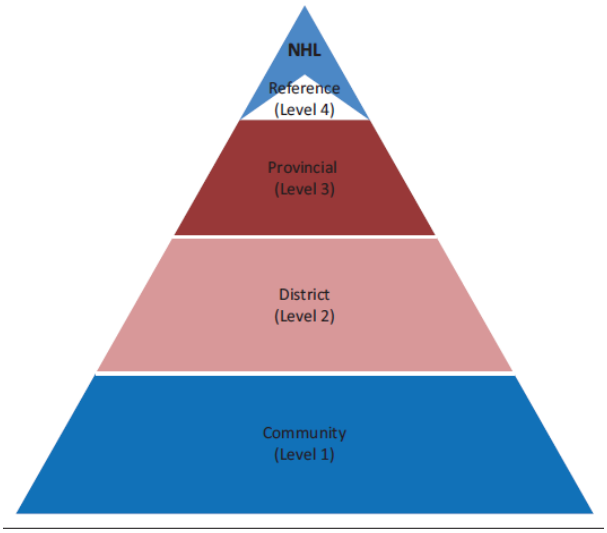
Many deaths from TB can be prevented with early diagnosis and appropriate treatment. Efficient and reliable laboratory services are pivotal at all stages of the tuberculosis care cascade , from diagnosis and drug resistance testing to monitoring of treatment response (10)(11). This brought about the realization of the importance of laboratories in TB care. A definitive diagnosis of TB is primarily based on the detection of the bacteria in any sample of the part of the body presumed to be affected. The traditional method of first detecting TB bacteria, which dates to a century ago, is by Ziehl Neelsen sputum smear microscopy (12). This is a basic method and is usually available in most of the laboratories including peripheral laboratories. It is a test method within the budget of all laboratories, small or large, even though its relatively insensitive (12). More complex tests are available for typing and to test for drug resistance. Examples are the GeneXpert, Culture/Drug sensitivity testing (DST) which is the gold standard and HAIN LPA 1st and 2nd line DST tests. These tests require more complex equipment and facilities which often cannot be implemented at the peripheral level (12)(13)(14).

TB Laboratory Structure

TB laboratories are organised into three, four or more tiers according to the country’s public health delivery system, thus establishing an integrated, tiered laboratory network (figure 1). Level 4 in some countries includes the reference laboratories and the National Public Health Laboratory is on top of the system. Tests and functions performed determine the tier thus creating a referral system for more complex tests to be performed at a higher tier. Tests conducted at each tier depend on the

equipment, infrastructure and patients' needs. Samples for testing may be referred up the pyramid with communication going both ways (15)(16).

Figure 1: The integrated Tiered Laboratory Network (15)



Tests performed at each level also varies from country to country. Example of functions and tests performed at different tiers of the TB laboratory can be found in Table 1.

Table 1: Laboratory tests and services proposed at each level of a tiered TB national laboratory network. Adapted from WHO Regional TB Program (17).

Laboratory Tier	Proposed tests conducted/ functions
Level 1: Community Level	Collection of samples +/- TB sputum smear and referral to level 2
Level 2: District level	Acid Fast Bacteria/ TB sputum smear GeneXpert Rapid testing
Level 3: Regional or provincial level	All tests listed in level 2 **In addition:** Microbiology culture
Level 4: National TB Reference laboratory	All tests in level 2 and 3 **In addition:** AFB culture TB culture (Solid and Liquid medium) including first line and second lin Line probe assays (LPA Hain) - First line and second line Supervision of peripheral laboratories Referral of testing to supranational reference laboratories. Producing surveillance data for National TB Program

National TB Reference Laboratories (NTRLs) exist either as part of the central public health laboratory or as a country's distinct principal TB institution (17). The reference laboratories may be responsible for developing guidelines, ensuring high quality and standardisation of TB tests (smear

microscopy, drug sensitivity testing and TB culture testing), overseeing training of laboratory staff, supervising peripheral laboratories, conducting surveillance of drug resistance, participating in epidemiological and operational research and ensuring supplies and reporting (17)(18).

The End TB strategy

WHO in its bid to reduce the global TB burden sets targets together with Ministry of Health(MOH) from various countries. NTRL strengthening is mentioned in the Stop TB and subsequently inferred in the End TB strategies. The End TB strategy was adopted in 2015 by WHO, it is a 20-year strategy with the aim to end the global TB epidemic. The main targets in the End TB strategy are (19):

- To reduce TB deaths by 95%
- To cut new cases of TB by 90% between 2015 and 2035
- To ensure that no family is burdened with catastrophic expenses due to TB.

The End TB strategy was preceded by the Stop TB strategy established in year 2000, which had a specific objective about the need for NTRL strengthening. The Component 1b of the Stop TB strategy says (7):

- Case detection through quality-assured bacteriology - Strengthened laboratory network. A wide network of properly equipped laboratories with trained personnel is necessary to ensure access to quality-assured sputum smear microscopy. This is likely to require additional investments in the laboratory network in many countries. In addition, every country should have a well-resourced and fully functioning national reference laboratory.

Quality Management Systems and Accreditation

“Quality Management Systems are coordinated activities to direct and control an organization with regard to quality. All aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality.” This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI) (3). Implementation of QMS is verified through a process of accreditation which is done by various accreditation bodies that are using the ISO 15189:2012 standard for medical laboratories. Laboratory accreditation schemes assess laboratories in accordance with ISO 15189, providing external validation that assures clients that laboratory services are accurate, traceable, and reproducible (14). Reliability and reproducibility tests performed can be increased, and frequency of errors can be reduced by implementing QMS (20). Evidence shows that accredited laboratories have improved both test quality and general quality of services which in turn has a positive impact on patient care and may, reduce deaths through accurate diagnosis, drug sensitivity testing and monitoring of success or failure of treatment (20)(21)(22).

Progress over the last decade

Efforts to strengthen laboratory systems have received increased attention in Africa. Key landmark events exist, such as the 2008 Maputo declaration to strengthen laboratory systems in developing countries, which has as one of the objectives to develop a consensus to guide the standardization of laboratory equipment at each level of the laboratory network (23). Many laboratory initiatives followed, such as The WHO AFRO Stepwise Laboratory Accreditation preparedness scheme which was launched in Kigali in 2009, which includes the Strengthening Laboratory Management Towards Accreditation (SLMTA) training and mentoring program (24)(25). The African Society for Laboratory Medicine (ASLM), established in 2011, is an organization that aims to strengthen Africa's laboratory standards and research capacity with one of its four goals aimed at laboratory accreditation;

- Goal 2: Laboratory Accreditation
  Enrol 2,500 laboratories in the WHO-SLIPTA and assist 250 laboratories to achieve accreditation (26).

WHO AFRO uses a Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist which provides a framework for the countries to strengthen their national laboratories through fulfilment of the requirements in the ISO 15189 standard by awarding stars from no star to five stars (25). This checklist specifies requirements for quality and competency aimed to develop and improve laboratory services to raise quality to established national standards. The elements of this checklist are based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A4 (25). After attaining a five star grade on the SLIPTA checklist, WHO AFRO encourages laboratories to enrol in an ISO 15189 accreditation scheme (27).

Justification of the study

Much attention has been given to TB laboratory QMS implementation in low and middle-income countries. In line with the Stop TB strategy and the End TB strategy some national TB laboratories in SSA have received donor support, started QMS implementation process towards accreditation and the ability of detecting new cases and testing for drug resistant TB cases has increased, though not at the rate that will enable these countries to reach the End TB strategy targets (1). Increased number of tests were mentioned in Botswana after accreditation and qualitative data indicated improved reputation, status and customer satisfaction with the NTRL's services (24). In 2015 Margaret Chan, WHO former Director-General (2007-2017) said

> *"Everyone with TB should have access to the innovative tools and services they need for rapid diagnosis, treatment and care. This is a matter of social justice, fundamental to our goal of universal health coverage. Given the prevalence of drug-resistant tuberculosis, ensuring high quality and complete care will also benefit global health security. I call for intensified global solidarity and action to ensure the success of this transformative End TB strategy."* (24).

It is therefore imperative that challenges and issues resulting in those challenges be explored, and strategies machinated to overcome them with urgency, in order to achieve the End TB strategy and have better health for the people.

Problem Statement

National TB Laboratories run by national governments process the bulk of patient tests, however many remain un-accredited, most of the TB care including laboratory tests for diagnosis and monitoring treatment is done at Government run facilities and many of these in the sub Saharan region have not been accredited and some haven't started the process of QMS implementation (6)(25). QMS implementation is important to ensure quality of laboratory performance and increasing reliability of results (20). For example in July 2009 an online survey showed that of the 312 accredited laboratories in South Africa 90.4 % were private with only 9.6 % government run which have to serve the greater population who cannot afford private health services (11). Quantitative studies done in the above-mentioned countries highlighted some reasons for challenges faced in implementation of quality management systems. Various reasons were given such as lack of finances to carry out quality management and lack of advocacy for laboratory needs (28). The national budget usually doesn't include funds for laboratory QMS implementation (1). However, many other factors such as lack of laboratory personnel, lack of equipment, insufficient training, poor staff motivation, lack of regular supervision, inadequate staff knowledge have been

seen to hamper the implementation of QMS at various laboratories (29)(30)(31) but nothing is known yet about context specific factors resulting in these challenges.

Overall objective

The overarching objective of this study was to explore factors influencing the implementation of quality management systems by NTRLs in 5 sub Saharan countries: South Africa, Lesotho, Namibia, Zambia and Kenya and to recommend strategies to NTRL managers and Policy makers on how to surmount the challenges.

Specific objectives

1. To assess familiarity of NTRL Managers and Head of Departments (HOD) with various tools and approaches that can be used when implementing QMS and monitor progress in implementing QMS by laboratory personnel.
2. To explore general challenges and strengths in NTRL QMS implementation faced by NTRL Managers and HOD.
3. To explore issues contributing to these challenges and strengths in NTRL QMS implementation as perceived by NTRL Managers and HOD
4. To formulate recommended strategies to improve QMS implementation for NTRL managers and Policy makers.

