

Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance
Towards a Systems Quality Improvement Approach



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DECLARATION

The research that forms the foundations of this thesis was conducted at the NPHL. Permission for the study was granted by the Director of the Laboratory.

The work presented in this thesis is mine and has never at any time been acquiesced for an award of a degree or any other qualification.

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TABLE OF CONTENTS

ACKNOWLEDGEMENT	iv
DECLARATION	v
TABLE OF CONTENTS	vi
List of figures	x
List of tables	xi
List of Acronyms	xii
Abstract	xv
Chapter One: Introduction	1
1.1 Organizational Background	1
1.2 Problem and Context	2
1.3 The Kaizen Approach.....	13
1.4 The potential contributions of the research	15
1.5 Thesis structure and content	16
Chapter Two: Literature Review	18
2.1. Literature Outline	18
2.2 Literature Search Strategy.....	19
2.3. Overview of Laboratory Quality Management System.....	20
2.4. Laboratory system’s dynamics, Quality indicators and Quality Improvement.....	24
2.5. Laboratory Systems vulnerabilities, environmental pressures, shocks, and coping strategies	27
2.6. Regulatory Compliance Revisited-Recoupling compliance in contextual idiosyncrasies ..	31
2.7. International Standardization Organization (ISO) Laboratory Quality Frameworks	32
2.8. Decolonization of ISO frameworks and National Standards.....	36
2.9. Post-adoption of ISO’s: Laboratory systems heterogeneity and standards implementation	38
2.10 Institutional isomorphism	39
2.11. Laboratory Total Quality Management Practices	42
2.12. TQM and Tacit knowledge: coevolution and diffusion?	43
2.13. Adoption of context-based measures for TQM	45
2.14. Institutional Theory and TQM practices	46

2.15. Institutionalism	48
2.16. Organizational culture, stakeholder readiness and TQM mediating effects	51
2.17 Institutionalizing TQM Practices	53
2.18. Summary of literature review and scaffolding for current research	55
Chapter Three: Research Design	57
3.1. Background and introduction	57
3.2. Philosophical approach	57
3.3. Methodology	58
3.4 Research Participants	61
3.5. Ethical considerations and approval	62
3.6 Role duality and ambiguity of being an insider-researcher	63
3.7. Managing biases	65
3.8. Data Collection	66
3.8.1. Data Collection Protocols	66
3.8.2. Interviews	66
3.8.3. Surveys	66
3.8.4. Secondary Data collection	67
3.8.5. Integrated data collection methods	67
3.9 Data collection approaches and timelines	68
3.10 Data analysis	69
3.11 Summary of Research Methodology	72
Chapter Four: Problematization	74
4.1. Introduction	74
4.2. Problem Construction Phase	75
4.3 Problematization Phase I	76
4.4 Emerging Action Research Theme 1: Development of Regulatory Mechanisms	77
4.5 Emerging Action Research Theme 2: Process Control	77
4.6 Emerging Action Research Theme 3: Regenerative Supply Chain	79
4.7 Emerging Action Research Theme 4: Laboratory Partnerships, Collaborations and Engagement	80
4.8 Mop up of broad issues	84

4.9 Problematization phase II	85
4.10 Laboratory partnerships, collaborations, and engagements.....	85
4.11 Process control.....	89
4.12 Regulatory and Policy Guidelines Review	92
4.13 Regenerative Supply Chain.....	95
4.14 Conclusion of problematization process.....	97
Chapter Five: Laboratory Empirical Work Action Planning Phase	99
5.1. Introduction.....	99
5.2. Defining Thematic Priority Areas	100
5.3. Details of Action Themes	107
5.3.1 Formation of Cohesive actor engagement.....	107
5.3.2 Process Control reengineering	109
5.3.3 Development of internal regulatory mechanisms	110
5.4 Summary of action planning Phase of PAR.....	111
Chapter Six: Project Implementation Action Cycle One:	112
6.1. Introduction.....	112
6.2. Thematic action 1: Re-engineering process control	115
6.3. Thematic Action 2: Development of Regulatory Mechanisms	119
6.4. Thematic Action 3: Formation of cohesive actor engagement.....	120
6.5. Evaluating Action Research Cycle One.....	122
6.6. Action Research cycle one evaluation conference	122
6.6.1. Action Cycle One: Process Control	125
6.6.2. Action Cycle One: Developments in regulatory mechanisms	126
6.6.3. Action Cycle One: Formation of cohesive actor engagement.....	127
6.7. Summary of cycle one evaluation conference.....	128
Chapter Seven: Project Implementation Action Cycle Two	130
7.1. Introduction.....	130
7.2 Development of Regulatory mechanisms: a framework for policy-practice review, systems evaluation, and networking	131
7.3 Process Control: Develop SOP Masterfile and Institutionalize SOPs	133

7.4 Formation of Actor Engagement: Value co-creation, knowledge sharing via mentorship circles and storyboards	135
7.5 Summary of cycle two actions implementation	138
7.6 Evaluating Action Research cycle two.....	139
7.7 Summary of cycle two evaluation	146
Chapter Eight: Discussion and conclusions	148
8.1 Introduction.....	148
8.2 Integrated Quality Framework.....	149
8.3 Research Questions.....	152
8.4 What exists between TQM knowledge and its implementation in real context of action?	162
8.5 Research implications, future directions, and Limitations	163
8.5.1 Practical and policy implications	163
8.5.2 Theoretical implications	165
8.5.3. Research Limitations	166
8.6 Conclusions.....	168
8.7 Reflections, development and learning in scholarship and practice	169
8.7.1 What went well	173
8.7.2 What could be improved	175
8.7.3 Generating actionable knowledge.	176
Bibliography.....	178
Appendices	196

List of figures

Figure 1: Quality Systems Essentials (Adapted from CLSI/ NCCLS, 2004)..... 22

Figure 2: Demings Model of PCDA Adapted from W. Edward Deming institute, 2009..... 24

Figure 3: The Quality Cycle (adopted from Badrick et al., 2017)..... 25

Figure 4: A laboratory Quality Management Framework (Source: Westgard and Klee (2006)..... 42

Figure 5: A model for Institutionalization (Source: Silimperi et al., 2003)..... 54

Figure 6: Relationships between core and action research Adopted from Zuber-Skerrit and Perry ,200261

Figure 7: Thematic Analysis Diagram 71

Figure 8: Mapping of the Stakeholders of National Public Health Laboratory in Timor Leste 88

Figure 9: Swiss cheese Model deploying FMEA to evaluate Laboratory system adapted from Reason (2000)..... 91

Figure 10: Regulatory guidelines problematization..... 94

Figure 11: Existing laboratory workflow as constructed by participants..... 116

Figure 12: Laboratory Integrated Quality Framework..... 149

List of tables

Table 1: Preliminary Laboratory Quality System problematization and thematic classification.....	83
Table 2: Summary of PAR action Planning workshop outcomes	106
Table 3: Summary of thematic actions and their immediate outcomes	114
Table 4: Matrix of PAR cycle one evaluation of laboratory quality improvement	124
Table 5: Matrix for evaluation of PAR cycle two for laboratory quality improvement	142

List of Acronyms

Anti-microbial Resistance Surveillance AMR	Proficiency Testing PT
Australian Department of Foreign Affairs and Trade DFAT	Quality Improvement QI
Catch, Reflect, Improve, Scrutinize, and Pass CRISP	Quality Management System QMS
Clinical and Laboratory Standards Institute CLSI	Quality Systems Essentials QSE
Complex Adaptive System CAS	Strengthening Laboratory Management Towards Accreditation SLMTA/ SLIMPTA
Enzyme-Linked Immunosorbent Assay ELISA	Thematic Action Group TAG
External Quality Assurance EQA	Total Quality Management TQM
External Quality Assurance Programs EQAP	Total Testing Process TTP
Failure Mode Effects Critical Analysis FMECA	Turnaround Time TAT
Focus Group Discussions FGD	U.S Centers for Disease Control and Prevention CDC
Internal Quality Control IQA	United States Agency for International Development USAID
International Standards Organization ISO	World Health Organization WHO
Laboratory Information Management Systems LIMS	
Laboratory Quality Management system LQMS	
<i>Material Safety Data Sheets</i> MSDS	
Ministry of Health MOH	
National Health Public Health Laboratory NPHL	
Participatory Action Research PAR	
Plan-Do-Study- Adjust PDSA	
Polymerase Chain Reaction PCR	

List of Appendices

Appendix 1: Supplementary Themes	196
Appendix 2: University of Liverpool Ethics Committee Approval Letter	198
Appendix 3: Institutional Support Letter	199
Appendix 4: Participant Consent Form	200
Appendix 5: Participant Information Sheet	201
Appendix 6: Laboratory Quality Improvement Evaluation-Survey Questionnaire	202

Abstract

This thesis explores quality improvement (QI) by providing insights into real-world laboratory problems and then suggests temporal and contextual change interventions. The laboratory under study plays a significant role in public health by providing data for use at the national, regional, and global levels. This role notwithstanding, the stakeholder and regulatory authorities cast doubt on laboratory service quality, prompting QI efforts. This multi-method qualitative research combines grounded theory and ethnography and employs critical realism and social constructivism philosophical approaches. The study utilizes participatory action research (PAR) models in interactive problem identification, action planning, implementation, and evaluation. I address the specific research objectives (1) build a contextualized evidence-based integrated framework for laboratory systems quality improvement; (2) understand macro-processes for institutionalizing quality improvement and (3) explore the role of knowledge management within a research community in the realization of Total Quality Management (TQM). This research addresses the question: What exists between TQM knowledge and implementation in a real context of action?

The study involved eleven participants identified through purposive and convenience sampling. Participants completed two cycles of extensive actions in the specific laboratory setting for 21 months. The research cycle, iterative in design, takes an inductive-subjective-contextual approach. It yields researcher mindset paradigmatic shifts, drawing on pragmatist accounts and reflexivity. I locate manifestation of institutional change in institutional entrepreneurship as laboratory practitioners leverage actions, extending value for the patients and the stakeholders, following improved work and knowledge-sharing practices.

The findings suggest the permeability of quality frameworks to social interaction, enabling practitioners to conceptualize what works in temporal settings. As social entrepreneurs, participants decide modalities for staging, framing, and propagating change. Participant connections to intersubjective realities, innovative engagement, and collaborative inquiry provide legitimacy in the process. Finally, I reflect on my experiences in conducting an empirical qualitative study from scholarship and practice contexts.

Chapter One: Introduction

1.1 Organizational Background

The laboratory, on which the work of this thesis is founded, has been in existence for slightly over three decades. Prior to its designation as a National Public Health Laboratory (NPHL) in Timor-Leste, it functioned as a provincial laboratory under the jurisdiction of colonial authority. It is relatively complex in its functions and structure, and, although autonomous, to an extent, some of its functions are still being controlled by the umbrella Ministry of Health (MOH) in Timor-Leste. It has four distinct departments, Immuno-serology, Microbiology, Quality Control, and Administration. Besides, more recently, the department of Toxicology was created but is still juvenile. The quality control department has its work distributed through all the other departments.

Microbiology and Immuno-serology are in a new building with decent internet connectivity, a resource for virtual data collection. Employees working in these two departments are characterized by multidisciplinary, dissimilar work practices inter-bench and across benches. The laboratory has had no certifications or accreditations at the national or international levels. This is mainly because of the absence of a national body that is recognized to offer accreditations. Through aid, however, the laboratory has networked with some leading experts in diagnostics within the Asia-Pacific region with vast experiences in the general diagnostic field. Although the laboratory is medium-sized, it supports several public health projects for communicable and non-communicable diseases. These include malaria, microbiological investigations, pathology, emerging diseases, and surveillance. Besides, the laboratory offers water, food, and cosmetics toxicological testing. The NPHL has 52 staff distributed through its departments, of which 38 are technical staff with various specialties. These include skills in biochemistry, microbiology, cytopathology, quality assurance, hematology, immunology, and virology. In recent years a few laboratory staff have obtained post-graduate qualifications, majorly from foreign universities, building their skill set. Older technical employees got non-degree qualifications in life sciences from Indonesia.

1.2 Problem and Context

Since June 2011, I have worked as a consultant and Senior Advisor to the executive and presidency of the NPHL. This position has no direct supervisory role to the laboratory employees. At the request of the Laboratory Director, I have ensured that there is an organization-wide understanding of regulatory compliance for medical laboratories. Despite the sound understanding of the regulatory framework, clinicians, patients, and other stakeholders still raised complaints about the performance of the laboratory. In practice, the regulatory framework helped create an organizational defense system enabling engulfment in hidden traps, and information availability heuristics. The defense clouded our understanding of quality improvement (QI) frameworks, and rather than regulatory compliance as the key driver, QI could still be achieved by default in system-wide innovation processes and culture. As a scholar-practitioner, I envisage that my colleagues and I have an opportunity to define an organization-wide innovation to create new organizational capabilities and (QI) framework, a foundation of this thesis.

In May 2019, an external party from New Zealand, seasoned in laboratory quality systems and regulatory standards was invited to undertake an audit of the laboratory. The audit report revealed the dark corners of quality practices within the organization. Broadly, the key revelation was that the laboratory failed to meet not only stakeholder expectations but also the prescriptions of the regulatory authorities regarding the quality of diagnostic services. Nevertheless, the laboratory is acting on the gaps identified in the quality audit using the World Health Organization (WHO) accreditation checklist (Gershby-Damet et al., 2010). The laboratory's response to these failures is oriented towards addressing regulatory compliance requirements in the hope that stakeholders will equally be satisfied. These stakeholders are critical organizational agencies and consist of laboratory employees, partners, and physicians with the potential to influence organizational directions. The influence could be enacted through institutional social movement, by making implicit demands when pressed with external organizational pressures presenting a complexity (Campbell, 2007; Lawrence and Buchanan, 2017). It is, however, evident that the non-conformities present external pressures and demands to the organization (Rosko, 1999). The pressures present the organization with inadequacies, thus a need to develop

coherent strategies or a salient framework in response, and in my view, the responses often come in forms that are messy and emergent. As a scholar-practitioner, first, I find the search for compliance an approach deficient in steering meaningful change, due to its narrow and prescriptive nature. Secondly, compliance predisposes the organization to bare, and superficial scrutiny of organizational dark corners. Critical to advancing the current empirical work is the argument that even if the laboratory obtained accreditation, an indicator of compliance, practitioners must aim for continuous system improvement (Tibbets et al., 2006). For our laboratory, notably, the audit results painted a bleak picture of our systems. However, scholars acknowledge that the quality of laboratory diagnostic services is a wicked problem in most developing countries (Olmsted et al., 2010; Guarner et al., 2012). In equal measure reiterating these challenges has been policy statements (WHO, 2008). This thesis seeks to shed light on potential home-grown solutions to these problems.

