A MULTI CASE ANALYSIS OF CRITICAL SUCCESS FACTORS IN VIETNAM LABORATORIES IMPLEMENTING QUALITY MANAGEMENT SYSTEMS TO EARN INTERNATIONAL ACCREDITATION

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Dedicated to my husband, Chuck, and our children, Catherine, Tommy, and Richard, for their unconditional love and encouragement. You are the best.

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ABSTRACT

A MULTI CASE ANALYSIS OF CRITICAL SUCCESS FACTORS IN VIETNAM LABORATORIES IMPLEMENTING QUALITY MANAGEMENT SYSTEMS TO EARN INTERNATIONAL ACCREDITATION

by Catherine Douglass Robinson

After decades of global intervention to conquer diseases, healthcare in many countries is still lacking. Assessments of medical laboratories in developing countries today find poor infrastructure conditions with no standardized processes or quality assurance to guarantee accurate results and enable quality healthcare. Bringing healthcare programs in developing countries up to international standards remains a challenge.

Currently, there is a scarcity of scientific research related to the determinants of success in implementing quality management systems (QMS). There has been little research dedicated to identifying the critical success factors for medical laboratories striving to improve the accuracy and reliability of their testing services in developing countries.

In over nine years of research, the author realized there was a need for incorporating Critical Success Factor (CFS) methodology into laboratory modernization efforts. This time frame included CDC sponsored trips to several African countries and collaborating with the Vietnam Administration for Medical Services/Ministry of Health (VAMS), Centers for Disease Control-Vietnam (CDC-vn) and seven universities to build laboratory capacity and initiate laboratory improvements to meet national and international laboratory standards. In 2017, VAMS approved a proposed study to identify CSFs in four laboratories in Vietnam.

The research question this study sought to answer was "What are the top five critical success factors for successful implementation of QMS into laboratories in Vietnam?" with an outcome of improved accuracy and reliability of testing results. This study utilized both

qualitative and quantitative research methods employing principles of descriptive research. A demographic survey, semi-structured interview, content analysis, and benchmarking were utilized to identify the top five CSFs and barriers. Content analysis was employed to review CSF definitions and categorize all 220 listed CSFs into ten comprehensive and mutually exhaustive categories. Two research assistants assisted the researcher place each CSF into one of the ten categories. Rigorous and non-rigorous methods measured interrater reliability with the categorization of CSFs. Cohen Kappa values were > 0.85 indicating excellent reliability and accuracy between the assistants and the researcher. Chi-square values were all > 0.05 ($p < 0.05$) indicating demographic variables did not statistically impact findings.

Qualitative responses were gathered through personal interviews, a demographic survey, and benchmarking. Using a stratified convenience sampling, participants represented four levels of stakeholders: laboratory staff, laboratory managers, hospital administrators, and clinicians utilizing laboratory services.

Data from this study found the top five CSFs were: staff knowledge of QMS, laboratory management leadership knowledge and skills, staff commitment to the QMS change process, mentorship, and hospital administration support. In addition to determining the top five CSFs, the study revealed information about encountered or perceived barriers to successful QMS implementation. The participants in this study identified lack of staff knowledge on QMS, lack of financial support from the hospital administration, ineffective laboratory manager leadership knowledge and skills, lack of laboratory infrastructure, and lack of sufficient resources

The study's findings add to the body of knowledge in strengthening medical laboratory services and may serve as a basis for continued research in this area of health care. Local,

national, and international partners may use this information to tailor training materials and activities to better meet the needs of participating laboratories across Vietnam.

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KEY TO ACRONYMS

1. AJLM: African Journal for Laboratory Medicine
2. ASCP: American Society for Clinical Pathology
3. ASLM: African Society for Laboratory Medicine
4. BME: Benchmarking Expert
5. CDC: Centers for Disease Control and Prevention
6. CDC-vn: Centers for Disease Control and Prevention – the Vietnam Office
7. CSF: Critical Success Factors
8. HIV/AIDS: Human Immunodeficiency Virus, Acquired Immunodeficiency syndrome
9. ISO 15189: International Organization for Standardization 15189 specific standards for quality and competence in medical laboratories
10. MOH: Ministry of Health
11. PEPFAR: The U.S. President's Emergency Plan for AIDS Relief
12. PT: Proficiency Testing
13. QMS: Quality Management System
14. SLIPTA: Stepwise Laboratory Quality Improvement Process Towards Accreditation in the African Region
15. SLMTA: Strengthening Laboratory Management Toward Accreditation
16. VAMS: Vietnam Administration for Medical Services/Ministry of Health
17. WHO: World Health Organization

KEY TO DEFINITIONS

1. Critical Success Factors: Those factors that guide goal development which, when well-managed, significantly contribute to success. The primary benefit CSFs offer organizations are their ability to focus the organization (medical laboratory) efforts for project success. Rockart, in 1979, developed CSFs to help executives pinpoint those strategies, goals, and objectives the organization should actively promote and spend time and resources to achieve.

2. SLIPTA: According to the African Society for Laboratory Medicine Website, the Stepwise Laboratory Quality Improvement Process Towards Accreditation is "a framework of auditing developed in line with the ISO 15189:2007 Standards and to a certain extent with the 12 Quality System Essentials of the CLSI Laboratory Quality Management System Guidelines. It measures and evaluates the progress of laboratory quality systems and awards a certificate of recognition (five-star levels). It applies at baseline, during supervision, and for monitoring and evaluation of laboratory progress towards accreditation."(ASLM, n.d.)

3. SLMTA: According to the Strengthening Laboratory Management Toward Accreditation Website, the program offers structured quality improvement, and "teaches laboratory managers how to implement practical quality management systems in resource-limited settings using available resources. With a series of short courses and work-based improvement projects supported by site visits and mentoring, SLMTA design is to achieve immediate, measurable improvement in laboratories." (SLMTA, n.d.).

MANUSCRIPT DEVELOPED FOR SUBMISSION TO AJLM

A Multi-Case Analysis of Critical Success Factors in Vietnam Laboratories Working to Earn International Accreditation

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Abstract

Background: The value medical laboratory services contribute to patient healthcare has led the global community to implement a quality management system (QMS) in their laboratories as a pathway to improve quality and earn ISO 15189 accreditation. This study aims to identify the top five Critical Success Factors (CSFs) and barriers for implementing QMS in medical laboratories, especially those in developing countries such as Vietnam.

Methods: This study utilized both qualitative and quantitative research methods. Data was collected using a demographic survey, key stakeholder interview, and benchmarking interview with experts. Participant responses were sorted into exhaustive and mutually exclusive categories by the researcher and two research assistants independently. Rigorous methods measured intercoder reliability with the categorization of CSFs. Pearson's Chi square test was used to identify any association between the demographic variables and the listed CSFs, and Cohen's Kappa was used to measure intercoder reliability.

Results: The top five CSFs identified in this study were: (1) staff knowledge of QMS, (2) manager leadership knowledge and skills, (3) staff commitment to QMS project change, (4) mentorship, and (5) hospital administration support. The top five barriers identified include: (1) lack of staff knowledge on QMS, (2) insufficient hospital support, (3) Ineffective Laboratory Management, (4) Insufficient laboratory infrastructure, and (5) lack of sufficient resources. Cohen Kappa values were > 0.85 indicating excellent validity and accuracy between the assistants and the researcher. Chi-square values were all > 0.05 ($p < 0.05$) indicating demographic variables did not statistically impact findings.

Conclusions: Identifying both the CSFs and the barriers to successful QMS implementation benefits all laboratories in Vietnam working to improve laboratory services. Identifying CSFs and recognizing potential barriers was a needed step to identify those factors and barriers a manager should devote time and resources to increase laboratory accreditation success. These findings benefit partners by uncovering possible gaps in staff training and where addition of materials may offer clarity and greater depth of knowledge. This study's findings increase the body of knowledge on productive ways to improve the accuracy of laboratory services in Vietnam.

Introduction

Medical laboratories provide critical services used by physicians in decision-making processes to diagnose and treat patients. One of the President's Emergency Plan for AIDS Relief (PEPFAR) initial focus goals for developing countries included providing anti-retroviral (ARV) treatment to 2 million people. [1] To meet this goal, laboratory staff training, infrastructure and other resources were required to accurately diagnose patients positive or negative for HIV/AIDS. Laboratory services moved from the background of healthcare into the forefront**,** as accurate test reporting was paramount in identifying and controlling the spread of HIV. Infectious diseases know no boundaries, making laboratory testing vital throughout the world, whether laboratories are in developed or developing countries.[2] Unfortunately, challenges still exist and prohibit the analysis and reporting of accurate diagnostic testing.

In response to the need for more accurate and reliable diagnoses in support of the HIV care and treatment, in 2009 two programs were launched concurrently by WHO African Regional Office, the US Centers for Disease Control and Prevention, and partners: Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA). SLITPA provides a benchmark framework that measures a laboratory's level of compliance with ISO15189 requirements and recognizes its progress using a 0-5 star scale. SLMTA, on the other hand, is a training and mentoring program designed to teach the "how-to" for implementing a practical quality management system (QMS).

Previous studies [3,4, 5] evaluated the outcome of the SLMTA program by comparing baseline, exit, and surveillance audits in terms of improvement in the percentage audit scores and

star ratings. However, there is a lack of published literature identifying the critical success factors (CSFs) for effective implementation of QMS in medical laboratories in developing countries in general and specifically in Vietnam. While CSFs exist for other industries, there is little information regarding the CSFs for medical laboratories in developing countries striving to earn accreditation. Medical laboratories have their own sets of processes and interactions with other departments within the hospital organization and identifying the CSFs unique to them is paramount to improving accuracy and reliability of laboratory results.

The aim of this study is to identify the top five CSFs and barriers for medical laboratories in Vietnam to successfully implement a QMS into their laboratories to improve the accuracy of reported results and move toward earning ISO 15819 accreditation.

Research Methods and Design

This study employed a mixed design of both qualitative and quantitative methods using surveys and interviews to help determine the "why" and "how" answers to the quantitative study findings. Characteristics of the collected data were reviewed using content analysis methods and the data categorized with the purpose of formulating descriptions and phrases into conceptual categories.[6] The strength of mixed studies comes from applying qualitative findings to explain in depth the quantitative statistics.

Demographic Survey and Key Stakeholder Interview

The data collection methods for this study included demographic surveys, key stakeholder interviews, and benchmarking interviews with experts. To increase the validity of the

data collected by the study, triangulation was used by cross-checking the data collected from multiple sources.[7]

This study used stratified convenience sampling due to time and budget restraints. Four laboratories Ho Chi Minh City, Vietnam participated in this research. All labs shared three commonalities: 1) all completed the SLMTA training program, 2) all are in various stages of implementing a QMS with the goal of earning ISO accreditation, and 3) all volunteered to participate in this study.

To avoid bias in data collection, an equal number of volunteers from each lab participated in the survey and interview process. Stratified stakeholder levels included 1) personnel from each department within the laboratory, 2) laboratory managers, 3) hospital administrators, and 4) clinicians utilizing laboratory services. The total number of participants equaled 44 (N=44).

Participants first completed the demographic survey (age, gender, position, hospital level), and then responded to the interview questions asked by the researcher with translator assistance. The semi-structured interview questions asked each participant to identify, define, and rank the top five CSFs they considered critical to effective implementation of QMS in their laboratory. Each participant also identified and defined any barriers encountered during the implementation process. Finally, participants were queried as to why implementing a QMS and earning international accreditation was important and their reasons for committing to the improvement process.

Benchmarking

To increase the validity of the data collected from the study laboratories, the researcher contacted three QMS experts in Kenya, Tanzania, and Ukraine for benchmarking purposes. They

all responded to the same survey questionnaire and the interview questions. These QMS experts shared similar characteristics: (1) each was a national from a developing country, (2) each was directly involved in managing one or more QMS implementation projects, and 3) each is currently worked with laboratories reporting various levels of implementation success and ISO accreditation.

Data Analysis

The researcher and two research assistants performed a content analysis of the terms and phrases used by interview participants and derived ten mutually exclusive and exhaustive CSF categories.[8, 9] Each of them then independently sorted all listed CSFs from the participants into these categories based on word, phrase, and concepts similarities. The same process was used for the barriers.

Each CSF category was assigned a frequency response rate and a weighted value. Frequency response rates were determined by adding the number of times each study participant response matched a CSF category. The CSF category with the highest frequency response was the most important CSF. Participants were also asked to rank order the CSFs they provided from 1 to 5, with one being the most important and five being the least important. Based on the ranking, each CSF received a numerical weight value. The CSF category with the highest weighted value was the most important CSF. Cohen's Kappa was the rigorous approach used to measure intercoder reliability.[10] Pearson's Chi square statistical test was used to identify any association between the demographic variables and the listed CSFs.

Unlike the CSFs, study participants did not list a specified number of barriers**,** or rank the barriers they listed. The researcher chose to evaluate the participant responses to barriers using a frequency response rate only. As performed for the CSF evaluation, the frequency response rates

were determined for the barriers by simply adding the number of times each participant response was applied to a barrier category. This approach is not regarded as one of the more effective means to determine intercoder reliability; however, it does provide some degree of data comparison and interpretation between coders. Using this approach, the percentage agreement is calculated by dividing the number of times the research assistants and the research categorized a response into the same category, divided by the total number of responses.

Results

Each of the 44 participants provided five CSFs resulting in a total of 220 individual CSFs. Results from both the frequency and weighted ranking analyses found identical CSF content categories for the top five positions (Table 1 and Table 2).

The number one CSF from both the study participant interviews and the benchmarking interviews was staff knowledge of QMS. Specifically, all groups felt strongly that continuing education options were crucial to ensuring staff knowledge and skills implementing QMS principles. The other four CSFs identified varied in their rankings though all five CSFs were identical. Laboratory manager leadership ranked as CSF number 2 by the study participant data while all BMEs ranked laboratory manager leadership as the fourth CSF. Staff commitment to the change process necessary to implement QMS was the third CSF from the study participants and BME 3, while this CSF was ranked as number two by BME 1 and BME 2. Hospital administration support ranked fifth by the study participants but received a higher score by the benchmark experts. Based on comments from the study participants, all agreed hospital support was critical, though budgetary support was not a current reality. This perception may account for the fifth-place ranking.

Mentorship, as a CSF, was in different positions between all groups. The variation in ranking may be due to many types of mentorship options. BME 1 specifically listed embedded mentorship while the others simply listed "mentorship." When study participants discussed the mentorship at their laboratories, they all agreed on the value of the mentorship without regard to whether the mentor visited the laboratory weekly or monthly or the time spent in the laboratory at each visit. Previous articles suggested embedded mentorship, and longer mentorships resulted in better outcomes for the laboratories, though those were not the findings in this study.[4, 9] Often, due to time constraints with both the lab staff and mentor, email communication became an invaluable part of the mentorship package. The importance of this finding suggests either editing continuing education materials or demonstrating how short, frequent training can augment daily laboratory processes without affecting turn-around-time for delivering reports back to the clinicians.

Table 3 lists the top five barriers based on the frequency of 132 responses. The barrier most often listed was the lack of QMS knowledge among the laboratory staff. This lack of knowledge supports CSF (1)**,** which states laboratory staffs' need for QMS training. The other four top barriers listed include (2) lack of hospital administration support, (3) absence of effective manager leadership skills, (4) deficiencies in laboratory infrastructure, and (5) lack of resources to perform lab duties and implement a QMS. When participants described the time restraints, their replies were related to not understanding what the expectations were or how to perform new procedures according to QMS directions. As the QMS changes had become routine, the staff became more familiar with the new processes and procedures and therefore had more time. Again, this barrier is directly related to the concept of how ‘change' affects a staff. Laboratory managers listed knowledge or skills they wish they had received before becoming

managers. Though not statistically analyzed, the knowledge and skills listed were similar and worth mentioning. Only three out of the 44 participants (6.8%) reported completing a management or leadership course during their university studies. Conversely, all three of the benchmark experts reported completing at least one management or leadership course. The skills managers wished for included training on staff orientation, time management, conflict resolution, quality control, internal assessment, and effective communication. Even the three participants completing management/leadership courses, listed time management and conflict resolution as useful refresher skills.

Based on Landis and Koch,[10] this study demonstrated a strong, positive intercoder reliability (CSFs) with Kappa values between 0.85 and 0.95 ($p < .001$). The percent-agreement method applied to the barrier data resulted in overall match rates between the researcher and the two assistants of 97.5% (assistant # 1) and 98.5% (assistant # 2).

Based on a two-tailed analysis with a $p < .025$, the Chi-square test found no statistically significant associations between the top-ranked CSFs and the demographic variables listed above.

Discussion

In order to identify the top CSF for laboratories in Vietnam to successfully implementing QMS, the study employed a multi-method approach using both qualitative and quantitative methods. Content analysis was employed to sort the CSFs, according to the words, phrases, and concepts used in the definitions, into 10 mutually exclusive and exhaustive categories. Frequency ranking and weighted average ranking methods were employed to identify the top five CSFs from the interview data collected. Both methods produced identical lists of the top

five CSFs with only slight variation between the study's findings and the benchmarking data. Based on the demographic survey, key stakeholder interview, and benchmarking results, there is a significant agreement between developing-countries as to the CSFs necessary for successful implementation of QMS to improve laboratory quality and earn ISO 15189 accreditation.

