Identifying Influencing Factors in the Quality Management System Implementation of National TB Reference Laboratories in WHO South-East Asia Region

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"IDENTIFYING INFLUENCING FACTORS IN THE QUALITY MANAGEMENT SYSTEM IMPLEMENTATION OF NATIONAL TB REFERENCE LABORATORIES IN WHO SOUTH-EAST ASIA REGION."

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 "IDENTIFYING INFLUENCING FACTORS IN THE QUALITY MANAGEMENT SYSTEM IMPLEMENTATION OF NATIONAL TB REFERENCE LABORATORIES IN WHO SOUTH-EAST ASIA REGION" HAS BEEN CAREFULLY ACKNOWLEDGED AND REFERENCED IN ACCORDANCE WITH DEPARTMENTAL REQUIREMENTS. THE THESIS IS MY OWN WORK.

SIGNATURE: 

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Abstract

Background The tuberculosis endemic is a major concern for countries in WHO South East Asian region. One of the main reasons of a rise in the incidence of tuberculosis in the developing world is the inability to detect the disease in time. Weak laboratory management, poor maintenance of laboratory equipment, inadequate number of skilled staff and limited resources all add to the inadequate quality of laboratory results. Though National Tuberculosis Reference Laboratories (NTRLs) are required to provide quality services throughout the diagnostic networks of a country, there are certain factors that these laboratories face while implementing laboratory quality management systems (LQMSs) to ensure quality results that delay accreditation.

Study Objective The purpose of this study is to understand the factors which influence the implementation of an LQMS in the NTRLs of the WHO South East Asian (SEA) region.

Method A mixed method explorative research was conducted in the NTRLs of WHO SEA region from June to July, 2018. A literature review was conducted along with a mixed methods research design. Survey questionnaires were sent to 15 NTRLs and 7 Supranational Reference Laboratories (SRLs) and five semi-structured interviews were conducted with laboratory managers, technicians and officers for further exploration of the factors that emerged from the survey influencing the LQMS implementation.

Results Eight of the fifteen NTRLs and two of the seven SRLs responded to the survey sent. A total of five semi-structured interviews were conducted. The literature review identified a dearth of published studies on the implementation of LQMSs in the WHO SEA region. After conducting the survey and interviews the main difficulties that emerged were lacks of support from higher authorities, uneven distribution of work which leads to over- or underutilization of employees, a lack in organizational planning and inadequate infrastructure of the laboratories. The laboratories who have already achieved accreditation have overcome most of these challenges while the NTRLs yet to achieve accreditation are struggling.

Conclusion To overcome the difficulties while implementing an LQMS, higher authorities and governments need to prioritise and support laboratory strengthening in their countries. It was found that weak management, constraints on human resources and financial limitations along with inadequate infrastructure can cause poor execution of quality assured laboratory service.

Keywords: Tuberculosis, WHO South East Asia, National Tuberculosis Reference Laboratories, Supra Reference Laboratories, Quality Management System, Accreditation.

Word Count: 11, 950

Abbreviations

AERSCC	Accreditation Education Research & Scientific Services Centre
DST	Drug Susceptibility Testing
DST	Drug Susceptibility Testing
GLI	Global Laboratory Initiative
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
LMIC	Low and middle income countries
(L)QMS	(Laboratory) Quality Management System
MDG	Millennium Development Goal
NTP	National TB Programme
NTRL	National Tuberculosis Reference Laboratory
SDG	Sustainable Development Goal
SEA	South-East Asia
SOP	Standard Operation Procedure
SRL	Supranational Reference Laboratory
SSI	Semi-structured Interview
TB	Tuberculosis
WHO	World Health Organisation

Operational definitions

Strengths:	The supports and assistance that laboratories got which made it easier to implement QMS.
Challenges:	The obstacles that the laboratories face during the implementation of QMS.
Organisational structure:	The activities, assignments, coordination and management as well as the presence of well-structured organogram and SOPs.
Infrastructure:	The design and setup of the laboratory facility (excluding equipment) for implementing quality services.
Staff training:	Training of employees involved with quality implementation on medical LQMS and its tools.
Technical staff:	Staff or employees who are professionals working on laboratory procedures and testing.
Resources:	The presence of human resources, equipment, finance, and supplies.
WHO South East Asia:	There are now eleven Member States in the WHO South-East Asia region. The countries are Bangladesh, India, Nepal, Bhutan, Sri Lanka, Myanmar, Timor-Leste, Indonesia, Maldives, Thailand & Democratic People's Republic of Korea.
Millennium development goal and Sustainable development goal:	The MDG and SDG are goals with targets and indicators to improve the lives of people worldwide, especially of the poorest.
National Tuberculosis Reference Laboratory:	Laboratory that has as its main purpose to provide support to activities carried out within the national laboratory network which includes training and quality assurance.

Supranational Reference Laboratory:	Laboratory that may or may not be in the country, which provides capacity development, technical resources for laboratory scale-up, and provides support to the drug resistance surveillance activities in countries they are linked with.
(L)QMS:	The organizational structure, processes and procedures that need to be addressed to assure quality (of laboratory results).
Accreditation	It is the process of certification of competency, reliability and credibility.

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First of all, I would like to thank Allah SWT for His blessings and opportunities provided to me. I am indebted to my parents for making it possible for me to choose my own path in life through supporting my education abroad. Without their support I would have not dreamt and ventured out of my comfort zone and have learned what I have learned. I am forever grateful to them for all they have done for me.

I would like to extend my gratitude to DATOS for giving me such a unique chance to be an intern and carry out research work under their supervision. I would also like to thank all the teachers, my back-stopper and the administrative department of KIT for the continuous support provided to me throughout my Master's study.

Finally, I am grateful to my husband for his constant support, encouragement, and patience throughout my journey in The Netherlands.

Introduction

After attainting my Bachelor on Dental Surgery, I completed a Master of Public Health (MPH) in Bangladesh. Afterwards I worked for a national NGO working in the health sector in remote areas in Bangladesh. Working in an NGO made me realize that there is so much more to learn on the different aspects of public health. I was fortunate enough to get a chance to study in Royal Tropical Institute to attain my second Masters on International Health.

Coming from and working in a low and middle income country to a certain extent, I have seen the challenges and the strengths that comes along with the establishing a primary laboratory services. The national organisation I used to work for previously had basic laboratory settings in the floating ship hospitals and satellite clinics in the remotest and almost inaccessible part of the country. According to a study by KIT and other organisations 'Better laboratories are the key to better health'. Laboratories help to identify an infection or diseases and allow timely diagnosis which can as well as help prevent its' spread or timely diagnosis. Good quality laboratory set-up will significantly improve patient care. However, there are many challenges associated with ensuring quality health services, especially in hard to reach areas of low and middle-income countries. In hard to reach areas quality service greatly depends on the implementation of quick testing tools that provide affordable diagnosis and ease of access.

Though I have no experience in accreditation process of any laboratories but it is based on an assessment of whether a product or a service meets the standard requirements or fulfils certain criteria set by organizations through accreditations bodies. Tuberculosis is a heavy burden disease in the South East Asian (SEA) region. The detection of TB mainly relies on timely detection through reliable laboratory testing. Since a TB reference laboratory requires procedures for diagnosis, monitoring, surveillance and disease prevention, it can face many challenges to receive accreditation. Major challenges include inadequate infrastructure, lack of equipment and maintenance, lack of knowledge or trained human resource, good leadership, commitment and planning. These are just some of the known challenges with several underlying problem. These are just some of the problems with varying underlying issues which needs further extensive research.

With the chance of working as research intern for DATOS it gave me opportunity to look at the factors which either helps or creates a challenge in implementing Quality Management System in SEA region.

1. Background

TB problem worldwide and in the South East Asian (SEA) Region

In 2016 an estimated total of 10.4 million people fell ill from tuberculosis (TB), among which 6.3 million were reported as new cases of TB (1). The TB endemic is a great concern for the SEA region. It is estimated that almost 4.3 million cases are missing from the TB databases (2). Either they were not reported or did not fall under the National TB Programme (NTP). Some of these 'missing patients', are not diagnosed properly and data from those detected by the private sector are not shared with the Government's NTP (2). Also, inadequate laboratory serices along with inadequate screening and follow-up of the patients from most affected populations are just some of the reasons which contribute to the number of missing cases (3). Globally, ten countries attribute to around 76% of the missing cases which includes some of the SEA countries such as India, Bangladesh, Myanmar and Indonesia (4). South East Asia accounts for 41% of the global TB burden while hosting only 26% of the total world's population (3). Six member states of the SEA region fall within the top 30 high TB-burden countries of the world. This includes The Democratic People's Republic of Korea, Indonesia, Myanmar, Bangladesh, India and Thailand (4).

The role of the laboratory in TB diagnosis

In order to provide better treatment it is imperative that TB is detected quickly and reliably. Detection of TB is done by various methods which include sputum smear detection using microscopy, culture and drug sensitivity testing (5)(6). To detect TB accurately and rapidly, it is important to have high-quality laboratory services (7). The detectability of the presence of TB also depends on how diligently the samples are collected, delivered to the laboratory.

In most low and middle income countries (LMIC) TB laboratories are organized in a tiered laboratory network, parallel to the health system. The tiers generally include the peripheral level, district/regional level, and national level with the NTRL mainly supporting the laboratories in lower tiers of the network and doing confirmatory and specialist testing.

Supranational Reference Laboratory and National Tuberculosis Reference Laboratory

Effective response to detect TB cases may be delayed due to lack of diagnostic capacity and quality systems that are in place (8). A system of Supranational Reference Laboratories (SRLs) was setup by the WHO in 1994 to support the strengthening and scaling up of tuberculosis laboratory capacity in member countries. The main function of an SRL is to assist the National Tuberculosis Reference Laboratories (NTRLs) by providing technical support and quality assurance for laboratory scale-up through training on TB diagnostic procedures (9). The SRLs for the SEA region are located in Belgium, Australia, Germany, Thailand and India (9). NTRLs have the responsibility to ensure quality tuberculosis services throughout the diagnostic testing network of a country and oversee the implementation of the relevant policies. Most NTRLs are engaged in implementing some form of a laboratory quality management system (LQMS) towards national or international accreditation.

Developing countries often face difficulties in detecting TB which arises from poorly maintained laboratory equipment, inefficient laboratory settings, insufficient training opportunities for staff and a lack in capacity to handle high-volume workload (5). Even though laboratories services are important for disease control, they are often not prioritised and therefore receive inadequate resources (10). The End TB Strategy emphasises strengthening laboratories around the world.

End TB strategy

The World Health Organization (WHO) End TB strategy aims at curbing the rise and spread of TB around the world. This strategy was developed during the transition from the Millennium Development Goals (MDGs) to the Sustainable Development Goals (SDGs)(11) and was approved by 194 members of the World Health Assembly in 2014 (11) (see Figure 1).

End TB STRATEGY

- Aims to end global TB epidemic.
- Reduce TB deaths by 95% between 2015-2035
- Reduce new TB cases by 90% between 2015-2035

Principles

- Government stewardship and accountability, with monitoring and evaluation.
- Strong coalition with civil society organizations and communities.
- Protection and promotion of human rights, ethics and equity.
- Adaptation of the strategy and targets at country level, with global collaboration.

Textbox 1: End TB Strategy and its principles

The target of the End TB Strategy is to reduce TB mortality by 95% and TB incidence by 90% by 2035 (compared with 2015 status) (12). Presently, the global TB mortality rate is falling by 3% per year, while the TB incidence rate is falling by 2% per year. Around 16% of TB cases result in deaths annually (1). To achieve the target set by the End TB strategy the mortality rate and incidence rate from TB needs to fall by 5% and 10% per year, respectively (1). Thus, it is crucial to detect and diagnose TB in time which requires reliable and accurate laboratory testing facilities. Since clinicians are dependent on test results by laboratories to diagnose and provide appropriate treatment, TB laboratories are an essential part of any NTP (13).

The End TB strategy calls for drug susceptibility testing (DST), which is a huge challenge due to the requirement for technically complex procedures and, especially in resource poor settings, the number of laboratories performing DST is limited (14). In resource poor settings the laboratories have often suffering from neglect leading to a poor quality services and results (15). According to the End TB Strategy, a global approach for prevention of TB through early diagnosis and use of DST should be universally adopted within the period of 2015-2035 (13). This means that there should be reliable and accurate testing facilities for TB which provide quality services. To ensure quality services to its customers, it is essential for laboratories to implement a Laboratory Quality Management System (LQMS) (14). An LQMS is a set of policies that laboratories follow to measure and achieve objectives that improves the quality of laboratory services and testing through minimizing errors, resulting in better patient care (14)(16)(17). A priority of SEA region countries and a specific goal of the

Global Plan to Stop TB is to achieve formal accreditation of all National Tuberculosis Reference Laboratories (NTRL) (14)(10,18–20).

Accreditation

Accreditation is a method by which a verified and authorized agency provides and assesses, at regular intervals, the functioning quality of an organization (in this case a laboratory) based on a set of predetermined standards (21). To achieve accreditation, the laboratory must have a fully functional LQMS to lower the chance of errors and variability of test results. This guarantees that the laboratory meets the standards for correct and reliable patient testing along with the ensuring safety of the staff working in the laboratory (15)(22).