Chapter 2

Methodology

Study design

This study is a biphasic exploratory mixed method research. Firstly, quantitative data collection was done through a questionnaire in order to have a situational analysis of the selected NTRLs. Qualitative data collection in the form of interviews with HODs and key informants was subsequently done. A literature review was also conducted to understand TB disease morbidity and mortality, QMS implementation and the role of laboratories in TB care. On PubMed, Google scholar and the WHO website several searches were performed using different combinations of the key words: Tuberculosis, Laboratories, Accreditation, Quality management systems, Sub Saharan Africa.

Analytical framework

The data was analysed to identify challenges and enablers/strengths in the process of QMS implementation based on the quality systems essentials(QSEs) model (figure 2) developed by the Clinical and Laboratory Standards Institute (CLSI) (3). The quality model used here organizes all the laboratory activities into 12 QSEs as described below (table 2). The model is fully compatible with the ISO standards used to accredit medical laboratories and the 12 QSEs included in the model serve as the assessment points in the WHO SLIPTA checklist (32). Areas of strengths and challenges were examined for each QSE in the model. The quality cycle (figure 2) can be divided into three stages starting with resource management (Facilities & safety, Organization & personnel, Equipment, Purchasing & inventory), followed by process management(Process control, Information management, Documents and records) and improvement management (Occurrence management, Customer surveys, Assessment and Process improvement) (33). This division is used in the discussion to help consolidate and analyse results. Other issues that arose during the interviews which are beyond the conceptual framework were grouped into additional specific themes.

Figure 2: Quality Management System model (3)

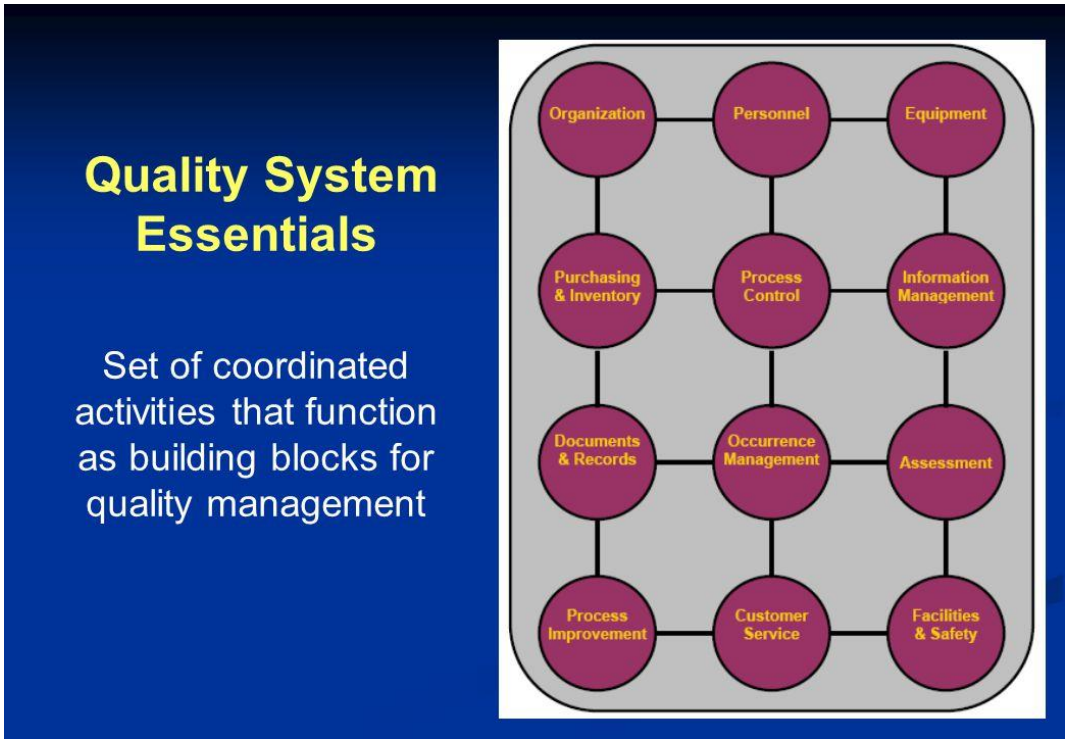


Table 2: Attributes of Quality Systems Essentials: Adapted from Quality Management Systems Handbook (3)

QUALITY SYSTEM ESSENTIAL	ATTRIBUTES
Organization	Organization is the backbone of a laboratory for a well-functioning QMS implementation and maintenance. With good organization quality policies can be established and implemented. The organizational structure should be supporting, and there must be a mechanism of implementation and monitoring of QSEs
Personnel	Recruitment and retaining qualified staff is essential to laboratory quality. Appropriate number of staffs should be available to cover workload, with a complete and thorough job description**.** Competent and motivated staff are an important laboratory resource. The laboratory setting should be encouraging, safe and motivating for the staff through awarding opportunities for continuing education, performance appraisals, trainings etc.
Equipment	A laboratory should have an equipment management programme in place ensuring proper procedures for selection and purchasing of equipment, installation, calibration and performance evaluation, maintenance, troubleshooting, service and repair and lastly retiring and disposing of equipment. Ensuring that all equipment is working properly and that there is a system for maintenance, are all part of the quality management system
Purchasing and inventory	The quality management system requirements in purchasing and inventory involve development and implementation of organised procedures that are designed to ensure that all reagents and supplies are available, of good quality and that they are used and stored in manner that preserves quality and integrity
Process control	To ensure the quality and accuracy of the laboratory testing process various factors should be put in place such as quality control for testing, appropriate management of the sample, including collection and handling of samples and method verification and validation. Laboratories should achieve this by having written policies for sample management which includes information needed on requisitions or forms, handling urgent requests, collection, labelling, preservation and transport, safety practices (leaking or broken containers, contaminated forms, other biohazards), evaluating, processing and tracking samples, storage, retention and disposal
Information management	The product of a laboratory is information in the form of a test result. It should be handled well to ensure accuracy, timeliness, security, confidentiality and privacy of patient information and accessibility to laboratory staff and health care providers. Information can either be managed in a paper-based or electronic system or both. There should be unique identifiers for patients and samples, standardized test request forms (requisitions), logs and worksheets, checking processes to assure accuracy of data recording and transmission, protection against loss of data, protection of patient confidentiality and privacy, effective reporting systems and effective and timely communication
Documents and records	Documentation in laboratories is important to show how things are done. Records must be kept well to ensure accuracy and accessibility

QUALITY SYSTEM ESSENTIAL	ATTRIBUTES
Occurrence management	An “occurrence” is an error or an event that should not have happened. There should be a system to detect these events, handle them properly, learn from them and put measures in place ensuring that they don’t reoccur
Assessment	This is a tool of comparing laboratory performance against standards, benchmarks or the performance of other laboratories. An important way for a laboratory to be recognised as delivering accurate and reproducible results is to go through evaluation and assessment process conducted by a credible and qualified organization. Assessment may be internal (performed within the laboratory by its own staff) or external (conducted by a group or agency outside the laboratory)
Process improvement	The primary goal of quality management systems is continuous improvement; therefore, several activities for example identifying potential sources of any system weakness or error, developing plans to implement improvement, implementing the plan, reviewing the effectiveness of the action through the process of focused review and audit, adjusting the action plan and modifying the system in accordance with the review and audit results should be carried out to ensure this
Customer Service	Laboratories are service organizations and it is important that their clients receive what they need. Performing customer surveys is pivotal to ensure that they meet their clients’ needs and for making improvements. Other examples including providing adequate information, both for collection of a specimen, and also information about the laboratory, providing good collection facilities, having available trained and knowledgeable personnel (personnel should know how to collect a sample properly, and should be trained to be courteous to all patients), giving assurance that the laboratory records are maintained properly so that they can be easily retrieved, and also giving assurance of protection of the confidentiality of the records
Facilities and safety:	Various factors are part of the quality management of facilities and safety
	Security a process of preventing unwanted risks and hazards from entering the laboratory space
	Containment which seeks to minimize risks and hazards from leaving the laboratory space and causing harm to the community
	Safety includes policies and procedures to prevent harm to workers, visitors and the community
	Ergonomics which addresses facility and equipment to allow safe and healthy working conditions at laboratory site

Study area

NTRLs of the top five English speaking sub Saharan countries in the 2016 global list of top 30 TB burden countries were selected: South Africa, Lesotho, Namibia, Zambia and Kenya.

Study population

The primary study population consisted of NTRL Managers and HODs since they are directly involved in the majority of activities of QMS implementation and, as such, they are considered a good information source regarding the challenges and enablers to QMS implementation in their local laboratories. Triangulation of data was done by including key informants such as NTRL Quality officers (QO) and a Supranational TB laboratory (SRL) representative officer who provide technical support and help mentor QMS implementation.

Sampling and Recruitment of Participants

Purposeful sampling of information rich participants was conducted. HODs, managers of NTRLs, NTRL QO and an SRL officer responsible for all the countries were interviewed to ensure maximum variation.

Identifying and contacting laboratories for the study was done in collaboration with DATOS, an organisation with experts in the field of laboratory strengthening.

Data Collection

Firstly, a questionnaire and informed consent form (see annex 1&2) were sent by email to the five NTRL managers for a general assessment of their familiarity with QMS implementation tools, progress towards accreditation, programmes and partners supporting strengthening of QMS in their laboratory and challenges and strengths experienced in QMS implementation.

In-depth Interviews (IDIs) were subsequently conducted with HOD and key informants in the countries that completed the questionnaire. A topic guide (see annex 3-5) was used consisting of issues on knowledge and awareness of QMS implementation, elements of the conceptual framework (Fig 1) and challenges and strengths experienced in QMS implementation. The PI took notes during the IDIs and read a summary of all notes to the participant at the end of the interview to check if everything was correct. Questionnaires and IDIs were used to cross validate the data collected.

Interviewees were asked for consent before each interview (Annex 6). A total of eight IDIs of maximum 45 minutes duration were conducted.

Data processing and analysis

The PI conducted the interviews and survey, transcribed and analysed the data. Data processing and analysis was an ongoing process throughout the study. Topics in the interview topic guides and questionnaire were coded and used as initial categorization. As data was being collected and analysed emerging issues were added and specifically coded. The PI sent follow up emails to participants verifying if information was recorded correctly. Ordering, coding and summarizing of data was done manually.