Data from this study supports findings from earlier studies.[3,4, 5] All studies, including this one, linked successful QMS implementation and accreditation to hospital support, effective laboratory leadership, lab staff training, laboratory staff commitment to QMS, and mentorship.

When each study participant explained why earning ISO 15189 accreditation was important to their laboratory as well as to Vietnam itself, the responses were almost the same within each laboratory and similar between the four laboratories. These responses may be indicative of the laboratory manager's strategy, awareness of their staffs' motivational needs, or of hospital goals. In the laboratories studied, differences in manager style and communication techniques were apparent from the staff responses when asked their reasons for committing or not committing to the change process. Employees from one hospital reported their motivation came from their manager's dedication and adherence to improving patient diagnoses, treatments, and outcomes. All staff in this hospital cited reporting accurate patient results had increased the number of patients using their laboratory services**,** which increased laboratory revenues. Increased laboratory revenues offered the potential to raise salaries, improve staff ability to provide for their families, and ultimately increase their retirement benefits.

Staff from another hospital reported the purpose of implementing QMS into their laboratory processes was to improve the accuracy of reported patient tests, earn ISO 15189 accreditation, and thereby gain peer recognition for working in an internationally accredited laboratory. Staff in the third hospital in this study experienced multiple staff turnovers, and at

the time of the interviews, the researcher found no staff consensus on commitment or motivation to achieve success. The laboratory staff in this hospital reported even though they all worked together as a team to improve their laboratory, the hospital administration simply did not have the necessary funding to support their improvement efforts.

Staff participants in H4 responded earning ISO 15189 accreditation gained global recognition for their laboratory and made inter-country collaboration on research studies possible. Study participants from all four laboratories commented that if patients moved from one hospital to another in Vietnam and both laboratories held ISO accreditation, laboratory tests did not need repeating thereby saving the patient both time and money. The inverse was true between ISO accredited and non-accredited laboratories. When asked to select their manager's leadership style most participants (40/44 = 91%) selected the situational leadership choice. The situational leader believes there is no single "best" style of leadership. Effective leadership is task-relevant, and the most successful leaders are those that adapt their leadership style to the maturity of the individual or group they are attempting to lead or influence.

Limitations

This research study focused on a small number of laboratories located in one city in Vietnam. While these findings may or may not be representative of laboratories throughout Vietnam, a larger study involving more laboratories representative of each region might find variations in the CSFs and barriers identified here.

A translator assisted the author of this research in the interpretation of the response terms and phrases reported by study participants. For clarity and to minimize variations in the cultural understanding of similar words in Vietnamese and English, the researcher and translator

reviewed each participant's response to ensure accuracy and consistency in translation. A small degree of unintentional bias is possible.

Asking study participants to make a forced ranking by only listing one CSF for each position is another limitation. What if a participant wanted give equal importance to two CSFs they list? This option was not included. This study used simple weights. A CSF mentioned by 15 participants as least important may have a heavier weight than a CSF listed by only two participants as the most important.

Conclusions

The strength of this study lies in the close alignment of the identified CSFs and barriers between the study participants in Vietnam and the benchmark experts in three other developing countries. Analysis of the CSFs and barriers in this study noted three of the barriers listed were antithetic to their corresponding CSF. This finding may indicate staff desire for implementing a QMS once barriers are removed. One of the listed barriers is a perceived**,** or real**,** lack of knowledge or skills for both laboratory managers and laboratory staff on QMS. Stakeholders, partners, and hospital administrators should acknowledge this finding and consider prioritizing support to eliminate this gap of knowledge. Sharing the top five CSFs and barriers identified in this study with laboratories in other developing countries considering QMS implementation and accreditation may provide positive guidance and eliminate some barriers. Data from this study can strengthen laboratory services throughout Vietnam and act as a guide for the development of new materials for dissemination and strengthening the improvement process.

Acknowledgments

This study had the approval of the VAMS and assistance from CDC-Vietnam. In 2017, there was a concern among Vietnam stakeholders about why laboratories experienced varying levels of success implementing QMS and why not all laboratories were earning ISO 15189 accreditation. This study offers insights into that concern.

Additional Forums

In addition to this manuscript, it is anticipated that its author and committee members will develop other manuscripts for publication.

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Table 1: Top Five Critical Success Factors by Rank (Weighted Average)

Rank	Critical Success Factor	Weighted Ranking
1	Staff Knowledge of QMS	.290
2	Laboratory Manager Leadership Knowledge	.215
3	Staff Motivation to Change Process	.163
4	Mentorship	.115
5	Hospital Administration Support	.088

Table 2: Top Five Critical Success Factors by Frequency Score

Rank	Critical Success Factor	Frequency Score
1	Staff Knowledge of QMS	43
2	Lab Manager Leadership Knowledge and Skills	41
3	Staff Motivation to Change Process	37
4	Mentorship	35
5	Hospital Administration Support	32

Table 3. Top Five Barriers to QMS Implementation Success by Frequency Score

Rank	Barrier	Frequency Score
1	Lack of Staff knowledge on QMS	41
2	Insufficient Hospital Administration Support	39
3	Ineffective Laboratory Management Leadership	31
4	Insufficient Laboratory Infrastructure	28
5	Lack of Sufficient Resources	27

Table 4. Benchmarking vs. Study Participants Comparison of Top Five CSFs

Vietnam Staff	BME 1	BME 2	BME 3
1. Staff Knowledge of QMS	1. Staff Knowledge of QMS	1. Staff Knowledge of QMS	1. Staff Knowledge of QMS
2. Lab Manager Leadership	2. Staff Motivation to Change Process	2. Staff Motivation to Change Process	2. Hospital Admin Support
3.Staff Motivation to Change Process	3. Hospital Admin Support	3. Mentorship	3. Staff Motivation to Change Process
4. Mentorship	4. Lab Manager Leadership	4. Lab Manager Leadership	4. Lab Manager Leadership
5. Hospital Admin Support	5. Embedded Mentorship	5. Hospital Admin Support	5. Mentorship

Table 5. Benchmarking vs. Study Participants Comparison of Top Five Barriers

Vietnam Study	BME 1	BME 2	BME 3
1. Lack of Staff Knowledge of QMS	1.Lack of Staff Knowledge of QMS	1. Lack of Staff Knowledge of QMS	1. Lack of Staff Knowledge of QMS
2. Insufficient Hosp Admin Support	2. Insufficient Lab Infrastructure	2. Insufficient Hosp Admin Support	2. Insufficient Hosp Admin Support
3. Ineffective Lab Manager Leadership	3. Insufficient Hosp Admin Support	3. Insufficient Lab Infrastructure	3. Lack of Resources
4. Insufficient Lab Infrastructure	4. Ineffective Lab Manager Leadership	4. Ineffective Lab Manager Leadership	4. Ineffective Lab Manager Leadership
5. Lack of Resources	5. Lack of Resources	5. Lack of Resources	5. Insufficient Lab Infrastructure

CHAPTER I

INTRODUCTION

Overview

Currently, limited scientific research exists about medical laboratories in developing countries implementing quality management systems with the goal of earning laboratory accreditation. The problem presented in this research is determining those factors laboratory staffs in Vietnam cite as critical to successfully implementing QMS and to improve laboratory accuracy and services. Accredited laboratories in other developing countries include national reference laboratories, provincial laboratories, HIV-laboratories, and district laboratories, suggesting neither the level of the laboratory nor its testing menu is the primary factors for achieving accreditation. Laboratory testing in developed and developing countries is vitally important to patient diagnosis, treatment, and healthcare in general. A mixed study using qualitative and quantitative analysis identified critical success factors.

Research Needs

It is essential for organizations to understand the critical impact CSF identification or lack of identification can have on an organization (O'Sullivan, 2008). Essential practices and processes that may be essential to the survival of an organization may never surface without going through the process of identifying CSFs. Goldstein (1995) recommended that instead of using generic CSF models, healthcare leaders should locate organization-specific CSFs. Unfortunately, there has been little published on CSFs for medical laboratories. This study identified success strategies by conducting interviews at four laboratories in Vietnam. Data from this study can strengthen laboratory services throughout Vietnam and guide design and

development of new materials for dissemination in additional laboratories and in other developing countries.

In developing countries, there are often barriers affecting the laboratory's ability to implement quality management practices into daily operations such as financial constraints, political decisions, cultural considerations, and staff knowledge and competency. Discussions with CDC-Vietnam and VAMS (MOH) resulted in four medical laboratories in Vietnam agreeing to participate in this study. These laboratories selected for this study completed all components of the SLMTA Program training. The SLMTA training package is prescriptive assuring similar didactic and practical training for staff at all four hospitals while limiting training variables. The four hospitals in this study are coded to ensure confidentiality. Table 1 shows the hospital laboratories participating in this study along with their current quality status.

Table 1. Vietnamese Hospitals Participating in This Study

Hospital Identification	Level of Hospital	Completed SLMTA Training Program	Current Laboratory Status
H1	City Level	Yes	Currently, ISO 15189 accredited for laboratory tests participating in QC and EQA programs
H2	City Level	Yes	In the process of ISO accreditation for laboratory tests participating in QC & EQA programs
H3	City Level	Yes	Barriers impeding QMS implementation currently (infrastructure, administration support, staff turnover)
H4	District Level	Yes	Earned four stars in 2016, Working toward to ISO 15189 Accreditation

The HIV/AIDS epidemic received priority from the United Nation's Security Council as a global threat to world peace and security in 2001. This recognition was the first time the world's

top political body addressed a health and development issue ("AIDS as a security issue," 2001). The Security Council stressed the need to address the spread of the HIV during peacekeeping operations. In 2003, the US Congress authorized the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to combat global HIV/AIDS - the largest commitment by any nation to combat a single disease in history (Sessions, n.d., p. 142). This commitment is "a United States government initiative to address the global HIV/AIDS epidemic and help save the lives of those suffering from the disease…" (Five-Year Strategy Fact Sheet for HIV/AIDS, para. 3).

Global Health History

There have been two major trends that shaped global health organization activities in the past five centuries: population health through the control of infectious diseases and individual health through the delivery of healthcare. In the 16th and 17th centuries, European countries began traveling to new lands and establishing settlements. Faced with infectious diseases and harsh climates, both native populations and the European colonists suffered devastating epidemics and thousands of deaths. In response, the practice of Tropical Medicine developed as the medical field advanced and applied new ideas, like germ theory, in the fight against diseases. Tropical Medicine physicians needed to provide medical services in the colonies, where innovations in healthcare at both the population and individual level occurred. During both World Wars, the military was responsible for establishing medical facilities to care for both their members and the native populace. An example is the beginning of medical care in Vietnam as the United States military set up their bases to provide medical care for their soldiers. As colonial medicine was expanding at the population level, religious organizations were also sending missionaries to colonies, which began to offer individualized medical services. Tropical

medicine encompasses the international health measures between imperial nations and their territories. At about this same time, countries began to see the need for collaboration for effective health policies (Palilonis, 2015, p. 3).

Nowhere in the history of global healthcare is there a reference to laboratory services. Meanwhile, as laboratory data was gaining value and use to support empirical diagnosis in developed countries, developing countries struggled to fund resources for basic health care.

Role of Medical Laboratories in Global Healthcare

Clinical diagnosis, treatment, and disease management was often based primarily on the clinician's appraisal of the patient in developing countries (personal communication with clinicians in Namibia and Lesotho, 2013). Clinicians relied heavily on their appraisal of the patients and their symptoms, and less on unreliable laboratory reports not supporting the empirical diagnosis (AJCP, 2015). Identifying the HIV status of patients demanded accurate diagnostic testing and catapulted the medical laboratory into the forefront of medical diagnosis and care and treatment monitoring. With little knowledge and no funding to improve medical laboratory infrastructure, laboratories could not support their new status that demanded accuracy and reliability in reporting.

Medical laboratories provide critical services. In the United States, the Centers for Medicare & Medicaid Services report laboratory testing occurs for 98% of hospital admissions (Woodcock, Fine, McClure, Unger, & Rizzo-Price, 2010). Further, the report stated "Laboratory testing is no less important in laboratories around the world, whether they are in developed or developing countries" (Woodcock et al. 2010). Unfortunately, there are challenges in many countries prohibiting the analysis and reporting of reliable diagnostic testing. Infrastructure, lack

of staff and manager knowledge**,** and training on quality management systems, reagent stock shortages, and quality control deficiencies are but a few of the challenges affecting the quality of laboratory services. Despite evidence that National Laboratory Services (NLS) are required to meet universal access for treatment of HIV/AIDS, these services remain one of the "most neglected components of the health system in resource-poor countries" (Nkengasong et al., 2010, p. 369). Laboratory results should be accurate and reliable for every patient and every specimen. Clinical diagnosis without quality laboratory testing often leads to significant misdiagnosis resulting in unnecessary or inappropriate treatment, drug resistance, or mortality (Nkengasong et al., 2010, p. 369).

To address challenges in quality laboratory testing and reporting, representatives of countries, governments, multilateral agencies, development partners, professional associations, and academic institutions participated in a series of international meetings Alemnji, G. A., Zeh, C., Yao, K., & Fonjungo, P. N. (2014). Outcomes of these meetings included declarations and initiatives to bring laboratory systems improvement to the forefront of health systems strengthening.

The Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization convened in Maputo, Mozambique in January 2008 ("The Maputo Declaration," 2008, p. 1). There were two important outcomes from this meeting. Identification of challenges faced by resource-limited countries supported the initiative to implement quality management systems (QMS). The second outcome was the recognition that integration of laboratory support for tuberculosis, malaria, and HIV disease programs were crucial to sustain improvements as part of the overall health system from a public health perspective (p.2). The Maputo Declaration outcomes successfully gained global recognition of the challenges resource-limited countries

faced trying to improve their inadequate laboratory systems and support the scale-up of health care programs. During the Maputo meeting, national governments were urged to establish a department of laboratory systems within their Ministry of Health departments to prioritize support for laboratory systems. Finally, the Maputo Declaration endorsed four actions to strengthen National Laboratory Services. Actions taken in developing countries were: (1) cultivate comprehensive national laboratory plans and policies; (2) establish public-private partnerships; (3) launch field epidemiology and laboratory training programs and centers of excellence to meet short- and medium-term laboratory training and retention goals. And, (4) implement practical and affordable quality management systems, accreditation, and improve clinician and laboratory interactions (Nkengasong et al., 2010, p. 372).

Following the 2008 meeting in Mozambique, government health officials from 13 African countries met again in Rwanda in 2009. The outcome of the Rwandan meeting included a push for laboratories in resource-limited countries to begin strengthening their laboratories and health systems. The Rwanda meeting went one step further suggesting laboratories work toward international accreditation after successfully implementing quality management systems.

Laboratory accreditation has emerged as the preferred framework for measuring quality between medical laboratories. After mostly successful implementation of quality management systems into daily laboratory practice, countries and laboratories gained confidence to continue implementation of standards with the goal to reach International Standardization Organization (ISO) 15189 accreditation. ISO is a worldwide federation of national standards bodies known collectively as ISO member bodies. ISO works closely with the International Electro-Technical Commission (IEC) about matters of electro technical standardization. ISO 15189:2012, based on

ISO/IEC 17025 and ISO 90001, specifies requirements for competence and quality specific to medical laboratories ("ISO 15189:2012," n.d.).

Accreditation based on ISO 15189 standards was introduced slowly and first offered to laboratories on a volunteer basis. Laboratories not volunteering were provided the opportunity to participate in workshops developed to educate laboratory managers and staff in how to implement a simplified quality management system.

As more laboratory equipment and automation became available, the medical laboratory increased its options to expand testing menus and methods. More hardware and resources aided in diagnosing patient HIV status, monitoring the effectiveness of treatment protocols, and identifying secondary conditions associated with HIV infections. The outcomes from the Maputo and Rwanda meetings in combination with increased global awareness of the HIV pandemic accelerated donations and offers of assistance from many countries and partners.

PEPFAR Countries

The fifteen original PEPFAR-SUPPORTED countries had high HIV infectivity rates using WHO criteria (World Bank Data Team, 2015). Table 2 lists the fifteen original PEPFAR-SUPPORTED countries.

Table 2. Original 15 PEPFAR Countries

Botswana	Kenya	South Africa
Cote d'Ivoire	Mozambique	Tanzania
Ethiopia	Namibia	Uganda
Guyana	Nigeria	**Vietnam**
Haiti	Rwanda	Zambia

Source: 2006-2009 Archive for the U.S. Department of State

To build capacity to analyze, identify, diagnose, and monitor the HIV status of patients, laboratories in these countries required complete renovation and better training of professional laboratory staffs. According to the American Journal of Clinical Pathology (2015), few developing countries have established laboratory quality standards (Gershey-Damet et al., 2010). "Laboratories form the backbone of health systems around the world, providing physicians and other healthcare workers with results of a battery of tests for deadly diseases" (Woodcock, Fine, McClure, Unger, & Rizzo-Price, 2010, p. 388). According to data from the Centers for Medicare & Medicaid Services, laboratory testing occurs for 98% of hospital admissions in the United States and other developed countries. This high percentage demonstrates the importance of laboratory testing and supports its role in patient diagnosis and treatment. Laboratory tests are often more sensitive and specific than clinical decision criteria alone (Peter, T. F., Rotz, P. D., Blair, D. H., Khine, A., Freeman, R. R., & Murtagh, M. M., 2010). In his editorial, Nkengasong states laboratory testing is an essential component of improved health care for patients in resource-limited settings (Nkengasong, 2009, p. 550). His article continues to say laboratories in developing settings are often under-resourced, and clinicians report not trusting reported test results. The lack of clinician and patient trust promotes under-investing in improving lab services.