Compliance promotes a sense of consensus and cohesion but denies the benefits of risks and uncertainties, the sociological prospects, and conditions in which policymakers work (Moen, 2021), and other forms of innovation in enhancing change. Further, my cognitions as a practitioner provide that acknowledgment by regulatory authorities, that a laboratory meets regulatory compliance prescriptions may raise grounds for lethargy, and cement regulatory group pathologies (Hart, 1998). Settling at compliance could also deny an organization the utility of further empirical shreds of evidence, pragmatism, and risk-blocking continuous improvement efforts, and sustained behavior modifications (Hui and Soltes, 2018). It is, therefore, critical that our collective focus as practitioners should transcend compliance to continuous descension into the laboratory technical and operational swamps. Such a focus broadens my lenses to influences emerging from internally and externally yielding context-dependent institutional order (Greenwood and Hinings, 1996).

Prior to addressing compliance, a laboratory should be concerned with its workflows and implementation plans drawn from achievable goals and objectives, and depicting the laboratory context in its entirety. To harness the efficiencies of a laboratory, therefore, requires the development and ownership of a quality management system (QMS), integral to improving functional and structural capacities, and meant to further direct organizational activities (Carey

et al., 2018). The QMS, thus, is an overarching tool with discrete processes for its fulfillment. QMS is the alma mater that nourishes the quality ambitions of a laboratory, from which it develops streams of quality initiative (Kubono, 2004). It is also critical for the overall objectives and goals of a consistent, cohesive, and reliable laboratory system. For the purposes of internal laboratory operations, QMS embodies principles guiding an emergent quality system, thus, critical for implementing agencies. It is a tool for monitoring and evaluating internal performances, and offers opportunities for learning and unlearning specific aspects of laboratory quality practices and guiding decisions far and above serving compliance purposes.

The understanding of QMS highlights a few elements which are critical for the advancement of this thesis. First, the need to develop a QMS, and keeping the focus on its implementation is a strategic competitive tool (Kim-Soon, 2012) for the NPHL. This aspect links to the second part that depicts the realization of quality in a laboratory as a journey painted by micro-processes, with end products, yet its paths never end and go beyond the purview of the original intention. Third, at the center of QMS are the laboratory workforce and stakeholders, that is, the implementing agencies who must steer the process (Crossan et al., 2005) potentially navigating organization defense systems and structures. Considering the implementation of micro-processes, the people involved, and the organization's cultural orientations draw in knowledge management as a critical component of this thesis. Nevertheless, there are the customers whose appreciation of the product or service draws in what is available in the marketplace, and for which they are ready to pay (Drucker, 1985; Majava et al., 2014). To actively research implementation mechanisms and involvement of context, the research TAG has adopted a participatory action research (PAR) methodology to bridge the gap between scholarship and practice. This approach takes into consideration the context of daily operations at the place of implementation such that the outcomes are tailored to the unique needs of the NPHL. To aid the grounding of this thesis I provide an emphasis on the foundations and formation of micro-processes in quality improvement.

By their nature, any quality improvement involves iterative processes, where change is realized through micro-improvements that are measured, and evaluated for effectiveness. The lessons learned from the micro-processes are harnessed, reflected upon, amplified, and used to

plan and execute further improvements within the organization. This thesis finds these approaches consistent with critical action learning (CAL) and action research (AR), yielding synergy and offering intuitions for organizing (Vince, 2004). It enables participants to draw critical perspectives from initial processes and direct them into their routine operations.

Critical is the individual and collective reflection on practice, experiences, and actions in the prior processes. Here, participants question their own cultural and historical assumptions, blending them as they pursue alternative approaches, and this enables further knowledge construction (Denzin and Lincoln, 2008). It, therefore, brings into the confines of this thesis the science of knowledge management. The team consisting of participants with multidisciplinary backgrounds documents the processes by which change has built up from micro-activities. Constantly the team synthesizes information available to enable building of the next phase and further discoveries. For the purposes of gaining clarity and assisting in the implementation of a quality framework, I was led to my conception of the first aim, which is to: *understand micro-processes for institutionalizing quality improvement*.

The role of laboratory practitioners as change agents is vital in understanding the overall change and associated micro-process. First, change is driven through paradigmatic shifts in the mindsets of the practitioners through individual and collective reflection on the prevailing practices (Butman, 2013). These practices may have been ingrained in historical and cultural norms and are difficult to break away from (Butman, 2013). Secondly, they are the “street-level bureaucrats” who translate policies into practice as they implement change (Cohen and Frisch-Aviram, 2021). Primarily, the participants develop collaborative and communicative skills permitting shared values and cultures, and knowledge sharing. For TQM implementation to occur effectively and efficiently, the participants must actively be involved and empowered. Their contributions are an essential ingredient for organizational learning and a critical tool for quality improvement. Here, the participants feel empowered and creative and can freely determine their constraints and strive to address them via communicative action (Carvalho, 2017). Moreover, good coordination between participants permits individual members to take leadership roles, be enthusiastic in influencing their peers, without formal authority (Gottwald, 2008), and without solicitous for results. It can, however, be difficult to implement QMS in a

laboratory when laboratory practitioners retain old traditional mindsets and cultures. Naturally, QMS stretches the practitioners' ordinary operational capabilities and challenging skills. It requires effective and coordinated executive management reinforcement and motivation, especially at the initial stages of implementing QMS. This thesis, therefore, considers that laboratory practitioners' roles transcend the revelations in this chapter and require deep literature and empirical probing to extend both scholarship and practice.

Central to the effectiveness and success of QMS is the ability of laboratory practitioners to work and have a strong link between themselves and others. These may be people in the same field external to the organization. At the organizational level, for instance, networks can be a significant pillar in determining disease outbreaks (Bogich, 2013). Such linkages also leverage the estimation of disease burden, enable planning of disease eradication, and are useful in quality control (WHO, 2020). Here the laboratories enter strategic partnerships with local or international entities for collaboration and complementarity. The NPHL is a member of the Southeast Asia regional laboratory network and has strategically benefited from some of the initiatives created by the World Health Organization. These include Dengue Fever Surveillance, Influenza Surveillance, and Anti-microbial Resistance Surveillance (AMR), where short-term technical support and diagnostic reagents have been provided. These networks have not only benefited the NPHL but have also assisted, for instance, in providing data to the Global Disease Surveillance Systems. The network has also created an opportunity to share information with the regional laboratories and with manufacturers of reagents and vaccines. The challenge is that these networks appear to be external to the NPHL, with key decisions made elsewhere, or are characterized by loose engagement. The NPHL needs to prioritize networks internally even as it expands the network rhizomes already in existence. Within the organization, networks enable practitioners to continually build and leverage relationships and deliver feedback both upwards and downwards, to aid decision-making (Gibson et al., 2014). Given that QMS implementation, in a chosen form, involves change whose dimensions are complex, the organization can only rely on its people, who themselves possess informal and formal networks. According to the social capital theory (Burt, 2001), the way the organization manages these networks, and the perception thereof determines the value of networks to the organization (Barchiesi et al., 2008).

Moreover, QMS implementation is a pervasive process that requires that an organization be deeply engaged in rethinking its structure, value, and age. Traditionally, organograms are an excellent way of showing how people relate to an organization formally, but they are deficient in assisting in understanding informal networks (Burt, 2001). The quality of informal relationships, therefore, remains a pillar for advancing this thesis and will be explored further in the literature review. In consideration of the aspects discussed in this paragraph, I came to the second aim which is: *to explore the role of knowledge management among the laboratory workforce in the realization of TQM.*

QMS originated from industry, with the proponents primarily aiming to improve organizational performance (Vieira et al., 2011) within contextual dependencies (Prescot and Silva, 2006). Debates on QMS utility have always arisen from the need to address practice irregularities, culminating in the development of “Good Laboratory Practices (GLP)” (WHO 2006). Moreover, GLP is supported by the progressive issuance of regulatory guidelines, with the most current regime building on the articulations of the previous versions. In advancing the QMS debates, some scholars argue that the pursuit of accreditation is a critical driver for laboratory system improvement (Plebani, 2003; Gachuki et al., 2014; Yao et al., 2010). Yet, other scholars argue for a QMS that is practical and solution-oriented, that holds the laboratory practitioners’ accountable stewards to their in-house actions and hinged on the laboratory’s resource accessibility (Audu et al., 2012; Yao et al., 2014). In the context of the country, the QMS takes the form of regulatory standards in implementation, thus following guidelines external to the specific laboratory context. This means the practitioners do not interact with and inform contents of their own QMS. Any thinking fashioned towards an internally structured- internally-driven QMS may leverage its implementation and enhance the possibilities of successful QMS implementation under an internally agreed framework. For practitioners, the judgment of a quality improvement framework depends on its credibility with the implementing team that assists in crafting it and, in the process, yields practitioner satisfaction (Ratner and Pignone, 2019). The framework is permeable to being challenged, and in turn, it constructively challenges prevailing practices as it evolves and matures. Thus, it provides insights beyond conformance and premising value for the stakeholders.

In scholarship and practice, QMS is substantially implemented based on the requirements of established regulatory bodies such as the international standards organization (ISO). The ISO provides a framework for laboratory systems assessment and corrective actions (Tashi et al., 2016). Consequently, the corrective actions form the next part of possible planning. The regulatory guidelines, on the other hand, seek to standardize practices across laboratories (Yu, 2017) such that practices are legitimized. While this homogeneous approach may have its benefits, plurality and rationality considerations are appropriate given real-world practice as laboratories present differing contextual realities. These differing contextual considerations include laboratory practitioners' skill sets, resource variabilities, organizational actor psychology, and cultural orientations, among other differences. It does not mean that laboratories cannot make improvements toward compliance with these regulatory guidelines, but compliance should not be the ultimate focus or goal. My scholar-practitioner experiences provide that there is a plausibility of additional benefits transcending compliance, particularly with an embrace of institutional entrepreneurship. Nevertheless, the practice of standardization in its institutionalized form, and the legitimate purpose it serves also enhances organizational chances of survival at field-level, when in conformity (Ashworth et al., 2009). However, in practice, differing environmental contexts combined with the search for efficiency demand scrutiny of legitimacy. In doing so, practitioners begin to experience gaps between the institutionalized form as prescribed by standards, yet the actual world of practice context differs substantially. This is a situation of the policy-practice gap. However, regulations, standards, or such frameworks only function within existing organizational systems and must be properly aligned with the internal organizational needs and strategy (Villadsen et al., 2017). An institutional theory perspective, first, provides a framework for analyzing the historical directions of laboratory systems. Second, the understanding of institutionalized forms of practices, and purposive action of organizations and individuals may assist in thinking innovations in the laboratory field such as TQM. The laboratory practitioners in collective action have opportunities to think about their practice world through the embedded institutional logic. In equal measure, practitioners need to think of alternative ideas in the wake of the organization's wicked problems, which they need to reframe. This aspect will be revisited in regulatory frameworks in this introductory chapter of this thesis.

In keeping with the prevailing practices that consider compliance as the backbone of quality improvement, practitioners at the NPHL are in strict allegiance to the regulatory guidelines. The practitioners are purely trapped in the bureaucracies and rational controls of the guidelines, thus conservative. As a co-practitioner, my view although may be overdrawn, the bureaucratic trappings are quickly becoming routine and a tradition to which laboratories radically need to struggle for decolonization. By nature, the guidelines dim the collective, individual actions and thought patterns that can be harnessed and weaved into a laboratory quality improvement initiative. Reflecting on our practice, I see an iron cage with no room for insights or considerations for context. In contrast, when implementing TQM, practitioners deploy evidence and reflect on their own practices, cognition of their practice biases, and reasoning flaws. This approach allows the integration of evidence-based practice into priority areas on a micro-basis to aid improvements (Westgard et al., 1991). TQM's principles are anchored on customer satisfaction and securing organizational and team commitment (Ooi et al., 2011). The practitioners must develop a passion for quality, combining scientific rigor with sustained systems improvement efforts drawing from the social streams of their practice. This approach challenges the status quo bent on maintaining control, and helps raise and empower hot groups (Kusumah, 2013). Hot groups are those that are able to accept embarrassment that threatens self-esteem, share failures that everyone should have access to, court disruption, and creatively generate ideas (Lipman-Blumen and Leavitt, 2009). The group survives and thrives in perpetual openness and renewal, taking work as experiments meant to enrich understanding. TQM framework is built on action-oriented methods, in search of collaborative actions, and appreciation of knowledge management in its dynamics.

TQM has the capacity to deliver change by closing the organization's existing gaps (Schouten et al., 2003; Wilson et al., 2007; Nahyan and Abdel-All, 2017). For instance, laboratories are painted with ambiguities like other critical departments of any health system and require practitioners to engage in cyclical sensemaking and sense giving (Antonacopoulou and Tsoukas, 2002). These ambiguities require sustained reflections and collegial decision-making, and efforts for practitioners to design their own world (Chia, 2003). The laboratory practitioners as key stakeholders must be instrumental and pragmatic in interacting with others

and recognizing the metamorphosing insights of laboratory practice and contextual orientations. A candidate TQM model is thus contingent upon two functions. First, a demonstration of moderating effects for capacities for institutionalization. Secondly, the implementation of TQM must be integrated with contextual factors in readiness for change (Anil and Satish, 2018). Such a model, therefore, offers a platform for knowledge generation and innovation diffusion.

Several frameworks document efforts in laboratory strengthening, aiming for quality improvement. One such framework is “strengthening laboratory management towards accreditation” -SLMTA/ SLIMPPTA, (Yao et al., 2010), with both observable and measurable outcomes. Other frameworks for quality improvement are advocated for in Northouse (2006), in which leaders permit tasks and routines to be the basis of all improvement efforts. The SLMTA framework (Yao et al., 2010) and that advocated by Northouse (2006) rely on the capacity of the laboratory employees to engineer their own laboratory improvement and work in respect of the present resources. However, in settings where this has been tried, a myriad of challenges including resource limitations and unsupportive hierarchical leadership models do not advance efficiency.

This thesis first, recognizes that standards as advocated for by the regulatory bodies, the TQM approach, and tailored guidelines arising from efforts to simplify them. It then becomes clear that there is no “one-size-fits-all” approach, but the task to make improvements in the laboratories remains. In view of the realities of the frameworks discussed here, I concluded that it is the application of drivers for quality at an organizational level by the front-line workforce (hot groups) that constitutes a framework. Bringing this closer to the NPHL, the workforce would take a peer-driven approach not only to live but also led by quality, take actions, and fill the organization environment with quality culture. This led this thesis to one of its aims, which is:

to build a contextualized evidence-based integrated framework for quality improvement.