Ethical Consideration and clearance

The KIT Research Ethics Committee approved the research proposal on 28th of May 2018 (Annex 7). Maintenance of confidentiality, anonymity, and respect was ensured throughout the study. Removal of possible identifiers of respondents from the report was actively done. Interviews were conducted when participants were at a venue and time of their choice and comfort since issues that may be

considered sensitive may be uncomfortable to discuss in a work environment. The data is stored in a password protected computer only accessible by the PI and supervisor and data will be stored for five years following publication.

Quality Assurance

The data collection tools were developed in English. Triangulation of respondents, data collection techniques and data analysis were done to ensure quality by using variety of respondents, data collection techniques and having a colleague of the PI to analyse the results independently. Checking whether all themes on the topic guide were asked was done actively throughout the data collection process. Daily review of data was done to check whether the data was complete and consistent, appropriate adjustments to questions in the topic guide were made before the next interviews and documented well.

Chapter 3

Results

Questionnaire responses were received from three countries and eight IDIs conducted with HOD and QO in the NTRLs of the three countries that participated and one SRL. Two countries did not respond. The data presented in this study is from three countries (60% response rate).

Table 3: List of interviews with respondents and key informants

Job Title	Qualifications	Laboratory Accreditation status.	Country Code
Overall Head of Department	BSc Applied Medical laboratory Sciences	Actively implementing QMS to achieve accreditation	Country A
Deputy Head of Department	BSc Applied Medical laboratory Sciences	Actively implementing QMS to achieve accreditation	Country A
Quality Officer	BSc Medical laboratory Sciences	Actively implementing QMS to achieve accreditation	Country A
Quality Officer	BSc Medical Laboratory Sciences	Accredited	Country B
Head of Department DST	BSc Applied Medical laboratory Sciences and MSc in molecular medicine	Accredited	Country B
Quality Officer	BSc Medical laboratory Sciences	Actively implementing QMS to achieve accreditation	Country C
Head of Department LPA	BSc Applied Medical laboratory	Actively implementing QMS to achieve accreditation	Country C
SRL representative	BSC in medical laboratory Sciences and master's in molecular biology	SRL	

Situational Analysis of NTRLs based on completed questionnaires

Country B NTRL had recently achieved accreditation according to ISO 15189, others were actively implementing QMS to achieve accreditation. All laboratories were familiar with tools SLIPTA and SLMTA used to help in QMS implementation. Country B and A were enrolled in SLMTA in 2010 and Country C in 2013, with Country A at two stars and Country C, at three stars during their last audit. The countries' baseline score was no star for A and C and one star for B at the time they enrolled (in eight years, Country A improved from no star to two stars, Country B from one star to achieving accreditation and in five years Country C improved from no star to three stars). They all had formal

collaboration agreements with an SRL which provided technical support. All laboratories reported having a QO.

Table 4:Tests conducted at NTRL and staffing

	Country A	Country B	Country C
External Quality Assurance participation			
Sputum smear	☑	☑	☑
Xpert/Rif	☑	☑	☑
TB Culture	☑	☑	☑
1st Line DST	☑	☑	☑
2nd Line DST	X[#]	☑	X[#]
LPA	☑	☑	☑
Perceived number of laboratory staff in relation to workload	Inadequate*	Adequate	Adequate
Number of laboratory staff holding the following qualifications			
PhD/Doctorate	0	0	0
Master's Degree	0	2	1
Bachelor's Degree	3	10	2
Diploma	6	9	7
Certificate	0	0	0
None	3**	3***	0

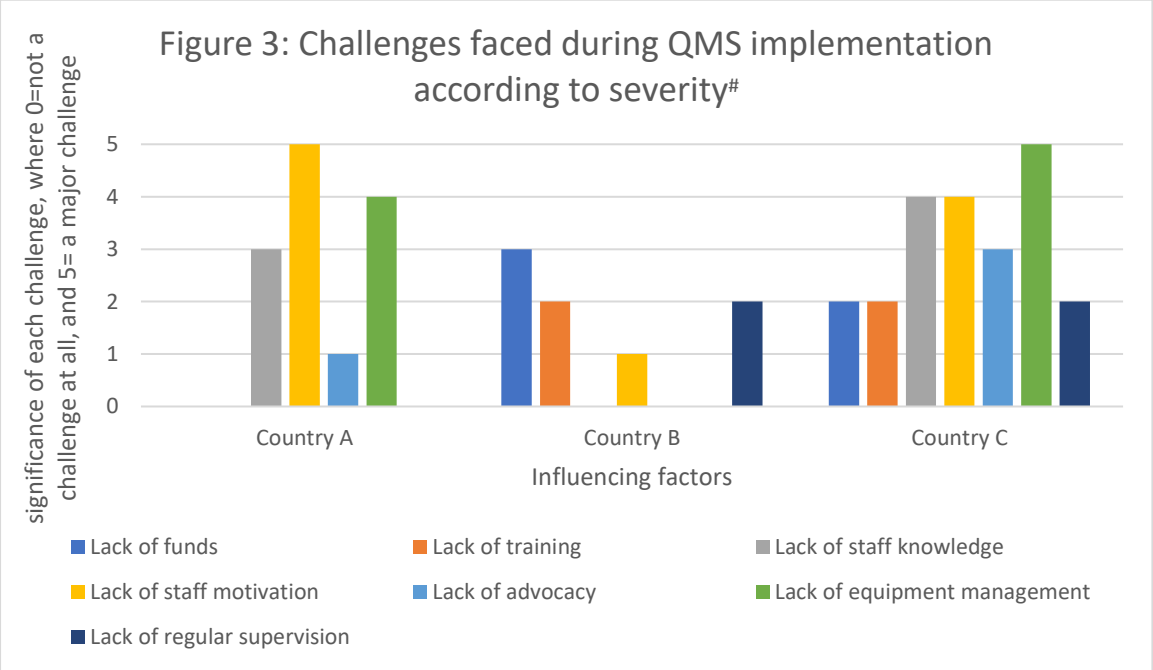
[#]Country A&C do not conduct 2nd line DST
*The NTRL with a total of nine staff do technical work, quality management systems implementation, district laboratory supervision to 35 sites and student training work amongst themselves.
** Two Data clerks and one cleaner
***One Office assistance and two Subordinate staff

Two out of three NTRL Managers perceived their number of staff is adequate for their workload and one reported their staff to be inadequate in number.

The main streams of funding for these NTRLs are the same. They are funded by their governments via the Ministry of Health and by international donors. One of the reasons for the NTRL from country C to seek accreditation was that technical support was offered on QMS implementation (Table 5). The challenges faced during the enrolment process and implementation of the QMS is context specific (i.e. differed per NTRL) as seen in the graph below (figure 3). Various factors influencing success of QMS implementation including availability of funds, advocacy, regular supervision, trainings, staff motivation, staff knowledge and equipment management were explored in the questionnaire. One country had challenges related to all the seven aspects and the other two had challenges related to four out of seven aspects, showing that each laboratory has mostly unique challenges and strengths in QMS implementation. One common challenge is lack of motivation of staff.

Table 5: Reasons for seeking accreditation.

	Improving quality of laboratory services	Increased laboratory output	Seeking greater regional recognition	Financial support was offered	Technical support was offered	Other
Country A	☑	☑	☑	X	X	X
Country B	☑	☑	☑	X	X	X
Country C	☑	☑	☑	X	☑	X



Results from IDIs

Organization

Strengths and challenges

The organizational structure of NTRLs is generally similar: they all fall under the Ministry of Health (MOH) through either the Directorate of laboratory services or the National Public Health Laboratories. There is existence of a non-formal NTRL organizational structure which involves international partners who are independent from the government MOH but seem to play a management role in various circumstances. Partners are involved in supporting QMS implementation activities through provision of funds, equipment management and providing mentors. All participants interviewed mentioned the importance of good organization in

implementation of QMS in their laboratories. Two NTRL mentioned good support from top management as a strength in their QMS implementation. The strengths of top management commitment mentioned was in terms of communication, payment of the courier services, timely shipping and any other challenges that could be there in referring of samples to the lab.

> *"I have a strong team, I don't work alone, I have my deputy and strong commitment from the management." said a QO*

> *"Right from the director, the director of the Public health laboratory and there is also the support from the unit head and manager of NTRL and the deputy. We also work closely with the National TB Program, they are also part of it and invite them in our management meetings. We also consider them in as much as we are not directly under them, but we also consider them as management because they also support us in one way or another. So, there is commitment from the management." explained one HOD*

One NTRL said that their top management did not show commitment. There was a lack of support from both the government and the international partners. They lacked proper coordination of activities, there was poor information flow within the organizational structure , lack of commitment or earmarked budget and equipment management programme.

> *"The people in the higher management take over the project handed over by the partners and come to us to implement thing we don't know, and they don't expect hustles. Most of the projects are held up there and they expect things to happen without involving us." said one HOD*

> *"Suppose you come with a project in the middle of the financial year and we have to ask for the fund for calibration and you have to justify it. It doesn't just happen after you took something and then you tell the government you have this and that and we require money. No! You need to put justification. They will ask you why you implemented this without maintenance, why did allow these partners to come and yet they are the ones who allowed the partners to come without maintenance plan. Because when we put a machine, we expect that partner to help us, we have to know everything, like clear proposals like for a machine after you leave the country, how are you going to sustain it. But with these partners they should be very very clear, they come and give us white elephant and leave the country and it's not good for us." said one HOD*

The issues of funds is a root cause for many challenges encountered in QMS implementation, it was mentioned in many areas of QSEs

> *"You know money is always a problem, whenever you plan to do something requiring finances you will face challenges." said one QO*

Ways in which challenges were overcome:

Lobbying and involvement of management in various meetings were used to improve organizational support in one NTRL. A QO and HOD of one NTRL went on further to share how they managed to improve commitment of management in their laboratories. They noticed a change in both government and partners commitment and support which led to easier implementation of QMS.