Many laboratories in all 15 PEPFAR-supported countries have implemented quality management systems to some degree due to the high demand for diagnostics to meet the needs of expanded treatment and prevention programs for HIV and other major diseases. Public and private partnerships in addition to PEPFAR funding aided some countries by increasing training opportunities and mentorships to sustain implemented improvements. However, the question remained as to why some labs were able to gain staff commitment and move forward more

quickly than other labs. Studying these laboratories provided insight into those factors considered critical for successfully advancing laboratory quality. Equally important was identifying those factors presenting the most significant challenges to quality management implementation.

While visiting laboratories in Africa and Southeast Asia between 2007 and 2018, the author toured medical laboratories with little to no existing infrastructure, no clean water sources, and no stable electricity. There were, however, numerous high-tech instruments, covered in plastic, without consumables or supporting equipment, and no controls or standards. When asked, the laboratory managers replied donors, public or private, only had approval by their respective Board of Directors to purchase equipment for laboratories as equipment is more easily monitored and provides services for years versus consumables that expire in 4-6 months. The automated machinery often sat idle without consumables or trained staff to operate them. Other laboratories visited had similar challenges, yet, were able to come together as a cohesive laboratory team and overcome the obstacles and move forward with improvements. There are articles written by individuals in some African countries describing the successes and challenges they faced while implementing QMS into their daily laboratory services (Andiric, L. R., & Massambu, C. G.; Maina, R. N., et al, 2014) The VAMS in Vietnam is interested in comparing the success factors and problems reported in African countries with those found in this study of Vietnam laboratories.

Accreditation Requirements

The July 2008 reauthorization of PEPFAR in the United States included a new requirement for reporting on specific indicators of progress related to laboratory improvement:

The number of labs supported, and the number of labs accredited. The number of laboratories accredited is a key indicator used to measure progress made in strengthening laboratory systems in developing countries. The successful Kigali meeting introduced a blueprint of the path toward accreditation. By obtaining key stakeholders' support for laboratory accreditation, this meeting highlighted a task-based, training program designed to make accreditation a reality using a stepwise method.

Benefits of Accreditation

Accreditation in this study is verification by an outside entity that the laboratory follows best practices in all aspects of its testing services. Laboratory accreditation provides tangible evidence laboratories are adhering to established quality and competency standards as defined by national and international organizations (Peter et al., 2010, p 552). Error reduction is possible by implementing and monitoring a laboratory comprehensive quality management system. While there is little-published data linking accreditation to reduced laboratory errors, there are studies that show laboratory participation in Proficiency Programs lead to increased accuracy in reported patient test results (Peter et al., 2010). Participation in a Proficiency Testing program (PT) is a crucial component of accreditation. Furthermore, laboratories must pass all PT specimen analyses with a minimum 80% accuracy.

Many researched articles supported laboratory accreditation stating, "International standards are an important source of technological information for developing countries and offer economic and societal benefits ("ISO and developing countries, n.d.). Developing countries can use international standards to access knowledge in areas where they have identified lack of expertise and resources.

Medical laboratories play a central role in health care and are taking a focused and stringent approach to quality system management (Jang et al., 2017, p. 213). Korea's recent study on the accuracy of laboratory values, between 2010 and 2013, does provide positive support for the benefit of laboratory accreditation. The Korean Laboratory Accreditation Program (KLAP) and the Korean External Quality Assessment Scheme (KEQAS) monitor and accredit standardization of laboratories. Since there were no prior fundamental studies showing laboratory standardization (and accreditation) is useful, their study sought to prove or disprove this hypothesis. KLAP researchers' analyzed results from 19 chemistry parameters measuring variance index score (VIS) for each parameter from the KLAP accredited laboratories versus the unaccredited laboratories. Comparison results showed the accredited laboratories group produced significantly lower geometric means ($P<0.0001$) with lower VIS scores. Their findings justify a higher level of confidence in the values reported by accredited laboratories (Jang et al., 2017, p. 215). Jang et al. concluded that laboratory standardization and the accuracy of test results cannot be treated separately.

With the increased number of international travelers, laboratories quickly became center stage in not only providing test results supporting medical diagnosis for all nationalities but also in monitoring treatments and conditions from one locale to another. The demand for laboratory services in developing countries increased exponentially in recent years to meet the needs of expanded treatment and prevention programs for HIV, TB, malaria, and other diseases. This need motivated country and ministry investment in improving access to testing, improving quality and accuracy of testing results, and expanding test menus in all facilities. Accreditation benefits serve as significant motivators in developing countries that want to encourage or enforce improvements in the quality and reliability of laboratories. For example, for a patient with HIV,

their CD4 cell count provides information needed by the clinician to stage the disease and prescribe appropriate treatment correctly. If the CD4 results are inaccurate, treatment outcomes for the patient are likely to be poorer, with more illnesses and higher mortality. (Peter et al., 2010, p. 551).

In their article titled "The Impact of Laboratory Accreditation on Patient Care and the Health System," Peter et al. state, "Accreditation is emerging as a preferred framework for building quality medical laboratory systems in resource-limited settings" (Peter et al., 2010, p. 550). Even though there are few accredited laboratories to date, laboratory accreditation has the potential to improve health care quality by reducing testing errors. As laboratories in developing countries become accredited, they will also become more accountable and sustainable. Peter et al.'s 2010 study indicates that as laboratories implement a QMS into their daily practices, other hospital departments may follow their example of quality service delivery yielding increased quality of care across all sections of health care including patient satisfaction. Accurate laboratory testing, in addition to addressing HIV/AIDS, TB, and malaria, also impacts the quality of testing for many other diseases including non-communicable conditions such as diabetes and heart disease. As people are living longer with HIV/AIDS and TB, medical attention now focuses on conditions related to lifestyle, environment, and nutrition (Shi & Johnson, 2014, Chapter 3).

Laboratory testing involves several consecutive steps for many procedures with an error at any stage resulting in an inaccurate result and possible incorrect diagnosis. Studies in the United States and Europe have documented up to 12% laboratory errors putting patients at risk of inappropriate care and up to 30% of errors that had a negative impact on other aspects of patient care (Nutting et al., 1996). Errors can occur at any point in the testing process, including

pre-analytical (specimen collections, transport, processing), analytical (quality control and analysis), and post-analytical stages (reporting and storing). Implementing quality management protocols into laboratories reduces errors by making them more visible and easier to detect before releasing the results. Miligy, a medical school professor in Cairo, Egypt, reported similar findings in his study performed in a private hospital in Cairo, Egypt in the International Journal of Health Care Quality Assurance (Miligy, 2015).

Unfortunately, many clinicians in developing countries report they lack confidence in laboratory results due to the inaccuracy of results as well as delays in receiving results (personal interview with clinicians in Namibia, Kenya, Ethiopia, Lesotho, Vietnam, 2012-2015). Consequently, these clinicians rely on clinical diagnosis and empirical treatment instead of laboratory-confirmed results (Nkengasong et al., 2010, p. 369). The problem with the clinical diagnosis without quality laboratory testing is the possibility, in many cases, of either misdiagnosis or over-diagnosis, which leads to inadequate or inappropriate treatment, drug resistance, and higher mortality rates (Nkengasong et al., 2010, p. 369).

Peter et al. state international standards are the backbone of accreditation as they offer the framework for laboratories to establish standards in daily processes. ISO began operations in February 1947 and today has grown to a confederation of delegates representing over 150 countries and 16,500 international standards published.

Each standard supports a specific industry. However, the universal benefits across the certifications include widened market potential, compliance to procurement tenders, improved efficiency and cost savings, a higher level of customer service, and therefore satisfaction, and heightened staff morale and motivation. A recognized management standard tells your customers that you are serious about their needs ("What is ISO?" n.d.)

ISO 15189:2012 has gained worldwide recognition as a reference standard for medical laboratories (ILAC, 2017). As developing countries initiated improvements and implemented quality management systems into their laboratories ISO 15189:2012 became recognized as the 'gold standard' for quality in medical laboratories" (Boucher, 2015, p. 3). He also states, "Laboratories must use the ISO standard to move toward accreditation to ensure the trust of patients and to gain national and international respect" (Boucher, 2015, p. 3).

Vietnam Medical Laboratory Status

Vietnam, one of the original fifteen PEPFAR-supported countries, is a Southeast Asian country. Its size is roughly three times the size of Tennessee and slightly larger than New Mexico (https://www.cia.gov/library/publications/the-world-factbook/geos/vm.html, 12-14-17). There are over 2,000 medical laboratories within four levels of laboratory services: National, Regional, Provincial, and District. Laboratory services exist in hospitals, public health facilities, and tuberculosis and HIV centers within each level. These facilities receive funding from the government, private sector, faith-based organizations, or the military. Presently, Vietnam's focus prioritizes improving laboratories at the national, provincial, and regional levels which include 600+ laboratories. The Ministry of Health (MOH) has taken an active and visible role as a stakeholder by supporting improvements and issuing mandates for laboratory improvement. Circular No. 01/2013/TT-BYT issued by the Ministry of Health in 2013 is a guideline for the implementation of quality management in medical laboratories, mandating implementation of quality management systems in all healthcare facilities with laboratories (VAMS, 2013). Assessments conducted in both northern and southern laboratories found varying levels of

compliance with many laboratories reporting difficulty interpreting the standards (Robinson assessment reports to ASCP).

The wording and terminology used in the SLIPTA checklist proved challenging to translate into Vietnamese and was difficult for assessors to apply objectively during laboratory audits. To alleviate this problem, the MOH issued Decision No. 2429/QD-BYT promulgating criteria for quality level assessment of medical laboratories (personal conversation with Dr. Bui, May, 2018). The criteria were based on the WHO SLIPTA and ISO 15189 standards, meet the same international standards, but uses terminology easily interpreted by Vietnamese laboratorians. All recent policies issued by the MOH now include goals and indicators to motivate laboratories to meet ISO standards. For example: Decision No. 316/QD-TTg was issued by the Prime Minister's office in 2016 upon approval of the proposal for improvement of quality management system capacity in medical laboratories in the period between 2016 and 2025 (personal conversation with Dr. Bui, May, 2018)

Vietnam was one of the first countries to build laboratory capacity by developing their own national training team. Laboratory managers and staff from provincial level laboratories trained together in cohorts. Provincial laboratory graduates were then responsible for providing training on quality management principles to staff in the district laboratories within their provinces. Employing this method, more laboratories, and staffs get quality management training, and more laboratories reach their goal of measurable improvement in over 2,036 laboratories.

A Vietnam country initiative developed between 2009 and 2013 called for universities with medical departments to improve training curriculum for their medical laboratory science programs. Faculty from seven universities held curriculum review and

revision workshops to ensure curriculum requirements included quality management systems training. The Vietnam MOH created two Laboratory Quality Control Centers supporting the improved university training curriculum for medical laboratory science programs. Students now receive both knowledge and skills related to quality management systems and management and leadership preparing them for entry level laboratory positions. The participants in this study did not indicate taking management or leadership courses prior to this study indicating a future study might find differences in this demographic survey question. This initiative allows students to graduate with knowledge and skills in QMS. A recently developed master's program offers additional knowledge and skills in laboratory management. This revision to medical laboratory curriculum requires some time before the graduates become laboratory managers. Including the curriculum revision in their country plan demonstrates Vietnam's commitment to strengthening laboratory systems and providing for future human resource capacity. While benefits from the QMS course materials are not noticeable yet, it is anticipated in the next five to ten years laboratory staff and managers will be equipped with knowledge and skills to maintain and sustain the implemented QMS and international ISO 15189 accreditation.

CHAPTER II

METHODOLOGY

Overview

This study answered the research question employing both qualitative and quantitative methods using the principles of descriptive research. Descriptive research is conducted to study and summarize characteristics as completely and accurately as possible with the purpose of formulating these descriptions into conceptual categories (Shi, 1997). Qualitative research methods are increasingly being used in healthcare research.

Pope and Mays suggest that sampling strategies should be determined by the purpose of the research project.[12] Mays and Pope, as cited in Pope and Mays, suggest that statistical representativeness is not normally sought in qualitative research and the size of the sample requires no need to be calculated by set rules.[9] For these reasons, specific statistical methodology was not utilized for this research study. Rather, the sampling methods used were determined by the characteristics of medical laboratories in developing countries: a new field of study and practice without a common definition that is supported by a limited scope of (laboratory) professional participation.

Descriptive research allowed the researcher to integrate both qualitative and quantitative methods of data collection. Qualitative research methods were designed to address questions of meaning, interpretation and socially constructed realities. Quantitative research methods ensured objectivity and reliability in the data generated, allowing it to be generalized to a larger population.

Research Design

This study answered the research question employing both qualitative and quantitative methods using the principles of descriptive research. Descriptive research collected data utilizing demographic surveys, interviews, and benchmarking. Characteristics of the collected data were reviewed using content analysis methods and the data categorized as completely and as accurately as possible with the purpose of formulating descriptions and phrases into conceptual categories.[13] Pope and Mays suggest that sampling strategies should be determined by the purpose of the research project.[12] Mays and Pope, as cited in Pope and Mays, suggest that statistical representativeness is not normally sought in qualitative research and the size of the sample requires no need to be calculated by set rules.[9] For these reasons, specific statistical methodology was not utilized for this research study. Rather, the sampling methods used were determined by the characteristics of medical laboratories in developing countries: a new field of study and practice without a common definition that is supported by a limited scope of (laboratory) professional participation.

Descriptive research allowed the researcher to integrate both qualitative and quantitative methods of data collection. Qualitative research methods were designed to address questions of meaning, interpretation and socially constructed realities. Quantitative research methods ensured objectivity and reliability in the data generated, allowing it to be generalized to a larger population. The strength of mixed studies comes from applying qualitative findings to explain in depth the quantitative statistics.

Sampling Methodology

Ritchie and Lewis (2003) suggested members of a sample should be "chosen with a 'purpose' to represent a location or type about a key criterion" (Westrum, 2010). Regarding sampling, this study's goal was to include all stakeholders involved in the implementation of a QMS in four Vietnamese laboratories. This study used stratified-convenience sampling. Utilizing stratified sampling enabled the researcher to gather data from each of four levels of stakeholders relevant to this study (Marshall, 1996). The four stratified levels included: (a) laboratory staff, (b) laboratory management, (c) hospital administration, and (d) physicians utilizing laboratory services. "Convenience sampling is a non-probability-based sampling method where subjects are selected because of their convenient accessibility and proximity to the researcher" ("Convenience Sampling," n.d., p. 1). The unit of measure for this study was the CSF listed by each study participant completing the interview.

The purpose of the demographic survey and interview were to solicit each participant's identification of the top five CSFs for success in improving laboratory quality and earning ISO 15189 accreditation. The participants also identified any barriers encountered or perceived to challenge the successful implementation of a QMS into medical laboratories with or without gaining ISO 15189 accreditation.

Demographic Survey and Interview Sample

While in Vietnam assisting Vietnam healthcare professionals with laboratory training, this researcher and government officials determined that convenience sampling of four laboratories in Ho Chi Minh City would meet the needs of both the government and this researcher's study. Hospital administrators and laboratory managers from four hospitals

volunteered to participate in the study. All laboratories shared three common characteristics, helping to minimize study bias resulting from confounding variables. These three characteristics included (1) completion of the SLMTA training program, (2) implementation, though in various stages of QMS with the goal of earning ISO accreditation, and (3) agreement to participate voluntarily. Additionally, an equal number of participants from each laboratory participated in the demographic survey and interview process. The total number of participants equaled 44 (N=44) and all participants completed both the demographic survey and interview components yielding a 100% response rate. This high response rate is most likely attributable to the volunteer status of the medical laboratories and the individual study participants. Table 3 shows the breakdown of study participants by category.

Table 3. Study Participants by Category

Category	No. of participants
Laboratory staff	20
Laboratory management	12
Hospital administration	8
Clinicians utilizing laboratory services	4

Benchmark Sample

Benchmarking involves the identification of industry best practices for improving organizational performance. As the improvement of laboratory services in developing countries is a relatively new field of study, the researcher chose QMS experts in other developing countries concurrently implementing the QMS programs. There were no published CSF studies found related to implementing a QMS in medical laboratories in developing countries specifically.

Therefore, the researcher contacted respected and expert directors currently implementing QMSs in Kenya, Tanzania, and Ukraine. The QMS experts selected to participate in the benchmarking sample met three criteria: (1) each was a national in their country, (2) each was directly involved in managing one or more QMS implementation projects, and (3) each worked with laboratories reporting various levels of implementation success and ISO accreditation. Each benchmark expert signed an IRB consent form before responding to the same survey and interview questions.

Demographic Survey Administration

All demographic surveys and interviews conducted by this researcher occurred with assistance from a Vietnamese translator, highly fluent in the English language. Though the participants spoke some degree of English, using a survey translated into Vietnamese increased their comprehension of the questions and the accuracy of their responses. The researcher utilized a translator and peer previously used on many occasions in the delivery of QMS materials to assist with the translation of participant responses from the demographic survey and interpretation of responses in the interview. After each laboratory visit concluded, the researcher and translator reviewed the data collected a second time to ensure accuracy in translation and comprehension.

Survey and Interview

Both the surveys and interviews used the same questions for all participants. Appointments were scheduled with each of the four laboratory managers to ensure adequate time for staff to complete both the survey and the interview without interfering with laboratory duties or services.