Turning to the other side of the adoption of regulatory frameworks, I draw from two main institutional approaches, that is, “institutional entrepreneurship” (Maguire and Hardy, 2004) and “institutional isomorphism” (DiMaggio and Powell, 1983; 2000). As laboratories try to conform to the quality management systems, their efforts are driven by institutional-isomorphic pressures. The cumulative effect of the behaviors of these laboratories is that each unit imitates

the other without actual cultivation of what quality really means in each laboratory's context. In this, Barreto and Baden-Fuller (2006) postulate that even though it promotes organizational legitimacy, the very efficiencies and effectiveness premised by a QMS are lost. In earlier sections of this chapter, this thesis lays grounds for the evaluation of the role of organizational actors. However, individuals' behaviors and cultures are shaped by the environment in which individuals act, which is likely to draw from institutional forces (Seyfried, 2019) and reinforce institutionalism. Conversely, recent literature suggests that field-level isomorphism does not necessarily direct organizational change. Rather, the change process is permeable to actor interpretations and pacifications at macro and micro-level contexts (Beckert, 2010; Claeys and Jackson, 2012). The norm arrived at due to field-level isomorphism is then a product of actor (agency)-structure interactions (Nicholls, 2010), which espouses the utility of institutional entrepreneurship. It permits the scholar-practitioners in decanting the garbage-can type of decisions in change processes to search for institutional forms compatible with the context and prevailing values. As institutional entrepreneurs, the organizational actors and their networks can achieve their full potential riding on peer involvement. In practice, my colleagues and I can locate our shortcomings, which in essence, therefore, creates an opportunity for this thesis. As institutional entrepreneurs and researchers, we can reflect on institutionalized practices in implementing change under a framework the team rationally envisions as alternatives (Wijen and Ansari, 2007; Hardy and Maguire, 2008; Battilana et al., 2009). As a scholar-practitioner, the future I envision for the NPHL is where the workforce does not necessarily mimic other laboratories by following guidelines but embraces quality discourses while acting on identified items. Practitioners would then choose paths for quality improvement based on their observations, evidence, and practice realities.

This thesis considers that TQM arises out of team contributions to quality improvement and innovation diffusion. Moreover, TQM's open approaches have the potential of raising platforms for continuous quality improvement. Although organizational innovation could be passive or active, practices of copying and importing innovation yield institutional isomorphism otherwise organizations have to develop their innovations. Discernment of the TQM approach here makes a lot of difference as institutional isomorphism outrightly depicts legitimacy.

However, for implementers, it raises grounds for decoupling (Meyer and Rowan, 1977), and brings to question the quest for functional efficiency. The benefits of deploying TQM arise from its open nature, which allows for adaptation to local contextual settings, enabling “organizational reengineering” (Alghamadi, 2018), rather than a canned management technique. These benefits notwithstanding, TQM has been criticized for its inability to deliver on its premises, especially in efforts to apply it in healthcare settings. This exploratory work sets aside these criticisms as there are a myriad of reasons traceable to these mixed results. The criticisms arise from weak or lack of support systems, inadequate organization-wide commitment, negative political economy, and tendencies of individuals to work in silos with a different conceptualization of TQM (Hanna and Sethuraman, 2005; Mosadeghrad, 2013). This thesis, therefore, finds its grounding in the very challenges of definitions of TQM, takes an in-depth look at its obstacles, and raises foundations for its practice in a healthcare laboratory. Here the thesis takes cognition that TQM might be perceived in several ways including being a program or strategy, a philosophy, or just an approach, a technique, or a sheer process. Moreover, the healthcare laboratory represents one of the trickiest sectors in any healthcare system in which the realization of change is difficult given that applied approaches must be divorced from the existing predictable, linear, and rational cognitive forms. In the next section, I evaluate the leadership roles and how they influence TQM. Before concluding, I draw in two critical elements from which conceptual models can be derived as a starting point in understanding change, such as quality improvement. These are the external environment as stimuli, which takes pre-eminence before I move to the role of leadership. For clarity, even though leadership has been discussed, as a function in which employees can fit, whether, with formal authority or not, an extended part here is of absolute importance.

Environmental stimuli originate from the stakeholder cognitive images of their desired laboratory, and these images may be external to the existing laboratory system. They may also stem from the search for compliance with established quality standards, audits, and performance reports. There are, however, factors that negate implementation in healthcare settings as environmental stimuli are taken with cynicism, given their appearance as outsider control, yet laboratories need to be independent and innovative. Yet there is still a wealth of

benefits that can flow from environmental stimuli, and their consideration in a TQM design as a vehicle for benchmarking improvements can produce an effective laboratory system. TQM, thus, emerges as a philosophical framework that provides structures for addressing laboratory needs both practically and conceptually.

The challenge remains how to build a framework for quality improvement into an institutional mindset to leverage the principles of Kaizen. Here, employees can adopt collaborative behavior and transform the mindsets of their peers and leaders, learning from each other as they perform their daily duties. Consequently, the laboratory practitioners and their leaders restructure the existing social networks yielding mindsets that challenge status quo settlement (Oakland, 2011) and thinking of new benchmarks of what is achievable in quality improvement. In sum, the inability of the TQM framework to form a core organizational strategy and plan predisposes healthcare laboratories to delays in quality achievement.

Leadership is an established key enabler in effective TQM implementation (Dale, 1994; Anil and Satish, 2018). However, leadership suffices when combined with enabling factors such as business strategy and requisite cultural dimensions (Nahyan and Abdel, 2017; Anil and Satish, 2018; Kumar et al., 2018). A closer look at these combinations of enabling factors, leadership hierarchies, organizational silos, and management approaches drawing their meaning from the top down must be re-evaluated for their contributions. Otherwise, an organization could adopt bottom-up approaches stressed by street-level bureaucrats to enable an integrated framework for realistic and sustainable improvement. Despite excellent concepts in TQM, if practitioners work in isolation, and leadership commitment is unsecured, TQM will remain unachievable.

1.3 The Kaizen Approach

Critical to the realization of change, is the “Kaizen” principle by Deming, a renowned American philosopher whose ideas revolutionized quality improvement in Japanese companies. In Kaizen’s approach, incremental improvement steps lead to substantial change and capitalize on any improvement opportunity (Lesser, 2009). Kaizen is practiced under the principle, of Plan-Do-Study-Adjust (PDSA) cycles, with mutual respect between stakeholders involved in episodic events, and who at times relate casually or informally which in our case we consider as the

predominant way of directing change. It places improvement science at the root of action by practitioners, as the agency, the influence of their mindsets, which includes social networking tendencies and peer effects, thereby presenting TQM as a journey (Berry, 1990; Mohanty and Behera, 1996; Prajogo and McDermott, 2005). Deming's approach to quality improvement and innovation is consistent with Lee and Dale (1998) philosophy of the "Catch, Reflect, Improve, Scrutinize, and Pass (CRISP) cycle". However, for this thesis, I will maintain PDSA.

In sum, this introductory chapter of my thesis provides the background of the organization and the inherent quality improvement wicked problems which the thesis sought to address. Here, the search for field-level legitimacy by adopting approaches prioritizing conformity to institutionalized practices. This chapter demonstrated that legitimacy is a critical ingredient for organizational survival and a factor that drives laboratory establishments to adopt regulatory standards. Moreover, legitimacy as a phenomenon has endured a prominent position in laboratory quality debates at collective levels but lacking in micro-foundations of laboratory systems, where individual judgments and behaviors occupy greater sociological collaborative space in laboratory science. Subsequently, regulatory standards sit as transnational governance tools that may be difficult to justify normatively as contextual real-world laboratory practices may differ substantially.

The present dominant approach of regulatory standards forming the basis of quality improvement precludes organizational actors' internal reflections. These actors can participate in defining their world (Chia, 2003) and that of their organization by acting both innovatively and strategically. This thesis builds on the value of institutional entrepreneurship rather than compliance. These contradictions between compliance and entrepreneurship notwithstanding, organizational members need to discern what makes them in control of quality in their organization. This thesis considers that the quality improvement frameworks are not in a contest of superiority, and existing regulatory guidelines and other frameworks could be integrated with other quality improvement methods. Mapping out organizational context, environmental pressures, and stakeholder aspirations are critical in this process. Again, by gathering empirical data, this research will enable the formulation of grounded theoretical frameworks in strengthening quality improvement initiatives. A candidate framework would, thus, benefit richly

from the investigation of the challenges and other demerits experiences within the processes of implementation. I conclude by revisiting the aims of this thesis, which are to:

- a) Build a contextualized evidence-based integrated framework for laboratory systems quality improvement.
- b) Understand macro-processes for institutionalizing quality improvement.
- c) Explore the role of knowledge management within a research community in the realization of TQM.

1.4 The potential contributions of the research

The research evaluates pragmatic constructivist approaches in improving healthcare laboratory systems and employs grounded theory to understand rising themes from the data gathered. My colleagues and I try to build a contextualized understanding of our laboratory system, its weaknesses and to draw and implement action plans beyond the simplicities of compliance. The foundation of this thesis recognizes that quality improvement borrowing from Deming (2000) can be an in-house effort. Such a conception places the stakeholders central to participatory action research (Selener, 1997) in driving the implementation of change. The study engages my colleagues and me as employees in creating change in a manner that influences the direction of our organization. As laboratory practitioners motivate ourselves and those in our network in search of quality improvement. We recognize that we can influence organizational climate and context to transcend ISO 9001 accreditation requirements (ISO, 2000) by engaging in sustained micro-improvements. The study employs a longitudinal approach over 21 months, with participants selected through a purposive and convenient sampling. The twelve work colleagues are envisaged to be engaged in social and practical change through participatory action research. The initial plan was to have the data collection happen in nine months, but this became unattainable due to the effects of COVID-19, and I will explain this in later chapters of this thesis. As I envisaged, there are propensities to quality improvement becoming an ingrained institutional value as laboratory practitioners take a paradigmatic shift in embracing TQM (Massoud et al., 2006). The emerging order demonstrates a resilient organization, whose DNA is based on change and learning (Stewart and O'Donnell, 2007). The TQM approach and

accompanying steps are envisaged to enhance confidence of the overarching body of laboratory practitioners, including myself, the patients, physicians, and potentially regulatory authorities. I am persuaded that an approach that serves as a gateway for learning is capable of reinforcing laboratory quality improvement and personal development as well.

1.5 Thesis structure and content

The following is the structure of the rest of the thesis chapters: I review literature quality management, focusing on medical laboratory practices, and draw lessons from other sectors to identify the extent to which QMS frameworks have informed quality improvement. I deploy institutional theory and seek to understand how laboratories respond to internal and external pressures for conformity. I identify criticisms of the existing QMS and regulatory frameworks arising from scholarship and practice orientations in chapter two. I work with the action research (AR) team and agree on a qualitative research design, as participants envision their future laboratory and work on an institutional order in chapter three. I engage the research participants in a search conference, starting with an audit report presentation and eventually problematizing our laboratory in chapter four. This conference was also an opportunity for me to introduce participatory action research to the participants. The action researchers use histories to understand the depth of the problem and the extent to which NPHL efforts have yielded improvement and causal transitions. The problematization process reveals relationships between our laboratory efforts with the existing QMS. The participatory approach birth debates and communal agility in QI within the prevailing laboratory context. I engage participants in thematic analysis of the data and present it in a plenary for discussion and consensus among participants. These are re-engineering process control, development of regulatory mechanisms, and cohesive actor engagement.

In chapter five, I detail the planning of the empirical work post-thematic analysis. I use the opportunity afforded by this thesis in chapters six and seven to demonstrate the dynamics of collaborative action in implementing QI actions within the NPHL on the foundations of these

themes. I detail a corresponding evaluation for each action implementation cycle and outline issues demanding further debate and action.

I present the discussion and conclusions in chapter eight. I use the opportunity in the chapter to review the thesis objectives and use the data to answer the research questions. I simultaneously muscle the literature contributions to laboratory quality improvement. I underscore the value of action research, reflecting on how the researchers created a collaborative inquiry space sharing their lived experiences, and knowledge, influencing, and learning from one another in the process. I reflect on the importance of collaborative learning and undertake personal reflections and professional and personal developments. Finally, I discuss the practical, research, and policy implications and the limitations of this research.

Chapter Two: Literature Review

2.1. Literature Outline

Foremost, to aid understanding of the steps taken by the literature review, I would like to state the aims of the present study, which are three-fold:

- a) To develop a contextualized evidence-based integrated framework for quality improvement in research laboratories.
- b) To explore the macro-processes for institutionalizing quality improvement in research laboratories.
- c) To explore the role of knowledge management within a research community in the realization of TQM.

This literature review is organized in the following format. First, it seeks to provide an overarching understanding of the laboratory quality management system (LQMS), followed by an exposition of laboratory dynamics, quality improvement, and measurements. Within the same frame, the review explores laboratory systems vulnerabilities and strategies deployed for institutional survival. The review then turns its focus to regulatory compliance as a means of organizational survival against the backdrop of organizational contextual peculiarities and complexities. Connected to regulatory compliance is the International Standards Organization (ISO) whose frameworks and accompanying debates are revisited. In connecting laboratory heterogeneity, their contextual idiosyncrasies, and vulnerabilities, the thesis provides a thinly veiled approach in the decolonization of ISO frameworks and highlights ISO Standards post-adoption challenges. Although practically heterogenetic, yet standardization devices deploy mimetic and coercive methods for monopoly which are expressed in institutional isomorphism, defining a temporary emphasis, and its accompanying institutional theory. Following the challenges expressed with ISO standards as a Quality Management System (QMS), this thesis provides insights into Total Quality Management (TQM), its conceptions and practices an alternative innovative approach to advancing continuous quality improvement in laboratories. Finally, the review revisits the debates on organization culture in supporting TQM

implementation. The literature review keeps an emphasis on the context of TQM adoption and implementation, knowledge management, and explores institutionalism and institutionalization of TQM.

2.2 Literature Search Strategy

I deployed a meta-ethnographic orientation (Noblit and Hare, 1999; Montgomery et al., 2020) approach in the literature review to explore and understand laboratory quality improvement. Subsequently, I integrated the findings of the reviewed materials from scholarship and practice to gain a holistic perspective. Ethnography is theoretically entrenched and embedded in the balance between contextual observations and lived experiences, feedback, and the interpretations thereof. This method generates self-reflexive data permitting practitioners to derive QI within their work contexts with scalable quality insights. Context dependency and ethnographic approach to QI research are critical in systems thinking, creativity, and reflection (Allen, 2013; Dickson-Woods and Shojanian, 2014; Vougiokalous et al., 2019; Black et al., 2021). In their arguments, these scholars suggest an understanding of evidential backstage to support ensuing debates. These scholars, however, caution ethnographers to retain a uniform approach enabling harnessing the accounts of data and questioning the often taken-for-granted contextual behaviors.