The Switzerland-based International Laboratory Accreditation Cooperation (ILAC) is an international arrangement between member accreditation bodies based on peer evaluation and mutual acceptance (23) and is made up of accreditation bodies throughout the world (24). Of the 11 members states of the SEA region, the accreditation bodies from India, Thailand and Indonesia are full members of ILAC while Nepal's Accreditation Education Research & Scientific Services Centre (AERSSC) is an affiliate member.

Purpose of Accreditation

In the Maputo Declaration of 2008 it was highlighted that there is a need to strengthen laboratory networks, systems, and services in LMIC. Implementing an LQMS is the most straightforward way to assure quality laboratory services. The current standard for medical laboratories is ISO 15189:2012 (International Organization for Standardization 2012). Accreditation is the process of formal recognition of competence and maintenance by an independent authorised body. The purpose of accreditation is to ensure reliable and high standard services by medical laboratories (14).

ISO 15189

There are three versions of ISO standards for medical laboratories: ISO 15189:2003, ISO 15189:2007 and ISO 15189:2012. The second edition, ISO 15189:2007, for quality standard measurement has been replaced by the third edition or ISO 15189:2012. The difference between ISO 15189:2007 and ISO 15128:2012 is that the latter is a revised version of

the standard requirements for laboratories. The major difference between the two versions are the additional details of the clauses and sub-clauses that does not change the intent of the content of the standard (25).

Tools to implement an LQMS

There are several methods and structures that help a laboratory to implement an LQMS. A network of international partners forms the Global Laboratory Initiative (GLI) which helps laboratories worldwide to accelerate and develop access to quality assured TB services (26). The core group of GLI is comprised of members from national and supranational reference laboratories, high TB and MDR-TB burden country programmes, technical partners, donors and civil society and the WHO Global TB Programme (27). GLI has developed the GLI tool aimed at helping managers and staff, especially those from TB laboratories. The GLI tool provides a step-by-step approach towards TB laboratory accreditation. It is a web-based tool with provides a plan to guide medical laboratories towards implementing a QMS in accordance with the requirements of ISO 15189.

In addition to the GLI tool, there are other tools that aim to assist medical laboratories with the implementation of a QMS:

- WHO Laboratory Quality Management System Handbook and Training package: This is a laboratory management handbook for managers, administrators and lab technicians on quality management of clinical laboratories (7).
- SLIPTA-Stepwise Laboratory Improvement Process toward Accreditation: A stepwise guideline for laboratory improvement towards accreditation (21).
- SLMTA-Strengthening Laboratory Management toward Accreditation: A structured quality improvement programme for managers in resource-poor setting on the implementation of QMS, launched in 2009 (28).

1.2 Problem Statement

Despite the availability of tools to assist with LQMS implementation, TB laboratories still face difficulties implementing an LQMS. This leads to delays towards achieving accreditation, especially in LMICs such as those in the SEA region. There is a lack of insight into the exact challenges and enabling factors faced by the laboratories when implementing an LQMS in the SEA

region. It is also unclear whether laboratories face similar difficulties in the SEA region. This study aims at uncovering the factors that the NTRLs in the WHO SEA region face in the implementation of an LQMS. Knowing these challenges and enabling factors in the SEA region will help policy makers in the Government and NTRLs to plan better for implementing LQMS in TB laboratories, in particular by anticipating and mitigating these challenges.

1.3 Study Objective

The purpose of this study is to explore the factors that influence the implementation of a quality management system in national TB laboratories in the WHO SEA region.

1.4 Study Questions

1. What are the enabling and challenging factors encountered in the LQMS implementation process in the WHO SEA region
    a. For TB Reference Laboratories that has not yet started implementing LQMS?
    b. For TB Reference Laboratories that are in the process of implementing LQMS towards accreditation?
    c. For TB Reference Laboratories that already achieved accreditation?
2. What are the root causes of the challenges faced in the SEA region during the implementation of LQMS?
3. What are the recommendations that could be synthesized from the challenging and enabling factors faced during the implementation of LQMS?

2. Methodology

2.1 Study Type

A mixed method approach was used for this study. Both qualitative and semi-quantitative methods were used to meet the study objective.

2.2 Data Collection Methods

The study involved three data collection methods; literature review, semi-quantitative survey questionnaire and qualitative in-depth interviews, respectively. The study was conducted in two phases: first, the initial literature review, subsequently the semi-quantitative phase followed by a qualitative data collection phase. The information from the survey questionnaire was used to inform the individual interviews.

A. Literature Review: A literature search was carried out to further understand the LQMS implementation and accreditation process. This helped in gaining and overall understanding of issues for the SEA region related to current policies, the 12 quality system essentials (QSEs) of quality management, organisations working in support of TB laboratories, the status of TB laboratory accreditation, available funding and advocacy. The review was also used to compare the results found in the study with other studies. The literature review covered published articles, country reports, organisational reports and data and fact sheets. These articles were accessed through search engines such as Google Scholar and PUBMED, snowballing and included any reference material and grey literature that provided more insight (texbox.2).

Search Strategy

The literature review in different websites and search engines was done by searching of relevant articles by combination of key words.

The key words used for the searches were as follows:

'laboratories' in combination with 'South-East Asia', 'quality management', 'ISO 15189', 'LQMS', 'laboratory management', 'challenges', 'strengths', 'laboratory staff', 'laboratory technical education', 'quality system', 'accreditation'.

Textbox 2: Search strategies

B. Survey questionnaire: A questionnaire (Annex 2) was sent out to assess the enabling factors and challenges faced during the accreditation of laboratories. These questionnaires were sent out via mail to the contact persons of all SEA region SRLs and NTRLs. The questionnaires were sent to 15 NTRLs and 7 SRLs. These included laboratories which have not yet started implementing QMS, are in the process of implementing QMS or already received accreditation. The email contained a link to the Google forms, but a Microsoft Word version of the questionnaire was also attached for their convenience. The participants were asked to send back the completed questionnaires within two weeks. At the end of the first week, the participants were reminded to fill out the questionnaire by a follow-up e-mail. More follow-up reminder emails were sent to the participants to fill out the questionnaire after the weeks' initial deadline.
C. Semi-structured Interviews (SSI): To further explore the points that emerged from the survey questionnaire, a follow-up SSI was conducted. Five respondents who agreed in the survey questionnaire to be interviewed were contacted. The SSI was conducted with the staff and management of laboratories which are involved with either the process of QMS implementation, planning on QMS implementation or have already achieved accreditation. The interviews were conducted over Skype and WhatsApp based on the preference of the participants. The SSI was performed using a semi-structured interview guideline (Annex 3). This helped to explore more in-depth the challenges and enabling factors highlighted in the literature review and survey questionnaire. Five SSI's were conducted to ensure that saturation point was met and no new information emerged from the interviews that covered all three stages of accreditation status.

The data collections were all conducted in English which is commonly used as an official language in the SEA region. One interview was conducted in the native language of the respondent, as the researcher was also comfortable in the respondent’s native language. The two-step process of the survey and interview allowed for better triangulation of data and ensured data quality. The researcher was responsible for conducting the survey, interviews and also for analysis of the findings.

2.3 Study Area

Study area was the WHO SEA region.

2.4 Study Participants

The recruitment of the study participants was done with the help of DATOS, an organisation which is an expert in the field of laboratory strengthening. The selection of the study participants was done by purposeful sampling. The survey questionnaires were sent to managers of the NTRLs/SRLs. The NTRLs were from India, Bangladesh, Nepal, Sri Lanka, Thailand, Myanmar, Bhutan, Indonesia, Democratic People's Republic of Korea, Maldives, Timor-Leste and the SRLs from Belgium, India, Thailand, Germany, and Australia. An in-depth interview with managers, officers in charge and/or technical staff members was conducted based on the findings of the survey questionnaire. Before each interview, the participants were provided with a consent form (Annex 1) to allow for recording and use of the information for the research.

2.5 Analytical Framework

The Quality System Essentials Model (QSEM) was used to analyse the data and information collected from the survey and interviews (29).

The QSEM (fig 1 and textbox 2) has all the activities of a laboratory arranged into 12 QSEs. This model was developed by CLSI and is fully compatible with ISO15189. The 12 essentials for LQMS implementation will be further divided according to standard requirements as groups under a similar heading of its action (fig 2).

Figure 1: The 12 Quality Systems Essentials framework which was used as the analytical framework for this study

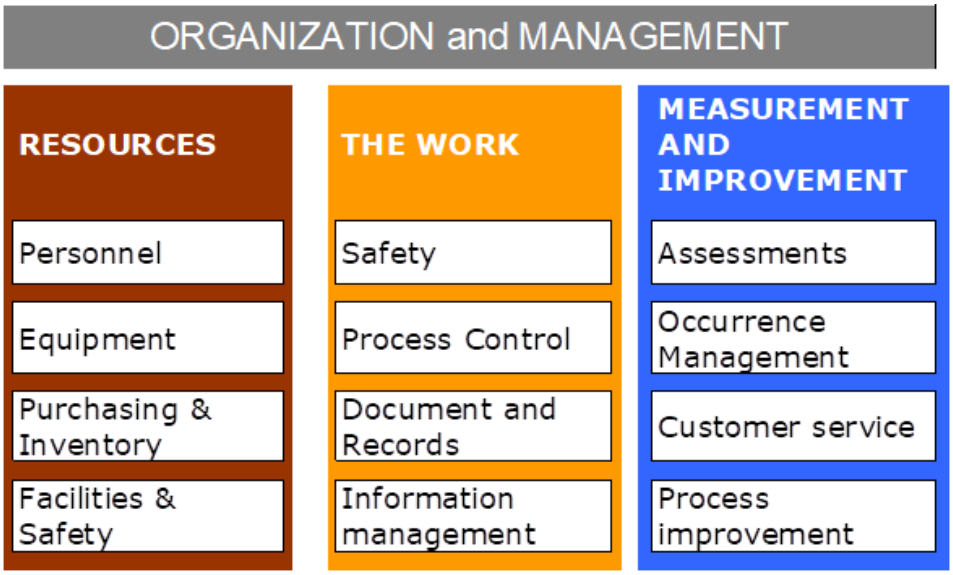


Figure 2: the 12 QSE frameworks divided according to the standard requirements of the stages in implementation of quality management system

Quality System Essentials Model

Organisation: A laboratory must have a well-structured organisation to implement a quality management system. Quality policies can be established and implemented if there are overall policies in place. The purpose of an organisational structure for LQMS is to provide support, management commitment and provide tools for monitoring the implementation of quality management.

Personnel: The most important component of a laboratory is motivated and competent staff. The organisation and structure of the laboratory both structurally and hierarchically should enable, motivate and encourage staff.

Equipment: It is important for laboratories to have well-functioning equipment. A system should be in place for installation, validation and maintenance of equipment.

Purchasing and inventory: The supply and management of reagents and consumables in a laboratory is very important. Proper management ensures the supplies are available when needed and used and stored in such a way that the quality of the reagents and consumables is not compromised.

Process control: The management of samples throughout the laboratory process (from patient to end result) should be done carefully. This includes collection of the sample, handling of the sample, method verification and validation and also includes reporting. It is one of the most vital roles as it ensures the accuracy of the testing.

Information management: Patient information and test reports are the main data of a laboratory. The information should be easily accessible by all relevant laboratory staff and health workers while maintaining confidentiality and ensuring accuracy.

Documents and records: Documents are necessary to show how things are managed in the laboratories, while records are necessary to maintain to prove accuracy and reliability.

Occurrence management: Whenever an incidence takes place which was not predicted, a system is necessary to record, report and learn from this non-conformity to prevent future similar incidents.

Assessment: This process is a tool to examine if the laboratory performance is up to the standard or benchmark. This is either done internally (by the laboratory's own staff) or externally (agency outside the laboratory). This helps to assess the performance of the laboratory compared to the quality standard.

Process improvement: The main objective of the quality management is continuous improvement and certain tools should be in place to ensure this (such as assessment and occurrence management).

Customer Service: Laboratories are in place to provide services to the clients. It is very important to ensure to meet clients' needs and understand their want for a satisfied service. It is pivotal to inform clients, take feedback and continue making improvements to provide better services.

Facilities and safety: It is important to ensure security, minimise the risk of containment and hazards of products from the laboratory to the community, and ensure safety for the staffs and address the need for a healthy work environment.

Textbox 3: Quality System Essential Model
From: Laboratory Quality Management System Handbook by WHO 2011

2.6 Data Processing and Analysis

The data processing and analysis were both done by the principal investigator. The data collected from the questionnaire were compiled and put into an Excel sheet to identify the frequency of the most recurrent enabling factors and challenges identified. The quantitative data from the survey were summarized in statistical graphs and pie charts. This also provided further direction for the guideline used during the semi-structured interviews (SSI).

The third part of the data collection was qualitative. The interviews took place over Skype/WhatsApp as it was not possible to travel to different locations of the participants. The main researcher was responsible for conducting, transcribing and coding the interviews. The interviews were recorded using recording software available for phone and windows 10. This allowed the researcher to refer back to the recordings later for transcriptions. During the interview, notes were taken which were checked back with the interviewee to ensure a clear understanding of their statements. The notes from the SSI were coded and arranged according to the QSQM framework and emerging themes and sub-themes. The emerging data were manually coded keeping in line with the QMSM and SWOT analysis frameworks.

2.7 Quality Assurance

To ensure the quality of the data, triangulation of the data was done through survey and interviews. During the interview process, the interview guideline helped to check if all the relevant questions had been asked. After each interview and transcription, the notes were reviewed to ensure that the data were complete and consistent with the objective.