The demographic survey asked participants both personal and professional questions. Each participant was asked their age, gender, their position in the laboratory, and the level of the hospital where they were employed. The open-ended interview questions prompted the participants to identify the top five CSFs they considered necessary for successful implementation of a QMS into their laboratories. Following the suggestion by Friesen and Johnson (1995), the researcher limited the list of CSFs to identify factors that were most important. Each study participant defined and ranked selected CSFs. The participants prioritized their responses employing a weighted ranking of the CSFs they identified using a numerical scale, where the number one CSF was the most important and the number five CSF was the least important. Additionally, study participants provided their opinions about any barriers they encountered and perceived to pose a challenge to successful QMS implementation.

Benchmark Survey and Interview

Benchmark interviews took place while the researcher was in two countries and via email conversation for the demographic survey and interview responses with the third QMS expert. Each expert completed the same demographic survey and interview questions as the participants. A further discussion included opinions about the barriers encountered during the processes of QMS implementation and earning ISO 15189 accreditation. The benchmarking interviews were conducted in English, as all experts were fluent in the English language. These experts offered an excellent degree of insight into both the critical success factors and barriers to the implementation of QMS helping confirm the findings presented in this study in Vietnam.

Data Collection

The data collection process for this study included conducting demographic surveys and interviews, benchmarking interviews, and evaluating the results. In order to ensure a reasonable degree of validity in the data collected by the study, a triangulation approach was used. As defined by O'Donoghue and Punch (2003), triangulation is a "method of cross-checking data from multiple sources to search for regularities in the research data."

The collection process incorporated several discrete steps. The first step was to gain approval from the Ministry of Health (MOH) and the Vietnam Administration for Medical Services (VAMS) to conduct the study. Second hospitals volunteered to participate and agreed to the reporting of aggregate findings only. Next, the laboratory manager approved staff participation. Before the researcher entered the hospitals and laboratories, the VAMS sent an authorization letter to each hospital and laboratory granting the researcher permission to conduct the demographic surveys and interviews. A copy of the authorization letter is in Appendix C, page 94. Next, the four laboratory managers selected a day when there would be adequate time for staff to complete both the demographic survey and the interview without interfering with laboratory services. A private room at each laboratory was reserved to ensure participant confidentiality. Using a stratified approach, participants from four levels within each hospital and laboratory completed the survey and interview. Participants included staff from each laboratory department as well as the laboratory manager (or representative), a clinician using the laboratory services, and a representative from the hospital administration.

Each participant received an explanation about the demographic survey and interview questions before signing an informed consent form and beginning the survey. A copy of the Adult Informed Consent Form (English) is in Appendix C, page 95, and the Vietnamese version

on page 97. The hospital and laboratory staffs voluntarily agreed to participate in this study resulting in a response rate of 100%, with a total of 44 respondents representing all levels of laboratory stakeholders. The average time for completion of both the demographic survey and interview was 35 minutes.

Survey participants first completed the demographic survey and then responded to the interview questions asked by the researcher with translator assistance. The semi-structured interview questions asked each participant to identify, define, and rank the top five CSFs they considered critical to successful implementation of QMS into their laboratory. The demographic survey and interview forms are in Appendix C, page 100. Each participant also identified and defined any barriers encountered during the implementation process. Finally, participants were queried as to why implementing a QMS and earning international accreditation was important and their reasons for committing to the improvement process change. The researcher informed each participant all responses would remain confidential and all study results would be reported in aggregate form only.

The benchmark interviews consisted of sharing the aggregate results from the demographic surveys and interviews in this study with each country QMS expert. Each offered opinions about the results of the research study findings. Experts' opinions were kept confidential and not shared between the experts. The benchmark experts then answered the same survey and interview questions as the other participants. A summary discussion concluded with each expert offering further insight into their opinions on CSFs in improving laboratory services and the impact International ISO 15189 accreditation exerted on laboratory services specifically, and on health care overall.

This study asked participants for demographic information including gender, age range, education, and position in the laboratory. The semi-structured interview asked participants to list the top five success factors they perceived as critical for successful implementation of QMS into daily laboratory activities. Open-ended questions yielded definitions and other descriptive terms of the CSFs participants listed. Lastly, open-ended questions identified barriers participants either encountered or perceived as interference in the process of implementing a QMS into daily laboratory activities and earning ISO 15189 accreditation.

Since research in this field is still new and this is the first study seeking to identify the top five CSFs in improving medical laboratory services in developing countries, benchmarking demographic surveys and interviews were conducted in Kenya, Tanzania, and Ukraine. According to the Benchmark Exchange (Benchnet, n.d.) benchmarking refers to the process of identifying best practices both within an industry and outside it, then adapting outstanding methods from other organizations considered to be best-in-class. The researcher first discussed the findings from this current study and solicited their opinions and insights on the CSFs and barriers identified. Then, each expert was asked to complete the same demographic survey and interview questions the participants responded to. Each offered their list of the top five critical success factors observed in medical laboratories in their country as well as barriers encountered or perceived to delay the successful implementation of QMS into daily laboratory activities or to earning ISO 15189 accreditation.

Sample Selection

This study used stratified convenience sampling due to time and budget restraints and included four laboratories in Ho Chi Minh City, Vietnam. All labs shared three commonalities:

1) all completed the SLMTA training program, 2) all are in various stages of implementing a QMS with the goal of earning ISO accreditation, and 3) all volunteered to participate in this study.

Survey participants were volunteers from the four laboratories. To avoid bias in data collection, an equal number of participants from each lab participated in the survey and interview process. Stratified stakeholder levels included 1) personnel from each department within the laboratory, 2) laboratory managers, 3) hospital administrators, and 4) clinicians utilizing laboratory services. The total number of participants equaled 44 (N=44) representing a 100% response rate most likely attributable to the volunteer status of the medical laboratories and the individual study participants.

Benchmarking

There were no published CSF studies found related to implementing QMS in medical laboratories in developing countries specifically. Therefore, the researcher contacted respected and expert directors currently implementing QMS in Kenya, Tanzania, and Ukraine for their opinions. The QMS experts selected shared similar characteristics: (1) each was a national from a developing country, (2) each was directly involved in managing one or more QMS implementation projects, and 3) each currently worked with laboratories reporting various levels of implementation success and ISO accreditation.

The terms and phrases used by interview participants were the basis for each of the ten categories and their definitions. The level of analysis in this study was consistent with each CSF or barrier listed by each participant (N=44). According to Friesen and Johnson (1995)[4], for CSFs to be of use to an organization, they should be concisely worded, so the individuals in the

organization understand them. To ensure internal validity, Neuendorf [10] suggests each category should match the conceptualizations, be mutually exclusive, and exhaustive of all responses.

Content Analysis

The goal of the data content analysis in this study was to transform verbal, non-quantitative responses into quantitative data (Shi, 1997). The data content analysis was conducted using aspects of the processes identified by Busch, et al. (2005), and Neuendorf (2002). Observational and content analysis methods assisted the researcher determine the presence of words, phrases, concepts, and themes and to objectively quantify these into categories (Palmquist, n.d.). According to the Terry College of Business at the University of Georgia, “content analysis is a research technique used to make applicable and valid inferences of interpreting and coding textual material” ("Content analysis," 2007, p. 1). The value of content analysis is that in organizational research it can serve as an important bridge between purely qualitative and purely quantitative research methods. Krippendorff (1980) suggested that there are six questions which must be addressed in every content analysis:

- Which data are analyzed?
- How are they defined?
- What is the population from which they are drawn?
- What is the context relative to which the data are analyzed?
- What are the boundaries of the analysis?
- What is the target of the inferences?

Krippendorff (2004) defined content analysis as "a research technique for making replicable and valid inferences from texts to the contexts of their use". Using this approach, the

researcher was able to quantify the presence of concepts and themes within the survey results and make inferences about the data. To increase intercoder reliability in the content analysis, two research assistants were asked to independently match each interview response to a category descriptor from Table 4.

The goal of content analysis is to identify and record relatively objective characteristics of messages and to ensure reliability. Without the establishment of reliability, content analysis measures would be useless (Neuendorf 2002). The research assistants provided a level of objectivity to the response data.

Category Identification

Content analysis is an approach to coding qualitative data that involves establishing categories following preliminary examination of the data (Haney, Russell, Gulek, & Fierros in Stemler, 2001). To ensure internal validity, Neuendorf (2002) suggests each category should match the conceptualizations, be mutually exclusive, and exhaustive. In this study, the researcher and two research assistants sorted all 220 listed CSFs into ten mutually exclusive and exhaustive categories to describe each response word, phrase, and concept listed. The terms and phrases used by interview participants were the basis for each of the ten categories and their definitions. This approach involves five discrete steps:

1. First, two or more people independently review the material and come up with a set of features that form a checklist.
2. The researchers compare notes and reconcile any differences that show up on their initial checklists.
3. The researchers use a consolidated checklist to independently apply coding.

4. The researchers check the reliability of the coding (95% agreement suggested; 0.8 if using Cohen's Kappa). If the level of reliability is not acceptable, then the researchers repeat the previous steps until an acceptable level is achieved.

5. The final stage is a periodic quality control check. This stage involves double checking the data for any clerical errors. The researcher and two research assistants utilized this coding scheme to create 10 conceptual categories to be used to describe each of the responses from each participant. The ten CSF categories are listed in Table 4.

Table 4. List of CSF Categories and their Definitions

CSF	Definition
Personnel commitment to QMS project	• Staff verbally agree to improve lab services • Staff agree to move outside their current comfort zones and implement procedural changes aimed to improve accuracy of reported results • Staff learn new methodologies as required • Staff continue even when faced with setbacks • Staff accept new protocols requiring overtime
Effective inter- and extra laboratory communication	• Communication clarity between lab manager and lab staff • Communication clarity between lab staff in all departments • Communication between lab staff and other hospital staff (nursing, clinicians) • Talk with other labs implementing QMS to share successes and challenges
Continuing education for staff on QMSs and how to perform tasks	• All staff should be trained using SLMTA materials • All staff need to be trained in QMS • On-going short training offered to lab staff • More than one staff should be trained to do the same tasks so if one is absent, the task still gets done • If more than one staff can do each task, staff turnover doesn't mean the end of improvements • Cross training of staff should be ongoing to maintain staff capacity • Standard orientation QMS training for new staff
Laboratory infrastructure	• Lab space conducive to perform testing • Adequate equipment to support test menu • Human resource capacity • Identification of gaps in laboratory quality

Table 4. List of CSF Categories and their Definitions (continued):

CSF	Definition
Work plan/Workflow	• Organization of workflow within the laboratory • Organization of documents describing processes and procedures • Acknowledgment of work plan by all staff
Lab Manager (LM) leadership knowledge and skills	• Knowledge of QMS • Has leadership skills • Has management skills • Has the ability to motivate staff • Has skills to communicate effectively with staff and hospital administration • Organize processes and procedures within the laboratory • Has the ability to resolve staff conflict • Arrange staff cross-training in performing task responsibilities • Arrange continuing education for new and old staff • Support/lead in identification of improvement projects
Mentorship to the laboratory	• Important to have a knowledgeable person work with the lab staff to answer questions • Mentors help organize staff to be more efficient • Mentors answer questions staff do not understand • Mentors motivate staff to keep working on IPs
Hospital Administration (HA) support: financial and psychological	• HA must support QMS implementation in the lab with needed funds • HA must recognize lab efforts in improving quality of services
Inter- and intra-laboratory teamwork	• Staff learn to work together to accomplish the goal • Staff work together to complete daily workload • Staff work together to overcome challenges
External stakeholder resource support	• Staff should be aware of all external stakeholders • External stakeholders should visit laboratories they support and offer monetary as well as emotional support • External stakeholders should have resources to assist laboratories in implementing QMS

A translator assisted this researcher in the interpretation of the terms used. For clarity purposes and being cognizant of variations in the cultural interpretation of similar terms in Vietnamese and English, the researcher and translator performed two separate reviews on each participant's terms and phrases to ensure accuracy and consistency in translation.

Data Analysis

The researcher and assistants evaluated the study participant responses by first identifying the frequency of a given answer and then applying a weighted value approach. Frequency response rates were determined by adding the number of times each study participant response matched one of the ten CSF categories. The CSF category with the highest frequency response was the most important CSF; the second highest was the second most important, et cetera. The weighted value approach consisted of asking the participant to rank their top five CSFs from 1 to 5, with one being the most important and five being the least important. Based on the ranking, each CSF received a numerical weight value. The CSF category with the highest weighted value was the most important CSF; the next highest was the second most important, et cetera. A rigorous approach using Cohen's Kappa measured interrater reliability. This study demonstrated a strong, positive inter-rater reliability with Kappa values between 0.85 and 0.95 ($p < .001$) (Haney, W., Russell, M., Gulek, C., Fierros, E., 2001.

While identification of barriers to successful QMS implementation was not a part of the research question, it was one of the study objectives. Both the researcher and the two assistants categorized all barrier responses to determine the top five barriers encountered in implementing QMS and earning accreditation. The percent-agreement method applied to the barrier data resulted in overall match rates between the researcher and the two research assistants of 97.5% (assistant # 1) and 98.5% (assistant # 2).

CHAPTER III

RESULTS

Results Overview

Critical success factors must be directly related to the organization type. Laboratories are a part of a hospital system and collect, analyze, and report accurate and reliable patient test results. The focus of this study was to answer the research question "What are the Critical Success Factors (CSFs) for medical laboratories in Vietnam implementing quality management systems in their laboratories as a pathway to implementing improvements and earning accreditation"? The first research objective was to identify and categorize the top five CSFs for medical laboratories in Vietnam implementing laboratory improvements and achieving international accreditation. The second research objective was to determine barriers preventing medical laboratories in Vietnam from implementing quality management systems with the goal of earning accreditation. The third objective was to expand the current knowledge base of what factors contribute to successfully improving medical laboratory quality.

Identification of Top Five Critical Success Factors

Results from both the frequency and weighted ranking analyses found identical CSF content categories for the top five positions. Refer to Table 5, below, for the top five CSFs identified by weighted rank score and to Table 6 for the top five ranked CSFs by frequency scores.

Benchmarking surveys in this study provided additional data to base identification of factors important to successful implementation of a QMS in laboratories. As with the interview data, there were commonalities between the top five CSFs identified by the study participants

and the CSFs identified during the benchmarking interviews. The most striking component gleaned from the benchmark data centered on the concurrence of the CSFs and the barriers identified even though all three benchmark experts represented different developing countries.

The number one CSF from both the study participant interviews and the benchmarking interviews was staff knowledge of quality management systems. Specifically, all groups felt strongly that continuing education options were crucial to ensuring staff knowledge and skills implementing QMS principles. The other four CSFs identified varied in their rankings though all five CSFs were identical. Laboratory manager leadership ranked as CSF number 2 by the study participant data while all BMEs ranked laboratory manager leadership as the fourth CSF. Staff commitment to the change process necessary to implement QMS was the third CSF from the study participants and BME 3, while this CSF was ranked as number two by BME 1 and BME 2. Hospital administration support ranked fifth by the study participants but received a higher score by the benchmark experts. Based on comments from the study participants, all agreed hospital support was critical, though budgetary backing was not a current reality. This perception may account for the fifth-place ranking.

Mentorship, as a CSF, was in different positions between all groups. The variation in ranking may be due to many types of mentorship options. BME 1 specifically listed embedded mentorship while the others simply listed "mentorship." When study participants discussed the mentorship at their laboratories, they all agreed on the value of the mentorship without regard to whether the mentor visited the laboratory weekly or monthly or the time spent in the laboratory at each visit. Previous articles suggested embedded mentorship, and longer mentorships resulted in better outcomes for the laboratories, though those were not the findings in this study.[3,6] Often, due to time constraints with both the lab staff and mentor, email communication became an

invaluable part of the mentorship package. The importance of this finding suggests either editing the training workshop materials or demonstrating how short, frequent training can augment daily laboratory processes without affecting turn-around-time for delivering reports back to the clinicians.

The researcher chose to evaluate the study participant responses by first identifying the frequency of a given response and then applying a weighted value approach. Frequency response rates were determined first by adding the number of times each study participant response matched a CSF category. The CSF category with the highest frequency response was the most important CSF; the second highest was the second most important, et cetera. The weighted value approach consisted of asking the participant to rank their top five CSFs from 1 to 5, with one being the most important and five being the least important. Based on the ranking, each CSF received a numerical weight value. The CSF category with the highest score was the most important CSF; the next highest was the second most important, et cetera. Table 5 shows the top five CSFs by weighted rank. Table 6 shows the top five CSFs identified in this study by frequency rank.

Table 5. Top Five Critical Success Factors by Weighted Average Rank

Rank	Critical Success Factor	Weighted Score
1	Staff Training on QMS principles and tasks	.290
2	Laboratory manager leadership knowledge and skills	.215
3	Staff commitment to QMS project	.163
4	Mentorship to laboratory	.115
5	Hospital administration support – financial and emotional	.088

Table 6. Top Five Critical Success Factors by Frequency Rank

Rank	Critical Success Factor	Frequency Score
1	Staff training on QMS principles and tasks	43
2	Lab manager leadership knowledge and skills	41
3	Staff Commitment to QMS project	37
4	Mentorship to the laboratory	35
5	Hospital administration support – financial and emotional	32

The researcher employed two research assistants to assist with the content analysis to ensure intercoder reliability in this content-based analysis. The assistants performed both the frequency response and the weighted approach methods for analysis. To objectively identify the top five CSFs the researcher and the two assistants compared results. The comparison results are in the Reliability Analysis section below.