The materials I was keen to capture were capital resources such as collaboration and relational, insights, and democratic space. Similarly, I was interested in coordination and influence brought by individuals without formal authority into quality improvement initiatives both from scholarship and practice. While acknowledging the phenomenon of interest, I used the SPIDER tool (Cooke et al., 2012) with a Boolean search operator to generate relevant studies. The search terms included the following word truncations; *“laboratory quality management*, institutional entrepreneurship*, “action research*” AND “change*” AND “TQM*”* NOT: *quantitative studies**, which generated 11,300 citations with duplicates removed. The SPIDER tool has a framework for generating terms for qualitative research. Out of the 11,300 citations, only five (5) citations were potentially relevant to change in the decision to ensure

inclusion of "*institutional entrepreneurship**" AND "*peer-reviewed**" AND "*qualitative research*". I kept an eye on evidence from the wider industry, but there were insufficient citations to support the literature review. The inadequacy of relevant scholarly materials demonstrates the challenge of finding literature in the chosen field of research. The laboratory has often studied from a technical rather than a sociological perspective that this thesis explored. The databases searched included Web of Science, Ovid databases, and EBSCOhost. The studies (if any) were to be in the English language (or with full translation into English language) and published within 15 years prior to this research. The word truncations I used in the search were related to laboratory quality improvement, continuous improvement, organization readiness for change, and employee involvement. At this point, I abandoned the plan and resorted to the traditional literature review approach, consulting Science Direct, JSTOR, PUBMED, and Emerald Insight to find studies spanning science and management journals that I included in the review.

I employed a priory approach to locate information in the area of interest, identifying the gaps in scholarship and practice while searching the literature. I identified methodologies and ambiguities and reviewed conclusions in the chosen articles. The search results produced heterogeneous articles, but I set the remits as follows:- I used bibliographies as a traditional source from which I retrieved linked citations. I then applied search filters that included language (English) and date restrictions to capture relevant and updated scholarly evidence. The bottom line was that the articles were peer-reviewed and published within 15 years. I also combed through the internet to find unpublished relevant literature sources.

I read each article 3 to 5 times depending on the complexity and identified key concepts, including commonalities, linkages, and themes. I looked for key concepts to generate constructs and lines of argument for further scrutiny and interpretation. In the subsequent sub-section, I begin the review by initially looking at the overview of laboratory quality systems.

2.3. Overview of Laboratory Quality Management System

Extensive literature has explored Quality Management Systems (QMS) as an integral component of Quality Improvement (QI) in medical laboratories in equal spirit to management systems in industrial models (Kubono, 2004; Allen, 2013; Ngo et al., 2017; Homolka et al., 2019).

A cornerstone of QMS is the emphasis on customer satisfaction through a repeatable system, which must be implemented and consistently maintains the path of improvement (Jovovic, 2016). The laboratory systems consult structured standards e.g., ISO frameworks, detailing requirements for implementing a quality management system. There are additional benefits conferred on laboratories that successfully implement standard-based QMS. The regulatory authorities offer these laboratories accreditations and certifications, demonstrating proficiency and institutional legitimacy (Baumann and Krücken, 2018). This legitimacy is, however, debatable, and central to the explorations of this thesis. Total Quality Management (TQM) is an alternative approach that builds on a system-wide quality improvement approach with prospects of meeting customers besides organizational needs (Kristianto et al., 2012). TQM places value on strategic planning and the involvement of everyone in the organization, supportive organization culture, and process improvement, and deploying failure mode effects critical analysis (FMECA) to ensure holistic continuous quality improvement (Fragassa and Ippoliti, 2016). This review will turn to the TQM approach at a later stage. Primarily, within the frame of QMS, in this section, I explore the insights of laboratory continuous quality improvement, given the laboratory system dynamics, complexity, and determination of quality indicators, and revisit the concept of quality systems essentials (QSE).

An inspiring corpus of research documents the criticality of medical laboratories in supporting clinical decisions (Kubono, 2004; Hickner et al., 2005; Lippi and Mattiuzzi, 2016; Ngo et al., 2017), highlighting the necessity of meeting patient and the technical capacity requirements. From these aspirations, given best practices, a competency strategy and a design framework emerge with specific improvement requirements, forming a basis for a laboratory quality management system (LQMS). A closer view of a quality management system (QMS) depicts a complex control system with integral components mirroring excellence and efficiencies obtainable in integrated processes, methodologies, procedures, and checklists tightly coupled into an outfit. An appreciation of QMS by a laboratory system demonstrates a commitment to enhancing the capacity to respond to medical diagnostic emergencies as it engages in the implementation processes and procedures (Nag and Soni, 2018). Its overarching aim is to ensure an understanding of the system from its complexities and operations and structures mapped in a

coordinated fashion, cohesive, and interdependent to produce acceptable laboratory performance (Mustafa, 2021). The overarching intention here is to enable error detection from the pre-analysis, analytical and post-analytical phases in a testing workflow (Laposata and Dighe, 2017; Teshome et al., 2021).

The ISO/IEC 17025:2012 and the Clinical and Laboratory Standards Institute (CLSI) conceives the laboratory QMS as organized into 12 closely linked quality systems essentials (QSEs) mapped out in the Quality cycle (WHO, 2011). In the existing practices, approaching testing in the cognition of QMS produces results deemed accurate, reliable, reproducible, and reported promptly (WHO, 2011). Figure 1 below shows the quality systems essentials conceived by ISO IEC 17025: 2012 and has an arrow running across that qualifies the QSEs as closely bound to a system.

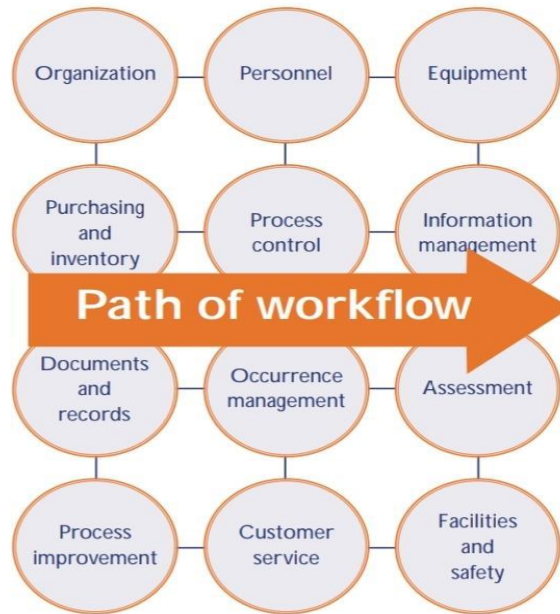


Figure 1: Quality Systems Essentials (Adapted from CLSI/ NCCLS, 2004)

Although the quality systems essentials map out key areas of a laboratory system and stand as a simple guideline or checklist for laboratories, their adaptation in specific laboratories remains institutional responsibility. The adaptation path and meeting technical and managerial requirements face economic and other resource constraints (Nkengasong, 2010). Moreover, integration and application of the QSE in the daily testing work is not a simple task for laboratory

personnel when leadership commitment is not guaranteed (Westgard and Westgard, 2014). The question that every laboratory then stands to ask is: How do we approach QMS in real-world pathology and laboratory medicine when details for implementation are lacking? This question is critical for this current thesis. However, a critical look at this question draws a researcher to implementation science and associated strategies.

The conception of QSE by the ISO/IEC 17025:2012 and CLSI first provide a requisite insight into thinking of laboratory medicine being a complex adaptive system (CAS), where the whole is dependent on the performance and functionality of the parts. Secondly, it places the standards at the center of laboratory systems reform strategies, with QSE as the core system drivers. Thirdly, researchers can then consider QSE as a contemporary critical thought area whose dynamic relationships provide a summary of evidence that impacts laboratory policy change (WHO 2011; Burnett, 2013). Nevertheless, laboratory practitioners' interpretation of complexity as other healthcare areas may disregard the sum value of complexity theory (Dattee and Barrow, 2010) in implementing QMS. I will be returning to these points in the later stages of this review.

Quality Management Systems are associated with Edwards Deming, who emphasized the systems philosophy dwelling on the role of management in the collective functioning of parts (Deming, 2000). In his conception, optimization of the functionalities of system components in production operation and excellent quality performance with decisions based on data in a Plan-Do-Check-Act (PDCA cycle) (Deming, 2000). The Deming model offers a fundamental precursor for directing the flow of an implementation of QMS, with notable individuals such as David Burnett, who has written from a practical perspective on implementing the ISO/IEC 15189:2012 (Burnett, 2013).

Deming's PDCA model in QMS demonstrates how continuous quality improvement can be achieved, with each step considered a precursor for the successive stages, with a feedback loop. It also depicts an organization as an ongoing process of organizing and benchmarking with employees and leaders at the center stage of quality improvement (Silimperi et al., 2003). The other facet of PDCA involves experiential learning with its roots embedded in the Kaizen

philosophy. Keeping with the core principle of QMS, PCDA has also been used to improve patient satisfaction with medical laboratory services (Gomulia, 2014). Figure 2 below shows the quality improvement steps of Plan-Do-Check and Act as a cyclical endeavor, between planning and action.

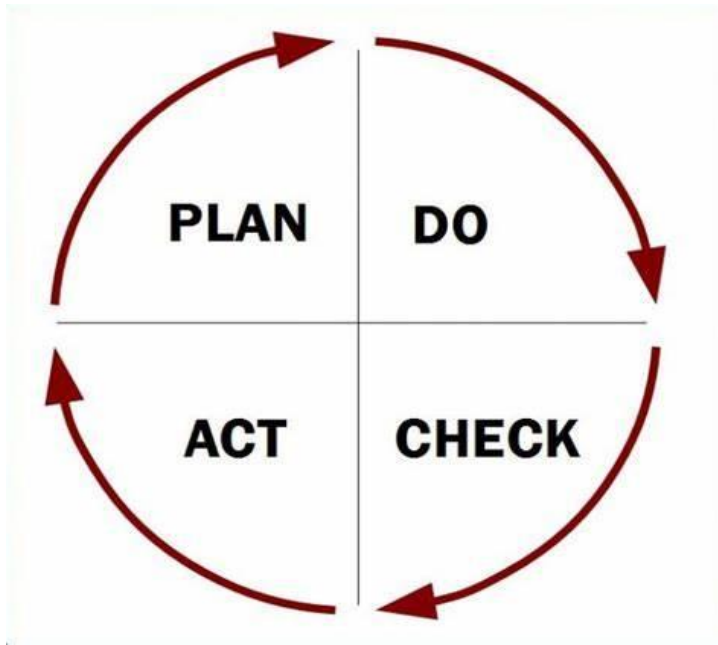


Figure 2: Demings Model of PCDA Adapted from W. Edward Deming institute, 2009.

2.4. Laboratory system's dynamics, Quality indicators and Quality Improvement

In experimental design, laboratory systems are highly dynamic in behavioral aspects, mechanical-structural orientations, geo-environmental, and types of materials used, thus attracting triple-bottom-line reporting (Elkingoton, 1997). At face value, however, the dynamism of medical laboratories has been met by dramatic investments in automation to improve accuracy, efficiencies, and lower costs (Genzen et al., 2018). These features leave laboratories struggling with incorporating behavioral components and propensity to incident reporting. Besides, numerous issues such as fragmented approaches in laboratory performance measurements, varied reporting methods, and lack of benchmarks limit opportunities for quality improvement.

Researchers have made significant efforts in clinical laboratory medicine by defining quality indicators (Sciacovelli et al., 2011) with varied outcomes given the total testing process (TPP). The reasons ascribed to such confusion are that laboratory tests involving too many methods are applicable in the laboratory sciences, which makes the development of indicators challenging. Most laboratories have not taken steps toward a shared reporting system in which specific indicators are prescribed and supported by evidence in standardized data. These challenges push laboratory systems and individual laboratories to define internal quality indicators based on their structural-setting orientation, technical complexity, and stakeholder knowledgebase (Sciacovelli et al., 2011).

For a typical laboratory, the performance through the lenses of stakeholders and the health system takes pre-eminence and the feasibility of demonstrating direct measurements (Shahangian and Snyder, 2009). Some scholars, however, argue for scientific soundness in quality improvement (Shahangian and Snyder, 2009) but omit social values not reasoned scientifically. From practice, to ease of follow-up, and implementation, indicators should be conceived with known goals, objectives, specific targets, and well-defined thresholds, spanning pre-analytical, analytical, and post-analytical processes (Nevalainen et al., 2000; Howanitz, 2005; Kirchner et al., 2007).

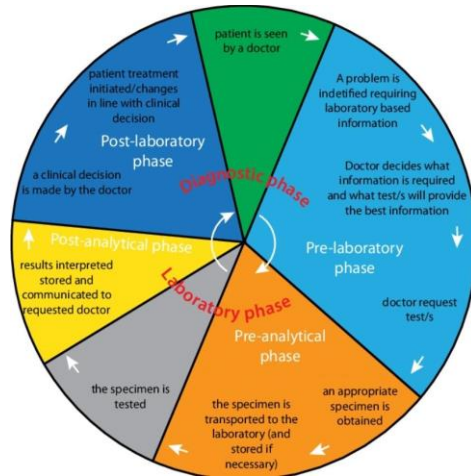


Figure 3: The Quality Cycle (adopted from Badrick et al., 2017)

One of the currently agreed methodologies of assessing the performance of laboratory indicators compliance and quality improvement is proficiency Testing (PT) or participation of laboratories in External Quality Assurance Programs -EQAP (Ehrmeyer and Laessig, 2004). Studies indicate that partaking in proficiency panel testing increases the commitment and confidence of individual laboratory staff (Dave et al., 2011; Halim, 2013). Proficiency panel testing is an essential laboratory component, and its benefits transcend regulatory compliance (Stang and Anderson, 2013). Other studies argue that PT offers a pathway to ISO 1589/17025 accreditation (Ricci, 2014).

In sum, connecting the seminal work of Kirchner et al. (2007), Shahangian and Snyder (2009), and Sciacovelli et al. (2011), this section has demonstrated that the laboratory is an adaptive system with varying structures and functions. This structure makes setting all-encompassing performance indicators difficult and establishes the need for performance indicators grounded on the organization's strategic objectives and goals, demonstrating contextual dependence. The general principle of quality improvement is simple indicators and steps that act as precursors for successive steps and overarching goals.