2.8 Financial Assistance

There was no financial assistance provided to conduct this research. This research did not require traveling or calling the participants over international pay calls.

2.7 Intended Audience

The insights gained from this study may support laboratories planning on implementing QMS, the Ministries of Health, the National Tuberculosis Programme, and agencies who need to provide resources and consultations by enabling them to anticipate the main challenges during the LQMS implementation process. It may also enable WHO, SRLs and developmental organizations to provide better guidance to laboratories in the process of implementation (and maintenance) of an LQMS.

2.8 Ethical Approval

Approval was requested from the Ethical Review Board of the Royal Tropical Institute (KIT). The researcher ensured the anonymity of the participants by removing any hint or altering any statement that contains a direct connection to the participant or the laboratory working. Only the researcher is allowed to access the raw data. The participants of both the survey and the SSII were informed of the intent and the use of information for the purpose of the thesis which may afterwards be published. All the collected data, recording and transcript of the survey and interviews will be kept with the researcher which will be deleted and destroyed five years after research. A consent form was provided to the participants explaining the nature of the study and confirming their privacy.

2.9 Timeline

The writing of the proposal of the study research started in March of 2018, after a meeting with DATOS to explore what the study should focus on. The whole month of March was used to develop a proposal and questionnaire to get approval from the Ethics Committee (EC) of the Royal Tropical Institute (KIT) for the primary data collection. The approval for the thesis from the EC was received in the first week of May.

The month of May was used to collect contact information of the different SRL and NTRLs of the SEA region and perform the literature review. The survey questionnaires were sent in the month of June to the different countries. The interviews of the participants who agreed to take part were conducted in the first weeks of July together with data analysis and processing. The writing of the report started in the second week of July. The thesis was submitted in the second week of August to KIT for final evaluation and grading.

3. Results

A. Literature review on LQMS implementation and challenges

During reviewing the literature, it was found that there were no articles or reports on the LQMS implementation in the SEA region. There are however some studies which explored the challenges of the LQMS implementation and the accreditation process in the African region. The factors cited in the African studies include a shortage of skilled staff, limited training opportunities, lack of leadership, absence of biosafety measures and lack of funding as reasons that delay the implementation of LQMSs (8). However, there is a lack of published studies from the SEA region that explore the difficulties or the journey laboratories take while implementing their QMS required for accreditation.

The findings below are from various regions which provide an insight into the limitations and strengths that may be similar to the laboratories in the SEA region.

Laboratories play an important role in the diagnosis of TB. Therefore it is necessary to have well-trained staff, standardised operating procedures and

a safe and well-equipped laboratories which follow clear national and international proficiency and quality standards (22).

The outcomes of the literature review were organized according to the QSEM. Observations were found for only 8 of 12 QSEs.

Organisation

It is important for TB laboratories to have an organisational plan with clearly defined job descriptions with roles and responsibilities of its employees (23). The organisational structure should include a designated manager who is responsible for the implementation as well as the monitoring of the LQMS (24)(25). Also, the role of the laboratory management team should be to carry out strategic planning in line with the quality management goals and objectives. Any such organisation should select the most efficient quality management system which is implemented by well trained personnel. Laboratory activities should be prioritized to strengthen the ability to provide quality service (26). This will increase the reliability of the laboratory to its customers (22).

Financing is most often cited as a neglected aspect of implementing an LQMS and requires more attention (27). Studies show that lack of finance delays the implementation of an LQMS since it negatively affects different aspects of the laboratory operation such as inability to provide training to employees on equipment calibration and maintenance, employ trained and experienced staff, purchase equipment or arrange for maintenance of equipment (28).

Resources

Personnel

To implement QMS and achieve ISO standardization laboratory staff should be appropriately trained with continuous education opportunities especially when new tests or methods are developed (29). Also competency of the staff needs to be evaluated periodically to ensure that quality service is being delivered (25) (30).

The speed of implementing QMS is often slowed down by lack of knowledge or skilled technical personnel (31). High turnover of staff remains a critical challenge for laboratories all over the world. Often increased workload with

the same number of staff has a negative impact on the quality of work and on the morale of the staff (32).

Equipment

Functional equipment is an essential component to provide reliable and accurate results to patients. Laboratories often face challenges when their equipment malfunctions (29). Equipment which is correctly installed and periodically maintained will reduce chances of equipment malfunction, repair cost and prevent delay in service delivery (29) (25).

Purchasing and inventory

Implementing QMS requires proper management of purchasing and inventory of reagents and consumables (hereafter "reagents"). An effective inventory management system is proven to be effective at reducing costs by forecasting reagent requirements and minimising expiry of reagents (33). In a study it was found that not having an effective inventory system was a major hindrance in implementing LQMS (34)

Facility and safety

To avoid hazards, a laboratory must have adequate and designated space for specimen collection and storage (37). Inadequate infrastructure can have detrimental effect on the operation of a laboratory. Laboratories with poor infrastructure face challenges to provide reliable services, which can affect LQMS implementation at all levels (34).

The Work

Process Control

Challenges related to handling of samples and reagents can be a problem for laboratories. Poor quality management, improper transportation and handling may lead to rejection of samples and reagents. A policy in place for proper handling and transportation increases the efficacy and efficiency of a laboratory (33) (35).

Documents & Records

It is necessary to preserve and be able to trace and retrieve all internal and external documents and policies related to the laboratory. Standard Operating Procedures (SOPs) are essential as verbal instructions can be

misunderstood, ignored or even forgotten which can greatly hamper work environment and quality of the laboratory results (29)(35). Laboratories can face difficulty in training of new staff on the process of the laboratory as well as limited progression towards accreditation due to problems in managing documents and records efficiently (36).

Measurement and Improvement

Assessment and continuous improvement

Audits and assessments carried out by internal teams or by external agencies prove to be beneficial for laboratories implementing QMS especially those that plan to achieve accreditation. It provides a laboratory scope to determine the readiness for their accreditation (38). An assessment helps the laboratory to determine the effectiveness of the implementation of the QMS and provides a guide for further improvement of the QMS (34). An audit or an assessment will also enable a laboratory to refine its quality management policies and procedures (39).

B. Semi-Quantitative Survey

The survey was filled out by the managers, officers in charge and/or technical staff members of the laboratories who are actively involved with the implementation of QMS and those labs who are yet to implement QMS.

Basic information on the participating laboratories

Numerical data was collected on the status of the NTRLs and SRLs to understand the capacity of each of the laboratories and their familiarity with the tools that support the implementation of an LQMS. Out of the 15 NTRLs of 11 countries in the SEA region that were invited, 8 participated. Of these 8 NTRLs, 2 had already achieved accreditation, 4 were implementing LQMS while 2 were not actively implementing LQMS.

There are 5 SRL for the SEA region of which 2 responded. Information provided by the SRLs was used for triangulation purposes.

Awareness on ISO 15189 accreditation

Seven out of eight NTRLs responded they are aware of the ISO15189 standard for medical laboratories that specifies LQMS implementation to achieve accreditation.

Status of QMS Implementation

LQMS is implemented by 6 of the 8 NTRLs who responded. These include the NTRLs who have achieved and the NTRLs aiming to receive accreditation. This implies that most of the laboratories are aiming towards accreditation and improve both the quality and reliability of their services.

Familiarity with existing QMS Tools

One section of the survey explored the familiarity of respondents with one or more of the LQMS tools implemented across the world. All the respondents are aware of more than one QMS tools. SLIPTA, SLMTA and LQMS are the most commonly known tools. Even though the NTRLs need to follow only one of the LQMS tools they are aware of the different tools through which the quality of a laboratory can be improved.

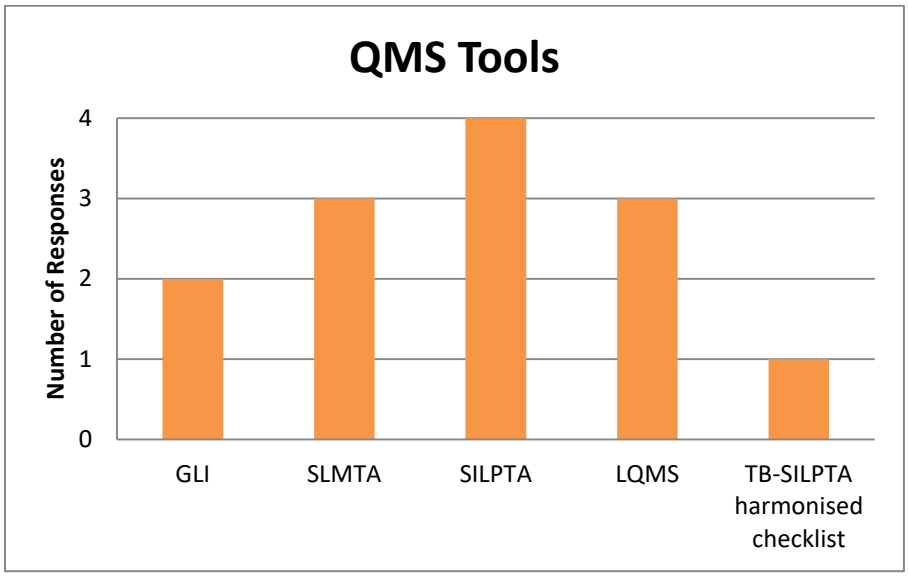
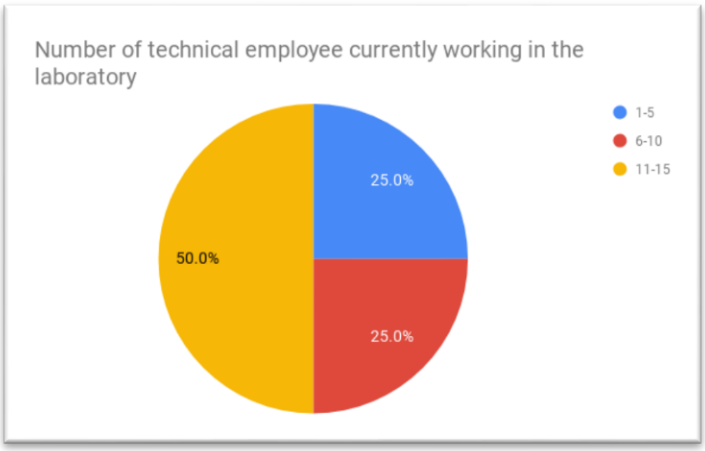
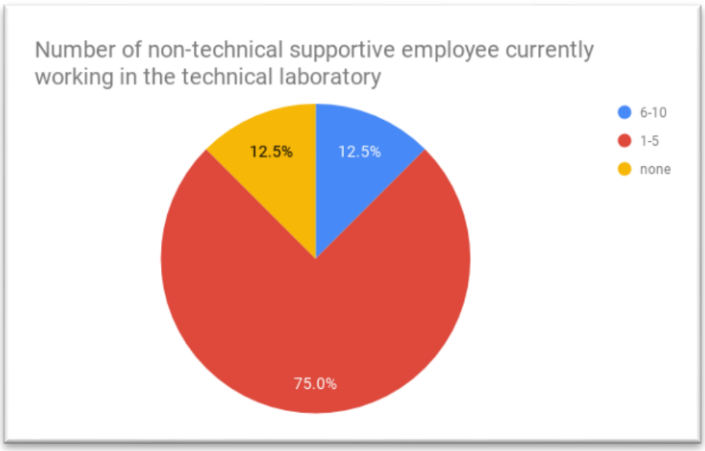


Figure 3: Knowledge on the tools of QMS among the respondents

Employee Status

The number of technical staff employed by most of the NTRLs is in the 11-15 persons range (see fig 4a). Three quarters of the respondents have 1 to 5 non-technical staff in their laboratories.





a. Number of technical staff *b. Number of non-technical staff*

Figure 4: Staff distribution in the NTRLs

Comparison of accredited laboratories, laboratories implementing QMS and laboratories not implementing QMS

Reason for Accreditation and Implementing LQMS

When asked the reason for seeking accreditation and implementing LQMS in the laboratories the most common response was to improve the quality of the services provided by the laboratory. Accredited laboratories also mentioned that LQMS will lead to increased output or uptake of services by patients. One of the reasons for implementing LQMS was that external technical assistance was being offered to the laboratories. The laboratories not implementing LQMS recognized that a quality system in place may ensure better services, but the main reason for not implementing was the lack of technical and financial support.

LQMS tools used to support implementation

Among the quality management tools being used by the different NTRLs across the SEA region, the most common tool used in NTRLs yet to achieve

accreditation is the Laboratory Quality Stepwise Implementation (LQSI) tool. The laboratories that have been accredited are using LQMS and SLMTA as the QMS implementing tool.

Audits done external agency

Auditing by an external agency is a pre-requisite of receiving accreditation. Both accredited NTRLs had been externally audited. Three of the four NTRLs implementing QMS were audited by an external agency. The two NTRLs not implementing any kind of QMS tool have not been audited by any external agency.