To demonstrate the strength of the content analysis approach and ensure consistent results the researcher utilized Pearson's Chi-square statistical test. This test identified any statistically significant associations between laboratory demographic variables and the top five CSFs selected by each study participant. The demographic variables compared included gender, age range, position in the laboratory, and the level of the hospital. Using a two-tailed analysis with a $p < .025$, the Chi-square test found no statistically significant associations between the top-five CSFs and the demographic variables studied. Table 7 shows the association between the top-five CSFs and the demographic variables.

Table 7. Chi-square Test: Top Five CSF Associations to Demographic Variables

Variable	Significance*
Participant age	0.146
Position in laboratory/hospital	0.261
Level of Hospital (laboratory)	0.157
Participant gender	0.109

*$p < .025$

Identification of Barrier Categories

The study participants identified and defined any barriers they perceived delaying either the QMS implementation process and or the time to earn accreditation. The researcher did not specify the number of barriers each study participant should identify, and there was no ranking as there was in determining the CSFs. In total, the study participants identified 132 barriers. As with the CSFs, the process of content analysis was used to categorize all the responses into ten mutually exclusive and exhaustive categories based on participant definitions and descriptive terminology. The barrier categories and their descriptions are in Table 8 below. The researcher chose to only evaluate the frequency response rates to the study participants' list of barriers. As such, there were no weighted values applied to this collection of barriers. The frequency response rates, determined by adding the number of times each study participant response matched a barrier to a category, were determined. The two research assistants independently matched each of the responses to one of the ten barrier categories and performed a frequency response analysis.

Table 8. List of Barrier Categories Identified through the Process of Content Analysis

Barrier Categories	Definition
Lack of QMS knowledge by all lab staff before implementation	• This included staff training pre-QMS implementation in the laboratory, both on SLMTA, SLIPTA, and ISO 15189 standards. • All lab staff should attend SLMTA/QMS training
Lack of resources	• This included resources in building human capacity, procuring equipment, consumables, and time
Long wait times between applying for accreditation and being audited for ISO	• Auditor capacity inadequate to schedule audits in beginning. Now, shorter times • Wait times encouraged reversal to old habits

Table 8. List of Barrier Categories Identified through the Process of Content Analysis (continued)

Barrier Categories	Definition
Lack of lab staff motivation and commitment to change process	• This included lab staff lack of awareness of the benefits of improving laboratory accuracy and the satisfaction level of patients, clinicians, and healthcare overall • Did not recognize value of improving laboratory quality
Lack of attention to laboratory infrastructure	• This included not providing funding to improve laboratory space to organize workflow for maximum efficiency • No service contracts to maintain equipment
Lack of hospital administration support	• Hospital administration did not acknowledge laboratory effort in improving services or • Did not provide the financial funding required to implement specific improvements • Lack of engagement with QMS project
Lack of laboratory manager knowledge and skills in managing and leading staff	• This included the laboratory managers' lack of skills in management, motivation, communication, and leadership • No manager engagement
Communication Challenges	• Ineffective communication with laboratory • Lack of communication between other professionals in hospital departments
Staff overtime to complete QMS implementation	• This included lack of time resource to implement QMS after completing daily responsibilities
Other This category used for comments not fitting into any other category	• Devolution of health services at government level • Lack of political will • Decreased customer satisfaction due to not meeting TATs while implementing QMS procedures

Reliability Analysis

Critical Success Factors

Reliability refers to the repeatability of findings. For example, would a second study find the same results? If so, the data is reliable. If more than one person is observing the same event, all observers should agree on the findings to claim that the data is reliable ("Reliability and Validity," n.d.). This study utilized both rigorous and non-rigorous methods to measure interrater reliability.

Percent Agreement Method

The percent agreement method is a non-rigorous method of evaluating reliability. However, many researchers agree that this method is not valid as the sole determinant of reliability. According to Lombard, Snyder-Duch, and Bracken (2010), a consistency rate of 80% or greater is acceptable in most situations. To perform this method, the researcher and two research assistants independently organized each of the CSFs the study participants listed as the top five in their order of rank in one of the ten categories. By dividing the number of times the researcher and the assistant rater categorized a response into the same category, by the total number of responses, a percent of agreement resulted.

Cohen's Kappa Test

Cohen's Kappa is a rigorous approach to measure inter-rater reliability. The two raters either agree in their rating or they disagree; there are no degrees of disagreement ("Real Statistics," n.d.). Ensuring inter-rater reliability was necessary for this study. To perform this measurement, the researcher used a matrix scoring approach for summarizing the coding results.

A 10 by 10 matrix included each of the CSF categories. Figure 1, shown on page 56, shows the matrix with the 10 CSF responses used by the researcher and the research assistant. The researcher and each assistant coded each of the 220 CSF responses into one of these 10 categories. For example, if the researcher determined that a response should be in the "Communication" category and the assistant rater determined the response should be in the "Manager Leadership" category, a tally mark appears in column 3, row 5. A separate matrix resulted for each of the top five CSF rankings, based on the coding scores by the researcher and each assistant. Each of the matrix results used the SPSS (Statistical Program for the Social Sciences) computer program, which automatically calculates Cohen's Kappa. SPSS allows for computing Cohen's Kappa value using two different raters.

		Researcher									
		LI	PC	C	CE	ML	HAS	PRO	TW	EF	M
Rater # 1	LI										
	PC										
	C										
	CE										
	ML										
	HAS										
	PRO										
	TW										
	EF										
	M										

Figure 1. Matrix Grid for CSFs to Determine Interrater Reliability

Cohen's Kappa is the ratio of the proportion of agreement divided by the maximum number of times they could agree (Hallgren, 2012). Cohen's Kappa statistical measurements range from -1.0 to 1.0. A Kappa score of 1.0 indicates perfectly reliable data while a Kappa value closer to -1.0 suggests that agreement has happened by chance. As suggested by Landis and Koch (1977), a reliability Kappa rating of 0.61 to 0.80 represents a substantial strength of

agreement while scores from 0.81-1.00 represent almost perfect agreement. The intercoder reliability of this study had a positive value, in which Kappa ranged from 0.85 to 0.95 ($p < .001$). Values of Cohen's Kappa are in Table 9 below.

Table 9. Values of Cohen's Kappa Reliability Scores

	The measure of Reliability: Cohen's Kappa	
	Researcher + RA # 1	**Researcher + RA # 2**
CSF ranked # 1: Continual training (on QMS)	0.846	0.857
CSF ranked # 2: Laboratory manager leadership	0.931	0.948
CSF ranked # 3: Staff commitment to project	0.886	0.943
CSF ranked # 4: Mentorship to laboratory	0.938	0.875
CSF ranked # 5: Hospital Administration Support	0.846	0.923

Results from both the percent frequency and weighted ranking analyses found identical CSF content categories for the top five positions.

Identification of Top Five Barriers to Success

The researcher chose to apply the non-rigorous methodology in scoring the barrier data to the QMS implementation in a laboratory and earning accreditation. Based on the high-reliability analysis found with the CSF data in this study, the researcher felt the non-rigorous method was acceptable and demonstrated the strength of the study's approach. The same non-rigorous approach applied to the CSF data also applied to the barrier data. The percent-agreement method applied to the barrier data with overall match rates between the researcher and the two research assistants was 97.5% (assistant researcher # 1) and 98.5% (assistant researcher # 2). Table 10 on page 61 lists the top five barriers to successful QMS implementation.

Table 10. Top Five Barriers to QMS Implementation Success

Rank	Barrier	Frequency Score
1	Lack of staff training on QMS	35
2	Insufficient Hospital Administration Support	27
3	Ineffective Laboratory Manager Leadership skills	26
4	Insufficient laboratory Infrastructure	24
5	Lack of Sufficient Resources	20

Study Results Compared to Benchmark Results

Table 11 below shows the top five CSFs reported by this study's participants, compared to the three benchmark experts.

Table 11. Benchmarking Versus Study Participants Comparison of the Top Five CSFs

Vietnam Study	BME 1	BME 2	BME 3
1. Staff Knowledge on QMS	1. Staff knowledge on QMS	1. Staff Knowledge on QMS	1. Staff knowledge on QMS
2. Lab Manager Leadership skills	2. Staff Attitude to Change Process	2. Staff Motivation to Change Process	2. Hospital Admin Support
3.Staff Commitment to Change Process	3. Hospital Admin Support	3. Mentorship	3. Staff Commitment to Change Process
4. Mentorship	4. Lab Manager Leadership skills	4. Lab Manager Leadership skills	4. Lab Manager Leadership skills
5. Hospital Admin Support	5. Embedded Mentorship	5. Hospital Admin Support	5. Mentorship

Benchmarking surveys in this study provided additional data to base conclusions on those factors critical to successful implementation of a QMS into laboratories. As with the interview data, there were commonalities between the top five CSFs identified by the study participants and the CSFs identified during the benchmarking interviews. The exciting component gleaned from the benchmark data centered on the concurrence of the CSFs and the barriers even though all three benchmark experts represented different developing countries.

The number one CSF result from both the study participant interviews and the benchmarking interviews was staff knowledge on QMS principles and tasks. Specifically, all

groups felt strongly that continuing education opportunities were crucial to ensuring staff knowledge on QMS principles. The other four CSFs identified varied in their rankings though all five CSFs were identical. Laboratory manager leadership ranked as CSF number 2 by the study participant data while BME 1, BME 2, and BME 3 all ranked laboratory manager leadership as the fourth CSF. Staff commitment to the change process necessary to implement QMS was the number three CSF from the study participants and benchmark expert 3 (BME 3). This CSF was number two by BME 1 and BME 2. Mentorship, as a CSF, was in different positions between all groups. The variation in ranking may be due to many types of mentorship options. BME 1 specifically listed "embedded mentorship" though the others simply listed "mentorship." When study participants discussed the type and length of mentorship at their laboratories, they all focused on the value of the mentorship without regard to whether the mentor visited the laboratory weekly or monthly or the time spent in the laboratory during each visit. Often, due to time constraints with both the lab staff and mentor, email communication became a valuable part of the mentorship package. The importance of this finding means either editing the training workshop materials or demonstrating how short, frequent training can add to daily laboratory processes without affecting turn-around-time for delivering reports back to the clinicians. Support from hospital administration ranked as the fifth CSF by the study participants and BME 2, the third CSF by BME 1, and second by BME 3.

Unlike the CSFs, study participants did not list a specified number of barriers**,** or rank the barriers they listed. The researcher chose to evaluate the participant responses to barriers using a frequency response rate only. No weighted values applied to this data. The frequency response rates were determined by just adding the number of times each participant response applied to a barrier category. The two research assistants independently matched each of the participant

responses to one of the ten barrier categories and performed the frequency response analysis. The forty-four study participants identified 132 barriers. A new coding scheme, as used with the CSF data, categorized the participant responses into 1 of 10 conceptual categories that could describe each response. The barrier most often listed was the lack of QMS knowledge among the laboratory staff. This lack of knowledge supports CSF (1)**,** which states laboratory staffs' need for QMS training. The other four top barriers listed include (2) lack of hospital administration support, (3) absence of effective manager leadership skills, (4) deficiencies in laboratory infrastructure, and (5) lack of resources to perform lab duties and implement a QMS. When participants described the time restraints, their replies were related to not understanding what the expectations were or how to perform new procedures according to QMS directions. As they became more familiar with the new processes and procedures, all participants laughed and stated now that the QMS changes had become routine, the staff had more time. Again, this barrier is directly related to the concept of how 'change' affects a staff. Laboratory managers listed knowledge or skills they wish they had received before becoming managers. Though not statistically analyzed, the knowledge and skills listed were similar and worth mentioning. Only three out of the 44 participants (6.8%) reported completing a management or leadership course during their university studies. Conversely, all three of the benchmark experts reported completing at least one management or leadership course. The skills managers wished for included knowledge on conducting staff orientation, time management, conflict resolution, quality control, internal assessment, and effective communication. Even the three participants completing management/leadership courses, listed time management and conflict resolution as useful refresher skills. Table 12 below show the top five barriers identified by the study's participants, compared to the three benchmark experts.

Table 12. Benchmarking Versus Study Participants Comparison of the Top Five Barriers

Vietnam Study	BME 1	BME 2	BME 3
1. Lack of Staff Knowledge of QMS	1.Lack of Staff Knowledge of QMS	1. Lack of Staff Knowledge of QMS	1. Lack of Staff Knowledge of QMS
2. Insufficient Hospital Admin Support	2. Insufficient Lab Infrastructure	2. Insufficient Hospital Admin Support	2. Insufficient Hospital Admin Support
3. Ineffective Lab Manager Leadership	3. Insufficient Hospital Admin Support	3. Insufficient Lab Infrastructure	3. Lack of Resources
4. Insufficient Lab Infrastructure	4. Ineffective Lab Manager Leadership	4. Ineffective Lab Manager Leadership	4. Ineffective Lab Manager Leadership
5. Lack of Resources	5. Lack of Resources	5. Lack of Resources	5. Insufficient Lab Infrastructure

CHAPTER IV

DISCUSSION

Summary of Key Findings

The critical success factor interview data scoring used frequency ranking and weighted ranking calculations. Both methods produced identical lists of the top five critical success factors with only slight variation between the study's findings and the benchmarking data. Based on the survey, interview, content analysis, and benchmarking results, there is a significant agreement between developing countries as to the critical success factors necessary for successful implementation of a QMS to improve laboratory quality and earn ISO 15189 accreditation.

Improving the quality of laboratory services in developing countries is a relatively new field. Identifying patients with HIV and other conditions and diseases meant laboratories had to have the resources to analyze and report accurate results. Many laboratories in developing countries did not have the infrastructure, human capacity, or resources to report accurate and reliable patient test results. To combat the global pandemic from HIV/AIDS infection, developed and developing countries met and reached consensus on a standardized plan to systematically implement QMSs in laboratories in order to meet the needs of accurate test reporting. Laboratory services quickly moved from the background of medical services into the forefront as clinicians required accurate and timely tests results to diagnose and to monitor treatment regimens to combat HIV/AIDS, tuberculosis, malaria, and other infectious and non-communicable diseases.

Unfortunately, there were no previous examples about best practices on improving laboratory quality in developing countries globally. Developing countries struggled in their

attempts to implement QMSs and improve their laboratory services reporting outcomes often less than successful. This identified gap in knowledge and ability to improve laboratory services prompted this researcher to design a study to identify critical success factors laboratories needed to carefully monitor to be successful at implementing QMSs into their daily laboratory policies and procedures. While other organizations and industries have identified CSFs to ensure company operational success, there have been no studies identifying CSFs needed to improve laboratory services.

This research study is the first to identify the top five critical success factors necessary for laboratories to implement a QMS as a pathway to improve the accuracy of patient results and earn ISO accreditation. Benchmarking with other developing countries also implementing a QMS into laboratories as a method to improve laboratory services and gain ISO accreditation found statistically relevant critical success factors as well as similar barriers. Based on the study results, the top five CSFs were laboratory staff knowledge on QMS principles and tasks, laboratory manager leadership knowledge and skills, laboratory staff commitment to the QMS project change, mentorship, and hospital administration support.

The Chi-square test identified any significant associations between demographic variables and the top CSFs reported. The demographic variables compared included gender, age range, level of the hospital laboratory, and position in the laboratory. Based on a two-tailed analysis with a $p < .025$, there were no statistically significant associations between the top-ranked CSFs and the demographic variables listed above. The independent variables did not statistically influence the study participants' CSF ranking. Significance levels were greater than .025 for all variables tested.

Study participants also provided either encountered or perceived barriers to successful implementation of a QMS and earning ISO 15189 accreditation. Though this was not the research question in this study, it was one of the objectives of the study. Information about barriers identified possible deterrents to successful QMS implementation and earning accreditation. Interview data for barrier categories compared only the frequency of impediments.

When asked about their reasons for committing or not committing to the QMS change process, staff from H1 reported their motivation and commitment came from their manager's dedication and adherence to improving patient diagnoses, treatments, and outcomes. They all cited reporting accurate patient results had increased the number of patients using their laboratory services**,** which increased laboratory revenues. Increased laboratory revenues offer the potential to improve their ability to provide for their families and ultimately increase their retirement benefits. Hospital H2 staff reported the purpose of implementing QMS into their laboratory processes was to improve the accuracy of reported patient tests, earn ISO 15189 accreditation, and thereby gain peer recognition for working in an internationally accredited laboratory. The staff in the third hospital in this study, H3, experienced multiple staff turnovers and at the time of the interviews, reported there was no staff consensus on how to achieve success. The laboratory staff in hospital H4 reported even though they all worked together as a team and were committed to improving their laboratory, the hospital administration did not have the necessary funding to support or sustain their improvement efforts.

The researcher found it interesting that staff within each laboratory listened and took the projected benefits and outcomes of QMS implementation seriously. After reviewing responses from the laboratory staff at H1, the researcher and translator noted all personnel responded much the same when asked the value of QMS implementation and the source of their commitment and

motivation. However, the pattern repeated itself as staff interviews at the other three hospitals found similar, though unique, responses. The influence, the commitment, and the motivation as modeled by each laboratory director support the findings of laboratory manager leadership as the number two CSF. According to Price and St. John (2016), value is one of the most discussed goals for everyone involved i health care (Price & St. John, 2016). The global community invested in strengthening laboratory services and by all metrics, laboratories are striving to implement a QMS in their laboratories to improve the accuracy and reliability of reported patient results. Identification of CSFs benefit these improvements by helping the laboratory managers, staff, and other stakeholders to focus their time and resources on the factors contributing to success.