> *"Well just the involvement of these partners, you see if they are supporting accreditation of labs they will come in and then you air your challenges. you sit down with partners then you give them your challenges, we have challenges with equipment, we have challenges with supplies, you name all the challenges preventing you from being accredited. And then since the partners are willing to support the lab to get accredited they pick what they can support and that is really what helped us." explained one QO*

"We lobby support from the various areas where we have challenges and the partners come to assist." said one HOD

Personnel

Strengths and challenges

Motivation was mentioned as an enabler to QMS implementation in one NTRL and the lack of it as a challenge in two NTRLs. Other challenges highlighted in the two NTRLs were lack of understanding of QMS principles, unclear job descriptions and increased workload due to QMS practices. Various factors were raised to explain the lack of motivation and QMS competency. The reason which was mentioned by most of the interviewees for lack of motivation is equipment breakdown and the long time it takes for it to be fixed. Some other reasons that were mentioned are poor salary, lack of promotions, lack of training. One of the QOs interviewed said it was easier to implement QMS in private laboratories compared to government.

"It is easier to implement QMS in private compared to government because staff in government are generally demotivated or should I say less motivated." said a QO

When asked of the reasons why they thought implementing QMS is easier in private than government laboratories, the respondent went on to further say:

"several reasons, firstly sometimes you want to work but the equipment is not working and that takes forever to get fixed. Secondly, it's extra responsibilities, you are a lab scientist, you do technical work, you are the quality officer and perform trainings for other laboratory staff and at the same time you get the same salary. Your salary doesn't change even when all these other responsibilities have been added. Promotions are not readily available, there may be a position but no funds for that position." explained the QO

And a HOD in another NTRL mentioned the same issue of delayed fixing of broken equipment and added that stock outs too are a reason of lack of motivation in their laboratory.

"You know people when we just don't have enough support, what I mean by support is when a machine is broken, and it takes forever to be repaired and even if it gets repaired, but it's doesn't happen at the right time. People get demotivated and say but then why do we bother then if we can continue with these things not being serviced. Even the stock outs people get demotivated because of that." explained HOD

In 2 NTRLs QOs mentioned having unclear job descriptions and increased workload as they were also involved in technical work. One of them highlighted this when asked about the challenges they face when performing their role in documentation and record keeping.

"The thing is I took the role of the quality officer but at the same time I am doing technical work." one QO describing his circumstances.

Staff in all laboratories were said to be trained either through a formal training or in-house training (where individuals who went for formal training came back and teach the other staff in the laboratory what they learnt) and competent performing tests, but a majority were lacking understanding of principles of QMS implementation across all interviewed laboratories. Talking to the SRL representative, he highlighted lack of understanding of principles of QMS and high workload as major hurdles for many laboratories in Sub Saharan Africa.

"For these countries in Africa, the great challenge is lack human resource both in quality and quantity. This is an issue for most labs…… the other big challenge is that principles of quality management systems are not something that is embedded in our curriculum during training school. There are some components of quality assurance and quality

protocol, but the implementation requires more than what is being taught. So, the concept becomes difficult for them to quickly adopt to practice when they are now working in the lab." said SRL representative

The other challenge mentioned was lack of comprehension by some NTRL staff during training to such an extent that the trainer must take it very slow.

"You find that somebody is trained but their training is very insufficient to be able to comprehend what you are talking about. So, you must take it slow, you really have to go slow to try adopting their level. You have to adapt to adult learning education skills to be able to communicate things." said SRL representative

Ways in which challenges were overcome

One NTRL introduced peer to peer departmental performance appraisal as a strategy to improve performance among staff resulting in improved QMS implementation and increased interest in performing their duties.

"We noticed that the human being tends to work when somebody is watching. We started doing peer reviews every week. We created indicators for each service and audit each other's sections looking for everyday things and we report it. So, the person auditing a section speaks to the head of that section first before presenting to everyone his findings so that we don't create a fault-finding exercise." explained QO

Facilities and Safety

Strengths and challenges

Two mentioned they are using a Biosafety Level (BSL) 3 Laboratory. One NTRL mentioned a challenge with their facility and that they were currently unable to perform some tests and conduct audits due to the infrastructure. All laboratories mentioned no challenges in safety measures.

Ways in which challenge was overcome

The laboratory which mentioned a challenge in its facility was undergoing renovation to a BSL 3 level laboratory during the time of the study.

"Currently our laboratory is under renovation to upgrade it to modern P3 [BSL 3]." said one QO

Equipment

Strengths and challenges

All participants were aware of the importance of ensuring fully functional and well-maintained equipment in QMS implementation. The main challenges mentioned were lack of service contracts, calibration, committed budget for maintenance of equipment and poor staff communication when reporting equipment in need of servicing. Two out of the three NTRLs had issues with equipment maintenance and mentioned that this caused a challenge in their QMS implementation. All the laboratories had all the equipment for performing standard tests for an NTRL, but the challenge came when there is a breakdown.

"Sometimes there are challenges. You find out that sometimes we run out of calibrators and our machines are not calibrated. And it takes long to arrive to the lab." said one QO

A HOD from another department shared the same sentiments and added that sometimes people in the laboratory who are responsible for notifying the due dates for calibration at times forget to do so.

"Sometimes it's not good because of poor staff coordination. The person responsible for reporting a faulty machine or calibration that is due doesn't report them." explained one HOD

The (accredited) NTRL that reported good equipment management mentioned that their strengths were having a calibration centre within their laboratory and service contracts for automated machines. Their partners also played an important role in funding for servicing of the automated machines.

"Well equipment management is now good because at least now we have calibration, we have a calibration centre within the laboratory and they are able to do most of the calibration expect for the automated. For the automated equipment we have service contracts with the partner, with the companies directly. And fortunately, enough, we have partners on board who fund for these calibrations for the automated. So this far for the last 2 years we are good with equipment." said one QO

On the same note another NTRL was displeased by the support they receive from their partners due to lack of commitment and support when it comes to the equipment provided by them.

"I will give you an example of GeneXpert in the country. It's really not a partner who left but they bring GeneXpert to the country, but they don't help with the maintenance and at the same time our government would not have budgeted for that." explained one HOD

Ways in which challenges were overcome:

Engaging partners and the government and lobbying resulted in arrangement of equipment service contracts for one NTRL.

"Initially it was a challenge with calibration, it was inconsistent because there was no commitment from either party, so we will go sometimes overdue without any calibration but now there is commitment so for now since last year 2017 its good with equipment." said one QO

A QO mentioned the usefulness of laboratory staff who are naturally good with fixing machines as of help in their laboratory. They sometimes fix machines and they start running before they receive any communication from the higher offices of people coming to fix them.

"I think it's that we have some people in our laboratory, you know men, who are naturally talented with handling equipment and gadgets, so they help us fix the equipment sometimes." said a QO

Having a calibration centre within the laboratory helped overcome challenges related with equipment for one of the NTRLs.

Purchasing and inventory

Strengths and challenges

The main challenge mentioned in all the NTRLs was a long procurement process and one NTRL mentioned stock outs of reagents. They are not able to run tests for a long time without reagents.

"…Even the stock outs people get demotivated because of that." said one HOD

The long procurement process delays their acquisition of things they may need immediately and thus compromises quality and compliance with QMS standards.

"…So in future, if labs can be able to handle their own funds that would be ideal and turnaround time for action would be will be short." said a HOD

"…There is a supply chain coordinating unit responsible for this, but it looks like it's a big process of procurement to get it done because it takes very very long, sometimes it takes even a year, for example something that we ordered this year comes next year." explained a HOD

Ways in which challenges were overcome

The International partners gave better support for some laboratories by shortening the procurement time after requesting for something when they seek support from their partners compared to the government.

"It takes long for us to receive the money from the government after requesting for it. it can take even a year. But at times our partners help and its quicker to receive fund from our partners compared to the government." said a HOD

Process Control

Strengths and challenges

All laboratories were aware and knowledgeable of standard practices involving process control.

Quality Control

They unanimously expressed awareness and good practice of quality control for all the samples they test for all the time. No one mentioned any challenges with ensuring quality control in the running of all the tests they do. Mentors provided strength in QMS implementation through supporting NTRLs by laying out Standard Operating Procedures (SOPs) and helping in implementing them in the laboratories.

"So the mentor will tell you if you have challenges with implementation they will tell you what tools you need to develop in your implementation and how you need to monitor things, how you need to monitor your turnaround time and continue quality improvement process." said a QO

Management of the sample

Challenges with sample collection and quality was not mentioned. 2 out of the 3 NTRLs interviewed mentioned poor sample handling from clients to the laboratories due to unavailability of a standard sample transport system. Health care providers send samples via National post services which are sometimes not dependable, they also use FedEx (a courier delivery service) and vehicles which come for other projects or supervisory visits.

"We do not have a national courier service, so samples and results are transported by any means." said a QO

Another noted that their health care providers lack knowledge on the standard times it takes for various test results to be ready. The customer surveys they received were complaints that the turnaround time is too long, but they were saying their turnaround time is standard for the tests they do.

"The main complaint from our customers is turnaround time. the turnaround time for the culture is 42 days when its negative and 21 days when it's positive, 12-21 days for DST…its normally around there but because they don't know the procedures, so they think it's taking long." said a deputy HOD

The other NTRL mentioned a good flow of samples as a strength in QMS implementation which resulted in protection against loss, spillage and safety during transportation and handling in laboratories.

"And in terms of movement of our samples now, it's streamlined, it like there no spaghetti movement that you go here and go there, there is a sample flow, there is a testing allocation, so it makes even the work easier because we are following now the laid down SOPs and the standard so." Said a HOD

Method verification and validation.

Two NTRLs mentioned availability of mentors who assisted in performing method verification and validation was a strength for implementation of QMS in these laboratories.

Ways in which challenges were overcome

Availability of mentors helped in two of the NTRLs to ensure that activities were in line with the requirements of the standard.

Information management

Strengths and challenges

All of the NTRLs have a paper-based information management system with one of the NTRL having both a paper-based and computer-based Laboratory Information Management System (LIMS). Lack of electronic LIMS was mentioned as a challenge in QMS implementation by one of the NTRLs. There are several QMS requirements for information management to ensure accuracy, confidentiality, accessibility to laboratory staff and health care providers. Ensuring access of results to health care providers was noted to be a challenge. The challenges varied from delayed turnaround time to verification whether results are received by the client:

"Generally poor, system is largely paper based so there is no way of us knowing that that our customers received their results. So, we calculate our turnaround time to the time we send the results." said a QO

"We used post results by email to the provincial lab in charge then they will further disseminate the results to the districts. So, we noticed that the results will be stuck at the provincial lab in charge and then we engaged them in meetings and incorporated a person to relieve them." said a QO

A Head of Department mentioned they had to use both paper-based and computerized LIMS as a safeguard against possible data loss (in case of failure of the computerized LIMS). This was a challenge in their QMS implementation as it increased workload and would sometimes delay turnaround time.