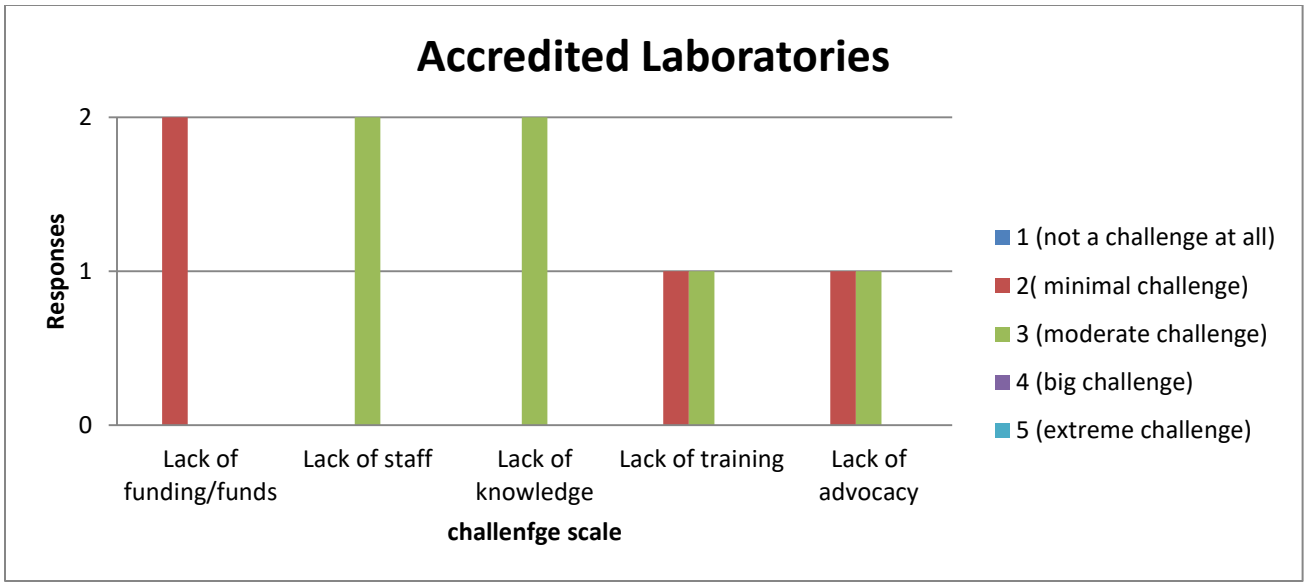
Challenges faced during QMS implementation

It became evident from the responses that while implementing LQMS all NTRLs faced challenges.

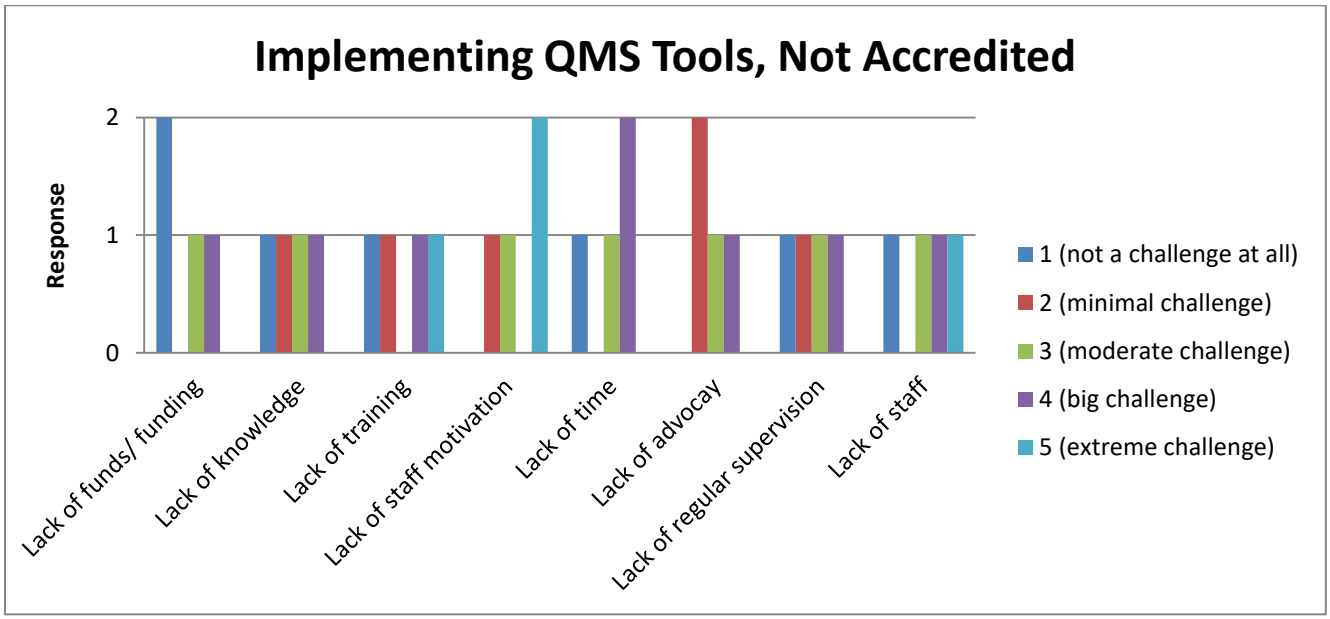
The most common challenges faced are lack of motivation, lack of knowledge and lack of personnel among all the NTRL staff levels. One of the biggest challenges faced by NTRLs implementing LQMS but yet to achieve accreditation, is lack of available time to spend on LQMS implementation for their staff.

When asked to score the severity of challenges, it became clear that accredited laboratories had fewer and less severe perceived challenges compared to the other laboratories (see fig 5a, 5b & 5c).

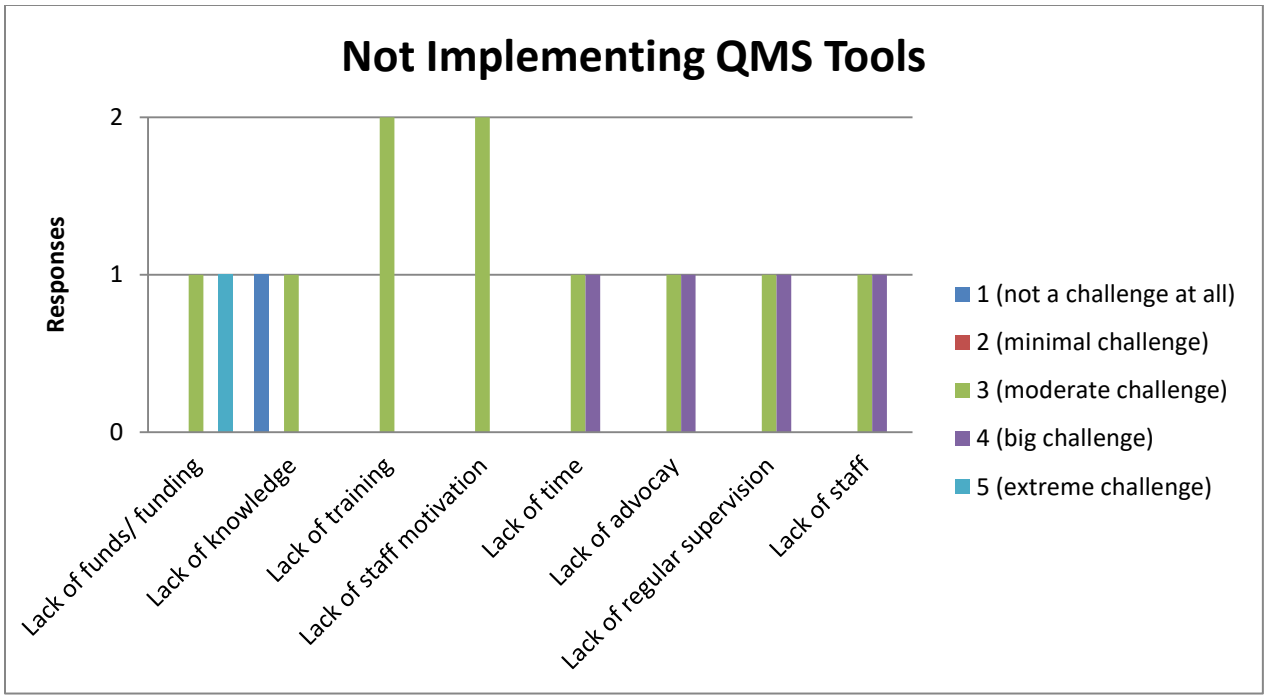
When asked to explain the difficulties faced during implementation of QMS all the NTRLs mentioned lack of resources and dedicated and skilled staff, and a stressful work environment. One of the NTRLs mentioned *"implementation of QMS, every staff in the laboratory has common goal with maximum effort on respective tasks in order to achieve accreditation".* To execute LQMS the management requires leadership and management skills to be able to organise a well-functioning laboratory. Most of the NTRLs stated that at times the work environment becomes too stressful due to the heavy workload which leads to an unpleasant atmosphere to carry out everyday activities. The presence of temporary employees from other organisations who are not permanent government employees holds a risk of sustainability of quality management.


Accredited Laboratories
Responses
2
1
0
Lack of funding/funds
Lack of staff
Lack of knowledge
Lack of training
Lack of advocacy
challenfge scale
1 (not a challenge at all)
2(minimal challenge)
3 (moderate challenge)
4 (big challenge)
5 (extreme challenge)

5a


Implementing QMS Tools, Not Accredited
Response
2
1
0
Lack of funds/ funding
Lack of knowledge
Lack of training
Lack of staff motivation
Lack of time
Lack of advocay
Lack of regular supervision
Lack of staff
1 (not a challenge at all)
2 (minimal challenge)
3 (moderate challenge)
4 (big challenge)
5 (extreme challenge)

5b

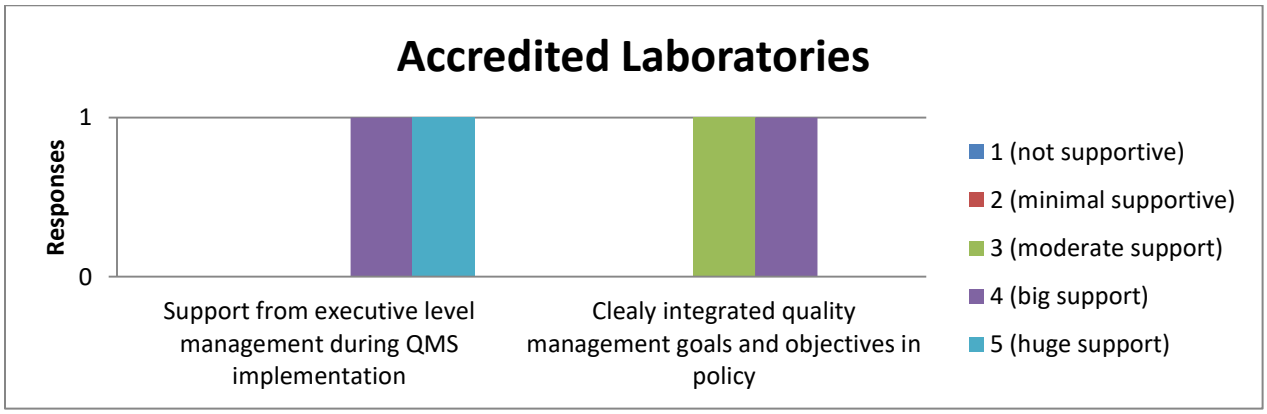


5c

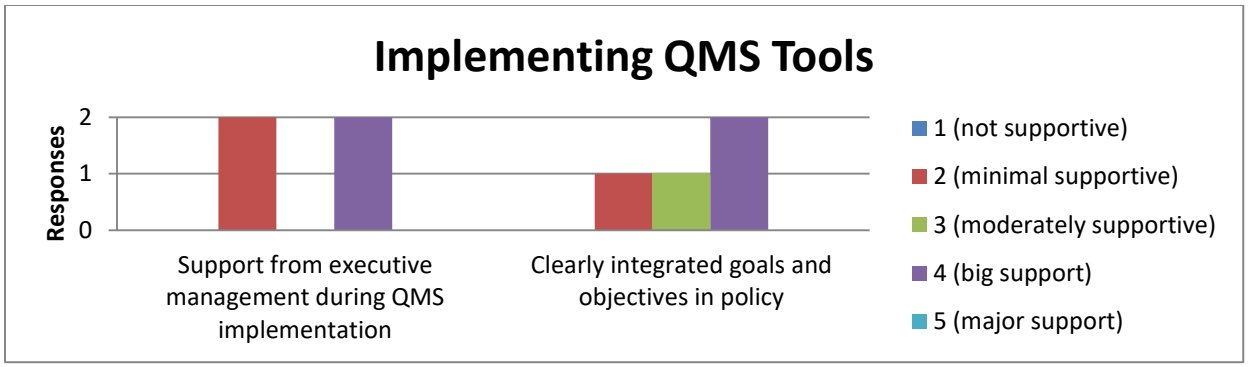
Figure 5: Challenges faced/perceived during the QMS implementation

Factors enabling QMS implementation

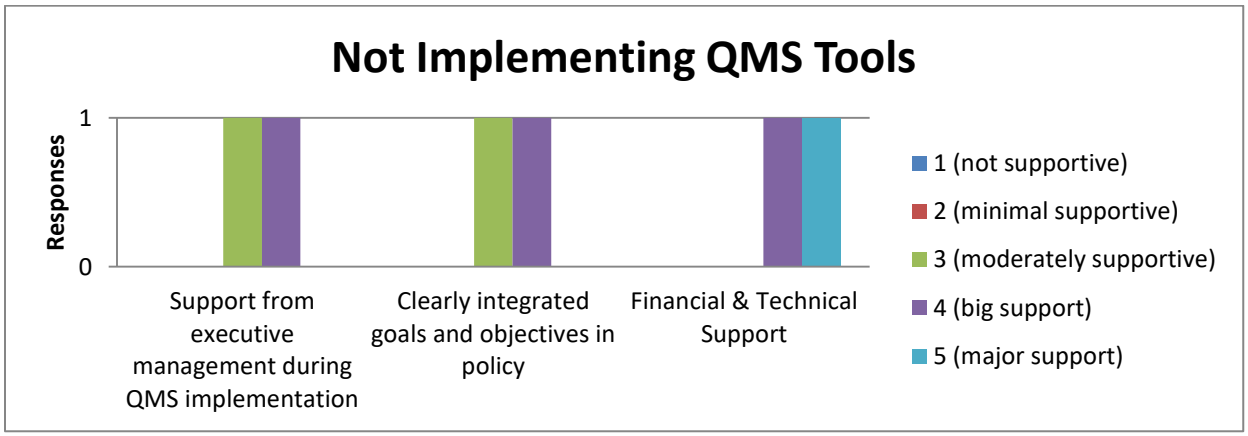
Figure 6a shows 6b. NTRLs implementing QMS mentioned that support from higher authorities or management and integration of LQMS goals and objectives in the policy is helpful. The laboratories not implementing QMS pointed out that both financial and technical support is required for ensuring good quality management (fig 6c).