However, in history, quality improvement in laboratories featured automation, external quality assurance programs, and other rigid scientific rigor-enhancing efforts. This leaves the sociology of coordination, cooperation, and partnerships, which are strategic in building effective and holistic quality improvement approaches. Successful implementation of quality improvement needs to be supported by a strategic direction tool. Quality indicators, for instance, explicitly represent critical strategic developments in laboratory total testing processes (Simundic and Topic, 2018). Quality indicators assist in monitoring and evaluating laboratory performance and are a prerequisite for quality improvement. Berlitz (2015) claims that strategic processes are often non-inclusive as only key personnel in leadership are involved. However, this scholar proposes a structured strategic approach to planning and execution. The review shows that laboratory quality systems face additional threats and complexities that make laboratory systems vulnerable and which are part of the very formation of the existing laboratory. I discuss

these threats and responses offered by laboratory systems in-depth in the next section of the literature review.

2.5. Laboratory Systems vulnerabilities, environmental pressures, shocks, and coping strategies

For a laboratory to engage in quality improvement processes and correctly perform fundamental functions while aiming to support treatment decisions, it should demonstrate competencies. The laboratory should have the correct infrastructure with desirable testing capacities, adequate and competent staffing, reliable testing processes, and timely delivery of the test results (WHO, 2011). From a broader perspective, these factors may be clustered into internal and external pressures, simply known as environmental pressures. It is, therefore, critical for practitioners and policymakers to not only understand these factors individually in-depth but also how associated weaknesses could constitute vulnerabilities in the laboratory system. In this review, I explore laboratory vulnerabilities, environmental pressures, and strategies that individual laboratories have deployed to cope.

The WHO for instance recognizes that strengthening laboratory systems has been a low priority for the sovereign governments in South East Asia (Shah et al., 2017), Timor-Leste the study location inclusive. The laboratory systems neglect is widely acknowledged in the scholarly body (Nkengasong et al., 2010) and spans the laboratory's physical infrastructures, which remain dilapidated. Inadequate or non-active specimen referral networks and systems, laboratory, and weak information integration are additional challenges (Nkengasong et al., 2010). Global organizations like the WHO recognize infrastructural variations between disease-specific supported laboratories, with growing calls for networking (Roush and Baldy, 2008). However, the current advancements in information technology have led to the adoption or development of Laboratory Information Management Systems (LIMS) (Durr et al., 2010). LIMS provides opportunities for assisting in the integration of all laboratory components and enhancing data interoperability (Durr et al., 2010). Laboratory network and LIMS implementation increase the capacity of laboratories to partake in quality improvement programs, thus enhancing compliance (Dean et al., 2018).

Literature suggests that several medical facilities do not have clinical decision support systems that suggest what laboratory investigations and tests to order, taking cognition of resource availability (Ferreira-Juniour et al., 2014; Oliveira et al., 2014). Moreover, the ordering pattern for laboratory tests indicates that the majority of the tests requested are not linked to clinical evidence (Vezzani et al., 2013; Giordano et al., 2014). The key suggestions on rational decisions following formal flow diagrams or strong suspicion deferring ordering tests results in low costs and patient improvement thereby significantly contributing to quality improvement (Vezzani et al., 2013; Ferreira-Juniour et al., 2014; Giordano et al., 2014). These decisions have to be arrived at or adopted by healthcare laboratories in discrete jurisdictions. Compounding the emerging and existing disease-causing pathogen, including novel viruses like Ebola, COVID-19, and hemorrhagic viruses, laboratories need greater attention to aid the timely identification of etiological agents and monitor treatment. Conversely, laboratories historically contend with decrepitude and under-funding (APHL, 2009; Chua and Gubler, 2013; Mangal and Maryogo-Robinson, 2014), negating all forms of capacity advancement. The funding gaps are a bottleneck to equipment planning, placement, maintenance, development of diagnostic technology, technical assistance, and knowledge co-creation among other elements critical to quality improvement (Wattanasri et al., 2010).

Multidisciplinary strategies in the harmonization of laboratory equipment and standardizing testing processes, reporting of results and LIMS is a growing concern (Tate et al., 2012; Schreier et al., 2019) and require the involvement of all stakeholders to gain effectiveness and generalizable acceptance. However, prevailing practices continue to take heterogeneous approaches, thus prone to errors in patient results interpretation, which may lead to misdirected regulatory decisions. Miller et al. (2011) suggest that a wholesome infrastructural approach is prioritized following technical feasibility, complexity in implementation, and in tandem with their importance to obtaining laboratory quality measurements.

Turnaround Time (TAT) is a critical component of performance measurement in any laboratory, with clinicians and patients soliciting faster TAT (Hawkins, 2007; Stotler and Kratz, 2012; Pati and Singh, 2014). These requisitions place pressure on the laboratory and the

laboratory technicians, with no consensus as it remains a grey blame-game element (Hawkins, 2007). Many factors determine the TAT, some of which are out of the control of the testing laboratory, particularly in the pre-analytical phase of the laboratory processes (Pati and Singh, 2014). Some laboratories employing equipment supported by advanced technologies may use accessioning to improve TAT (Stotler and Kratz, 2012) or related technology to prioritize specific patient samples. These stakeholders' TAT desires place the laboratory systems in a dilemma to invest in automated technology to decrease TAT.

The overarching role of Quality Management Systems for laboratories is to design systems that make it difficult for errors to occur and ensure the patient's safety. Interestingly, the workload has steadily increased in diagnostic laboratories in several parts of the world, yet human resources are declining, resulting in burnout (Graber et al., 2008). These human resource pressures are associated with the prevalence of laboratory errors (Raab and Grzybicki, 2006). The bottom line is that management expects laboratory officers to complete the work with all the accuracy needed, presenting the laboratory as quality-oriented, efficient, and competitive. Realistically, laboratories harboring these aspirations end up engaging in lean initiatives employing Six Sigma, which offers grounds for TQM (Westgard and Westgard, 2014).

In the diagnostic world, laboratory stakeholders are motivated to see the work they are doing become recognized publicly as credible by proprietary international standardization bodies. Besides, there are pressures from umbrella laboratory bodies and funding agencies such as the WHO towards the attainment of accreditation. Some scholars claim that accreditation improves customer satisfaction (Musanza et al., 2010), ensures reliability, and demonstrates competency (Elva, 2015). Conversely, Charlton and Andras (2002) among other critics believe accreditation is vanity or at best, the old emperor's attire which cannot be used to measure quality. These steps may be forced forms of isomorphism, disregarding sociological epistemology, while embracing paradigmatic monopoly. In laboratories as open systems, the validity of accreditation is contested, particularly if it is based on audits that measure outcomes rather than the process (Charlton and Andras, 2002; Wilson et al., 2016). The legitimacy could be simple affirmative action to market confidence to funding agencies and governments. Due to

external social pressures towards compliance, firms sometimes strategically decouple policy directions to appear legitimate and to maintain a balance between cognitive and regulatory institutional pressures (Bromley and Powell, 2012). This is a pointer to a grey zone existing between organizational world realities and regulatory prescriptions. This gap is a ground for logical innovation adoption approaches and is exploited in further parts of the literature review.

To provide a summary of this section, there is a positive aspect of the vulnerabilities of the laboratory as a supportive unit within the healthcare system. First, scholars suggest the development of treatment and diagnostic diagrams to support test requests and evidence-based treatment (Vezzani et al., 2013; Giordano et al., 2014; Ferreira-Junior et al., 2014; Oliveira et al., 2014). Looking within is the issue of collaboration, with a propensity to enhance the collective building and use of evidence and transform practice. Further, mapping laboratory workload and distribution should form part of quality improvement approaches to assist with the reduction of laboratory errors associated with burnout or stress. The literature points to the linkage of the utility of evidence, the improved turnaround time for laboratory results (Pokinsa et al., 2002; Douglas, et al., 2003; Hawkins, 2007), and the integration of data through a laboratory information management system (Tate et al., 2012; Schreier et al., 2019). These elements have the potential to create a value-centric laboratory model, thus critical for future research. I now turn to key debates in the literature and raise my first question.

Key debates on laboratory quality dynamics, system vulnerabilities, and coping strategies revolve around, strategic investments in planning and execution, data integration (Schreier et al., 2019), and laboratory heterogeneity against approaches supporting paradigmatic monopoly. Similarly, these debates are a call for evidence-based practice (Oliveira et al., 2014) against resource limitations and the prevailing lack of harmonization (Nkengaong et al., 2010). As laboratories grapple with these challenges, it becomes evident that they are vulnerable to environmental pressures, raising a platform for my question:

How (if at all) do responses to environmental pressures experienced by a field-level laboratory and internal ambitions support quality improvement?

Legitimacy and credibility constructs appear unresolved in evaluating compliance. Compliance itself is revisited in the next section of this literature review, while its paradigmatic monopoly manifests in the forms of the institutional theory of isomorphism (Meyer and Rowan, 1977; DiMaggio and Powell, 1983; Westphal et al., 1997) and associated contestations (Charlton and Andras, 2002; Wilson et al., 2016) discussed in further sections of this review.

2.6. Regulatory Compliance Revisited-Recoupling compliance in contextual idiosyncrasies

Scholars and practitioners debate compliance in diverse and copious literature and empirical works but fall short of theoretical frameworks that deliver compliance (Lindenberg and Steg, 2007; Gulati et al., 2012). No one system is tried and true. This section thus argues that compliance with policies that are unfit for context is unwarranted. Here, compliance is redirected and rethought within the context of the practice field. This thesis considers the nature of diagnostic laboratories and the realities of implementing quality programs at the field level against perceived isomorphism post-adoption. As a scholar-practitioner, my reflection provides that context consideration draws into a quality improvement plan some mundane artifacts e.g. a shared understanding of the complexity, with the capacity and propensity to influence behavioral and technical intervention.

The WHO, a leading international health body, recognizes that implementing ISO requirements depends on the laboratory situation and context (WHO, 2011). These statements outline the gap between the ISO prescriptions and the implementation world. The WHO's statement testifies that although the formal introduction of the ISO standards may occur, implementation processes may be defective, thus, in non-compliance. Organizations recognizing the challenges in implementing prescriptive regulatory obligations are beginning to self-regulate, redefining their internal processes to attain quality. Healthcare laboratories face field-level isomorphism but enact innovative approaches daily, thus, painted with post-adoption heterogeneity, an opportunity for decoupling to gain a deeper understanding of its micro-processes (Ferlie and Shortell, 2001). The adjustments indicate that policy and guidelines are white theses divorced from the realities of implementation (Bromley and Powell, 2012).

However, only a few scholars have challenged the traditional-regulatory approaches (Hwang and Powell, 2009; Jackson and Stoel, 2011; Egels-Zanden, 2014; Bree and Stoopendal, 2018).

Laboratories are regulated in their practices but are dynamic in implementing QMS. These features enable them to remain open systems recoupling and decoupling their structures experimentally in the real world of application. Under these lenses, regulatory compliance may be a coerced isomorphism resulting in symbolic adoption unless it respects organizational practices (Perezts and Picard, 2014). Compliance from a broader perspective reflects policy and context interaction, thus, subjectivist rather than objectivist. Could this be an opportunity to decolonize the ISO frameworks and embrace nuanced institutional logic and organizational behavior to attain knowledge of how micro-processes become internalized into normative practices? I revisit this subject in the subsequent sections of this literature review and re-evaluate ISO frameworks and International Standards for medical laboratories to unlock their “iron cage”.

2.7. International Standardization Organization (ISO) Laboratory Quality Frameworks

Standards are a monolithic, uniform framework guiding operations across organizations at the field level. However, standards are moving targets, and user discretion is called upon as the versions might change over time ranging from minor technical features to substantial changes (Egyedi, 2015). The ISO schedules revisions of standards periodically, and in some instances, specific regulation is withdrawn and replaced with a new one. Yet, even from a technical perspective, changes may be extraordinary and unplanned, ruling out expectance and setting lenses on impermanence as a potential approach to quality improvement and thinking standards. However, despite vehement criticisms of standardizing (Seddon, 1997; Wilson et al., 2016), there are mixed feelings among managers and staff to go for ISO accreditations (Alkhenizan and Shaw, 2012). Conversely, laboratories still pursue accreditation either to address environmental pressures or pursuit of internal motivations. In this section, this literature review explores the ISO frameworks related to medical laboratories, their historical backgrounds, scope, inconsistencies, and criticisms.

In many countries, national regulatory bodies set standards to promote and promulgate them to guide the laboratories within the socio-economic and political jurisdictions. The national standard organizations also assess the usage and adherence to tenets of the technical specifications. Often standards are set at the country level by committees comprising field-specific technical experts and are voluntary. However, once supported through country legislative organs, they translate into regulations to which compliance is mandatory, with practices referenced to the technical standard. It is the network of the national standard bodies that form the International Standards Organization (ISO, 1997) based on agreement.

The International Standards Organization (ISO) sets quality processes standards with technical roots for medical laboratories. Medical laboratory organizations complying with the ISO standards receive the ISO's symbolic stamp of approval. The ISO certification itself is “the law”, and institutions seeking its seal do so because of regulatory pressure (Anderson et al., 1999) and in search of legitimacy (Westphal et al., 1997). Other laboratories seek reputational benefits owing to large external audiences and brand identity arising from its conception as a “gold standard”. Laboratories adopting the ISO standards consider that it is an inseparable intrinsic component of their organizational culture. These laboratories subsequently go a long way to rationally defend the ISO's role (Kim et al., 2011). Many countries have a national accreditation body, however, some low-resource countries do not have a body specific to medical laboratories. If such a body existed, it would give formal written authorization recognizing a laboratory as competent, having met the specific requirements to undertake specified tasks. The ISO deems that the organization that gets its accreditation meets the accreditation body, the customer, and the regulatory authority.

Quality management systems of medical laboratories have progressively conformed to ISO 9000 series, which advanced to ISO/IEC 17025: 2005, and currently ISO 15189: 2017. The main aim of ISO standards is to decrease process variations (Terziovski et al., 2003) and create quality awareness among stakeholders (Sharma, 2005). Other scholars argue that ISO certifications drive effectiveness and efficiencies of internal processes, increase customer satisfaction and improve turnaround time (Pokinsa et al., 2002; Douglas et al., 2003). Regardless

of participation in ISO certification, firms with inherent quality culture backgrounds are likely to demonstrate satisfactory performance, thus meeting certification and accreditation requirements (Blind et al., 2018).