"But if we could have a consistency with our LIMS then we will be very safe and do away with paper work and do direct into the LIMS. So that at least will offload us some of the burden and will also improve the turnaround time because it realm time entry. But right now, we can't risk it yet because our LIMS is not consistent, and our internet activity is not really stable." explained a QO

However, all aspects of information management were currently performed well in this NTRL hence had good checking processes to assure accuracy of data recording and transmission, protection against loss of data, protection of patient confidentiality and privacy, effective reporting systems and effective and timely communication.

"Right now, we have development of something we call a dashboard. Through the dashboard, clinicians are able to monitor real time were the samples are at for example, if they are finished, they are able to know that we need results for these samples if they have come to NTRL, if we have changes in the email system. Initially we had a challenge because we didn't know who has moved from where but we able to decentralize that service to the county level. the county managers manage their counties and are able to interchange

the emails if there is any turnover of their staff. In that way we are now able to deliver results in a timely manner, so that is something that has improved from our end. and we also have a direct link to the clinicians, right now if there is any complaint of enquiry it's on real time basis right now." described a HOD

Ways in which challenges were overcome

Setting up a dashboard for health care providers to check in real time at which stage a sample is in the testing process strengthened information management in one NTRL.

Answering to interventions they have implemented to disseminate information of tests they perform, and standard turnaround times a deputy HOD said;

> *"We try so many different things, we have annual meeting with them and discuss these issues. and during our supervisory visit we also go to the clinicians and explain our services. And also, we have a National TB laboratory handbook that we give to all districts and clinics."*

Documentation and Records

Strengths and challenges

All interviewees understood the importance of documentation and records and expressed no challenges in carrying this out.

> *"At the moment there are no challenges there, everything is alright." said a QO*

One QO described that QMS mentors, allocated by partners to assist laboratories implement QMS, played a huge role in this QSE. The respondent highlighted that they had issues with implementation of QMS requirements related to documents and records.

> *"We looked thoroughly into our documentation starting with the quality manual, is it in line with the standard ISO 15189 and then our SOPs, how we do things here and is it in line with the requirements and once we ensured that our SOPs are adequate enough then we went to implementation. Implementing what we have stated in our standard operating procedures. So, this mentor is working with us all along even during the implementation process because that is where the biggest challenge is. Documentation and record development is not hard, but the hardest part is implementing. So, the mentor will tell you if you have challenges with implementation they will tell you what tools you need to develop in your implementation and how you need to monitor things, how you need to monitor your turnaround time and continue quality improvement process. So, it's just a continuous thing yah, with the mentor providing guidance." explained a QO*

Ways in which challenges were overcome

Two NTRLs mentioned the availability of mentors who assisted them in documentation and Records.

Occurrence management

Strengths and challenges

All NTRLs mentioned no challenges implementing QMS requirements related to occurrence management. Enablers for this QSE was staff knowledge, well documented SOPs, review meetings which they held occasionally to address incidents that would have occurred and availability of well stocked and serviced biosafety cabinets.

Assessment

Strengths and challenges

Strengths for QMS implementation for this QSE is that all the NTRLs were linked to laboratory external quality auditors and the help two of the NTRLs received from mentors. Mentors conducted the audits with them while teaching them.

> *"We also have mentors who help with these audits. We currently do not have a mentor because of construction work going on but mentors are really helpful they helped us translate theory to practical." said a QO*

A challenge mentioned by 2 NTRLs in performing internal quality audits was lack of trained staff in internal quality auditing.

> *"Yeah, we still have challenges in terms of implementation well at times its insufficient training, most of our staff are not trained like formal trainings. We have four people trained on internal audit and you see for QMS implementation it would be great if everybody understands QMS and it would be good if everybody understands and has been trained in internal auditor because you are able to critique were you err and do the audit yourself of your section. So, we disseminate this in staff meetings but again we still wish if everybody had been trained in internal audit. it will be of major use and ISO 15189 implementation because we have to keep repeating, we have to keep repeating in CMEs and Staff meetings." explained a QO*

Awareness and importance of both internal and external quality audits was seen in all participants. The frequency of internal audits varied from one NTRL to another but that of external audits was the same at once per year. Two NTRLs said they did internal audits once a year

> *"We divide ourselves into three or four people and check our lab using the SLIPTA checklist, we do this once a year. said a QO when asked about internal audits*

> *"Yes, we normally have them conducted once a year and internal audit once a year." said a deputy HOD*

and the accredited said twice a year.

> *"External audits we do once a year and internal audits twice per year." said a QO*

They all mentioned that both internal and external quality audits are relevant for the laboratories. One Head of department said that internal quality audits are relevant because they prepare them for the external quality audit.

> *"Yes, we think its useful cause our internal audit prepares us for our external audit." said a deputy HOD*

External audits were said to have brought a lot of improvement in the NTRLs and they found them relevant and needful.

> *"The external audits have made a great improvement to our lab. After the external audit we started to distribute duties among ourselves, before all of the Quality Systems duties were done by the Quality officer." said a deputy HOD*

And in another laboratory external audits were perceived as an external eye that sees things that they could have missed during their internal audits.

> *"We see external audits as an external eye, someone will see some things that we could not see and it's an opportunity of improvement for the lab because we don't consider it as fault*

finding, it's an opportunity of improvement and any gap that is found, we aim at closing that, the gap that has been found. So, they are quite relevant." said a QO

Ways in which challenges were overcome

One NTRL mentioned training in internal auditing as an intervention that is currently being implemented for all laboratory staff in their NTRL.

> *"And people are being trained in internal audits. I'm currently going through the training and 2 more have been trained." said a HOD*

Customer surveys

Strengths and challenges

Knowledge and relevancy of customer surveys in QMS implementation was seen in all the NTRLs interviewed for implementation of QMS. They all have various ways of conducting the surveys. Two NTRLs reported conducting annual customer surveys and the other reported that its usually quarterly during their meetings with health care providers. They would analyse and set up meetings with partners and customers to map ways to improve challenges raised. They mentioned that they also conduct several meetings as laboratory stuff to find ways to improve their service delivery.

> *"We conduct at least annually we do a customer survey. We meet our clinicians, we have meetings at least quarterly meeting, so we aim at those quarterly meeting to give them a survey tool, the questionnaires whereby they fill out those forms. These are quarterly review meetings with the clinicians". said one QO*

> *"We have clinicians at county level, we do meet every 3 months to review the performance, to review the challenges and to review the achievements. So, in those forums that is when we do our customer survey, we administer the questionnaire for them to give us feedback on what to improve, what we have done good and all that." Explained a HOD*

One NTRL reported challenges in conducting these surveys because of access problems. The transportation of surveys to health care providers is said to be not efficient, so some of the feedback or questionnaires get lost.

> *"Annually we do conduct customer surveys although the return is not 100%. Some clinicians complain and some of the surveys get lost on their way back, we have transporters using the motor bikes and sometimes hospital vehicles. So, we send out our surveys the same way." said HOD*

They said they act on the information they receive from these surveys to try to improve and the main complaint for all the NTRLs was the issue of long turnaround time. 2 NTRLs noted the gaps and had implemented ways to reduce the turnaround time.

> *"Right now, we have development of something we call a dashboard. through the dashboard, clinicians are able to monitor real time were the samples are at. for example, if they are finished, they are able to know that we need results for these samples if they have come to NTRL, if we have changes in the email system. Initially we had a challenge because we didn't know who has moved from where but we able to decentralize that service to the county level. the county managers manage their counties and are able to interchange the emails if there is any turnover of their staff. In that way we are now able to deliver results in a timely manner, so that is something that has improved from our end. and we also have a direct link to the clinicians, right now if there is any complaint of enquiry it's on real time basis right now." explained a HOD*

Ways in which challenges were overcome

One NTRL mentioned that they send their surveys via emails and take advantage of supervisory visits to conduct surveys to those who don't have access to emails.

> *"Yes, once a year we send emails to clinicians with surveys, for those who don't have access to emails we give them the surveys during our supervisory visits." said a QO*

They also noted that results would be stuck at provincial level and allocated an individual to help ease the workload at these provinces.

> *"The main challenge that our customers highlighted was not getting results. we used post results by email to the provincial lab in charge then they will further disseminate the results to the districts. So, we noticed that the results will be stuck at the provincial lab in charge and then we engaged them in meetings and incorporated a person to relieve them." said one QO*

Process improvement

Strengths and challenges

This principle is closely related to Assessment and Occurrence management described above. Availability of mentors was an enabler in two of the NTRLs in implementing QMS requirements related to process improvement. NTRLs mentioned that continuous and regular audits, especially internal audits, help them improve and motivate them to perform QMS principles better.

> *"Of course, there are a lot of audits for labs yah, internal audits. The more you do audits in the lab, the more you identify areas of improvement. Without audits you will never know the challenges and gaps you have in your system. So, you monitor your system by auditing." said a QO*

The respondent added more about how the availability of a mentor in their laboratory helped in process improvement.

> *"So, the mentor will tell you if you have challenges with implementation they will tell you what tools you need to develop in your implementation and how you need to monitor things, how you need to monitor your turnaround time and continue quality improvement process. so, it's just a continuous thing yah, with the mentor providing guidance." said one QO*

Emerging themes outside the analytical framework

Mentors

All laboratories were reported to have mentors to assist them in QMS implementation. However, the mentorship role was a success to some but not to other laboratories. 1 NTRL mentioned that mentors were not providing proper assistance and are hardly at their laboratories. This point was confirmed by the SRL informant;

> *"All countries have mentors just that the quality of the mentors themselves we could its wanting or the approach of doing the mentorship. If you have a good mentor, it's different with have a not so good one. The approach that these mentors give is different for example if a mentor is there for 2 weeks and he has a list of things to do people will not benefit what will benefit is being hands on. When you are going to develop an SOP with a person step by step that is specific to that laboratory but that's what you find lacking cause they just pick a document from another lab and they think by adjusting it will work. It's okay to start from a document form another lab but make sure you adopt it as much as possible to this new lab" explained SRL representative*

Networking with NTRLs in other countries

NTRLS mentioned networking platforms with other NTRLs and this has been a strength to implementing QMS. The SRL representative mentioned the improvement this networking has brought to laboratory QMS implementation in Africa. Collaboration of NTRL staff has been recently improved by the Regional Global Fund project goal one (Build a regional network of NTRLs for international laboratory quality assurance and management in East Central and Southern Africa Region) said the SRL representative.