APPENDICES

APPENDIX A

THE PROBLEM

Overview

Currently there is limited scientific research about medical laboratories in developing countries in general, and specifically in Vietnam, implementing quality management systems with the goal of earning international laboratory accreditation. This research determined those factors laboratory staffs in Vietnam cite as critical to successfully implement QMS and improve laboratory accuracy and services. Accredited laboratories in other countries, earning accreditation, represent national reference laboratories, provincial laboratories, HIV-laboratories, and district laboratories, suggesting neither the level of the laboratory nor its testing menu is the primary factor for attaining accreditation. Testing is essential to patient diagnosis, treatment, and healthcare in general in both developed and developing countries. A mixed methods study using qualitative and quantitative analysis identified critical success factors for medical laboratories as they implement quality management systems in their laboratories with the goal of earning accreditation.

Research Question

The research question in this study is: "What are the Critical Success Factors (CSFs) for medical laboratories in Vietnam implementing quality management systems in their laboratories as a pathway to earn accreditation?"

Research Objectives

The three research objectives were to:

- Identify and categorize the CSFs for medical laboratories in Vietnam to achieve sustained improvements and long-term accreditation.
- Identify any barriers that are preventing medical laboratories in Vietnam from implementing quality management systems with the goal of earning accreditation.
- Expand the current knowledge base of what factors contribute to medical laboratory quality in Vietnam.

Benefits of the Study

- Study results can assist laboratory managers in achieving their organizational goals
- Study results will help laboratory managers and their staff overcome barriers preventing them from implementing laboratory improvements
- Study results will provide an enhanced guide for laboratories and their managers to follow as they begin the improvement process
- Study results will increase international awareness of the number of accredited laboratories available to all people
- Study results may motivate other hospital departments to collaborate with the goal of improving hospital-wide services and patient care
- Study results will add to the CSF's knowledge base as other researchers conduct future studies

Identification of CSFs offer both short- and long-term stability for implementing improvements and assisting laboratories in moving closer to accreditation. However, other contributing factors also exist. Regardless of the political, social, and economic environments, identifying the CSFs will be valuable to medical laboratories.

Research Needs

There is a lack of published literature that provides in-depth analysis of factors associated with medical laboratories in developing countries as they implement quality management systems and apply for international accreditation. Laboratory services in these countries are critical to improving health care and health outcomes for all patients. While CSFs exist for other industries, little data exists regarding CSFs for medical laboratories in developing countries striving to earn accreditation. Medical laboratories have their own set of processes and interactions with other departments within the hospital organization and identifying the CSFs unique to them is paramount to improving accuracy and reliability of laboratory results. The laboratory system, as a sub-system within the global health care system to improve healthcare, is itself complex with many feedback loops. Identifying the top five CSFs continues the improvements processes already begun.

Understanding the critical impact CSF identification or lack of identification can have on an organization is essential (O'Sullivan, 2008). Practices and processes that may be fundamental to the survival of an organization may never surface without going through the process of identifying CSFs. Goldstein (1995) recommended that instead of using generic CSF models, healthcare leaders should locate organization-specific CSFs. Unfortunately, there has been little published on CSFs for medical laboratories. This study identified success factors by conducting interviews at four laboratories in Vietnam. Data from this study can strengthen laboratory services throughout Vietnam and guide design and development of new materials for dissemination in future training.

Purpose of Study

The purpose of this research was to study laboratories in Vietnam to identify those factors considered critical for laboratory managers to monitor closely as their staff implement a QMS, sustain the improvements, and continue to progress toward international accreditation. Whether a laboratory manager is just beginning the accreditation process or is struggling to achieve accreditation readiness, that person must know CSFs are essential. Identifying and making the CSFs available to laboratory personnel in Vietnam as well as globally benefit laboratories and laboratory managers in several ways. Email or open access websites are excellent ways to share CSFs. These CSFs can help accredited laboratories put policies in place to sustain improvements and accreditation status. Funding sources may be more motivated to donate to laboratories with CSFs identified and organizational systems in place to support and maintain success.

According to Burch and Heinrich, the demand for program evaluation has rapidly expanded in international contexts along with recognition of the value of applying mixed methods early in the research design to strengthen various components of the research (Burch & Heinrich, 2016, p.155-156). Findings from the qualitative study assisted in the interpretation and explanation of results from the quantitative analysis.

The Significance of the Study

Globally, there are concerns about the quality and accessibility of medical laboratories to patients. Disease knows no boundaries and epidemics occur in random locations without regard to available resources, staff capacity, or competency. Increased global trade and travel add to public health risks and the need for accredited laboratories in all countries. According to the *American Journal of Clinical Pathology*, national laboratory systems (NLSs) are a "key component of the overall health system. NSLs are needed to achieve the Millennial Development Goals (MDGs) for health and are required for meeting universal access for

treatment of HIV/AIDS, TB, and malaria" (Nkengasong et al., 2010, p. 369). Identifying the critical success factors can assist laboratories as they develop strategic plans and select metrics to measure success. Incorporating these critical factors from the beginning of the implementation process may also save time, money, and circumvent barriers often impeding reaching their set goals. In his 2012 dissertation titled "Creating an Effective Medical Laboratory Capacity in Limited-Resource Settings: A Case Study of Kampala, Uganda", Elbireer states "establishing effective medical services with efficient medical laboratories is a critical element to ensure the well-being of any population around the globe" (Elbireer, 2012, p. 15).

APPENDIX B

LITERATURE REVIEW

A comprehensive literature review sought to answer the research question posed by this study and compile laboratory status specific information. Several considerations were paramount during the literature review. As there is little literature specific to medical laboratory accuracy and international accreditation in developing countries, quality management systems, and benefits of international accreditation received emphasis to provide additional insight and background on the laboratory's role in healthcare. The literature on critical success factors in medical laboratories in developing countries is sorely lacking. This study focuses on medical laboratories in Vietnam that implement quality management systems with the goal to improve the accuracy of laboratory testing and move toward international accreditation. Benchmark studies from experts in three other developing countries supported this study's findings.

Laboratory Quality and Value of Healthcare

Though value is one of the most often discussed goals in the delivery of healthcare, it is not an easy concept to define and lacks precision in its delivery (Price & St. John, 2016, p. 101). The most straightforward definition of value in health care, according to Porter, is the "health outcomes achieved per dollar spent" (Porter & Teisberg, 2006, p. 101). Price and St. John add that the patient is the customer and the goal is maximizing benefit while minimizing risk. For laboratory services to add value to patient healthcare, there are several assumptions: (a) an appropriate test must address an unmet clinical need; (b) test results are an integral part of a "test and act" intervention; (c) test results should provide a benefit, and (d) multiple stakeholders contribute to the delivery of healthcare. Other assumptions include**:** (e) benefits and problems

likely to affect all stakeholders; (f) all stakeholders have a responsibility to deliver the benefit; and (g) a plan for implementation must exist. Meeting all the assumptions assumes a shift towards a value-based approach to lab support, and increased funding for the laboratory to achieve best practices in analyzing and reporting accurate results.

Amukele and Schroeder offer another perspective when considering the value of medical laboratory testing. Most reports relate the importance of laboratory testing by stating test results are the basis of 70% of medical decisions (Amukele, T., & Schroeder, L.,2016). These authors disagree about the actual value of medical laboratory testing depending on the medical setting and the frequency with which test results influence medical decisions. Laboratory testing accounts for only 2%-5% of the total cost of providing healthcare in the United States, and in developing countries (Amukele, T., & Schroeder, L., 2016). While the number of laboratory tests ordered per person is lower in some developing countries, the pattern is similar. A study of laboratories conducted in Kampala, Uganda found the number of laboratory procedures per person was like that in the U.S. (Elbireer, 2012, p. 1). Other studies discovered unexpected consequences to patient health where laboratory testing was not available. Two examples from a WHO study illustrate repercussions due to the lack of diagnostics: (a) 40% of children at a tertiary referral center in Ghana received a diagnosis as positive for malaria when, in fact, they had bacterial sepsis, (b) 50% of children in another study supposedly had severe malaria when in fact they all tested negative on blood smears (WHO: The Importance of Laboratory Quality, n.d.) These examples illustrate the value of laboratory testing. They also demonstrate the need for planning and investing in laboratory staff, space, supplies, equipment, and quality improvements.

The World Health Organization defines laboratory quality: "as accuracy, reliability, and timeliness of the reported test results" (WHO: The Importance of Laboratory Quality, n.d.). The

laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely. In their 2008 report to the Division of Laboratory Systems--Centers for Disease Control and Prevention, the Lewin Group reported: "laboratory testing has a major effect on clinical decisions. Additionally, it provides physicians, nurses, and other healthcare providers with information that aids in the prevention, diagnosis, treatment, and management of disease" (Wolcott, Schwartz, & Goodman, 2008, p. 1). Unfortunately, many laboratories in developing countries do not monitor testing procedures to measure their accuracy. Without maintained equipment, written procedures for performing test analysis, correct specimen collection, and quality assurance protocols, laboratories often report inaccurate results to clinicians with possibly dire consequences to their patients.

According to the WHO content sheet 1-1, "to achieve the highest level of accuracy and reliability, it is essential to perform all processes and procedures in the laboratory in the best possible way" (The Importance of Laboratory Quality-World Health Organization n.d.). The laboratory is a complex system involving many steps and many people. Each must be correct, and each person must perform each action the same way to reach a 99% level of accuracy. Baseline assessments in many laboratories found significant errors and non-standardized processes in addition to no monitoring of accuracy. For these reasons laboratory systems in developing countries require improving their methods to meet the need for accurately reported results.

Laboratory Needs in Developing Countries

With the introduction of PEPFAR-SUPPORTED in 2003 and its goal to test over 1.3 billion people in Africa and Asia to determine their HIV status, there was much discussion over

where and how to begin improving laboratory services. Accurately reporting HIV results meant medical laboratories had to have the capability of collecting, analyzing, and reporting patient results. But baseline evaluations of laboratory infrastructure, resources, human capacity, and knowledge varied widely. Add to these variations a multitude of international partners with differing approaches to the introduction of strategic planning, training, and selection of metrics equates, at best, to muddled efforts in many countries. The Ministry of Health (MOH) and Centers for Disease Control (CDC) personnel had difficulty selecting which recommendations and plans to follow (personal conversations with K. Bond, CDC-VN, 2009, and E. Makokha, CDC-KE, 2009). Often, different partners facilitated workshops on the same topics. Unfortunately, each partner used different teaching methodologies, calculation formulas, and measurement tools in their workshops (personal conversation with M. Nghipumbwa, National Institute of Pathology, Namibia, April 2010). Participants attending various seminars did not significantly improve their knowledge of laboratory practices as evidenced by pre-and post-test results (personal training reports to ASCP from W. Arneson and C. Robinson, 2007-2015). These results are not meant to negate differing partner's workshop approaches, materials, or evaluation metrics, but to emphasize the need for collaboration and a systems approach between partners to better serve laboratory management and staff needs by standardizing training materials, delivery styles, and metrics.

Global Response to Improve Laboratory Systems

At first, the global response to health care needs did not include improving laboratory services. However, Dr. Nkengasong and other laboratory champions advocated for the inclusion of laboratory services as a critical component of improving health care. The advocacy for improving laboratory services continued through international conferences dedicated to

recognizing the role laboratory services play in health care such as The Maputo Declaration (2008). After much deliberation and research, the decision to include strengthening of laboratory systems was added to the global response objectives. Implementing quality management systems into medical laboratories to achieve improvements and ensure sustainability was accepted by the global community with International ISO 15189 standards and accreditation considered the 'gold standard' for laboratory quality across all countries ("The Maputo Declaration," 2008, p. 1). As of January 2018, laboratories in more than 53 countries have adopted the implementation of QMSs as a method to improve their laboratory accuracy and quality. The next step after successfully implementing all QMS tasks was preparing for ISO 15189 accreditation. This study specifically focused on medical laboratories in Vietnam as a developing country.

Developed countries such as the United States, Great Britain, and Canada have their own accrediting bodies to recognize medical laboratories meeting essentially the same standards as ISO 15189. The College of American Pathologists (CAP) is a member-based physician organization founded in 1946. It is the world's largest association of pathologists certified by the American Board of Pathology and widely considered the leader in laboratory quality assurance. Under the authority of the Centers for Medicare and Medicaid, the CAP accredits medical laboratories in the United States as well as many international laboratories. To support the global initiative to improve laboratories in developing countries, the CAP 15189 quality management program formed to provide the following services: (1) assist laboratories with readiness and advisory services, (2) online education courses on quality management systems, and (3) assistance for earning ISO 15189 accreditation (Paxton, 2009).

Training and Monitoring Tool

Global partners combined their experience and expertise to develop a standardized training checklist based on the SLMTA training program (with its attached checklist). The standardized training checklist, The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), follows the SLMTA training materials as well as referencing laboratory tasks and practices to ISO international 15189 standards. The SLIPTA checklist assists laboratory managers in assessing their laboratory's improvement in implementing quality practices. It can be used as a reference document to review the exact wording of each standard, and can also be utilized when the laboratory conducts internal audits. "SLIPTA is a comprehensive way to monitor small incremental approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards the long-term fulfillment of the ISO 15189 standards" (Gomes, n.d.). SLIPTA recognizes laboratories using a 5-star approach. As a laboratory's compliance with checklist sections increases, they earn additional stars recognizing their improved quality or specific QMS element. After reaching 4-5 stars, a laboratory is ready to apply for ISO 15189 accreditation.

In July 2011, SLIPTA stakeholders met in Nairobi, Kenya to reach consensus on the WHO AFRO SLIPTA Policy Guidance and Checklist documents. This framework's goal was to improve the quality of public health laboratories in the African region, motivate laboratories to achieve ISO 15189 accreditation, and promote ownership of both the process and the sustainability of improved laboratory quality (Gomes, n.d.). Countries outside of Africa also adopted a QMS approach to implement improvements and used the SLIPTA checklist to guide improvements and measure compliance with each of the section standards.

In response to the need for standardization of training materials, several organizations collaborated on a joint international project called the "Strengthening Laboratory Management towards Accreditation" (SLMTA) training program. The SLMTA program is a structured quality improvement curriculum designed to train laboratory managers and other staff on QMSs with practical training on how to implement the tasks in their laboratories. The outcomes of the SLMTA training program yield immediate and tangible advances in laboratory services delivery (Luman, Yao, & Nkengasong, 2014).

Creation of a Laboratory Professional Body

The African Society for Laboratory Medicine (ASLM) stood up as a pan-African professional body to advocate for the critical role and needs of laboratory medicine throughout Africa and the international community. The ASLM recognized medical laboratories for their crucial role in global disease diagnosis, surveillance, outbreak investigation, initiation and monitoring of therapy, as well as research and development. The ASLM collaborates with governments, local and international organizations, and implementing partners to achieve the goals referenced in Table 1 by 2020. This body holds conferences every two years and invites laboratorians from the international community to attend and to submit abstracts for presentation on a plethora of medical laboratory health care concerns.

Table 1: ASLM 2020 Goals (retrieved from "ASLM," n.d.)

• Strengthening laboratory workforce by training and certifying laboratory professionals and clinicians through a standardized framework
• Transforming laboratory testing quality by enrolling laboratories in a quality improvement program to achieve accreditation by international standards
• Developing reliable, harmonized regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce
• Building a network of national public health reference laboratories to improve early disease detection and collaborative research

Mentorship Activities

To encourage participation and sharing of ideas in implementing quality management systems in their laboratories, the CDC sponsored a Writing Workshop in 2013 partnering mentors with laboratory managers and staff. The workshop helped laboratorians develop writing skills and publish papers on their experiences implementing a QMS into daily laboratory practice and working toward accreditation. The workshop was successful as evidenced by 28 published studies detailing experiences laboratories encountered on the path to improving the accuracy and reliability of their laboratory services. Many of these authors presented their studies at the 2014 ASLM meeting. This review of the SLMTA literature appeared in two parts utilizing both quantitative and qualitative data from the 28 published studies. The qualitative data published in part one reported on the content analysis compiled from local, national, and global studies to provide an overall view of the program and to identify "Next Step" and future priorities (Luman, Yao, & Nkengasong, 2014, p. 265). The part-two review included detailed information from 211 laboratories in 18 countries on utilizing the SLMTA program to implement QMS. The WHO-AFRO SLIPTA checklist measured laboratory improvement in these articles.

Laboratory Quality

Studies authored by in-country laboratorians detailing experiences encountered on their laboratory's journey to accreditation were beneficial to this study by providing both quantitative and qualitative data. Laboratories with ISO 15189 accreditation reported starting with a baseline audit score of less than 55%, (between 0-142/275 possible points), and zero stars (Luman, Yao, & Nkengasong, 2014).

A published study performed by the Kenya Accreditation Services (KENAS) identified non-conformities found in Kenyan laboratories based on pre- and post-assessment results (Maina

et al., 2014). Information and data contained in this study as well as in other published studies summarized laboratory or countrywide progress in implementing the 12 Quality Systems Essentials (QSE) into daily laboratory practices. All laboratories in this study reported they wished they had included all their laboratory staff in the improvement processes from the beginning. Involving hospital administration is important to maintain open communication demonstrating and stressing the importance of budget reviews and administration support.