The current regulatory guidelines for medical laboratories came into existence following considerations given to the weaknesses of previous guidelines. Consequently, the ISO reinforced past standards to provide more measures. The argument that preceded the formation of current regulatory requirements was that scientists viewed the previous versions as limited in scope. Some omissions included pre-analytical requirements post-analytical explanation and turnaround time, and the standard offered no chance for including additional needs (Thelen and Huisman, 2018). Proponents of current regulatory requirements argue that they extend opportunities for continuous improvement, development of systems that resist failure, identification of mistakes, error reduction, and keeping employees involved (Schneider et al., 2017). Interestingly, the discussions at the time of rethinking the previous guidelines supported its realignment to the tenets of other versions, and most recently, this was achieved (Johnson, 2019).

These standards and accreditation processes are not without protagonists. Some scholars argue that efforts towards strict compliance are wasteful and too involving considering financial, human, and technical resources that yield little in respect of quality improvement (Seddon, 1997; Wilson et al., 2016). Moreover, the benefits of implementing ISO 9000 are strikingly controversial (Kaziliūnas, 2010). Further, researchers document little evidence in the literature about ISO's post-implementation impact (Ab Wahid and Corner, 2009) beyond the evidence of sanctioned adoption period. The medical laboratory-specific ISO standards offer no clear pathways for continuous quality improvement beyond the point of compliance. Moreover, subsequent audits are preoccupied with compliance (Sachdeva et al., 2012) yet marked with excessive bureaucracies (Castell, 2007). Some countries, for instance, the United States that has Clinical Laboratory Improvement Amendments (CLIA), find the ISO/IEC 15189: 2012 inferior to their internal systems.

Literature suggests that ISO 9000 series implementation in a cross-section of organizations is driven by customer pressure (Martinez-Costa and Martinez-Lorente, 2003; Terziovski et al., 2003; Bhuiyan and Alam, 2010). Some scholars, however, posit that motivations for accreditation arise from the need to enhance institutional capacity, quality improvement (Pomey et al., 2004), and the pursuit of resource efficiencies (Church and Naugler, 2019). Although some regulatory standards prescriptions coincide with some TQM requirements, they are less comparable to the holistic approaches that underscore TQM such as employee engagement and customer/ shareholder-centric tactics (Zeh et al., 2010).

In ISO's principles, standards arise from consensus and "should be acceptable everywhere" (ISO, 2006). However, the standards body fails to demonstrate how administrative ideologies get married into its accreditation processes to sustain regulatory operation or at least the standards' broader values (Brook, 2010; Seddon, 2014). This approach prioritizes risk-based thinking and building confidence in scholarship. However, in practice, it sets aside systematicity, dynamism, open-mindedness, complexity, courting uncertainty, and the need for open inquiry, which are essential natural pillars of social research and cognitive maturity. The ISO admits that effective implementation is required for the standards to succeed (ISO, 2006), suggesting a more dynamic and flexible framework to effect standards.

Internal Quality Control (IQC) is one of the essential pillars of ISO/IEC 15189 and 17025, yet, neither the simple procedures nor the activities towards the realization of the requirements of the specific standard clarified by its proponents (Fuentes-Arderiu et al., 2007). Similarly, the ISO requirements for medical laboratories have the "customer" focus, justifying the need to ensure that patients are satisfied with the service. Yet, the laboratory stakeholders transcend patients (Pereira, 2017), including clinicians and other professionals in the medical field, the communities around the laboratory facility, governmental agencies, and even laboratory commodity vendors. The ISO/IEC 15189 standards rely on the auditing methodology, where an external independent certifying body is invited to review conformity to the specific standard, which in reality, puts at bay the very stakeholders who need to identify the gap and find an in-house solution.

2.8. Decolonization of ISO frameworks and National Standards

As demonstrated in the literature, the ISO/ IEC technical standards and the values they portray are vanities unless supported by specific frameworks or guidelines during implementation (Fuentes-Arderiu et al., 2007; Brook, 2010; Seddon, 2014; Wilson et al., 2016). Regulatory standards are, therefore, policies or checklists which may be lost on the laboratory office shelves unless an active stakeholder engagement takes place in conjunction with the will to implement them. Foremost, the prestige exercised by some scientists intending to cluster their expertise and issue instructions (Jacobsson, 2000) over the community implementors could be open to benign decoupling. Second, sidelining the street-level bureaucrats and implementers in preference of “visible” state-level players, multinationals, and seasoned experts, although conferring sociopolitical legitimacy on the guidelines, results in poor compliance due to disconnect from daily technical routines (Hoelsing, 2016). Third, it presents standards as tools of high-handedness meant to control and direct the street-level bureaucrats who are the implementing agency. It dumps technical innovation, self-emergence, organizational learning, particularly the creation of tacit knowledge at the institutional level, and the feedback loops compromising the legitimacy the standards should portray. Nevertheless, these arguments offer a foundation for breaking from the domination of existing ISO frameworks and other jurisdiction-based standards reasoned from the concept of impermanence. Moreover, these developments suggest that any standards and endeavors towards accreditation be subject to an active cycle of quality improvement, which, therefore, espouses the solid foundation of the Demings PDCA cycle.

ISO-specific standards, some external frameworks, or even efforts towards their harmonization stand challenged. First, there is a growing need for granularity and contextual knowledge with a standard with a more flexible scope (Thelen, 2017). Taking cognizance of these aspects invites stakeholders to think of the quality improvement framework as ingrained in strategic practices, pragmatic, and goal-oriented and exposes barriers while correcting inconsistencies (WHO, 2018). Third, a framework should be a stakeholder-focussed, social-modeled approach and leverage socio-pragmatic constructivism (Recker, 2007). This

arrangement promotes boundary spanners (Ansett, 2005) based on the processes and institutional plurality. Non-compliance with the standards, if ever standards or regulatory obligations are enforced due to the need for risk management, should be interpreted with discretion (Black, 1997; Hunter, 1997). The interpretation of the framework must be based on the lenses of the regulator and the regulated and in the interest of all stakeholders.

This angle of thought calls for standards to engage cognitive-behavioral approaches. Equal discretion should be exercised on compliance (Hunter, 1997; Parker, 1999), as it may be a simple reflection of surface-level transformation unless it presents opportunities for barriers to quality improvement or beliefs for prevailing practices to be addressed. These scholarly opinions may challenge best practices or what laboratory sciences argue as evidence-based practices or practice validity to embrace the theory of emergence. Naturally, even best practices decompose and lose cohesion, and emerging practices thrive in their place. Developments in the pharmaceutical industry have seen new regulatory orders or hybrid regulations arise against the presumed concept that there should be sector-wide standards adopted (Weyland, 2007; Jordana, 2012). Harmonization of standards, therefore, needs an abstract ontological architecture that releases tensions between standards and customized local practices potentially with no overlaps. The challenge with international standards is that jurisdictions have to adopt and implement them in their environments, yet they lack specifics of such constituency.

From scholarship and practice, considering the foregoing arguments, the neglected debate is the dynamics of standards implementation. The debates do not release the tension between the implementors and their potential desire to be part of the changes in practice. From an ontological perspective, in any case, if the architecture were a standardized practice, it would depict a practice's dead-end, which cannot be the case in laboratory medicine. The literature debates in this section point to the value of stakeholder engagement (Wilson et al., 2016) discretion, and criticisms on compliance (Hunter, 1997) standards flexibility scope (Thelen, 2017). Some scholars also question the post-adoption success of standards (Ab Wahid and Corner, 2009; Kaziliūnas, 2010), highlighting standards' disconnect with technical routines (Hoelsing, 2016). I, therefore, present the second question: *In what ways can laboratory*

members create a legitimate organization, within the confines of institutional quality culture without pressures for isomorphic conformity?

2.9. Post-adoption of ISO's: Laboratory systems heterogeneity and standards implementation

In scholarship and practice, there are limited writers about ISO post-implementation beyond the effectiveness of the processes leading to accreditation (Ab Wahid and Corner, 2009). However, Infrastructural breakdowns arising from organizational and governance pathologies that make standards implementation impossible remain unforeseen. Post-adoption challenges include a change in funding streams and volumes in resource-limited settings with restrictions on the scalability of implementation (Nkengasong et al., 2010; Zeh, 2010). The ISO has mechanisms for technical review, but they fall short of tools to determine the relevance, coherence, impact, or efficacy of ISO implementation (Delimatsis, 2014).

Organizational literature shows that diagnostic laboratories are far from passive and highly heterogenic, with variations in complexity (Dinnes et al., 2005; Rahmandad and Vakili, 2019), ambiguities, institutional logics, and demands, fragmented or converging institutional infrastructure and ideological goals. However, the ISO's optimistic rhetorics and conceptions could camouflage these complexities rather than seek to create institutional isomorphism or a neo-homogeneous institution (Heras-Saizarbitoria and Boiral, 2013). Although laboratories may strive to achieve isomorphism in adopting standards, it is highly plausible that the outcomes will be heterogeneous. The variations stream from institutional micro-level dynamics, dominant logics, innovative avenues, and decisional capabilities of a specific laboratory and tight coupling or loose coupling of the standard. This could be due to systemic complexities, varying interpretations of the ISO rhetorics and connections, or lack thereof, with institutional practices which explain post-adoption heterogeneity (Greenwood et al., 2011; Thornton et al., 2012).

The approaches taken by firms in standards adoption result in symbolic adoption when their source of motivation for the adoption arises from organizational contingencies and external pressures (Thujo, 2013). Nevertheless, the standards could be seen as outgrown and forced on the stakeholders - that includes employees and risk being met with resistance, cynicism, or just ambivalence, rejecting the values it upholds (Meyer and Rowan, 1977). Moreover, external

pressures constrain organizational decisional capabilities and direct institutional efforts far from primary established rational goals (Annosi and Brunetta, 2017), thus, inviting decoupling. In the light of meeting external legitimacy, employees may superficially welcome a “ceremonial standard” whose values would never see the light of effectively influencing organizational practices, nor would they create new organizational capabilities.

In another vein, motivations for ISO adoption sprout from internal organizational pressures, where the stakeholders are the drivers for standards adoption (Adane et al., 2019). Here, drivers for standard implementation arise from the need for quality improvement and are substantial and in-depth. In this case, standards are disconnected from the daily realities of organizational practices and will find opportunities for recoupling as implementors engage in constructive approaches. The challenges raise opportunities to make desired changes in the standard implementation processes in planning and rationally engaging in the enactment (Pitsakis et al., 2012). These aspects have been explored extensively in the previous section of this review. This review now turns to institutional isomorphic conformity as a discrete institutional approach to shed light on how it advances or negates quality management and implementation sciences.

2.10 Institutional isomorphism

Any institution has the prestige of being different, immitable, distinctive, reputable and outstanding. In their increasing diversity and structuration, plurality and heterogeneity, laboratories face dilemma, as they experience coercive forces to take a monolithic identity to enhance legitimacy (Meyer and Rowan, 1977). This section of the literature review revisits institutional theory especially the concept of institutional isomorphism (DiMaggio and Powell, 1983). The cumulative monolithic effect is reflected in the standards as a tool for quality management, a “management fad” that directs institutions to imitate one another. Looking at isomorphism in-depth reveals conformity and compliance with any standards will be passive as it takes the form of mere ritual. In some instances, there exists the institution-wide belief that firms that return good performance are “legitimate” a predictive stimulus for imitation will tend to occur, cementing the legitimacy. However, it limits institutional innovative capacities and

other proactive forms of strategic responses (Croucher and Woelert, 2015) settling institutions into a process of dependency, domination, or capitalism. Before concluding, I revisit institutional isomorphism under institutional theory as a sub-topic in this thesis. Institutional isomorphism provides a critical insight that explains the failure of coercive forces to produce quality improvement when performance measurements affect field organizations but varied from the organization's context. Further, the theory of institutional isomorphism contributes to highlighting the weaknesses of standards as a normative tool, as negativity bias may be overridden by positive biases arising from bounded rationality.

In sum, this section suggests some avenues with the potential to assist in advancing the current research, questioning practice, and enriching implementation science. First, it considers that standards are a moving target, with series translating into new ones and others are withdrawn (Johnson, 2009; Egyedi, 2015; Thelen and Huisman, 2018), yet there is little scholarship to justify their benefits beyond adoption (Ab Wahid and Corner, 2009) and pursuit of compliance. This review suggests that the implementers embrace the role of curiosity while engaging with standards in complementarity towards and parallel with institutional processes.

Equally, while engaging a potential quality improvement framework, this review suggests an expanded focus to encompass the satisfaction of all stakeholders rather than simply customer satisfaction (Nahyan and Abdel-Al, 2017; Pereira, 2017). The satisfied parties ought to include the direct implementers or street-level bureaucrats as the agency for implementing organizational processes. This thesis additionally leverages a quality improvement framework with a flexible scope supported by the seminal work of Thelen (2017). The framework should be socially modeled and customized to local contextual architecture. The conception of such a quality improvement framework means there is no room either for symbolic adoption or symbolic implementation due to collective stakeholder will and institutional axioms in every quality improvement effort.

This literature review has demonstrated contestations and inconsistencies of standards and exposed the need to develop a contextualized framework. It is, therefore, critical to work with all stakeholders and pay attention to street-level bureaucrats in advancing quality

improvement (Wilson et al., 2016; Adane et al., 2019). I have considered ambivalences in scholarship concerning standards (Seddon, 1997; Charlon and Andras, 2002; Brooks, 2010; Wilson et al., 2016; Adane et al., 2019) and taken this as a call to an appreciation of feedback loops, leveraging functional differentiation, plurality, and multiple institutional logics. Therefore, in the next section, this review turns to total quality management practices (TQM) and a stakeholder-driven quality improvement framework and appreciates management by process and value of feedback loops. This review carries yields lessons learned from earlier sections in courting uncertainty, change dynamics, and the concept of impermanence and emergence. Within the lens of this review, four arguments emerged that I considered in informing the next section of this thesis. First, regulatory standards portend incremental positivistic and mechanistic approaches to quality improvement. However, TQM in practice considers an alternative approach to change from the organistic-paradigm, and as discontinuous, planned, and disruptive. Second, given this paradigmatic approach, TQM applies to the challenges of the contemporary laboratory and offers opportunities for learning, organizational development, and addressing culture change. Third, TQM addresses the synergetic effects of maintaining compliance and continuous quality improvement as part of organizational change. Fourth, monopolistic approaches to improvement and forms that push for homogeneity be rethought, and the place of institutional entrepreneurs be explored for creativity and internal transformation.