> *"What used to be a challenge in the past but is now improving. It has been the linkages, the networking aspect, just to give an example laboratory in may be Somalia, Sudan or Kenya they want to do something, but they are not able to do it, they don't know who to ask. That has been a major challenge over the past. But now the networking has improved they know if we want to do this we don't just go look in the internet, but we can contact someone in Kenya or any other lab for example who knows about it."*

Transport or Courier System

Transport was mentioned in sample management and information management i.e. from the health care facilities of peripheral laboratories to the NTRL and transporting of printed results or survey documents from the NTRL to its customers. A poor network system within the country has been mentioned as one of the challenges to QMS implementation. One NTRL mentioned loss of customer surveys as they are transported to and from health workers by motor bikes.

> *"Some of the surveys get lost on their way back, we have transporters using the motor bikes and sometimes hospital vehicles. So, we send out our surveys the same way." said HOD*

University Curriculum

Participants also highlighted the paucity of their universities bachelor's training curriculum regarding QMS principles and practices. Introduction of QMS principles at workplace was resultingly perceived as an additional work burden rather than expected practices that are part of their routine work.

> *"It's because it came out like an additional responsibility. May be when training in colleges and universities, QMS starts from there most probably they will understand. It came when people had already started working and all that, so it looks like an additional workload." said a HOD*

Chapter 4

Discussion

Summary of main findings

This study set out with the aim to explore influencing factors of quality management systems implementation in five selected NTRLs in Sub Saharan Africa. Results were analysed using the 12 QSEs which were further divided into 3 categories (resource, process and improvement management) for the discussion. The main findings from three NTRLs that participated are as follows

- Knowledge and awareness on various tools, practises and requirements on QMS implementation is present.
- Audits have been a source of improvement in NTRLs and strengthened QMS practices in these NTRLs.
- Mentors did not offer the same and standardized help in different laboratories.
- NTRLs mentioned networking platforms with other NTRLs have been a strength to implementing QMS
- NTRLs also experienced problems external to their span of control, yet this affected their QMS implementation process. Examples are:
    - Poor/absent sample transport system
    - QMS not being part of pre-service training curriculum
    - Poor management/support from institutions the NTRL are part of.

Resource Management

Organisation

The NTRL organization is a major player to ensure proper QMS implementation. One NTRL which was struggling to implement QMS and had the least number of stars according to SLIPTA, mentioned challenges with management in various QSEs. They even highlighted that money was not a problem but there was a lack of coordination within the management system of the NTRL and long procurement processes.

This study adds to the growing body of evidence highlighting importance of a proper organizational structure in health care systems (34)(35)(36)(37). Gachuki et al. reported firstly to a good organizational structure of the Kenya HIV Reference laboratory in its journey attaining accreditation in 2005 (38). For example, in the study one NTRL attests to good organizational management and support which was more evident in the last 2 years before accreditation to have contributed to their accreditation. National level management and leadership typically includes setting policy and overseeing strategic direction, managing resource allocation, and monitoring policy targets and outcomes. At the operational level, hospital, district and primary health care facility managers are responsible for converting inputs and resources such as finance, staff, supplies, equipment and infrastructure into effective services that produce health results and are responsive to population needs(39). The guideline “WHO Towards better leadership and management in health” (2007) mentions the importance of good management to scale up services to reduce burden of diseases of public health concern (40). Despite increases in development aid and international partners assisting NTRLs in Africa, if the organizational management is weak, nationally set targets may not be achievable. There will be uncoordinated information flow as seen in our study (see page 14) which leads to health workers at operational level feeling like they are not included in the planning of implementation programs, but the management still expects results, consequently they are not fully aboard with the program. This observation is similar to findings of other studies that show that managerial capacity is one of the main contributory factors in failing to scale up effective health services and improving quality in laboratories (41)(42) (43).

Equipment, Personnel and Purchasing and Inventory

These QSEs are closely related as they form the resources that make up a functional laboratory. Availability of fully functional and serviced equipment and sufficient, high quality reagents and consumables has been seen to bring motivation to laboratory workers. Firstly, it is important to understand that one of the most important motivators for an employee is the ability to perform their duties without problems. Despite issues with equipment management, one laboratory in this study improved their staff performance and motivation by introducing peer to peer departmental performance appraisals. Willis-Shattuck et al. concluded that *"it is clear that recognition is highly influential in health worker motivation and that adequate resources and appropriate infrastructure can improve morale significantly."* (44). Recognition and/or appreciation by managers, colleagues or the community has been noted as one of the important motivating factors in many studies (45)(46)(47)(48)(49).

Other factors that led to less motivation among the staff are:

- stock out of reagents
- low salary
- career development or promotion
- increased responsibilities

Two out three of the QOs interviewed were doing both technical duties and QO duties and one complained about the salary still being the same despite increased responsibilities.

Another important finding concerning personnel in QMS implementation is the lack of inclusion of QMS principles and practises during training at universities. Most of the interviewees had a BSc in Medical Laboratory Science but expressed concerns in QMS practices and implementation and highlighted that it would have been better if they had learnt it as well during their pre-service training. Recently there has been a new focus on improving health workforce in low and middle-income countries looking at the labour market perspective. Policies addressing reinforcement of health workers in either quantity or quality have been seen to improve the health workforce (50).

Laboratories that indicated that their staff was less motivated, mentioned that this was due to broken equipment not being fixed for long periods of time. Equipment maintenance is pivotal in NTRLs for sample processing and accuracy of results. Delayed or inaccurate processing of test results contributes to increased morbidity and mortality from major diseases of public health concern, such as tuberculosis, malaria, cholera and HIV (31). It is observed in this study that one of the factors that aided the accredited NTRL in its accreditation was the availability of a calibration centre within their laboratory and existence of equipment service contracts. This has been seen to be important in QMS implementation in other laboratories too (35)(51)(52)(53).

Facilities and Safety

Facilities and safety are standardized for the NTRLs according to the SADC Region: Functions and Minimum Standards for National Reference Laboratories and WHO laboratory biosafety manual (54)(55). One NTRL had a facility challenge in this study, their laboratory was undergoing renovations during the period of the study to be a modern P3 laboratory. Laboratory design features such as construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups determine the required biosafety level and to ensure appropriate QMS principles (55). Effective treatment and preventative measures are available (55).

Process Management

(Process control, Information management and Documents and records)

An NTRL is a service provider and its clients have requirements that should be addressed satisfactorily. NTRLs reported knowledge and awareness of process management in QMS implementation. Two NTRLs mentioned the important role of mentors in implementing QMS requirements to process management. Mentors have been documented to have played a great role improving QMS implementation in many laboratories in Africa (34)(56)(57). SLIPTA and SLMTA were/are very helpful in QMS implementation. Both quantitative and qualitative studies have shown the usefulness of these QMS tools in Sub Saharan Africa (58)(59)(60)(61).

The NTRL mainly depend on paper based information management, this has been noted to be a challenge in other laboratories in QMS implementation (62). Paper-based LIMS are said to be tedious, costly and time consuming, not to mention the errors (62). Laboratories that employ computerized LIMS technology can see a 20-40 percent reduction in labour costs, in addition to reduced errors and more predictable and efficient turnaround and improved information sharing(63).

Improvement management

(Management reviews, Internal audit, Occurrence management, process improvement and Corrective action)

Performance of QSE falling in this category had no challenging issues raised. These QSEs are mainly within laboratory employees span of control and were said to be performed adequately. QMS implementation is a continuous process of improvement. NTRLs in this study had set up systems and strategies within their laboratories to ensure continuous improvement such as peer to peer departmental audits, journal club and regular review meetings with health workers.

Emerging themes

This study shows that mentorship received by these NTRLs differs and was not seen as beneficial by all laboratories. Mentors should offer services based on the context of the laboratory their assigned to for effective results and improvement in QMS implementation. Attesting to this finding, Maruta et al mentions the need of setting up a context based mentorship program to ensure its success (64)

One of the most important strength is the Networking between NTRLs in the region which has led to exchange of ideas, strategies and sometimes even resources. There have been recent developments in the NTRL world in Africa by creation a networking platform by the Global Fund to accelerate QMS implementation processes towards accreditation in these laboratories (62).

Limitations

Firstly, the limited sample size requires caution in extrapolating the study results to the whole African Sub-Saharan region and beyond. However, literature review, in which reports from other parts of the region were analyzed, showed similar findings to the ones in this study. Therefore, in my opinion, to some extent extrapolation of these findings to countries with similar conditions in the African continent or beyond is possible. Secondly, as data was collected via questionnaires sent by email, skype interview, zoom and telephone calls, the PI was limited on observing for herself the state of these laboratories and how the NTRLs performed.

Conclusion

In conclusion, there is general knowledge, awareness and use of QMS tools and practices by NRTL managers and Head of Departments. More strengths than challenges were found related to implementation of process and improvement management aspects of QMS. The major challenges found were related to implementation of QMS requirements for resource management with the QSE 'organization' being the most challenging element of the QMS implementation process. It is important to note that every laboratory is at a different stage of QMS implementation and their strengths and challenges vary.

Chapter 5

Recommendations

To NTRL Managers and staff

- Lobbying and engagement of management team and partners: The findings of this study shows that lobbying and engaging higher management and partners in NTRL strategic meetings encourages more commitment and support for QMS implementation.
- Introducing an open to all reminder calendar for equipment calibration and servicing dates to avoid having one person responsible who may sometimes forget resulting in delays which affect laboratory quality performance.
- Conduct performance appraisals by peers among departments in the laboratory to improve performance and interest in QMS implementation.