Those laboratories sharing both successes and barriers with their administrators reported more engagement from other hospital departments along with increased clinician and patient satisfaction. Some of the barriers reported in the KENAS study included a lack of local resources for staff continuing education, gaining staff buy-in to implement changes and processes, lack of support from vendors to validate equipment, and variability in mentor skills and support. Another country study reported staff turnover to be a challenge as the new staff was not always knowledgeable of current Quality Management Systems and practices. In these cases, laboratory practices often reverted to non-standardized methods delaying improvements and decreasing staff morale (C. Robinson personal communication with in-country laboratorians 2014).

For his dissertation titled: *Creating an Effective Medical Laboratory Capacity in Limited-Resource Settings: A Case Study of Kampala, Uganda*, Elbireer researched factors related to the poor quality of medical laboratory services in the limited-resource setting of Kampala, Uganda (Elbireer, 2012, p. 1). His findings indicated Africa's own political, economic, and tribal tribulations as well as resource limitations hampered healthcare advancement in Uganda. His study found not only limited resources but also limited knowledge by physicians of the value of laboratory results and how to use them in patient diagnosis (Elbireer, 2012).

A 2014 study conducted by Yao, Maruta, Luman, and Nkengasong described the SLMTA program in detail highlighting challenges, achievements, and lessons learned in countries implementing SLMTA workshops between 2009 and 2013. This 2014 study also reported the negative impact below-par laboratory services exert on healthcare systems in developing countries, including sub-Saharan Africa (SSA) (Yao, Maruta, Luman, & Nkengasong, 2014, p. 1). Five common challenges laboratories reported as barriers to implementing QMS discovered from the Yao, Luman, and Nkengasong study were: (1) program disruptions, (2) high staff turnover, (3) non-SLMTA staff involvement, (4) site support and mentoring, and (5) program sustainability.

Working personally in fourteen of these 53 countries between 2006 and 2018, this researcher found a varied implementation of quality management systems guidelines. This variation may be the result of delivering the materials in English as terminology differs between countries and cultures. Even when funding was available, recruiting qualified trainers, auditors and mentors proved to vary considerably. Building appropriate levels of human capacity take time, may account for delays in implementing QMS, and potentially be one indicator for the currently limited number of accredited laboratories. A critical finding from the Yao, Maruta, Luman, and Nkengasong study was the challenge mentorship and site visits presented (2014, p. 4). Longer mentorships and increased frequency of site visits positively affect a laboratory's ability to overcome barriers and fully implement improvement projects in their study. To circumvent time delays, some countries budgeted for in-country workshops aimed to increase the number of local trainers, provide more work-time enabling mentors to visit their assigned labs more frequently, and collaborate with international laboratories to bring mentors to the laboratories for more extended periods.

A study from the Caribbean Region in 2014 described how the decision to offer embedded mentorships for longer periods enhanced laboratory improvement outcomes (Guevara et al., 2014, p. 67). While laboratorians interviewed in this 2017 study agreed (26/44, 59%) their assigned mentors were helpful; there was no agreement on the number of visits or the length of the mentorship. When asked to rate the value of the mentor and the laboratory manager leadership, respondents ranked mentorship second to laboratory manager leadership (44/44, 100%).

Many authors from earlier studies commented their participants wished they had listened to the advice given in the SLMTA workshops and included all laboratory staff and administrators in planning, collecting data, reviewing the data, and implementing a plan in their improvement projects ("Lessons Learned from SLMTA Accredited Labs," 2014). Other comments referenced not fully realizing the costs associated with performing improvement projects or the staff time commitment, costs with purchasing and implementing quality control materials, and the costs of joining an external quality assurance (EQA) program. In developing countries, prioritizing costs and budgeting for them is a challenging and often a complicated process entwining social and political differences. The compiled data from these articles offer qualitative evidence as to why laboratories encountered the barriers and the innovative ways some laboratories overcame those barriers to continue laboratory improvement processes to reach accreditation.

In all the articles reviewed, only one looked for commonalities among the accredited laboratories (Yao, Maruta, Luman, & Nkengasong, 2014). This 2014 study surveyed all accredited laboratories. There were individual survey responses for each laboratory, but there was no analysis of inter-laboratory responses. Qualitative data did not categorize possible relationships between laboratories related to reported successes or challenges. Baseline and exit

audits took place, but there were no studies found using factor analysis to look for significant relationships between laboratory scores in each of the twelve sections and the total audit scores.

There were two articles describing challenges faced by laboratories as they implemented quality management systems and worked to earn accreditation. One study from Kenya included analysis of five laboratories using historical data mining from SLIPTA data reports and corrective action forms for each laboratory (Maina et al., 2014, p. 3). The Maina study looked at relationships between specific areas of improvement and overall success by comparing results of five laboratories. From this analysis, the study found ten challenges common to all five laboratories. Table 2 lists the challenges identified in the Kenya study. Overall, this study showed actions taken by laboratories to address deficiencies were often inadequate, and in most instances, causes not identified and eliminated. The level of implementation and the completeness of the laboratories corrective action work plans varied between the five laboratories but included the following ten challenges or deficiencies:

Table 2. Ten Challenges Common in Five Laboratories in Kenyan Study (2014)

No.	Challenge or Deficiency Identified
1	Lack of critical procedures
2	Lack of or incomplete management review records
3	Incomplete personnel files
4	Lack of equipment or method validation
5	Lack of equipment calibration records
6	Deficient internal audit
7	Inconsistent internal quality control monitoring
8	Unacceptable proficiency testing results
9	Ineffective corrective action
10	Inadequate quality indicator monitoring

The second study published in 2014, reported findings from five laboratories in the Caribbean Region. Their results indicated that early engagement of stakeholders was critical to the improvement process. This study also found involving laboratory staff in planning and

implementing improvement projects vital to gaining staff commitment (Guevara et al., 2014, p. 66). Another review of SLMTA literature conducted in 2014, *Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems*, concluded the SLMTA program is a global effort with demonstrated ability to transform and to improve laboratory services in developing countries globally (Yao & Luman, 2014, p. 43).

Several authors reporting baseline audit results found laboratories they studied had no prior experience with QMS (Andiric & Massambu, 2014, Gachuki et al., 2014, Maruti et al., 2014, Ndasi et al., 2014). In another study, the author reported that before the implementation of the SLMTA program "the idea of QMS was completely new to the laboratory staff, noting a general lack of quality culture" (Ndasi et al., 2014). The low level of baseline audit scores (39%, no star) using the WHO-AFRO SLIPTA checklist five-star scale confirms these reported comments. A second study in Kampala, Uganda found similar results with only 5% of the labs audited earning even one-star at the baseline audit. With little knowledge or experience with QMS, the training and mentoring were ineffective.

The SLMTA program, composed of both didactic and hands-on activities, offered real tasks for laboratory managers to practice and apply in their home laboratories. After implementing the QMS policies, countries began to develop five-year strategic plans with goals set to strengthen laboratories, implement a QMS, and earn accreditation. Lack of knowledge and experience with QMSs existed in three of the four laboratories studied in Vietnam in 2017 (3/4=75%). This finding requires immediate attention in revising current and future training materials. Staff isn't likely to commit to and implement a QMS if it does not comprehend what QMS is and why it's important. This finding also presented itself in responses to open-ended questions and comments during the interview process.

Part Two of the comprehensive review discusses quantitative evidence from the same 28 publications in addition to a meta-analysis of selected results (Luman, Yao, & Nkengasong, 2014). This review combined individual lab data and conducted a meta-analysis in Microsoft ® Excel 2013 to determine common areas of strengths, weaknesses, and improvements. The studies published in the comprehensive review of the SLMTA literature included individual laboratory and countrywide aggregate laboratory scores both by section score and total score using the WHO-AFRO SLIPTA checklist. The SLIPTA checklist has 12 sections representing the 12 Quality System Essentials (QSEs) as defined by the Clinical and Laboratory Standards Institute (CLSI, 2004).

The researcher only found one online resource to the laboratories currently accredited by ISO 15189. This study is on the SLMTA website and is a collection of Lessons Learned as reported from 19 of the 60 accredited laboratories as of January 2018 (19/60=32%) (SLMTA, n.d.). The published studies and articles are from 2012 -2014. During this span of three years, many national and international partners offered travel grants to laboratory staff in countries implementing the SLMTA program with the expectation they submit abstract proposals for presentation at the African Society for Laboratory Medicine (ASLM) conference in 2014. The African Journal for Laboratory Medicine (AJLM) launched in the same period and again, mentors and partners offered to assist, and fund research studies**,** and co-publish articles on individual laboratory or aggregate laboratory studies and their experiences implementing a QMS in their laboratories. The emphasis and momentum to publish continued through 2014 when the ASLM held its second conference. While there are fewer published articles after 2014, there is an increase in the number of laboratories earning ISO 15189 accreditation. Between 2013 and 2016, 32 SLMTA laboratories earned accreditation. From January 2017 through January 2018

another 27 laboratories reached ISO accreditation. Conclusions from these articles suggest more in-depth research about critical success factors related to earning laboratory accreditation is needed.

Implementation of a Quality Management System

Collectively, national and international partners researched and subsequently followed published recommendations on implementing quality management systems into laboratories as the path toward improving laboratory services. Clinical Laboratory Standards Institute (CLSI) is an organization "that brings together the worldwide laboratory community to advance a common cause" (CLSI, 2004). "Developed by CLSI members for use by the global laboratory community, CLSI's consensus-based medical laboratory standards are the most widely recognized resources for continually improving testing quality, safety, and efficiency" (CLSI, 2004). W.G. Miller, CLSI membership, states, "Standards are critical. The more standardization we can bring to the lab, the more consistent results are."

Innovative Delivery of QMS and SLMTA Training Materials

While maintaining standardization of material content and delivery style, there are examples of country innovation tailored to specific needs. Mozambique, to show country ownership of the SLMTA training program renamed the program using the Portuguese acronym FOGELA. Namibia invited nursing staff and administrators to join the workshops to better implement quality components throughout the whole hospital and patient experience. While auditing laboratories in Namibia in 2011, the researcher met personnel from nursing, emergency, and other departments that asked to share how all their hospital personnel worked together to improve not only laboratory services but hospital services as well. An emergency room nurse

noted that specimen collection protocols were now in place with a noticeable decrease in the number of rejected specimens. When governments acknowledge laboratory accreditation, individual laboratories benefit from the incentives they provide to continue improving their testing quality and to maintain their accreditation status (Peter et al., 2010). Cameroon opted to de-centralize training, and instead of bringing laboratory staff to a central location, the workshops took place in different provinces enabling more people to attend. The upfront costs for delivering the workshops in various areas were expensive at first, but as the number of trained facilitators and laboratory managers increased, the expenses decreased considerably. Other countries, such as Vietnam, prioritized development of a national training team, to build and sustain the capacity of in-country training facilitators.

Vietnam's Pathway to QMS Implementation

Many laboratories in Vietnam selected the SLMTA program to train managers how to improve the quality of their laboratory services and the accuracy of patient results. Four of these laboratories volunteered to participate in this study, allowing staff to respond to open-ended interviews questions and to complete a short survey. The SLMTA program is very prescriptive with the same trained facilitators conducting all three workshops and delivering the same information and activities following a standardized approach. Originally written and offered in English, SLMTA materials translated into Vietnamese significantly improved comprehension of each ISO standard. The VAMS has been a staunch supporter of enhancing laboratory services and is active in developing supportive memorandums and official mandates for all laboratories to begin implementing quality management principles into their daily practices. Circular 01 and the Vietnamese MOH Decision No. 2429/QD-BYT (quality level medical laboratory assessment

guidelines) are products designed for use in Vietnam and greatly enhance outcomes in training and assessment activities.

In May 2017, 25 laboratory managers and safety officers met in Hanoi to review the draft version of the Vietnam Decision Guidelines. The VAMS worked over 12 months developing the guidelines ensuring their version included standards referenced to all the ISO 15189 standards. Participants debated on the exact wording and meaning of terminology used before reaching consensus on the Decision guidelines often.

In October of 2017, two workshops occurred. The goal of each workshop was to train and then certify participants as Vietnamese auditors. Currently, laboratories are concentrating on ISO accreditation for those tests commonly ordered for HIV, TB, and Malaria patients including diagnosis, monitoring treatment, and secondary infections. All four laboratories participating in this study sent a minimum of two people to each of the SLMTA workshops to increase both knowledge and skills implementing a QMS in their laboratories. All four laboratories underwent baseline assessments, managers and staff analyzed results to determine gaps in their laboratory quality, and subsequently designed and implemented improvement projects to fill the gaps. The one comment consistently voiced from staff participating in this study concerned not fully understanding what quality management systems mean and why they are so important. All personnel completing the interview agreed the implementation process was difficult, required many hours of uncompensated overtime, and often delayed the turn-around-time returning patient results to the clinicians. The staff reported they saw no tangible evidence from the extra work at the beginning of the implementation process. Over time, however; staff commented the change in the laboratory workflow, the efficiency from the staff working as a team, and the

standardization of testing processes was overwhelmingly positive and made them feel proud to be a part of a quality lab.

Critical Success Factors Model

Researchers have studied many types of successful businesses and organizations to determine those factors they postulate as critical success factors. Daniel introduced the concept of CSFs into modern literature in response to what he saw as a crisis in contemporary management schemes (Daniel, 1961). Daniel developed the CSF framework with the concept the same framework might apply to multiple types of organizations. His research offered examples of CSFs in several major industries: the automotive industry, the food processing industry, the life insurance industry, and the grocery chain organization (Daniel, 1961). The grocery chain study found that organizational pricing strategy was a critical success factor and singly unique to their industry (O'Sullivan, 2008). Rockart (1979) believed CSFs might not be the primary goals of an organization or business instead suggesting they are the areas in which good performance is necessary to ensure goal success. "As identified by an MIT research group, Rockart (1979) describes factors that affect the identification of CSFs":

1. Structure of the industry: each industry has an inherent set of CSFs that are determined by the nature of the industry itself
2. Competitive strategy, industry position, and geographic location: every organization experiences a unique situation as defined by its history and current competitive policy
3. Environmental factors: include those factors often beyond the control of the organization but which have an impact on local and national levels (O'Sullivan, 2008, p. 21-22).

Rockart and Bullen referred to CSFs as "the limited number of areas in which satisfactory results will ensure successful competitive performance for the individual, department, or organization (Westrum, 2010, p. 13; Rockart & Bullen, 1981). Rockart and Bullen (1981) presented five key sources of CSFs: the industry, competitive strategy and industry position, temporal factors, environmental factors, and managerial position. Three years later Boynton and Zmud further suggested that CSFs are "those few things that must go well to ensure success for a manager or an organization" (Boynton & Zmud, 1984). CSFs "describe the things an organization must do well to achieve its strategic goals (…); they represent those managerial or enterprise areas that must be given special and continual attention to bring about high performance" (Friesen & Johnson, 1995, p. 2).

Projects are deemed successful if they have met their time and schedule constraints. Terms such as "on time" and "on budget" frequently measure success because they are the easiest to quantify (Pinto and Slevin, 1988). These characteristics support earlier definitions of project management (time, cost, and scope – also known as the "iron triangle") (Atkinson, 1999). Researchers use definitions for CSFs with varying degrees of uniformity. Belassi and Tukel refer to CSFs as "those factors outside the control of management which could determine the success or failure of a project" (Belassi & Tukel, 1996, p. 141). Milosevic and Patanakul prefer a strict Project Management perspective, stating CSFs are characteristics, conditions, or variables that can have a significant impact on the success of the project when properly sustained (Atencio, 2013).

CSF literature based on theory and framework organization has evolved over the years. For CSFs first developed for construction and defense businesses, success depended on meeting deadlines, staying within budget, and customer satisfaction. As more diverse businesses and

organizations began identifying CSFs for their individual needs and goals, the factors reflected more individual and organizational needs. General management literature suggests that a manager's leadership style and competence is a crucial factor to successful business performance and studies are confirming a correlation between these and the conformance of companies and organizations (Turner & Muller, 2005). However, CSFs seldom include leadership style and competence. In Jugdev and Muller's (2005) study titled: *The project manager's leadership style as a success factor on projects: a literature review*, they identified four periods of thought on success factors with each period widening the definition of success. Table 3 shows the evolution of time periods and overall researcher success factor focus on CSFs.

Table 3. CSF Evolution and Success Factor Focus from the 1970s to 2018

Time Period	Project Success Factor Focus
The 1970s	Implementation, measuring time, cost, functionality improvements, and systems delivery (Iron triangle)
The 1980s	Quality of planning and handover became important. CSF lists started looking at organizational and stakeholder perspectives. Project manager leadership style is not mentioned as a CSF though literature implies that managers should be knowledgeable and competent, e.g., have on-the-job experience (Turner, Keegan, & Crawford, 2003). Pitfalls occurred when managers did not adequately plan, organize, or control projects (Anderson, Grude, Haug, & Turner, 1987). Morris (1988) identified different factors at different stages of a project that could cause a project to fail and mentions poor leadership as a failure factor during planning, build-up, and closeout, but not in execution. Pinto and Slevin (1988) developed the most widely quoted list of CSFs, but do not mention the project manager.
The 1990s	Morris and Hough (1987) did a study of seven major projects in the United Kingdom, which Morris in 1997 developed into a project strategy model. Turner (1999) took Morris's model and remodeled it as the Seven Forces Model for project success.