This section of the literature review highlights critical debates in support of stakeholder curiosity and courting uncertainty in TQM implementation. The literature places value on stakeholder proactiveness in their strategic responses to TQM (Croucher and Woelert, 2015). The key debates place importance on standards interpretation and post-adoption variations (Thornton et al., 2012) when the pressure for adoption is internal (Adane et al., 2019). considering the debates in the literature, I raise my third question:

What are the effects of institutional isomorphism in TQM implementation? If there are, how do laboratory actors respond to these effects?

2.11. Laboratory Total Quality Management Practices

In the earlier sections of this review, I have shown how scholars have depicted quality as a tool of emergence and evolution. The understanding of emergence offers an infrastructure for an appreciation of an established system, model, framework, or process for managing organizational-wide continuous quality improvement in all aspects of work. Studies have shown that there is a significant correlation between TQM and organizational strategy (Perdomo and Javier González, 2004; Kumar et al., 2018). TQM serves a dual role of enhancing both quality and conformity to international standards (Vijande and González, 2007). Paradoxically, laboratories are under pressure to keep costs low, in concordance with their role in quality improvement (Westgard, 1999; Warwoods, 2003). The pressures push the laboratories to transcend their technical domains to embrace and engage in Six Sigma (Westgard and Westgard, 2017) and Lean principles (Mitchel et al., 2014) in process improvement. These scholars' arguments offer a connection to TQM, the Deming's PCDA cycle, and set laboratories on innovation and a systemic approach to dealing with uncertainties, challenges, and problems. Figure 4, below presents a framework for laboratory quality management.

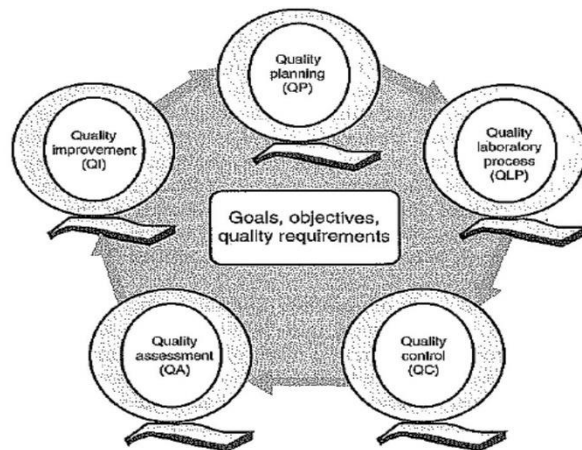


Figure 4: A laboratory Quality Management Framework (Source: Westgard and Klee (2006))

TQM is enshrined on dual philosophies of constant push for quality improvement, ensuring customers, and fulfilling organizational needs. TQM advances the abandonment of

mechanistic approaches toward adopting reflexive and subjective methods (Hoogervorst et al., 2005). It brings into perspective flexibility, courting uncertainty and complexity, rationality or subjective reasoning, and fitness for purpose. Further, TQM encourages knowledge co-creation through the involvement and participation of stakeholders and, by default, reweaves their organization and generates change. The readiness of an organization to learn in the complexity and real world is, therefore, critical in advancing TQM. This thesis engages cognate literature to explore how field-level laboratories in the complexity, heterogeneity, and varying contextual backgrounds practice TQM. Further, I leverage the place of emergence paradigm and the concept of impermanence. The thesis advances the connections between knowledge, innovation, and TQM under contextual emergence in the wake of failures of the traditional monopolistic laboratory management approaches. Moreover, there exists a significant correlation between TQM and knowledge management, and an institution could strategically place itself to gain from both (Honarpour et al., 2017). Nevertheless, the emergence paradigm hasn't been given the deserved attention in deriving change. Nonetheless, institutions that adopt TQM as a form of QMS either interpret it as an opportunity or a threat (Kennedy and Fiss, 2009). This laxity may be a result of external pressure or increasing demands from customers (Reiner, 2008; Elizabeta et al., 2014). Despite laboratories adopting TQM, a significant majority, however, need to proactively identify elements in their laboratory processes that need to be improved (Elizabeta et al., 2014). Øgland (2018), however, argues that quality could be advanced by employing critical systems thinking, and by default arriving at TQM, even when management commitment is unsecured.

2.12. TQM and Tacit knowledge: coevolution and diffusion?

Despite embracing TQM, organizations need further steps to acquire tacit knowledge and integrate it into their systems as an innovation. Here, innovation plays a critical role, and researchers see TQM diffusion and adoption as a strategic pathway to integrated tacit knowledge across incongruent constituencies (Mendes, 2017). Critical to knowledge transfer is the change in worker behaviors and values with an emphasis on collaboration and sharing of

ideas (Chang et al., 2019), thus generating a participative institutional culture critical for a learning organization (Senge, 1990). Reason (2001) postulates that learning could take shape from stakeholder experiences expressed by storytelling, learning from practice symbolized by competencies, presentations through drawings, and propositions via theories. Thus, knowledge is socialized, externalized, combined, and internalized (Nonaka and Takeuchi, 1997) inclining on prevailing workforce collaborations and relationships. Nonaka and Takeuchi (1995) present advanced forms of knowledge generation in the form of “Knowledge spiraling” between persons, groups, and organization-wide, portraying people and knowledge as strategic resources for TQM as a learning process. Central to the Nonaka and Takeuchi (1995) scholarship is internalization/externalization, where knowledge is reinvented and diffused. TQM, therefore, extends the concepts of emergence and impermanence and contributes to innovation, competitive edge, and large intellectual capital in the tacit-explicit knowledge cycle.

In TQM, learning opportunities abound in many forms, right from hearing the stories of the customers collected from suggestion boxes in the form of feedback, or storytelling sessions involving stakeholders. Such exchanges allow for real-time understanding of organizational challenges and permit members to learn most effectively (Easterby-Smith et al., 2008), consistent with Reason (2001) regarding experiential learning. Accordingly, members get the opportunity to reflect critically on their practices and work contexts, engage in dialogue and consensus-building, and plan and translate those plans into actions consistent with the PDCA cycle. This thesis recognizes the internal and external organizational complexities and does not imply that the learning is in any way linear. This sub-section dwelt on knowledge management (KM), preferring the Nonaka and Takeuchi (1995) scholarship, the internalization externalization cycle of knowledge translation, and the emergence concept. It places learning in the process of implementation in the hands of organizational members. This concept of KM draws a connection between organizational learning and key performance indicators and stakeholder knowledge base (Sciacovelli et al., 2011) to document changes in the performance of laboratory output indicators (Argote and Miron-Sepktor, 2011) with the potential of advancing the current research.

In scholarship, knowledge sharing is established to have a solid association with values and is a critical predictor of organizational performance (Hsu, 2008). However, Swan et al. (2010) warn that deficiencies in the documentation and the inability to use lessons learned from previous projects are responsible for poor knowledge sharing. Lin (2008), in connection with Hsu (2008) and Swan et al. (2010), suggests that these drawbacks stem from poor knowledge-sharing networks that build on actor relational capital. To reinforce knowledge sharing, Wang and Noe (2010) suggest a framework capable of assisting in understanding organizational context, individual actors, and group characteristics and motivating knowledge sharing. In this thesis project, knowledge sharing will be a core area for scrutiny in scholarship and practice.

2.13. Adoption of context-based measures for TQM

Quality initiatives, TQM inclusive, when implemented in organizations in varying contexts return dissimilar (Barry et al., 2018). Although drawing from the discussions on standards in earlier parts of this review, I find some connections between the adoption of standards and TQM, with a possible focus on mimetic, external pressures being the reason for adoption. In this review, however, I lend myself to a quality improvement approach that respects contexts and has a propensity to appreciate the TQM management philosophy. Further, such an approach allows practices to emerge around TQM guiding principles, mature within the organizational context of practice, and deliver on promised benefits. Moreover, the emergence of quality practices allows the deployment of TQM as a strategic resource to realize post-adoption benefits beyond quality management that impact continuous institutional change programs (van Kemenade and Hardjono, 2019).

The challenge experienced in TQM implementation is an external focus that the vast majority of organizations have deployed and obstacles, such as inappropriate infrastructure, lack of employee involvement, and motivation. Other challenges are a lack of leadership commitment and quality awareness, an inability to build a network and manage partnerships, poor information capturing and integration, and weaknesses in strategic planning. Due to these, TQM has failed, prompting criticisms and calls for its abandonment (Sadikoglu, 2014). First, these obstacles may present as threats, but their positive conception could turn into environmental

opportunities. The failures reveal the place of contingency factors and institutional theory in TQM advancement and customization to specific organizational needs. As with the ISO and other normative standards, TQM seeks no certification or accreditation, so no distinct structures are required to appear legitimate. Although organizations engage in TQM implementation, they will take divergent approaches that pronounce differentiation and emergence. To further explore this angle of thought, this thesis turns to institutional theory in the next paragraph.

2.14. Institutional Theory and TQM practices

Organizations and their managers are constrained by the internal and external environments, which then occupy the minds of managers as they rationally reconstruct and make sense of their world (Bates et al., 2014; Faundez, 2016). These scholars (Bates et al., 2014) and Faundez (2016) espouse the values of institutional theory by providing an insight on unpacking the premise of new institutionalism. For Meyer and Rowan (1977), Organizations contend with external pressures far from immediate environmental structures, rules, and strategies in order to fit into social expectations, and appear legitimate (Barley and Tolbert, 1997). The laboratory is such one institution that is constrained by external pressure, with high expectations for conformity, yet they must exist within the confines of institutional rules. Managers have no option except to act within what is legitimate and with bounded rationality. One such rigorous approach is the use of ISO standards and coded prescriptive guidelines for measuring the performance of a laboratory. When guidelines differ from local institutional logic and the actual context of work practices, it offers grounds for decoupling¹ (Graafland and Smid, 2009). This has been discussed in earlier sections of this review, under “Decolonization of ISO Frameworks”. The adoption of regulatory guidelines notwithstanding, over time, laboratories may deviate from regulatory prescriptions or ‘norms’. Although there might be a justification for deviation, laboratories are likely to have their survival threatened, and potential limitations in

¹ Decoupling is an organization actions that shed off rationalized myths of a formal structure and function (institutional pressures) and subsequent adaptation of new practices that define it as efficient, while only superficially abiding by the former structure.

funding. Laboratories are likely to sink into a further dilemma when the pursuit of contextual reality produces desired outcomes and adopts specific practices. Due to innovation diffusion, these new practices become embedded into similar organizations over time, and the practices end up being taken for granted (Tolbert and Zucker, 1983; Westphal and Zajac, 1994). This is the epitome of institutionalization.

In connecting institutional theory to TQM as a form of innovation, the logic for adoption notwithstanding, this review finds earlier adoption to have been driven by mimetic pressures (Di Maggio and Powell, 1983) in pursuit of functional efficiency or gain of economic edge. Core to the institutionalization of TQM is the role of the agency of institutional entrepreneurs. By reflexivity and collective action, institutional entrepreneurs intentionally disrupt existing institutional frames and create and maintain new practices (Lawrence and Suddaby, 2006). Contrary to this scholarship, Bitektine and Haack (2015) posit that by the same strategic approach, organizational actors destroy institutions in response to daily organizational needs. This lends itself to TQM implementation and serves to elude the rational myth of organized and straightforward institutional structures and edify the work of Meyer and Rowan's (1977) 'Institutionalized organizations: Formal structure as myth and ceremony. This review, therefore, demonstrates how the adoption of TQM in a single organization, may lead to the processes of institutionalization of similar practices in other field-level organizations, underlaid by institutional entrepreneurship. Referring to the laboratory pressures and vulnerabilities, in "*Overview of Laboratory Quality Systems Management*" this review found, inadequate laboratory infrastructures, higher work-volume to staffing ratios leading to increased laboratory errors, poor networks and partnerships, poor turnaround time (TAT), irrational use of laboratory services, and lack of equipment harmonization. This section explains the utility of TQM and shows evidence of advancing its concepts in continuous quality improvement in laboratory services. Traditionally performance of a laboratory is measured by an increment in turnaround time, which can be optimized considering the dynamics of laboratory workflow (Steindel, 1990; Steindel and James, 1991). A study by Kohli et al. (1995) in a hospital's pathology unit reveals that critical to enhancing TAT is teamwork, and information, which requires investment in an information system, education, or form of orientation. Kohli et al. (1995) findings reveal the

critical role of feedback and information dissemination in support of TQM. TQM implementation depends on employees as the agent who must take action. The employees must understand the full task characteristics, and make decisions regarding those tasks and the direction their organization should take (Luthans, 1995; Guimareas, 1996;). Organizations that adopt people-oriented strategies that clarify role ambiguities, build work relationships, networks, and collaborative spirit (Cooney and Sohal, 2004), and confer trust on the employees have competitive advantages over those without such strategies. Active participation and attitudes shape team approach and commitment to infuse efficiencies in the work process improvement, support creativity, innovativeness, accountability, optimize task handling, and reduces job-related stress and burnout (Hernandez, 2018).

In this review, I have demonstrated how the deployment of institutional theory in advancing TQM practices may lead to the destruction of institutional structures. As the adoption of TQM practices happens in a repeated fashion, it allows the manifestation of forces behind institutions. I now turn to explore institutionalism, in the neo-institutional perspectives of organizing, institutional change, and sensemaking around institutional practices.

2.15. Institutionalism

The impediment surrounding institutionalism is the many versions of its meaning embedded in scholarship and some taking contradictory paths, yet supported by empirical evidence that is valid in their own merit (Hall and Taylor, 1996). This thesis lends itself to three of these versions including historical, normative, and most exceptionally, rational choices. The institutional theory forms the very backbone of this thesis project current research finds its roots in some of the schools of thought. Moreover, institutionalization may assist explain decision-making practices in implementation sciences, why organizations adopt ISO standards, accept memberships in international regulatory bodies, or such policy frameworks. Lastly, the understanding of institutionalization has the potential of recalling and shedding some light on the tensions between environmental pressures seeking conformity and the fundamentals of internal organizational realities.

Starting from historical institutionalism scholars argue that structures and policies that guide an institution are initiated at the very foundation of the organization and constantly influence its behaviors for the rest of the organizational life (Steinmo et al., 1992). The central idea here first, is traceability, and then how existing axioms assist in policy direction. However, proponents of historical institutionalism portray an assumed linkage to sociological institutionalism (Saurugger, 2017). Although this is not within the domain of the current research interest, in scholarship, historical institutionalism portrays cultural embeddedness (Steinmo et al., 1992; Saurugger, 2017). Historical institutionalism, thus, offers the “true north”, the best view of the point of departure concerning policy implementation. Given this, policy development and its future borrow their influence from past policies (Pierson, 1993; Kennedy, 2006).