To NTRL Policy Makers

- To ensure implementation of laboratory strengthening policies and where necessary committed/earmarked budget for equipment maintenance and projects introduced by the national TB program or international partners to ensure success of all aspects of QMS implementation even after a long time from initiation.
- Lobbying for international aid for equipment calibration and automated machine service contracts to shorten equipment breakdown time and always ensure availability of fully functional equipment.
- Engagement of NTRL management by higher management in policy making and strategic planning so that the whole organization has one vision for a project to help better implement activities so that the implementers can voice out their feasible targets and any challenges they encounter to achieve those targets.
- Shortening the procurement process to avoid stockouts and delays from planning time to action time which affects both customer service and implementation of QMS and further prolongs achieving accreditation.

To Education Policy Makers

- Introducing QMS practices in the BSc Medical laboratory Sciences' curriculum (pre-service training) to ensure it's embedded in their work ethos so that application of these practises at work would not be seen as an added workload.

For future research

- Further research is still needed to evaluate the embedment of the NTRL organizational structure in the overall national TB program and to what extent it influences implementation of QMS. Findings from this study showed its influence on all the QSEs hence fully understanding it and addressing its challenges may lead to easier QMS implementation.

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Annexes

Annex 1: Questionnaire

	Title: Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region.	
	Questionnaire: Section A	
1	Name of NRTL…… Name of manager…… Period in current position…… Qualification(s)…… Contact details……	Questionnaire code…… Date……
2	Do you have a Formal Collaboration Agreement with a WHO Tuberculosis Supranational Reference Laboratory (SRL)?	☐ Yes ☐ No
3	If answer to question 2 is yes, what is the name of the SRL	……
4	If answer is no, please explain the reasons why?	…… …… ……
5	If answer to question 2 is yes, what is the nature of support you receive?	☐ Financial ☐ Technical ☐ Both ☐ None ☐ Other, *please explain* …… …… ……
6	Do you have a Quality Officer in your laboratory?	☐ Yes ☐ No
7	Does your laboratory participate in the following External quality assurance (EQA), also known as proficiency testing, conducted by WHO SRLs. *Please mention if conducted by other providers.* ……	☐ Sputum smear ☐ Xpert/Rif ☐ TB culture ☐ 1st line DST ☐ 2nd line DST ☐ LPA
8	How do you view number of workers which are currently employed by your laboratory in relation to workload?	☐ Overstaffed ☐ Adequate ☐ Inadequate *please explain* …… …… ……
9	How many of your staff hold the following qualifications?	PhD/Doctorate …… Master's Degree……

		Bachelor's Degree…….. Diploma…… Certificate……. None *Please explain their posts* ……. ……. …….
10	Are there safety measures in your laboratories according to WHO TB biosafety manual? *If yes, please explain*	☐ No ☐ Yes ……. ……. …….
11	Does an occurrence management procedure exist? *If yes, please explain*	☐ No ☐ Yes ……. ……. …….
12	What are your main streams of funding?	☐ Ministry of Health ☐ International Donor funding ☐ Local Donor funding ☐ Other *please explain* ……. ……. …….
13	Are you aware of the existence of the ISO 15189 standard?	☐ Yes ☐ No
14	In relation to achieving official accreditation in compliance with **ISO 15189**, at what stage is your laboratory?	☐ We have achieved accreditation (go to section D) ☐ We are actively implementing a QMS to achieve accreditation (go to section C) ☐ We are not actively implementing a QMS to achieve accreditation (go to section B)

	Questionnaire: Section B	
1	Are you aware of the Strengthening Laboratory Management Toward Accreditation (SLMTA) tool?	☐ Yes ☐ No
2	Are you aware of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist?	☐ Yes ☐ No

3	Does your laboratory intend to implement quality management systems towards accreditation in the future?	☐ Yes ☐ No ☐ Not Sure
4	How do perceive QMS implementation?	☐ Beneficial ☐ Non-beneficial *go to question 7*
5	In what ways do you think QMS implementation will be beneficial to your lab?	☐ Improving quality of laboratory services ☐ Increased laboratory output ☐ Seeking greater regional recognition ☐ Financial support was offered ☐ Technical support was offered ☐ Other *(please explain)* …… …… ……
6	What are the main hindrances to initiate the process of QMS? *Please indicate significance of each challenge, where 0 = not a challenge at all, and 5 = a major challenge)*	☐ Lack of funds 0 1 2 3 4 5 ☐ Lack of training 0 1 2 3 4 5 ☐ Lack of staff knowledge 0 1 2 3 4 5 ☐ Lack of staff motivation 0 1 2 3 4 5 ☐ Lack of advocacy 0 1 2 3 4 5 ☐ Lack of time 0 1 2 3 4 5 ☐ Lack of regular supervision 0 1 2 3 4 5
7	Are there any other major challenges that you are facing? *If yes, please explain*	☐ No ☐ Yes …… …… ……
8	In what ways do you perceive QMS would not be beneficial to your laboratory. Please explain briefly.	…… …… ……

	Questionnaire: Section C	
1	Has your laboratory been enrolled into the SLIPTA process?	☐ Yes ☐ No *(if no go to question 11)*
2	What year was it enrolled?	…….
3	How many stars did you have following your last audit?	☐ No star ☐ One (1) star ☐ Two (2) stars ☐ Three (3) stars ☐ Four (4) stars ☐ Five (5) stars
4	What were the main reasons for seeking accreditation and management directive?	☐ Improving quality of laboratory services ☐ Increased laboratory output ☐ Seeking greater regional recognition ☐ Financial support was offered ☐ Technical support was offered ☐ Other (please explain) …… …… …….
5	Did you face any challenges during the enrolment process? *Please indicate significance of each challenge, where 0 = not a challenge at all, and 5 = a major challenge)*	☐ Lack of funds 0 1 2 3 4 5 ☐ Lack of training 0 1 2 3 4 5 ☐ Lack of staff knowledge 0 1 2 3 4 5 ☐ Lack of staff motivation 0 1 2 3 4 5 ☐ Lack of advocacy 0 1 2 3 4 5 ☐ Lack of equipment management 0 1 2 3 4 5 ☐ Lack of regular supervision 0 1 2 3 4 5
6	Are there any other major challenges that you encountered? *If yes, please explain*	☐ No ☐ Yes …… …… ……
7	What measures did you put to address these challenges? *please explain*	…… …… ……

8	Are there any enabling factors that facilitated or are facilitating QMS implementation? *if yes please explain*	☐ Yes ☐ No …… …… ……
9	Are there challenges you are currently facing in QMS implementation? *if yes please explain*	☐ Yes ☐ No …… …… ……
10	Which strengths currently exist in your laboratory in QMS implementation?	…… …… ……
11	How are you implementing QMS systems?	…… …… ……

Questionnaire: Section D [only to be filled in when your laboratory was accredited]		
1	When was your laboratory officially accredited?	……
2	How long (in months) did it take from the start of the QMS implementation process to official accreditation?	……..
3	Is your laboratory accredited according to ISO 15189?	☐ Yes ☐ No, *please mention which one* ……
4	What were your main reasons for seeking accreditation?	☐ Improved quality of laboratory services ☐ Increased laboratory output ☐ Greater regional recognition ☐ Other (please explain) …… …… ……
5	What were the main challenges experienced during the QMS implementation process? *Please indicate significance of each challenge, where 0 = not a challenge at all, and 5 = a major challenge)*	☐ Lack of funds 0 1 2 3 4 5 ☐ Lack of training 0 1 2 3 4 5 ☐ Lack of staff knowledge 0 1 2 3 4 5 ☐ Lack of staff motivation 0 1 2 3 4 5 ☐ Lack of advocacy 0 1 2 3 4 5 ☐ Lack of time 0 1 2 3 4 5 ☐ Lack of regular supervision 0 1 2 3 4 5
6	Are there any other challenges that you experienced? *If yes, please explain.*	☐ No ☐ Yes …… …… ……

7	What measures did you employ to address the challenges? *please explain*	…….. …….. ……
8	What were the enabling factors during the QMS implementation?	…….. …….. ……
9	What are your advantages/strengths of being accredited?	…….. …….. ……

Annex 2: Questionnaire informed consent

Informed consent template from: World Health Organization(WHO). Informed Consent Form Template for Qualitative Research: WHO; Available from: http://www.who.int/rpc/research_ethics/informed_consent/en(65)

Questionnaire informed consent:

This informed consent form is for National Tuberculosis Reference laboratory (NTRL) managers of the WHO Sub Saharan region, who I am inviting to participate in a qualitative research titled "Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region. A cross-national analysis: South Africa, Lesotho, Namibia, Zambia and Kenya."

Name of Researcher: **Marjorie F. Jaffet** Name of Organizations: **Royal Tropical Institute, KIT and DATOS BV.**

This informed consent has two parts:

- Information sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Hello

I am **Marjorie F. Jaffet,** Master student at the Royal Tropical Institute, KIT and intern for DATOS BV. I am doing this research to know and analyse the challenges and strengths of QMS implementation that you experience. I am going to give you information and invite you to be part of this research. If you have any questions you would like answered prior to completing the questionnaire, please email me.

Purpose of research: Tuberculosis (TB) remains a global burden and this region is highest for TB incidence and mortality. Laboratories play a crucial role in the TB care cascade and it is important for laboratories to have quality management systems to assure quality of tests done. I want to find ways of improving the QMS implementation of NTRLs in your region. I want to know what you, who work here know about the process of quality management systems implementation, challenges and strengths you experience. I want to learn about the different ways you implement to overcome the challenges.

Participant Selection: You are being invited to take part in this research because I feel that your experience in TB laboratory work can contribute much to my understanding and knowledge of challenges and strengths for accreditation in your laboratory.

Voluntary Participation and Right to Refuse or Withdraw: This research will involve your participation in a 30 minutes Word file questionnaire. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, nothing will be done to you or your job post. You may change your mind later and stop participating even if you agreed earlier. You do not have to take part in this research if you do not wish to do so, it will not affect your performance appraisal or promotion opportunities.

Procedure: I will conduct a survey through a questionnaire. I will send by email the questionnaire after receiving a signed informed consent from you. A period of 1 week will be given to complete and email back the filled questionnaire. Please try to answer all relevant sections for your

laboratory. I remove identifiers from the questionnaires and used codes which will only be known by me. . I will keep all the data under lock and key for 1 year and then destroy it.