6a



6b

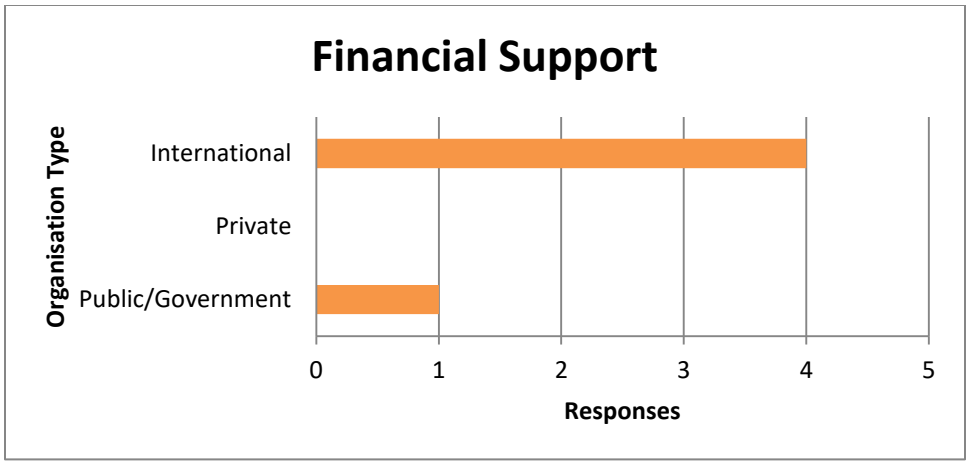


6c

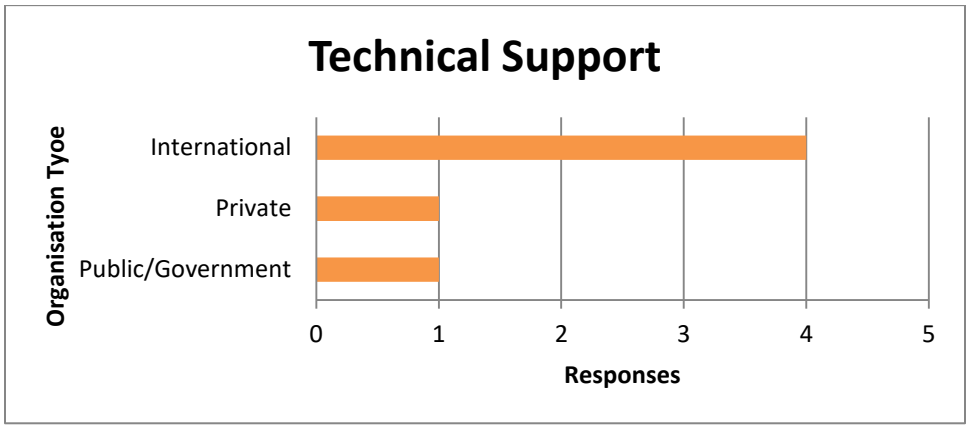
Figure 6: Support perceived helpful according to the NTRLs

Financial and Technical Assistance during QMS

Most of the laboratories that implemented LQMS, either accredited or not, had some financial or technical assistance from either the local government, private sector or international organisations such as the Global Fund (fig 7a & 7b). It was found that two of the NTRLs who implemented LQMS and one accredited NTRL had some financial assistance; however there also were three NTRLs who did not receive any sort of financial support. 3 of the 4 NTRLs implementing LQMS had technical support from an international organisation while one NTRL had no support.



7a



7b

Figure 7: Organisation providing financial and technical assistance to the NTRLs

Enabling and challenging factors according to SRLs

According to the SRLs inadequate funding, staff, advocacy, time and training can all be great challenges (see fig 8).

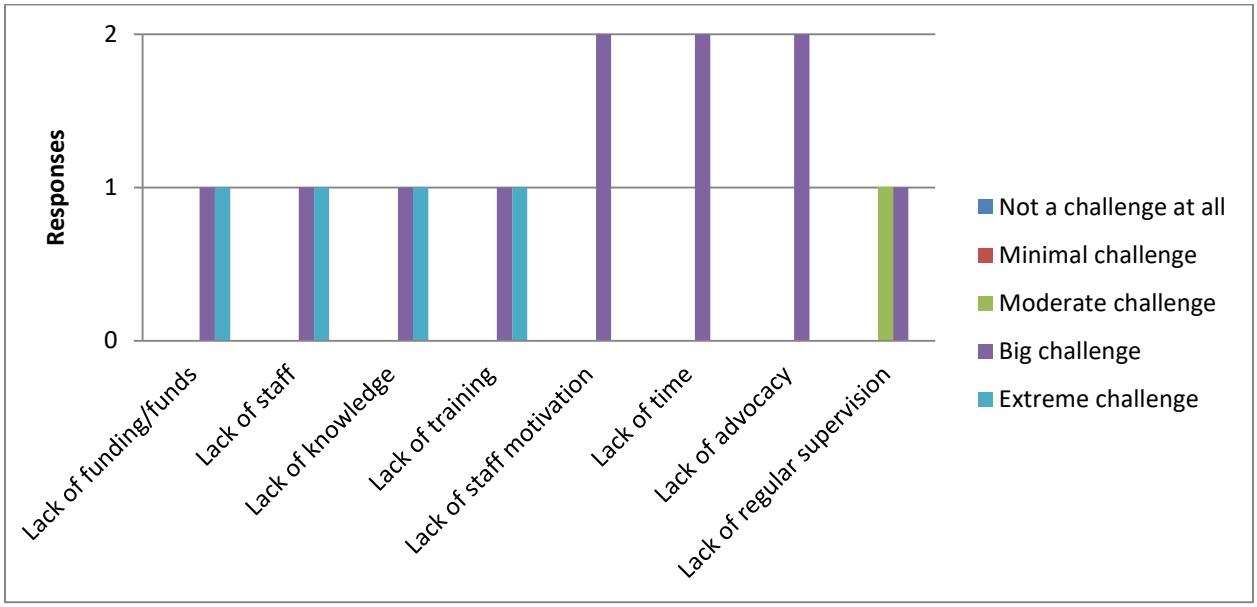


Figure 8: Challenges perceived by SRLs on implementing LQMS by the NTRLs

Both SRLs perceive that financial and technical support is required for the implementation of LQMS (fig 9). A major requirement is the supervision and assistance from the executive or higher level management and a clearly integrated policy with quality-related goals and objectives helps to easily implement the quality management system.

The SRLs which participated in the survey mentioned that they feel that the transportation of reagents and logistical issues (for example storage and handling of samples) are some problems that can be faced by the NTRLs of the SEA regions.

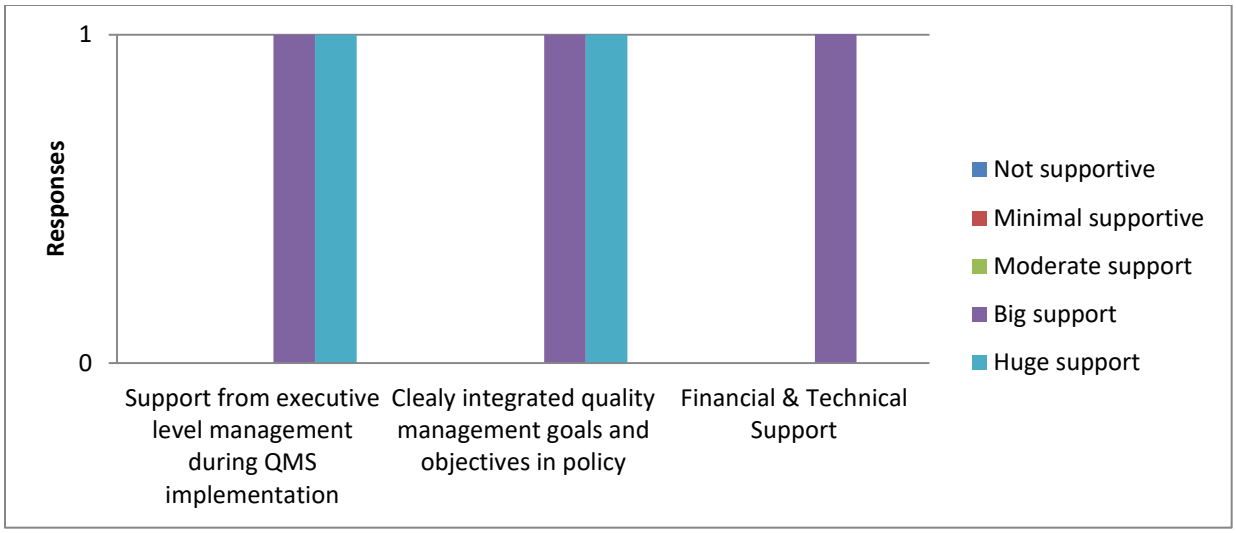


Figure 9: Supports necessary for implementation of QMS as perceived by SRLs

C. Interview Results

The SSI's were conducted with 5 NTRLs. Of the 5 NTRL 2 of them are about to achieve accreditation, 2 of the NTRLs are implementing QMS and 1 laboratory is not implementing QMS but follows certain WHO guidelines to maintain quality.

During the interview there were some common issues that were mentioned by all the participants.

Organisation and Resources

Organisation & Personnel

All the NTRLs in the SEA countries are independent institute under their respective governments. Some regional/district tuberculosis laboratories are under the influence of the NTRL. One of the NTRL mentioned that there is no proper organogram since some of the staffs are hired on a temporary basis from other organisations. Due to the absence of organisational structure in some of the NTRLs, it gives rise to hierarchical issues within the employees.

"The NTRL unit is a part of the national laboratory of which I am the manager"

> ***"There is manpower from other organisation that works in the NTRL…..So there is no specific organogram….so how can there be man power…and even if there is organogram, it is not an entitled/individual institution so they can't recruit."***

Even though there are no proper organisational arrangements, the laboratories follow and work according to Standard Operating Procedures (SOP) to get the work done. One laboratory mentioned that even though it is not implementing any QMS they work accordingly to SOP but the standard of quality is not equal to that of those managed or executing QMS.

> ***"We do have our own SOPs and we do have our own guideline for our own sputum microscopies and our own guideline for management of TB in (country) where we have incorporated some laboratory parts as well."***

One of the respondent mentioned that a change in organogram focusing on the required number of staff and personnel required at each level is important instead of a disproportionate balance of directors and staffs in the laboratory.

> ***"To have a smaller organogram instead of having too many directors and managers but make it smaller and have more people like senior staff or expertise to help the younger and new technicians in their work."***

All the respondents expressed that there are ***not enough staff or human resource*** in the laboratories. The technical staffs, in addition to their regular laboratory work are required to maintain quality of the laboratory as well. This leads to ***work overload***. This leads to monotony in work which results in staff being demotivated. When staffs retire they are not swiftly replaced. Some NTRL's mentioned there is a shortage of technical staff. The department of human resource management does not feel the requirement of adding more staff as they feel there are enough for the whole task. In some NTRL's human resources from other organisations are used to perform certain duties. There also is a high turnover of staffs due to better job opportunities abroad or within the country after receiving training. There are some NTRLs where the staffs are appointed on a contractual basis, this creates an uncertainty of retention of staff and also affects the quality of the work. Most of the NTRLs also stated that there is a lack of dedicated and motivated staff which creates difficulty with an already existing crisis in the number of staffs. With the lack of proper organogram there are no specific units or human resource for management and supervision of the quality implementation. Some of the laboratories mentioned out-sourcing of human

resources from different organisations to counter lack of staff while some refer to this as not a permanent solution.

> ***"so they think (human resource) it is enough to do all work….but they (technical staff) are doing all the laboratory work and do not have extra time for quality work"***

> ***"They don't sometimes return/ comeback……. they get better opportunities outside"***

> ***"Yes, Most of our staff is not government staff so we cannot guess the sustainability of our quality assured laboratory tasks as they are assigned only for just a temporary period."***

> ***"My technicians and all my staffs are overworked. We are running short of technicians. Right now I am fully into the administration, even though I am the head of the department and also assisting the director of the institute as well as hospital administration. I am also heading the teaching department of microbiology."***

In contrast to the above findings, one of the respondents stated that the staffs are underutilised. Most of the routine work is not enough to engage the staff; only during surveys or special TB cases screening sessions are the staffs busier. Lack of work distribution also results in some of the staffs being overworked than some of the technical staffs in the same department. However the salaries for the staffs of those who have more workload are equal to the ones whose are less.