The 2000s	Renewed interest in project success factors. Hartman and Ashrafi (2002) identified a list of ten factors for Information Systems projects, closely linked to Pinto, and Slevin's 1988 list. Though project success literature has ignored the project manager, much information exists about both projects and managers. Crawford's work in 2001 was the most significant correlating the project manager's competence to his or her success as a project manager. Studies began to include personality and leadership style in the manager's competence, suggesting these two factors make a manager more competent. Turner (1999) suggested there were four leadership styles based on how much the manager involved the team in decision-making and his or her flexibility. Turner also suggested that different leadership styles were appropriate at each stage of the project's lifecycle. Atencio's (2013) study suggested that a project manager's leadership style should be a CSF as well as team member style.

Belassi and Tukel introduced a new framework (1996) to measure success or failure based on cause-effect relationships initiated by the critical factors. They recommend grouping Factors into four areas: 1. Factors related to the project (accreditation); 2. Factors related to the lab/project manager and laboratory /team members; 3. Factors related to the hospital/lab organization; and 4. Factors related to the external environment (Morrison, 2014, Kewin, 1947).

Atencio's Ph.D. thesis, published in 2013, supports Belassi and Tukel's framework but recommends splitting the area encompassing lab managers and team members into two separate areas with the benefit of looking more closely at the individual impact managerial skills and team member competencies have on project success (Atencio, 2013). Her findings concluded that leadership competencies should identify CSFs accurately (Atencio, 2013). Her conclusions and recommendations support Turner and Muller who concluded in 2005 "the literature has largely ignored the impact of the project manager and his/her leadership style and competence, on project success" (Turner & Muller, 2005, p. 59). This study design incorporated concepts from Morrison, 2014, Kewin, 1947, Atencio, Friesen and Johnson, and Turner and Muller to

identify the top five CSFs in the Vietnamese laboratories. As recommended by Friesen and Johnson**,** only the top five CSFs identified by the study participants were used. Study participant identification of their top five factors aligns closely with three of the four categories suggested by Belassi and Tukel. This study's findings also support Atencio's dissertation findings that laboratory staffs and laboratory managers both offered valuable contribution to the success of this QMS project.

APPENDIX C

ADDITIONAL METHODS

VAMS approval letter authorizing the researcher to enter hospitals participating in the study:

BỘ Y TẾ
CỤC QUẢN LÝ KHÁM, CHỮA BỆNH

Số: 1506/KCB-QLCL
V/v đánh giá kết quả thực hiện nâng cao chất lượng xét nghiệm theo Chương trình thí điểm SLMTA

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Hà Nội, ngày 13 tháng 10 năm 2017

Kính gửi: .....
.....

Nhằm mục đích tăng cường năng lực quản lý hệ thống chất lượng xét nghiệm, trong khuôn khổ Dự án tăng cường quản lý hệ thống phòng xét nghiệm tại tuyến Trung ương và tuyến tỉnh của Cục Quản lý Khám, chữa bệnh do CDC Hoa Kỳ tài trợ; thực hiện chỉ đạo của Lãnh đạo Bộ Y tế, từ năm 2012-2015, Cục Quản lý Khám, chữa bệnh phối hợp cùng các đơn vị liên quan triển khai thí điểm Chương trình Nâng cao năng lực quản lý chất lượng xét nghiệm (SLMTA) với sự cam kết tham gia Chương trình của Quý đơn vị.

Đến nay, theo báo cáo, 26 phòng xét nghiệm tham gia Chương trình đã có sự cải thiện chất lượng nhất định và thực hiện đúng theo các văn bản hướng dẫn của Bộ Y tế, đặc biệt trên nền tảng quản lý chất lượng được tiếp cận khi thực hiện Chương trình, một số phòng xét nghiệm đã phấn đấu và đạt được chứng chỉ công nhận Tiêu chuẩn ISO 15189.

Nhằm đánh giá các yếu tố tác động đến sự thành công của Chương trình và thực tế triển khai, duy trì công tác quản lý chất lượng tại các phòng xét nghiệm, theo đề xuất của nhà tài trợ CDC Hoa Kỳ tại Việt nam, dự kiến có buổi khảo sát tại phòng xét nghiệm của Quý bệnh viện (có danh sách và thời gian cụ thể kèm theo).

Để bảo đảm kết quả đánh giá chính xác và Chương trình đạt kết quả tốt, đề nghị Quý đơn vị tiếp tục quan tâm, hỗ trợ và tạo điều kiện thuận lợi để Đoàn đánh giá hoàn thành tốt công việc./.

Nơi nhận:
- Như trên;
- Thứ trưởng Nguyễn Viết Tiến (để b/c);
- SYT Tp. HCM; (để biết và chỉ đạo);
- Lưu: VT, QLCL.

KT. CỤC TRƯỞNG
PHÓ CỤC TRƯỞNG

Nguyễn Trọng Khoa

APPENDIX D

ADULT CONSENT FORM TO PARTICIPANTS IN RESEARCH STUDY

CMU
CENTRAL MICHIGAN UNIVERSITY

Adult Consent Form

Study Title: A Multi-Case Analysis of Critical Success Factors Comparing Laboratories in Vietnam Working to Earn International Accreditation

Contact information:

Doctoral Student Candidate: Catherine Robinson, Doctor of Health Administration Department (DHA), Central Michigan University (CMU), Mt. Pleasant, Michigan, USA. robin1cd@cmich.edu

Dissertation Chair: Dr. James A. Johnson, DHA Department, CMU, Mt. Pleasant, Michigan, USA. Johns6ja@cmich.edu

Dissertation Committee:

Dr. Hien Bui, CDC Laboratory Branch, Hanoi, Vietnam. hnz0@cdc.gov

Dr. Katy Yao, CDC Public Health Educator, Atlanta, Georgia, USA. dbx4@cdc.gov

Introductory Statement: This study aims to answer the research question: "What are the Critical Success Factors for Medical Laboratories Implementing the Strengthening Laboratory Management Toward Accreditation (SLMTA) Program in Vietnam and Working Toward Earning International Accreditation?" There are no personal questions asked, and any study findings will include aggregate level data only. I am available to answer any questions before you sign the consent form.

What is the purpose of this study? This study proposes to interview stakeholders from multiple levels at four medical laboratories in Ho Chi Minh City, Vietnam to identify both the critical success factors and the barriers impacting successful quality management systems implementation and international accreditation.

What will I do in this study? Each volunteer subject will answer the same interview questions allowing the researcher to gather qualitative data. The responses will be analyzed and categorized to identify common factors related to improving laboratory services and earning accreditation. No procedures in this study are experimental.

How long will it take me to do this? The interview will take approximately 30 minutes.

Are there any risks of participating in the study? There are no known risks and discomforts to the subject expected as a result of participating in this study.

What are the benefits of participating in the study? There are very few published qualitative studies identifying critical success factors related to medical laboratories in Vietnam adopting the SLMTA program as a path to implement quality management systems to improve laboratory services and earn international accreditation. Your responses will assist in identifying the critical success factors.

Will anyone know what I do or say in this study (Confidentiality)? All responses will be kept confidential. Each participant will have a unique number. Collected data will be as aggregate findings only.

Will I receive any compensation for participation? There is no compensation or fee paid to any subject for participating in the study.

A copy of the research study results is available upon request.

Who can I contact for information about this study?

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation at any time without penalty.

If you are not satisfied with the manner in which this study is being conducted, you may report (anonymously if you so choose) any complaints to the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

My signature below indicates that all my questions have been answered. I agree to participate in the project as described above.

_____ _____

Signature of Subject Date Signed

A copy of this form has been given to me. _____ Subject's Initials

For the Research Investigator—I have discussed with this subject the procedure(s) described above and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

Signature of Responsible Investigator Date Signed

APPENDIX E

ADULT CONSENT FORM (VIETNAMESE)

CMU
CENTRAL MICHIGAN UNIVERSITY

Đơn đồng ý tham gia nghiên cứu cho người trưởng thành

Tên đề tài: Một phân tích nhiều trường hợp về các yếu tố thành công chính trong việc so sánh các phòng xét nghiệm ở Việt Nam thực hiện để tiến tới được công nhận

Thông tin liên lạc:

Sinh viên tiến sỹ: Catherine Robinson, Tiến sỹ khoa quản trị y tế (DHA), Trường Đại học Michigan (CMU), Mt. Pleasant, Michigan, USA. robin1cd@cmich.edu

Chủ tịch hội đồng: Dr. James A. Johnson, Khoa quản trị y tế (DHA), CMU, Mt. Pleasant, Michigan, USA. Johns6ja@cmich.edu

Thành viên hội đồng:

Dr. Hien Bui, CDC Laboratory Branch, Hanoi, Vietnam. hnz0@cdc.gov

Dr. Katy Yao, CDC Public Health Educator, Atlanta, Georgia, USA. dbx4@cdc.gov

Giới thiệu: Nghiên cứu này nhằm trả lời cho câu hỏi nghiên cứu: "Cái gì là yếu tố thành công chính cho chương trình SLMTA ở Việt Nam và hoạt động hướng đến việc được công nhận quốc tế? Không có câu hỏi cá nhân nào được hỏi và bất kỳ kết quả nghiên cứu nào chỉ được báo cáo ở mức độ tổng hợp. Tôi sẵn sàng trả lời bất cứ câu hỏi nào trước khi ký vào đơn đồng ý tham gia.

Mục đích của nghiên cứu là gì? Nghiên cứu này phỏng vấn các bên liên quan từ nhiều cấp độ ở 4 phòng xét nghiệm y học ở thành phố HCM, Việt nam nhằm xác định các yếu tố thành công và những rào cản tác động đến việc thực hiện hệ thống quản lý chất lượng thành công và việc công nhận quốc tế.

Bạn sẽ làm gì trong nghiên cứu này? Mỗi cá nhân tình nguyện tham gia nghiên cứu sẽ được hỏi những câu hỏi cho phép nghiên cứu viên thu thập số liệu định tính. Các câu trả lời sẽ được phân tích và phân tầng để xác định các yếu tố chung liên quan đến việc cải thiện các dịch vụ

phòng xét nghiệm và tiến tới được công nhận. Không có quy trình nào được thử nghiệm trong nghiên cứu này.

Cần bao nhiêu thời gian để thực hiện? Cuộc phỏng vấn sẽ mất xấp xỉ 30 phút.

Có bất cứ nguy cơ nào khi tham gia nghiên cứu không? Không có bất cứ nguy cơ nào/sự không thoải mái đối với người tham gia nghiên cứu.

Lợi ích của việc tham gia vào nghiên cứu? Có rất ít nghiên cứu định tính được công bố mà xác định các yếu tố liên quan đến các phòng xét nghiệm y học ở Việt Nam thực hiện chương trình SLMTA như một cách để thực hiện hệ thống quản lý chất lượng nhằm cải thiện các dịch vụ phòng xét nghiệm và tiến tới được công nhận quốc tế. Câu trả lời của bạn sẽ giúp xác định các yếu tố thành công.

Có ai biết tôi làm hay nói gì trong nghiên cứu này không? (một cách riêng tư)? Tất cả các câu trả lời sẽ được giữ kín. Mỗi người tham gia sẽ được xác định bởi một số duy nhất. Mỗi cuộc phỏng vấn sẽ được thu âm để hỗ trợ việc dịch các câu trả lời và được xóa sau khi dịch. Số liệu thu thập được sẽ được báo cáo chỉ khi các kết quả đã được tổng hợp.

Tôi có được nhận bồi dưỡng khi tham gia không? Người tham gia nghiên cứu sẽ không được nhận bất cứ khoản bồi dưỡng hoặc chi phí nào khác.

Có cách nào khác để tôi nhận được khoản bồi dưỡng hay lợi ích khi tham gia nghiên cứu không? Có thể yêu cầu một bản sao các kết quả nghiên cứu.

Tôi có thể liên lạc với ai để biết thông tin của nghiên cứu ?

Bạn có thể từ chối hoặc không đồng ý tiếp tục tham gia nghiên cứu vào bất cứ khi nào mà không bị phạt .

Nếu bạn không hài lòng với cách thực hiện nghiên cứu, bạn có thể báo cáo (ẩn danh nếu bạn chọn) đến hội đồng y đức bằng cách gọi điện đến số 989-774-6777, hoặc gửi thư đến địa chỉ Hội đồng Y đức, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

Chữ ký của tôi dưới đây khẳng định rằng tất cả các câu hỏi đã được trả lời. Tôi đồng ý tham gia nghiên cứu như đã mô tả ở trên

_____ _____

Chữ ký người tham gia Ngày

Một bản sao của đơn này được gửi đến tôi. _____ Chữ cái đầu của người tham gia

Đối với nghiên cứu viên—Tôi đã thảo luận với người tham gia nghiên cứu về quy trình đã được mô tả ở trên và những nguy cơ liên quan; Tôi tin anh/chị hiểu nội dung của đơn đồng ý tham gia nghiên cứu và chịu trách nhiệm với việc đồng ý tham gia nghiên cứu này.

_____ _____

Chữ ký của nghiên cứu viên Ngày

APPENDIX F

CRITICAL SUCCESS FACTORS DEMOGRAPHIC SURVEY AND SEMI-STRUCTURED INTERVIEW QUESTIONS

Participants, please respond honestly to each of the questions below. All laboratories will be coded with a number and individuals will also receive a code to maintain the confidentiality of responses; only aggregate results will be reported.

DEMOGRAPHIC SURVEY QUESTIONS

Section 1: Laboratory/Health Facility Information: (questions 1-9)

1. Location of Laboratory (City/Providence/Country):_____
2. What is the level of your laboratory: _____
3. What is your gender?
   a. Male
   b. Female
   c. Do not wish to share information
4. How many years of laboratory experience do you have."
   a. Less than 3 years
   b. 3 to less than 5 years
   c. 5 to less than 10 years
   d. 10 to less than 15 years
   e. 15 to less than 20 years
   f. 20 years or more
5. How many years of management experience do you have?
   a. Less than 3 years
   b. 3 to less than 5 years
   c. 5 to less than 10 years
   d. 10 to less than 15 years
   e. 15 to less than 20 years
   f. 20 years or more
6. What is the highest degree you hold?
   a. No degree
   b. BS degree
   c. Master's degree
   d. Ph.D. or equivalent
7. What is your age range? Please select the range that includes your age.
   a. 20-29
   b. 30-39
   c. 40-49
   d. 50-59
   e. 60 and over
8. Did you complete a course at the university/school you attended containing leadership

and management principles? Please describe

a. Yes

b. No, management/leadership course not included in the curriculum

9. Select the one leadership style that best describes your leadership approach to Implementing QMS into your laboratory project. Below are the definitions for your reference.

___ a. Laissez-Faire Leadership - The laissez-faire style is sometimes described as a "hands-off" leadership style because of the leader delegates the tasks to their followers while providing little or no direction to the followers.

___b. Autocratic Leadership - An autocratic leader keeps strict, close control over followers by keeping close regulation of policies and procedures given to followers

___c. Bureaucratic Leadership - Bureaucratic style is based on following normative rules and adhering to lines of authority.

___d. Transactional Leadership – Transactional leaders focus their leadership on motivating followers through a system of rewards/punishments.

___e. Situational Leadership - The situational leader believes there is no single "best" style of leadership. Effective leadership is task-relevant, and the most successful leaders are those that adapt their leadership style to the maturity of the individual or group they are attempting to lead or influence.

SEMI-STRUCTURED INTERVIEW

Section 2: Semi-structured interview questions 1-5

1. Describe the most difficult management task you/your laboratory faced in the journey to QMS implementation/earning accreditation?

2. List five CSFs you think most important in the successful implementation of QMS and earning ISO 15189 accreditation. Please define each factor to clarify terminology and interpretation. Finally, list them in descending order of importance (i.e., the CSF you consider most critical would be # 1 and least critical as # 5.

Critical Success Factor	Definition of Critical Success Factor
1.	
2.	
3.	
4.	
5.	

3. List barriers you perceived caused challenges and delays in the laboratory implementation process of a QMS and in earning ISO 15189 accreditation

Barrier to QMS Implementation	Definition of Barrier
1.	
2.	
3.	
4.	
5.	

4. What advice would you share with other laboratories/facilities working to implement QMS into their laboratories and earn accreditation?

5. Are there any management/leadership skills you wish you had had before beginning quality management implementation in your laboratory?

a. Yes. Please list
b. No

APPENDIX G

ADDITIONAL RESULTS

Table 1. CSF Categories and acronyms

No.	Category Name	Acronym
1	Laboratory Infrastructure	LI
2	Personal Commitment	PC
3	Communication	C
4	Continuing Education	CE
5	Manager Leadership	ML
6	Hospital Administration Support	HAS
7	Project Work Plan	PRO
8	Teamwork	TW
9	External Funding	EF
10	Mentorship	M

APPENDIX H

BARRIER GRID USED TO MEASURE INTERRATER RELIABILITY

Table 2. Barrier grid to measure interrater reliability of coding, content analysis

	Researcher										
interrater # 1		SQMS	LOR	TINT	LOKSOP	INFRA	WAIT	LHAS	LMIN	CC	OTH
	SQMS										
	LOR										
	TINT										
	LOKSOP										
	INFRA										
	WAIT										
	LHAS										
	LMIN										
	CC										
	OTH										

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