Risks and Benefits: There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, I do not wish for this to happen. You do not have to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you uncomfortable. There is no direct benefit to you, but your participation is likely to help improve the process of QMS implementation and increase numbers of accredited NTRLs in your region.

Confidentiality: The information collected will be kept with high caution to preserve confidentiality . Any information about you, will have a number instead of a name and only I will know what your number is.

Sharing results: Nothing that you tell me will be attributed to you by name. The knowledge that I get from this research will be shared with you before it is made widely available to the public. The thesis report will be sent to you by email and any misinterpretation corrected before its available for public.

Who to contact: If you wish to ask questions later, you may contact: **Marjorie F. Jaffet, marjoriejay@gmail.com, Call: +31619350388**

If you wish to ask for additional information or submit any complaints please contact; Pamela Hepple @ p.hepple@datos-advice.nl; Telephone +31(0)208946250. **Part II: Certificate of Consent**

I have been invited to participate in research about challenges and enablers of quality management systems implementation for NTRLs in WHO Sub Saharan Africa region. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked, have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of participant: …… Signature of participant…… Date…….

Statement by the researcher taking consent

I have made sure to the best of my ability that the participant understands that the following will be done:

1. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

2. I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

3. A copy of this ICF has been provided to the participant.

Name of Researcher: …… Signature of Researcher: …… Date: …….

Annex 3: IDI Topic guide for Head of Departments

Interview Topic guide

In Depth Interviews topic guide for **Laboratory Scientists Head of Department**, for a research to explore factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region. A cross national analysis: South Africa, Lesotho, Namibia, Zambia and Kenya.

Start by greetings and introducing yourself

Ask if they read and understood the consent form and answer any questions they have.

Personal details

Name:…… Age:…….. Sex……

Job title:…… Code:……..

Qualifications: ……..

Duration in the current job post:……

Name of NTRL……..

1. What do you know about laboratory quality management systems (QMS)?
2. What do you think is your role in the process of laboratory quality management in various areas I will mention below?

    i. Safety rules and precautions.
    ii. Equipment management. Are you trained to use all the equipment you use?
    iii. Documentation and record keeping?
3. What are your strengths and challenges in playing your role in these various activities mentioned above?
4. What do you understand about internal quality control?
5. Does your laboratory conduct customer satisfaction surveys?
6. If yes, how do you handle information you get from these surveys?
7. How do you view internal audits in terms of relevancy?
8. How do you view external audits in terms of relevancy?
9. Do you have time for QMS on top of your other responsibilities?
10. Do you participate in continuous education activities?
11. How do you view information flow in different levels of your laboratory organization?
12. What is your opinion on allocation of funds in the laboratory system?
13. How do you think this (question 9,10, 11 and 12) affects QMS implementation your laboratory?
14. Do you have something to add?

Thank them and close the interview.

Annex 4: IDI topic guide for Quality Officers

Interview Topic guide

In Depth Interviews topic guide for **Quality Officer**, for a research to explore factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region. A cross national analysis: South Africa, Lesotho, Namibia, Zambia and.

Start by greetings and introducing yourself

Ask if they read and understood the consent form and answer any questions they have.

Personal details

Name:…… Age:…….. Sex……

Qualifications: …….. Code:……..

Duration in the current job post:……

Name of NTRL……

1. What do you think is your role in the process of laboratory quality management in various areas I will mention below?

    iv. Safety rules and precautions.
    v. Equipment management.
    vi. Documentation and record keeping?
2. What are your strengths and challenges in playing your role in these various activities mentioned above?
3. How do you ensure internal quality control?
4. Does your laboratory conduct customer satisfaction surveys?
5. If yes, how do you handle information you get from these surveys?
6. How do you view internal audits in terms of relevancy?
7. How do you view external audits in terms of relevancy?
8. How do you feel about your workload?
9. Do you participate in continuous education activities?
10. How do you view information flow in different levels of laboratory organization?
11. What is your opinion on allocation of funds in the laboratory system?
12. How do you think this (question 9, 10 and 11) affects the implementation of quality management systems of your laboratory?
13. Do you something to add?

Thank them and close the interview.

Annex 5: IDI topic guide for SRL representative

Interview Topic guide

In Depth Interviews topic guide for **Supra National Reference laboratory representative**, for a research to explore factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region. A cross national analysis: South Africa, Lesotho, Namibia, Zambia and Kenya.

Start by greetings and introducing yourself

Ask if they read and understood the consent form and answer any questions they have.

Personal details

Name:…… Age:…….. Sex……

Qualifications: …….. Code:……..

Duration in the current job post:……

Name of SRL……..

Name of NTRL you support…….

1. What support do you offer to this NTRL?
2. What are your strengths and challenges in playing your role in various activities of quality management systems implementation in the NTRL you support?
3. What are the main challenges faced by this NTRL in quality management system(QMS) implementation?
4. What are the enabling factors for this NTRL in QMS implementation?
5. Do you have something to add?

Thank them and close the interview.

Annex 6: Informed consent form for IDIs

Informed consent template from: World Health Organization(WHO). Informed Consent Form Template for Qualitative Research: WHO; Available from: http://www.who.int/rpc/research_ethics/informed_consent/en(65)

In-depth Interview Informed consent:

This informed consent form is for National Tuberculosis Reference laboratory (NTRL) employees, National Quality Officers and Supranational Tuberculosis Reference Laboratory staff/ representative of the WHO Sub Saharan region, who I am inviting to participate in a qualitative research titled "Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories (NTRL) in the WHO Sub Saharan Africa region. A cross-national analysis: South Africa, Lesotho, Namibia, Zambia and Kenya."

Name of Researcher: **Marjorie F. Jaffet** Name of Organizations: **Royal Tropical Institute, KIT and DATOS BV.**

This informed consent has two parts:

- Information sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Hello

I am **Marjorie F. Jaffet,** Master student at the Royal Tropical Institute, KIT and intern for DATOS BV. I am doing this research to know and analyse the challenges and strengths of QMS implementation that you experience. I am going to give you information and invite you to be part of this research. If you have any questions you would like answered prior to the interview please email me.

Purpose of research: Tuberculosis (TB) remains a global burden and this region is highest for TB incidence and mortality. Laboratories play a crucial role in the TB care cascade and it is important for laboratories to have quality management systems to assure quality of tests done. I want to find ways of improving the QMS implementation of NTRLs in your region. I want to know what you, who work here know about the process of quality management systems implementation, challenges and strengths you experience. I want to learn about the different ways you implement to overcome the challenges.

Participant Selection: You are being invited to take part in this research because I feel that your experience in TB laboratory work can contribute much to my understanding and knowledge of challenges and strengths for accreditation in your laboratory.

Voluntary Participation and Right to Refuse or Withdraw: This research will involve your participation in a 40-minute individual interviews. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, nothing will be done to you or your job post. You may change your mind later and stop participating even if you agreed earlier. You do not have to take part in this research if you do not wish to do so, it will not affect your performance appraisal or promotion opportunities.

Procedure: I will conduct a skype interview with you. No one else but me will be present in room where I will be while conducting the skype interview with you. You also should be alone in a room with doors closed to increase confidentiality. During the interview, I will connect with you while you

are at a comfortable place and time of your selection. Feel free to communicate if you do not wish to answer any questions during the interview. You do not have to give me reasons for not choosing not to answer some questions or even requesting to stop during the interview. I will take notes during the interview and read a summary of the notes to you after the interview to check if I got everything correctly. I will remove any identifiers on my notes. I will keep all the data under lock and key for 1 year and then destroy it.

Risks and Benefits: There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, I do not wish for this to happen. You do not have to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you uncomfortable. There is no direct benefit to you, but your participation is likely to help improve the process of QMS implementation and increase numbers of accredited NTRLs in your region.

Confidentiality: The information collected will be kept with high caution to preserve confidentiality. Any information about you, will have a number instead of a name and only I will know what your number is.

Sharing results: Nothing that you tell me will be attributed to you by name. The knowledge that I get from this research will be shared with you before it is made widely available to the public. The thesis report will be sent to you by email and any misinterpretation corrected before its available for public.

Who to contact: If you wish to ask questions later, you may contact: **Marjorie F. Jaffet, marjoriejay@gmail.com, Call: +31619350388**

If you wish to ask for additional information or submit any complaints please contact; **Pamela Hepple @ p.hepple@datos-advice.nl; Telephone +31(0)208946250.**

Part II: Certificate of Consent

I have been invited to participate in research about challenges and enablers of quality management systems implementation for NTRLs in WHO Sub Saharan Africa region. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked, have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of participant: …… Signature of participant…… Date…….

Statement by the researcher taking consent

I have made sure to the best of my ability that the participant understands that the following will be done:

1. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

2. I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

3. A copy of this ICF has been provided to the participant.

Name of Researcher: …… Signature of Researcher: …… Date: …….

Annex 7: Ethical Approval

KIT | Health

Contact
Meta Willems
Telephone +31 (0)20 568 8514
m.willems@kit.nl

KIT Health| P.O. Box 95001, 1090 HA Amsterdam, The Netherlands
BY E-MAIL:
marjoriejaffet@gmail.com

Our reference KIT Health Amsterdam, 28 May 2018

Subject Decision Research Ethics Committee on Proposal S91

Dear Marjorie,

The Research Ethics Committee of the Royal Tropical Institute (REC) has reviewed the proposal entitled "Factors affecting implementation of quality management systems by National Tuberculosis Reference Laboratories in the WHO Sub Saharan Africa region. A cross-national analysis: South Africa, Lesotho, Namibia, Zambia and Kenya (S91)"

The decision of the Committee is as follows:

The Committee has reviewed the revised protocol and has taken note of your changes and clarification, and is pleased to see that you have addressed our concerns and questions to our full satisfaction.

The Committee is of the opinion that the proposal meets the required ethical standards for research and herewith grants you ethical approval to implement the study as planned in the afore mentioned protocol.

Kind regards,

P. Baatsen,
Chair Research Ethics Committee, KIT

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1090 HA Amsterdam
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Royal Tropical Institute