> ***"During a normal routine day, the workload is quite low and in a day our Gene expert, one of them can do about three to four tests, which is very low." "So the NTRL only has technical staff, but we do not have non-technical staff. There is a department called 'Administration' in supporting services, they part management support to all the laboratories."***

> ***"Work definition is not available which needs to be stream lined and strengthened." "for example I get 200 sputum samples everyday but I have 2 staffs there. It becomes very difficult to do the tasks in one day."***

> ***"A single person has to do everything from collection of sputum to preparation of culture and testing."***

Another NTRL mentioned there is enough staff to maintain the day-to-day activities.

> ***"In the lab we have senior microbiologists as the HOD (Head of Department) and under him there are specialist and we a separate section for outreach activities, under which we have three more microbiologists and four technical staff."***

Most of the respondent mentioned that there isn't ***enough training*** on quality management. Some of NTRL's mentioned that enough though the staffs were well trained but they have not received any kind of refresher training for a long time. This all causes staff to be demotivated due to the monotonous nature of work. Some of the trainings are general to all the departments to achieve ISO accreditation or implement quality management system rather than being specific on Tuberculosis. Some of the NTRL's suggested that international training on QMS on the specific tools they are implementing would be of help as most of the training is taking place nationally. When something new is introduced or there is an update on the procedure of the work they do, there is no formal training. They learn by trial and error or by applying the procedure during their work.

> ***"Our staffs are being trained on only laboratory works….like culture and DST….microscopy and quality molecular testing and all….but not specifically on qualitation (quality management)."***
>
> ***"There are no international trainings"***
>
> ***"They need one kind of refreshment or refresher training. When a new need training."***

Equipment

All the NTRLs mentioned that they have enough equipment to carry out all the functions. The equipment is of good quality and purchased from renowned manufacturers.

> ***"Our equipment is state of the art technology."***
>
> ***"Regarding the equipment we have all the equipment we need."***
>
> ***"We have all equipment required for TB diagnosis like smear microscopy to molecular testing of fast-line drug resistant and bio-safety laboratory and recently we got new generation sequencing equipment which we are in the process of making it operational."***

One of the NTRL mentioned that they provide purchase request for the needed equipment to the National Tuberculosis Programme (NTP). NTP verifies the need of the request and upon purchase then helps install the equipment. The equipment is calibrated yearly and they are also provided with a certificate after each calibration.

> ***"Yearly calibration and certification and all are also done by the NTP. So in this case we feel its ok."***

The maintenance of the equipment is usually contracted out to the manufacturers. In one interview the respondent mentioned that the manufacturers provide technical trainings to some staff that will help them to be able to take care of minor malfunctions that may arise while working. However, one of the respondents mentioned that staffs do not have any maintenance skills which are required to be able to manage sudden malfunctions of the laboratory equipment to avoid unnecessary and avoidable delays. This ***insufficient knowledge on maintenance*** is a difficulty which sometimes hampers the smooth implementation of QMS.

> ***"The part of contract with the manufacturers is to prepare our team. They provide some training to our staff. So if there are minor malfunctions they can assist but if there are big problems that requires engineers they will send them."***

> ***"Each equipment is under the annual maintenance contract as per the guidelines of the Government. We enter into agreement with service centres for maintenance."***

> ***"We do not have people who are trained on equipment maintenance which would help save us time and any delay"***

Inventory and Purchase

All the interviewed participants stated that ***purchase*** of reagents and inventory is not a problem. Most of the NTRLs have departments who are responsible for the purchasing reagents and goods needed for the laboratory. The laboratories provides with the list of requirements to the department in charge of the procurement. One the laboratories had an electronic system which they use to check stock supply and predict stock-out and requisition requirements. All the NTRLs purchase some of the required reagents needed for the laboratory from other countries. There are sometimes delay when a reagent is ordered but they always have enough stock to face any sort of unwanted delays.

> ***"We have a governing body that works autonomously. They do the procurement and warehouse for us. So we provide the forecasting and the quantifications and they do the procurement for us."***

> ***"Yes there are times when there are delays. But because of the delay the work is not hampered."***

> ***"We stock for one year"***

However countries which are geographically distant have troubles when reagents and goods are being supplied from other countries. According to

one respondent delay of procurement also occurs when budgets for the regents purchase are not acquired on time and the ***higher management*** does not response to the needs of fund on time.

> ***"The problem in our NTRL is the procurement, the supply chain. As we are far from big countries, sometimes there are delays when the goods are delivered by the sea route."***

Facility & Safety

All the NTRL's implementing QMS have sufficient space and building area needed to have proper functioning laboratory. There are separate sections in a building for lab works and administrative work. Those not implementing, mentioned ***lack of infrastructure*** creates a challenge to place all the equipment and also maintain an open working space. However, additional rooms are being allocated to some NTRL's to overcome the shortage of adequate work space.

> ***"We have different rooms for administrative work and also for laboratory work"***

> ***"The rooms we have I don't think those are according to ISO or LQMI or enough to maintain them. We need a separate infrastructure on a prior basis."***

Separate space for laboratory work and administrative/ paper work was a problem as mentioned by one respondent. Laboratories do not have a place for the staffs to relax and do other desk related jobs.

> ***"The number of staff is less but also I do not have the space to accommodate them. Work space separate and sitting space separate which I do not have."***

There are different cabinets for sputum collection and storage within the laboratory to ensure safety of the staffs and avoid contamination of the sample during storage. There are some bio-safety cabinets in place in the laboratory. They do not have any policy or rules but practice safety according to the WHO bio-safety guidelines.

> ***"The sputum collection room we have there are separate bio-safety cabinet for sputum collection and storage."***

> ***"But we follow these WHO guidelines"***

All of the NTRL's interviewed had health and safety manuals in place. When new staffs join the laboratory they have to undergo a safety protocol management session after which they have to undertake a proficiency test of the safety rules of the laboratory was stated by one NTRL.

"There is safety policy. Those who work they maintain safety."

"We have safety manuals located in the laboratory"

"Whenever there are new staffs we give them health and safety induction. Some senior staff gives training to the new staffs"

"The staffs have to pass a competency test to be able to work with the equipment"

The Work

Process Control

The NTRLs are all aware of the importance of quality control for testing and appropriate management of samples and reagents. They are well aware of the caution and care to be taken during handling and collection from the patient to the laboratory.

Documents and Records & Information Management

Most of the NTRLs stated that ***documentation and record keeping*** is done manually with some exceptions where it is done digitally. The manuals and documents in some of the NTRLs are saved as both a manual and electronic copy for easy availability and access. Stated by one of the respondent that though keeping track of records manually is not a huge challenging factor, it would ease work and workload if they are done digitally. One of the respondents mentioned that manual records take up space which could be used for other functions.

"We have both hard and soft copies of all the manuals. In the hard copy we write down the location of the soft copy. This makes it easier to find the documents."

"Right now it is all maintained manually."

There are some laboratories that they use software to store patient's information/profile, reagent and product shipment record and details, and lab reports digitally. Some of the NTRLs said that digital documentation would help and make work easier.

"We use digital software which is a sort of lab information system. However for sputum and slide culture we still keeping it manually"

"Throughout the country the labs associated with us we have a web-based sharing where each lab can upload the results"

Measurement and Improvement

Occurrence Management

All the NTRLs are using bio-safety manual of WHO to avoid any type of unwanted incidences at the laboratories. One of the NTRLs mentioned they have occurrence management which they always refer back to correct any difficulties that lead to past incidents as a part of their safety policy.

> ***"We have occurrence management to make sure if something goes wrong we records and try to provide corrective actions."***

> ***"We have infection monitoring committee which monitors accidents and any occurrence."***

Assessment

The 5 NTRLs mentioned that they are audited by external sources almost every year while 4 NTRLs mentioned that they have an internal auditing department which is responsible for auditing all the laboratory set-ups (haematology, bio-chemistry) within their compound. They all mentioned that an audit helps them to make the necessary improvements which will eventually help them to receive the accreditation of the laboratory.

> ***"We recently had a visit in 2017 and external audit visit. There are some things that need improvements and training of our staffs"***

> ***"Apart from being a public health laboratory we also function as an internal audit team that provides audit to other laboratories in public health sector. We use the checklist from LQMS which we adopted from the ISO 15189 to conduct our internal audit."***

All the NTRLs mentioned that an international audit is conducted once a year.

> ***"It's part of our programme, like once in a year someone from international body comes to do the audit to check where we can improve".***

> ***"We have a division called (.....) previously they looked into biochemistry and haematology but now they also look in to microbiology which also includes TB. Routine for risk management which is also a part of quality assurance. They are helping us do QMS. They also do audit."***

> ***"We are been externally quality assessed by SRL every year."***

On-site internal evaluation and proficiency have been continuously done in one of the laboratories to maintain quality of the lab as stated by one of the respondent.

> ***"We conduct regular on-site evaluation and proficiency testing along with retesting of labs which are under our jurisdiction."***

According to one NTRL, it is required to carry at least one internal quality assessment before applying for the application for accreditation at the national board of accreditation body.

> ***"We have to carry out one internal audit which is compulsory before submitting an application for accreditation. It is compulsory and we have conducted that."***

One of the accredited NTRLs mentioned that it took them more than 5 years to achieve accreditation since they started implementing quality management system.

> ***"We started implementing the quality system in the year around the end of 2005 or beginning of 2006 and we got accreditation around the year 2011/ 2012"***

Customer Satisfaction

All of the NTRLs implementing some sort of quality management mentioned it greatly increases customer's satisfaction and also ensures rust among the clients on the services provided by the laboratories. They have customer satisfaction surveys of different types some of which are focused on the services provided while others on the environment of the diagnostic space. But since the NTRL are not in an individual building it is based upon the whole of the services and other laboratories present in the complex.

> ***"We just had one (survey) which is one of our measures of quality improvement. The NTRL is within the National Health Laboratory, so we have one reception. Everyone who comes to the reception we give them one question and ask them to fill it up. "***

> ***"For getting this national board of accreditation we need to have this in place. When a patient comes we will take their phone number and next day we will call the patient to get a feedback regarding to OPD services, in-patient services, lab services, and consultation services and they do give us feedback."***

Process Improvement

The respondents of all the NTRLs are continuously trying to improve and do emphasise on further growth of the laboratory.

> ***"Part of it or overall is the integration of QMS in the entire department. We have an advisor and a quality manager who is just focusing on checking everything and makes sure everyone is well aware of improving quality of diagnostic we provide. We have an education officer who continuously assesses the competency of our staff."***

> ***"All my technical staff needs to undergo training once in two years or time to time whenever we find deficiency during internal quality assessment."***

Role of SRL

All the NTRLs stated that they mainly receive ***technical support*** from their respective SRL and at times they also provide ***assistance*** for conducting any research. The SRLs also conducts ***proficiency test*** yearly to maintain the quality of the laboratory tests.

> ***"They give us technical assistance and assist on performance cultural, DST, molecular etc…molecular TB….send us strains to check proficiency."***

Emerging Themes

Support

Three of the five NTRLs interviewed expressed a need for ***financial and technical support***. Even though in the survey it was seen that most of the NTRL implementing QMS had some financial and technical assistance from public, private and international funds which were limited. Due to lack of financial support most of the staff cannot go for trainings which include training for maintenance of laboratory equipment and on quality management tools. In some of the NTRL the staffs lack technical knowledge. They believe that if more budgets are allocated for capacity development of the staff for either a refresher training or technical knowledge development it would make a huge positive impact on the quality of laboratory services. International trainings on quality management would not only motivate the staffs from the monotonous range of work but also increase their technical capacity.

But 2 other NTRLs mentioned that finance was not a problem for them. One of the NTRL are acting independently with total control of their budget while another stated that enough fund is allocated for the operation of the

tuberculosis laboratory. However, the access to funds is not easy when there are elections in the country or any major political issues arising.

> ***"We function as an autonomous institute, we operate like private companies and we allocate our own funding's. At the moment funding is not an issue. But if there is an election we have difficulty in accessing the budget." "We are partially funded by an international organisation, at the moment the international agency slowly ending this responsibility. So certain things are funded by the international agency but certain thing funded by the laboratory for example the staffing and the reagent procurement".***

These 2 NTRLs also mentioned that they have collaboration with international agencies like WHO to provide trainings for staff skill and knowledge development.

> ***"We also have on-site training on quality management system. We also send some staffs abroad to train them on management of TB laboratories."***

One of the NTRL laboratory mentioned that they provide in-house trainings for laboratory maintenance.

> ***"We also conduct trainings and re-trainings on labs."***

Some of the NTRLs stated that the ***higher management level*** (the national tuberculosis programme) and the Government should prioritise NTRL. Whenever staffs need new equipment/training/infrastructure the request is processed by many levels. A strong support from the higher level management would make it easier to get the necessary or request on time. Most of the NTRLs feel that there is not enough commitment and mentoring from the higher management.

> ***"They (higher management) need to give more importance to this but they don't."***
>
> ***"limited budget and regarding technical experts…we lack technical competencies"***
>
> ***"I need to send manpower for training abroad or internal training…..i can't send them because of lack of fund…."***
>
> ***"I would say fund and technical support are the two main challenges we face and the most important one"***

Another respondent mentioned that the NTRL has international board of advisors who are providing enough support to maintain and manage the laboratory.

"We have an international staff working with our staff. They sort of provide us a set of management, so they assist our local staff providing training technically and management and overall operation of the laboratory"

Curriculum on quality management

One the laboratory stated that most of the technicians had earned their degree in another country where the curriculum did not have the topic or syllabus on quality management. The staffs lack the basic knowledge of quality system before they begin their work in the NTRLs.

> ***"Most of the technicians or technical staff studies abroad. The curriculum about lab doesn't include quality management as a part of subject in school. So when they finish school they sort of not know what quality is and the proper way of working in the laboratory."***

Language

One respondent mentioned that there are language barriers during work and quality implementation, especially when the manuals and guidelines are all in English as some staff do not have complete grasp of the language. The manuals have to be translated into the native language which is time consuming and not an easy task.

> ***"All documents like LQSI tool, WHO and other documents are all in English. Our staffs do not know English so they face problems."***

Recommended Changes to overcome the Challenges by the NTRLs

Upon asking for recommendations all the participants agreed that implementation of a quality system is helpful to increase the standards of the laboratory and also the staffs working. However as they face challenges in their day to day work which affects their environment and morality the participants suggested the following recommendations.

1. More technical training on the quality management system with some training on laboratory work which can be incorporated with quality training.
2. Increase financial support

i. To buy more reagents which are required daily to make fresh batches of media for culture.
ii. To be able to hire more administrative staffs so that the workload of the staffs working in the laboratory are reduced and they are able to concentrate only on technical aspect.
iii. Some fund to be allocated for the laboratory to be earmarked for quality management system.

3. More support from the higher management with more structure to the organisation.
4. Employing a person with specific knowledge on Quality Management.

4. Discussion

The purpose of this study was to determine factors which support or hamper implementing a Quality Management System according to ISO15189 in TB laboratories of the WHO South-East Asian Region.

National laboratories implementing QMS are working towards accreditation to assure quality laboratory services (30). Laboratories are made up of people, guidelines and systems and not just based on technologies, equipment and infrastructure which is needed to provide quality service to patients (31). Attaining accreditation is not only about receiving a certificate or recognition but more about delivery and maintenance of quality service (32).

The main challenges for implementing an LQMS that were identified by this study are:

1. Shortage and huge turnover of staff
2. Increased workload
3. Inadequate funding for laboratories
4. Lack of pre-service education in QMS and continuous professional training
5. Lack of support from higher management
6. Inadequate advocacy for Quality Management

One of the most common challenges frequently mentioned by NTRL and the SRL staff interviewed was the lack of human resources and funding for developing and training employees for their career development. Previously done assessments have found that laboratories in resource-poor countries/

low-middle income countries often face such challenges (33). Organisation of the laboratory and the resources required by it are key necessities which help to develop the QMS (34). Many of the findings found in this study have appeared as challenges in implementing QMS in previous studies conducted.

Organisation and Personnel

According to our study it was found that lack of organisational structure and defined job responsibilities lead to underutilised employees, unclear division of work and an imbalance of the workload. In line with previous studies it was seen that a well-organized laboratory supported by the Ministry of Health or relevant government departments is deemed necessary for proper QMS implementation. National level management should set policies and give strategic directions to the NTRLs (35). It is very important that the organizational plan defines job roles and responsibilities in a clearly defined way (36). This study, along with other studies, highlights the importance of an organisational structure

Non-availability of trained personnel in the laboratory is a major obstacle when implementing QMS (37). In most cases there is an lack of employees with required skill sets (38). This often leads to increased work load that can cause employees to be demotivated. As in the study, the large amount of work to maintain proper documentation, reporting system and all of laboratory process has been difficult to maintain. This is one of the major internal challenges which hampers the ownership of the QMS among the employees (32).

Retention of well-trained staff is another major challenge which was consistent with other study findings (39)(38). A reason for staff turnover that came up in the study is the lack of knowledge of quality management among the work force during their educational years; a number of employees leave their jobs due to better opportunities within the country or out of the country after receiving training (39). But lack of refresher trainings leads to monotonous work among the employees which acts as a demotivation. A high turnover not only causes a loss of highly competent staff but also increases the cost when implementing the QMS (34).

Infrastructure

From this study it was found that infrastructure is an important aspect for QMS implementation. A study by Grima et al. in 2017 showed comparable

results where the author found that laboratory buildings and setup should be in accordance to ISO 15189 standards (40).

Quality manager

Executing QMS in a laboratory requires proficient personnel. As expressed by the NTRLs in this study, there is a need for a specific person responsible for the implementation of QMS. Therefore it is important to have a 'Quality Manager'. A quality manager is the key person who is responsible for ensuring all the aspects of ensuring the quality of a laboratory along with the support of the technical and administrative staff (41).The NTRLs which already have a quality manager in place are doing better than the laboratories that do have a specific person ensuring the QMS.

Financial and technical support

Both NTRL and SRL staff interviewed suggested that finance is an extremely important factor which is often overlooked before the implementation of QMS. In many of the high burden countries there is little or no extra funds available for TB laboratory services. In the review of literature it was seen that QMS implementation is greatly affected by the lack of financial support. Most of routine funds are used to pay for salaries of existing staff and manage reagent costs (42). The extra funds required for QMS implementation is sometime managed with the help of external funding such as Global Fund. Results of the survey suggest that laboratories which have been accredited or implementing QMS have had some external funding which they suggest is not enough to maintain quality service. However, considerable investments in infrastructural upgrades of laboratories have also been made. One of the primary responsibilities of higher management is to ensure sufficient, earmarked funding availability for training of staff (26).

Auditing

A laboratory must first implement better management and aim to improve to reach the standards of accreditation. These steps can be done simultaneously (43). All the NTRLs implementing QMS covered in this study have been audited by external agencies. An audit is an essential first step that helps laboratories to improve their services and progress towards accreditation. This helps laboratories to take into considerations the recommendations provided during and after the auditing and take corrective and preventive measures (14).

Support from higher management and advocacy about QMS

The road to accreditation is an lengthy and expensive process and requires a strong commitment from higher management. Policy makers do not always assist in raising awareness of the impact and importance of an improved tuberculosis laboratory (44). It is observed in this study that NTRLs feel they are not advised on the importance of a QMS for their laboratories. As mentioned in this study there is a lack of support from governments to prioritise QMS in their country's laboratories. In a study by Albert et al. in 2017 in line with our study it was found that strong political commitment and leadership is a necessary to move forward the efforts for accreditation and quality systems (14). Especially in resource limited settings the lack of support from the government and inadequate policies along with a shortage of funding opportunities create challenges to implement a QMS as found in a study previously conducted (32). In another study it was seen that support by top management on laboratory strengthening resulted in success of the QMS implementation (39).

Role of SRL

From the current study it is seen that SRLs play a role in developing the NTRLs by supporting in conducting external quality assurance to ensure the reliability of the results generated. This is in line with a finding in a previous study on quality assurance programmes (45). The SRL helps in policy making decisions of NTRLs and provide technical assistance when required. The NTRLs in the study mentioned that the technical assistance required is provided by the SRLs.

Strengths of the Study

Both qualitative and quantitative methods were used to collect and analyse the date. This helped to get insights from those working in the laboratories and provided an in-depth view of the challenges and enablers that are involved while implementing quality management systems.

Limitations of the Study

The scope of this survey was to obtain information which gives an overview of the conditions that facilitate or challenge the implementation of QMS, and

not to provide in-depth information about the NTRL laboratories. There are some limitations to the study. Firstly, the number of people responding to the survey questionnaire was small due to the limited timeline and lack of resources to extensively follow-up on the participants. Some of the SRLs and NTRLs did not want to take part in the study as they were not comfortable with sharing information. Secondly, the participants may have recall bias or give answers which they might feel are desired by the interviewer. All the interviews were conducted over Skype/ WhatsApp/Viber which are internet dependent app have resulted in communication interruptions several times during the interview. Thirdly, due to time and fund limitations a pre-test of the survey questionnaire and the interview was not possible. Finally this research was only done targeting the countries that fall under the WHO South-East Asian region which only has 11 state members; therefore the results of this study should not be generalised for the whole world.

Conclusion

After review of literature and evaluation, using mixed methods, it can be deduced that there are several challenges faced when implementing or planning to implement QMS in TB laboratories. The laboratories that participated in the study were at different stages of the QMS implementation process and not all of them had achieved accreditation. There are efforts of maintaining and improving quality of the laboratory and its services. This study highlighted the need for a strong commitment and better advocacy towards the implementation of QMS from higher management or relevant authorities.

There are some laboratories that are not yet using any quality management tool but are following international guidelines to ensure quality of their service. From the findings of this study it can be concluded that implementing QMS leads to effective and reliable laboratory services. However, it was found that weak management, constraints on human resources and financial limitations along with inadequate infrastructure can lead to poor execution of quality assured laboratory service. More funding needs to be directed towards improving shortage of human resources and increased trainings opportunities. The routine workload makes the job monotonous and there should be more training as an incentive and to help create interest and improve knowledge among the staffs. It should be

remembered that developing technology are not the only method to foster quality management system in a laboratory.

Scope for further Research

There is a huge scope to investigate and continue further research work in the quality implementation of Nation Tuberculosis Reference Laboratories in the WHO South-East Asian region. There is further scope on researching:

- The challenges of increased workload that are faced by both the technical and non-technical staff while implementing the QMS tools.
- The differences in the effectiveness of implementation and quality of services of the laboratories in the region implementing different QMS tools, to find out the best QMS tool for the region.
- The role of Governments and the National Tuberculosis Programme in ensuring implementation of quality management services in the laboratories.
- In-depth analysis and study on the reasons behind frequent staff turnover.

Way Forward

During this study it was found that the participants believe that implementing QMS is a rigorous process and requires commitment not only from the staff but also from the higher management.

Recommendations

1. Develop a national policy and wider strategic plan that prioritises and provides sufficient budgetary support for Quality Management System implementation in medical laboratories standardisation of laboratory commodities and design of a reward system/ better appraisal system for staff motivation and to help lowering staff turnover rate.
2. Higher management should be more involved in advocacy of and ensuring and supporting implementation of QMS and assist the laboratory management with seeking financial and technical support from partners.

3. All employees should have a proper job description according to their specific line of work; a quality manager should be appointed at each laboratory to ensure proper supervision of quality management system implementation.
4. Separate spaces for laboratory work and administrative work should be in place.
5. Pre-service training and refresher training for employees on QMS and equipment maintenance should be provided and included in the laboratory budget.
6. Documentation should be translated into the language most commonly used by the employees.
7. SRL experts should assist NTRL technical staff to gain admission to quality management courses, encourage and push NTRLs to start implementing QMS tools to those that have not yet started, and perform external audits to encourage the positive work towards quality implementation to achieve accreditation as well as identify points for further improvement.

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6. Annexures

Annex 1: Informed Consent Form

This informed consent form is for National Tuberculosis Reference laboratory managers, NTRL Quality Officers, SRLs staff of the WHO South East Asian Region, who I am inviting to participate in a qualitative research titled 'Identifying the Enablers and Challenges in the QMS Implementation of National TB Reference Laboratories in WHO South-East Asia Region'

Name of Principle Investigator: Samia Naz Isha

Name of Organization: Royal Tropical Institute (KIT) & DATOS

Information Sheet: I am Samia Naz Isha, Master student at the Royal Tropical Institute (KIT) and intern for DATOS. I am conducting this research to identify the strengths and challenge the NTRLs face during QMS implementation to receive accreditation ISO 15189. I am going to invite you to be part of this research. If you have any questions, please email me for further clarification.

Purpose of research: TB remains a huge global burden for the world. The WHO South-East Asian Region has high number of prevalent cases of TB. The role of TB laboratories is crucial in detecting TB cases. The implementation of QMS is the way to ensure quality of test which eventually leads to accreditation. The purpose of this research is to find out the challenges and strengths during implementation of QMS. The aim of the research is to help other countries to overcome the challenges faced during QMS implementation.

Procedure and participation: The research data collection will be done in two parts. The first part will be survey questionnaire which will be sent out by mail. The second part will consist of an interview through any mode of communication which will last about 30 minutes. The interview will take place at a time and via Skype/ Viber. During the interview except for the interviewer, no one else will be present and it will be recorded with your permission. The record will be made only for the purpose of transcription to enable the researcher to analyse for the research. The participant has the right to withdraw from the study at any time of the study and also has the right to not to answer a question. The recorded interview, transcripts and survey forms will be kept with the researcher for 1 year after which it will be deleted.

Participation: The participant has the right to not participate or withdraw at any point of the survey or the interview.

Benefits: Your will receive no direct benefits from participating in this research study. However, your responses may help us learn more about the challenges and strengths faced during implementation of Quality Management System (QMS). The aim of the research is to help other countries to overcome the challenges faced during QMS implementation.

Risks: There are no foreseeable risks involved in participating in this study.

Confidentiality: The personal information of the participant will not be shared and disclosed with anyone else without their permission.

Who to contact: If you wish to ask questions later, you may contact: Samia Naz Isha, samia_isha@hotmail.com, Call: +31685045209

This proposal was approved by KIT Ethics Review Board.

Informed Consent for Interview

1. I…… voluntarily agree to participate in this research study.

2. I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.

3. I understand that I can withdraw permission to use data from my interview within one week after interview, in which case the material will be deleted.

4. I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.

5. I understand that I will not benefit directly from participating in this research.

6. I agree to my interview being audio-recorded.

7. I understand that all information I provide for this study will be treated confidentially.

8. I understand that in any report on the results of this research my identity will remain anonymous.

9. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.

10. I understand that disguised extracts from my interview may be quoted in dissertation.

11. I understand that signed consent forms and original audio recordings will be retained with the researcher for 1 year after the interview.

12. I understand that a transcript of my interview in which all identifying information has been removed will be retained for 1 year.

13. I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

14. I understand that the report from the findings will be used for publication.

Electronic Consent:

Name of participant: ……

Please select your choice below. You may print a copy of this consent form for your records. Clicking on the "Agree" button indicates that

- You have read the above information
- You voluntarily agree to participate

☐ Agree

☐ Disagree

Consent Form for Online Survey

You are invited to participate in an online survey on for National Tuberculosis Reference laboratory managers, NTRL Quality Officers, SRLs staff of the WHO South East Asian Region, who I am inviting to participate in a qualitative research titled 'Identifying the Enablers and Challenges in the QMS Implementation of National TB Reference Laboratories in WHO South-East Asia Region' This is a research project being conducted by Samia Naz Isha, a student at Royal tropical Institute (KIT), in Amsterdam, Netherlands as a part of Master's thesis and as an intern for DATOS. It should take approximately 10-15 minutes to complete.

PARTICIPATION

Your participation in this survey is voluntary. You may refuse to take part in the research or exit the survey at any time.

BENEFITS

Your will receive no direct benefits from participating in this research study. However, your responses may help us learn more about the challenges and strengths faced during implementation of Quality Management System (QMS). The aim of the research is to help other countries to overcome the challenges faced during QMS implementation.

RISKS

There are no foreseeable risks involved in participating in this study.

CONFIDENTIALITY

Your survey answers will be saved in electronic form with the researcher. Other than the researcher no one else will have access to the information. Five year after the survey all the documents will be deleted from all the places it has been saved.

At the end of the survey you will be asked if you are interested in participating in an additional interview by Skype, Viber or WhatsApp. If you choose to provide contact information such as your phone number or email address, your survey responses may no longer be anonymous to the researcher. However, no names or identifying information would be included in any publications or presentations based on these data, and your responses to this survey will remain confidential.

CONTACT

If you have questions at any time about the study or the procedures, you may contact me by email at samia_isha@hotmail.com or call on +31685045209.

ELECTRONIC CONSENT

Please select your choice below. You may print a copy of this consent form for your records. Clicking on the "Agree" button indicates that

- You have read the above information
- You voluntarily agree to participate

☐ Agree

☐ Disagree

Annex 2: Survey Questionnaires

National Tuberculosis Reference Laboratories

Basic Information of the Laboratories

A.	Name of the National Tuberculosis Laboratory (NTRL)	
B.	Address of the NTRL	
C.	Head of NTRL	
D.	Contact Details of the Head of the NTRL	
E.	SRL supporting the NTRL	
F.	Name of the person filling out the survey	
G.	Position	
H.	Email	
I	Phone Number	
J	Would you be willing to be contacted for an interview?	☐Yes ☐No

	Status of the Laboratories	
1	Number of technical employee currently working in the laboratory	O 1-5 O 6-10 O 11- 15 O _____ (if more than 15, please write it down in numbers)
2	Number of non-technical supportive employee currently working in the technical laboratory	O 1-5 O 6-10 O 11- 15 O _____ (if more than 15, please write it down in numbers)
3	Are you implementing Quality Management System (QMS) in your laboratory?	O Yes O No
4	Which of the following QMS tools have you heard of?	☐ Global Laboratory Initiative (GLI) Stepwise Process Towards TB Laboratory Accreditation ☐ Stepwise Laboratory Management Towards Accreditation (SLMTA) ☐ Strengthening Laboratory Management Toward Accreditation (SLIPTA) ☐ TB-SLIPTA (harmonized checklist) ☐LQMS
5	Are you aware of the existence of ISO 15189 standard?	O Yes O No
6	At present, which stage of accreditation is your laboratory, in accordance to ISO 15189	O We have achieved accreditation (Please continue with questionnaire A.) O We are actively implementing a QMS to achieve accreditation (Please continue with questionnaire B) O We are not actively implementing a QMS to achieve accreditation (Please continue with questionnaire C)

Questionnaire A		
	Accredited Laboratories (Part 1)	
1	When did your laboratory achieve formal accreditation?	
2	Did you achieve re-accreditation?	
3	If yes, which year?	
4	Which accreditation did you achieve (choose one)	O ISO15189:2007 O ISO15189:2012
5	How long did the entire accreditation process take from the time of the application?	1. _____ Years 2. _____ Months
6	What were the main reasons for seeking accreditation? (multiple answers possible)	☐ Improving quality of laboratory services ☐ Increased laboratory output ☐ Seeking greater regional recognition ☐ Financial support was offered ☐ Technical support was offered ☐ Other (please explain) _____
7	Which tool(s) did you use in the QMS implementation process? (multiple answer possible)	☐ Global Laboratory Initiative (GLI) Stepwise Process Towards TB Laboratory Accreditation ☐ Stepwise Laboratory Management Towards Accreditation (SLMTA) ☐ Strengthening Laboratory Management Toward Accreditation (SLIPTA) ☐TB-SLIPTA (harmonized checklist) ☐ LQMS ☐Other, Please name them _____ _____ _____

	Accredited Laboratories (Part 2)	
1	What were the major challenges faced during QMS implementation process	select one with 1= not a challenge at all 2= minimal challenge 3= moderate challenge 4= big challenge 5= extreme challenge
A	Lack of funding/funds	1 2 3 4 5
B	Lack of staff	1 2 3 4 5
C	Lack of knowledge	1 2 3 4 5
D	Lack of training	1 2 3 4 5
E	Lack of staff motivation	1 2 3 4 5
F	Lack of time	1 2 3 4 5
G	Lack of advocacy	1 2 3 4 5
H	Lack of regular supervision	1 2 3 4 5
I	Did you have any other challenges faced? (please specify)	O Yes _____ O No
2	Did you receive any financial support for accreditation?	☐Yes ☐No
3	If Q2 is affirmative, please state what type of organization	☐ Public ☐ Private ☐International
4	Did you receive any technical support for accreditation?	☐Yes ☐No
5	If Q4 is affirmative, please state what type of organization.	☐ Public ☐ Private ☐International
6	What were the major supports during the QMS implementation?	(select one with 1= not supportive 2= minimal supportive 3= moderate supportive 4= big support 5= a major support)

A	Support from executive level management during implementation	1 2 3 4 5
B	Clearly integrated quality management goals and objectives in policy	1 2 3 4 5
C	Are there any factors that other than the ones mentioned above which is helping in the implementation of QMS	

Questionnaire B		
	On the Process of Implementing QMS (Part 1)	
1	When did your laboratory start implementing QMS apply for formal accreditation?	
2	Was there any mock Audit conducted by External Parties?	O Yes O No
3	What were the main reasons for implementing a QMS?	O Improving quality of laboratory services O Increased laboratory output O Seeking greater regional recognition O Financial support was offered O Technical support was offered O Other (please explain)_____
4	Which tool(s) are you currently following to help you with implementing a QMS??	O Global Laboratory Initiative (GLI) Stepwise Process O Towards TB Laboratory Accreditation O Stepwise Laboratory Management Towards Accreditation (SLMTA) O Strengthening Laboratory Management Toward Accreditation (SLIPTA) O TB-SLIPTA (harmonized checklist) O LQMS O Other, Please name them_____

	On the Process of implementing a QMS (Part 2)	
1	What are the major challenges faced during QMS implementation process	select one with 1= not a challenge at all 2= minimal challenge 3= moderate challenge 4= big challenge 5= extreme challenge
A	Lack of funding/funds	1 2 3 4 5
B	Lack of staff	1 2 3 4 5
C	Lack of knowledge	1 2 3 4 5
D	Lack of training	1 2 3 4 5
E	Lack of staff motivation	1 2 3 4 5
F	Lack of time	1 2 3 4 5
G	Lack of advocacy	1 2 3 4 5
H	Lack of regular supervision	1 2 3 4 5
I	Are you facing any other challenges? (please specify)	O Yes

		_____ O No
2	Did you receive any financial support for accreditation?	☐Yes ☐No
3	If Q2 is affirmative, please state what type of organization	☐ Public ☐ Private ☐International
4	Did you receive any technical support for accreditation?	☐Yes ☐No
5	If Q4 is affirmative, please state what type of organization.	☐ Public ☐ Private ☐International
6	What were the major supports during the QMS implementation?	(select one with 1= not supportive 2= minimal supportive 3= moderate supportive 4= big support 5= a major support)
A	Support from executive level management during implementation	1 2 3 4 5
B	Clearly integrated quality management goals and objectives in policy	1 2 3 4 5
C	Are there any factors that other than the ones mentioned above which is helping in the implementation of QMS	

Questionnaire C		
	Have Not Implemented QMS Yet (Part 1)	
1	Do you intend to start implementation of a QMS?	☐ Yes ☐ No ☐ Unsure
2	Was the laboratory ever audited for licensing, certification or accreditation?	☐ Yes ☐ No
3	Do you perceive implementation of QMS accreditation as being beneficial to your laboratory?	☐ Yes ☐ No
4	In what ways do you think implementation of a QMS would be beneficial?	☐ Improved quality of laboratory services ☐ Increased laboratory output ☐ Greater regional recognition ☐ Other (please explain)_____

	Have Not Implemented QMS Yet (Part 2)	
1	What challenges do you perceive as barriers to starting the QMS implementation process?	(select one with 1= not a challenge and 5= a major challenge and hurdle)
A	Lack of fund	1 2 3 4 5
B	Lack of staff	1 2 3 4 5
C	Lack of knowledge	1 2 3 4 5
D	Lack of training	1 2 3 4 5
E	Lack of staff motivation	1 2 3 4 5
F	Lack of time	1 2 3 4 5
G	Lack of advocacy	1 2 3 4 5
H	Lack of regular supervision	1 2 3 4 5
I	Were there any other challenges faced? (please specify)	O Yes _____ O No
2	Are there any other challenges that have prevented your laboratory from beginning an accreditation process? If yes, please explain.	O Yes, …….. O No
3	For what reason(s) do you perceive accreditation as not being beneficial to your laboratory?	

4	Do you believe that the following can be supportive during QMS implementation?	(select one with 1= not supportive 2= minimal supportive 3= moderate supportive 4= big support 5= a major support)
A	Support from executive level management during implementation	1 2 3 4 5
B	Clearly integrated quality management goals and objectives in policy	1 2 3 4 5
C	Financial and Technical support	1 2 3 4 5

Supranational Reference Laboratories

	Basic Information	
1	Country of the SRL	
2	Address	
3	Countries of the supporting NTRL's in the WHO South East Region	1. 2. 3.Others,_____
4	Name of the Head of the SRL	
5	Contact details of the Head of SRL	
6	Name of the person filling out the survey	
7	Position	
8	Contact details	

	Strengths and Challenges of NTRL implementing QMS	
1	What do you think are the main challenges for implementation of QMS in South East Asian countries	(select one with 1= not a challenge at all 2= minimal challenge 3= moderate challenge 4= big challenge 5= extreme challenge)
A	Lack of fund	1 2 3 4 5
B	Lack of staff	1 2 3 4 5
C	Lack of knowledge	1 2 3 4 5
D	Lack of training	1 2 3 4 5
E	Lack of staff motivation	1 2 3 4 5
F	Lack of time	1 2 3 4 5
G	Lack of advocacy	1 2 3 4 5
H	Lack of regular supervision	1 2 3 4 5
2	What according to you are the supporting factors for implementation of QMS in South East Asian countries	(select one with 1= not supportive 2= minimal supportive 3= moderate supportive 4= big support 5= a major support)
A	Support from executive level management during implementation	1 2 3 4 5
B	Clearly integrated quality management goals and objectives in policy	1 2 3 4 5
C	Financial and Technical support	1 2 3 4 5
D	Is there anything else that would support	

	implementation of QMS? Please specify	

Annex 3: Interview Guidelines

Part 1: Introduction

1. Thank the interviewee for taking part
2. Introduce oneself
3. The objective of the interview
4. Expected duration of the interview
5. Explaining how the results of the interview (privacy, confidentiality, no name mentioning) will be handled
6. Explaining why the interview will be recorded
7. Explaining that the interviewee can stop the interview at any time if the interviewee feels that need

Part 2: Interview

1. Is the NTRL you are working with accredited/implementing QMS in the laboratories?
2. If Accredited:
   a. What process did the laboratory have to go through during the QMS implementation process to receive accreditation?

   If not accredited:

   a. What is the current stage of the laboratory on the process of QMS implementation?
3. Please can you say something about the challenges faced during the QMS implementation?
4. Please can you say something about the supports during the QMS implementation?
   (Probing question on the different issues from the framework will be asked)
5. According to you please can you elaborate on the challenges faced or support during:
   - Internal and external audits.
   - Recruitment and retention of laboratory staff.
   - Competency assessment, training and continuous education opportunities.
   - Implementation of continuous improvement.
   - Information flow in different levels of laboratory organization
6. If you were to recommend on the any changes that would significantly overcome the challenges faced during the implementation of QMS.

Part 3: Closing the interview

1. Ask interviewee if he or she has any questions or remarks
2. Again thank the interviewee for the interview

3. If there is a possibility to have contact again if there are still things unclear
4. Final outcomes of the research to be shared with the interviewee.