I now extend this review to Rational-choice institutionalism (Shepsle, 2009), which may explain the choices on the rational and irrational use of laboratory services and influence the volume of test requests. It is a testament to the practical importance of rationality but also to its relevance both in the implementation discourse and policymaking. Rationality action pathways are drawn in what is expected to increase functionality and effectiveness in a process whose centrality is found in human cognitive architecture (Baron, 2007). Change in institutions is thus a consequence of a shift in people’s preferences (Bell, 2002), which may yield suboptimal results. In the implementation phase, however, given the complexity of the diagnostic laboratory, the challenge in rational-choice institutionalism may be human cognitive biases, action out of bounded rationality, and simple intuition, with potential negative experiences (Goldstein and Gigerenzer, 2002).

Normative institutionalism is founded in the seminal work of March and Olsen (1984: 1996), in which the scholars postulate that the outstanding method of understanding organizational behavior is through the “logic of appropriateness”. This approach extends rational choices where the standard norm is compared to the consequences of not belonging to the regulatory body. Organizational members here function with the guidance of institutional structures (Pitts and Clawson, 2008), and not because of cognitive prescriptions with the potential to maximize their individual and collective capacities. This explains why organizational members may shy from opportunistic behaviors, rather than appearing averse, and instead of

being explicit in decision-making in submission to institutional norms. Normative approaches depict regulatory bodies as value repositories from which members ought to draw.

In sum, drawing from Institutional theory and literature on institutionalization processes, this section has documented reasons why institutional structures for implementing TQM may be far divorced from actual organizational behaviors and practices. Moreover, the institutional theory explains why organizations may create structures, but eventually deviate from practicing or enacting. Instead, the organization takes a different approach or mechanism in the implementation. This may redirect the focus of the laboratory in the use of institutional viewpoints, in achieving efficiencies and advancing the organizational functionality in the TQM implementation under the current research.

Institutions work as a set of cultural practices in contravention of the myths and ceremonies that characterize the organizations (Meyer and Rowan, 1977). Consequently, the institutions are incorporated for their stability, attaining legitimacy, and improved chances of survival (Mayer and Rowan, 1977; Guiso, 2008; Alesina and Guiliano, 2015). Meyer and Rowan's (1977)'s scholarship is a predictor of organizational behaviors and explains why some organizations engage in collaborations and networking, which in turn explains homogeneity between organizations in a similar field. Organizations in the same field, experiencing uncertainty, therefore, imitate the successful ones by adopting the approaches of the superior ones (Scott, 2001). Given that culture is a consequence of social reality and a determinant of frames with which meaning is constructed, this review turned to organizational culture to shed light on how it may influence TQM, in a process congruent to institutional change. Primarily this review considers that cultural orientations and consequences may determine the behaviors and values enshrined in an organization to which organizational members pledge allegiance. Such values and behaviors determine organizational responses to external threats and opportunities, rules and regulations, the direction of its decision-making framework, amplifying innovation, and institutionalization. Further, understanding how organizational culture influences quality improvement is critical for the current study.

2.16. Organizational culture, stakeholder readiness and TQM mediating effects

Several studies show organizational culture and TQM have a strong relationship (Green, 2012; Kumar et al., 2018; Chang et al., 2019; Tenji and Foley, 2019). Indeed, people working in an organization must understand quality improvement approaches like TQM, its underpinning concepts and philosophy, and deploy them in enhancing quality. First, Chang et al. (2019) established their work on the fact that clinical laboratory systems, contrary to inert systems, are also controlled by people with emotions and act with rationality, determinants of creativity and innovation, and find these incentives both for cultural value transformation and TQM. Green et al. (2012) postulate that cultural traits critical for advancing TQM are integration, differentiation, sociability, and collective work approach. Importantly, Green (2012) argues that TQM implementation at the workplace depends on how the organization links to internal and external environmental factors. While this is the direction of the vast majority of scholars, Haffar et al. (2019) find no connection between organizational culture and TQM and instead propose that improvements arise from self-efficacy and individual value, shifting the influence of group flexibility to TQM.

Revisiting the context of this review, this review supports the seminal work of Sila (2007), distinguishing organizational culture from quality management and arguing for its contextual adaptability. Here, TQM as a quality management tool and a set of practices is pure and modified to fit into any culture. Considering that organizational backgrounds are as varied as the cultural backgrounds in which TQM implementation occurs (Prajogo and McDermott 2005), the separation of organizational culture and TQM is here clarified. Nevertheless, the organizational cultural setting determines its capacity to deploy quality tools and practices capable of influencing its performance. In this case, culture may determine which management practices are deployable toward quality improvement within the confines of the existing culture. For instance, the deployment of hierarchical cultures, which prescribes top-down approaches in implementation (Van der Maas, 2008), may demotivate and negatively affect the readiness of street-level bureaucrats and work against TQM as a quality initiative.

As TQM is stakeholder-driven, it predisposes TQM processes to a rational culture, and Zu et al. (2010) find this approach suitable for driving quality management practices and goal attainment. Further, top management has a role in providing a clear vision for their followers and empowering rational choices in quality management (Paliukas and Savaneviciene, 2018). It casts the die on leadership, the rest of the organizational members, and their collective choices. This literature review, therefore, redirected efforts in understanding the role of individual values and their search for efficacy. Here, the literature review outcomes settle on the employees as stakeholders and how their approaches may influence TQM adoption and implementation.

Employee readiness is an essential element in change realization, as each contributes ideas, networks, and collaboration with others in their team to improve organizational performance (Elizabetha et al., 2014). Interestingly, Yeh (2003) is an empirical work that argues for workforce self-efficacy, interpersonal support to the organization, and standard organizational structure. Yeh (2003)'s study orientation draws a connection with the institutional theory offering contradictory and supportive aspects. First, contradictory due to organizational structures being under constant transformation and the maintenance of existing organizational structures being a simple myth. Then, supportive as it leans towards normative institutionalism as employees as members of the organization operate within a specified structure. Nevertheless, Nahyan and Abdel (2017) find employees key stakeholders that must be satisfied, ahead of the customers. The employee contribution to TQM implementation effectiveness is enhanced by creativity and the ability to network in the form of steering committees or work teams (Loomba and Spencer, 1997). Here employees allow themselves to be led and to lead without formal authority or legitimacy (Raelin, 2010). Employees also advance the TQM discourse through their feedback to the organization, thus, reinforcing teamwork and open collective learning opportunities. Critical to the institutionalization of TQM is agency-wide capacity building through training and workshops, with the potential for a paradigmatic shift in culture (Loomba and Spencer, 1997). Equally important is collective rethinking and engaging organizational structure at a team level (Barrick et al., 2013), opening doors for communication and networking to aid better functionality and competitiveness under TQM.

Management and leadership engagement with TQM is viewed as a double-edged sword and trivial (Dale, 1994). First, management contributes to effective organizational culture lending support to TQM implementation. Conversely, employees' experiences demonstrate leadership is an impediment and destructive in the TQM implementation processes (Verma, 2014), as it causes significant problems. One plausible cause is the bureaucratic approaches of leaders, and the attempt to defend the organizational structure. To summarise key debates in this section, scholars suggest systemic approaches away from mechanistic methods in implementing quality improvement. The other scholarship rhizoms focus on proactive identification of processes that need improvement, people centred approaches that build on collaboration (Cooney and Sohal, 2004) and employee readiness to lead and be led. I therefore raise the question:

In what forms does institutional entrepreneurship function towards quality management system (QMS) change effectiveness?

2.17 Institutionalizing TQM Practices

In this review, I revisit the lenses of DiMaggio and Powell (1983) on institutionalization, in which they posit that it is a consequence of the convergence of organizations in the same field. I find that TQM exercises embody such institutionalized practices, which arise due to institutional pressures and taking coercive forms, driven by legitimacy rhetoric. Kennedy and Fiss (2009) citing DiMaggio and Powell (1983), consider that functional and competitive pressure was behind the early adoption of TQM. Organizations then started shifting from short-term plans to long-range ones, enhancing their networks, and improving partnerships (Deming, 1986; Silimperi et al., 2003) in the development of a framework for institutionalization and sustaining quality came across process precursors, spanning pre-awareness to the maturity phase, depicting emergence. Here Silimperi et al. (2003) established factors critical for an internal organization supportive environment to be policy, resources, leadership, and organizational core values. Besides are support structures for implementation which include means for rewarding quality, training, and knowledge management.

Silimperi et al. (2003)'s model in Figure 5 demonstrates the immediacy of structure to institutional core intentions underlaid by the need for Quality Improvement, Quality Development, and Quality Management. The tripod functions to keep the structure under constant transformation and enhanced performance. Moreover, as Meyer and Rowan (1997) have argued in informing institutional theory, institutional structures are a myth, without sustained cognitive legitimacy, and any ambiguity is an opportunity for decoupling.



Figure 5: A model for Institutionalization (Source: Silimperi et al., 2003)

Taking cognizance of the conceptions of TQM around Silimperi et al. (2003)'s quality assurance institutionalization model, a system's approach, and resource-gap analysis is critical for contributing to process value, goal attainment, and continuous quality improvement. Further, the institutionalization of TQM reveals the agency's role in successful implementation, particularly in employees and their managers (Loomba and Spencer, 1996). It is worth noting that institutionalization may be derailed when TQM raises the employee expectation, yet these organizational agents find constraints within the realities of the organization's traditional structure (Loomba and Spencer, 1997). However, employees may navigate the traditional organizational structures by embracing institutional entrepreneurship (Maguire, 2007), knitting together desperate agency interests to transcend "best practices" in the TQM implementation. The breakthrough and epitome of TQM implementation is in the embeddedness of the unobstructed power of the agency in creating a pathway through radical and mindful deviation

from old institutional patterns. The literature reviewed questions legitimacy rhetoric in the coercive forms of institutional pressures and their capacity to sustain quality improvement. The literature argues for paradigmatic changes, correcting the traditional consequentialist nature approach of regulatory standards. Instead, scholars urge institutional dynamics built on processual legitimacy and social justice. These include supportive quality culture, flexible organizational structure, leadership, and resource utility (Silimperi et al., 2003). Pursuit of social justice requires organizational entrepreneurs to network and embrace partnerships (Deming, 2003). This brings me to the question:

To what extent do partnerships and networks contribute to TQM implementation processes?

2.18. Summary of literature review and scaffolding for current research

Prior to raising the frame for current research, I revisit and summarize the various concepts exposed by the reviewed literature, which may be applicable in understanding organizational contextual issues and in advancing the current research. First, quality reflects daily laboratory work practices, thus a living part of a laboratory. Repetition of what other “best practices” other laboratories are already doing elsewhere is ineffective, as contextualities differ. Second, the environment in which organizational actors’ function, their embeddedness, the organizational structural features, struggles for resources, and politics will determine the extent and direction of quality improvement. Third, TQM supplements the regulatory standards, nevertheless, the adaptation of TQM practices risks repeating the weaknesses of regulatory standards, due to field-level isomorphism. Therefore, contextualized, in-house TQM approaches and models that avoid such repetitive risks are critical. Fourth, the laboratory workforce is fundamental in quality improvement, beyond the maintenance of quality. What lies in the way is a difficult choice between social and rational systems to guide the decisions of the workforce in finding an appropriate answer to both external and internal environmental pressures, thereby finding legitimacy in their strategic actions.

In another vein, I reviewed the methodological approaches deployed by the authors of the reviewed articles. It is noteworthy to state that the literature on TQM implementation spans a wide research base, both in scholarship and practice. As such empirical, theoretical, and

conceptual articles were consulted during the review. These were further enriched by texts including commentaries, periodicals, books, and conference proceedings.

In summary, the empirical question underlying this thesis, and arising from the literature review is: *What exists between TQM knowledge and its implementation in real context of action?*

In order to answer this question, the empirical work will be guided by the following sub-research questions:

- a) What are the effects of institutional isomorphism in TQM implementation? If there are, how do laboratory actors respond to these effects?
- b) In what forms does institutional entrepreneurship function towards quality management system (QMS) change effectiveness?
- c) In what ways can laboratory members create a legitimate organization, within the confines of institutional quality culture without pressures for isomorphic conformity?
- d) To what extent do partnerships and networks contribute to TQM implementation processes?
- e) How (if at all) do responses to environmental pressures experienced by a field-level laboratory and internal ambitions support quality improvement?

Chapter Three: Research Design

3.1. Background and introduction

This chapter discusses the research design I adopted for this thesis, the reasons for their use, and how these methods supported the inquiry. I then discuss the research design, sampling and data analysis, interaction with ethical issues, and how I managed them. In the background of data collection were sensemaking of our laboratory system and practices from a multi-layered point, tapping participant perspectives and experiences. In the previous chapters, I highlighted the problems with our laboratory settling for quality compliance under defined regulatory frameworks, given the uncertainties surrounding laboratory practices. Subsequently, I draw from Greenwood and Hinnings (1996) context-derived institutional order to show that teams interacting with their institutional structures can call their laboratory into quality improvement order, transcending compliance. I demonstrate that teams should envision the future of their laboratory and cultivate entrepreneurship and investment towards the achievement of that future, based on context and practice evidence.

3.2. Philosophical approach

This thesis offered an opportunity for the researchers to practically know and construct their world (Chia, 2003; Coughlan, 2011) through work and action research (AR). During this research, the practitioners individually and collectively engage in sensemaking and find frames of meaning in the very work context (Gioia and Chittipeddi, 1991; Weick, 1995; Coughlan, 2011). Group dynamics, individual and collective historically embedded knowledge, perceptions, and values assisted in the sensemaking of context. On the other hand, it nullifies a single known truth associated with a positivist underpinning. On the whole, given this situation, my preference and choice were social constructivist philosophical paradigm (Charmaz, 2006) and also drew from post positivism, in particular, critical realism ontology (Lawani, 2020). Through qualitative research, as researchers, we inquired and made sense of our laboratory practices by social constructivism as we interpreted the practice realities in our context (Creswell, 2013). Finally,

critical praxis, values, and researcher collaborative behaviors yielded a way of thinking and shared understanding (Greenwood and Levin, 2007), informing subsequent cycles of inquiry and freewheeling practice reforms. These philosophical approaches and their applications are further elaborated in the data collection methods in the next section.

3.3. Methodology

The research was entirely “exploratory” (Saunders et al., 2012) in its form and nature. At the search conference, researchers acknowledged that the NPHL had a wicked quality problem. Additionally, we appreciated the uncertainty surrounding the pathway to a solution and invited ourselves to collaboration, interaction, and knowledge sharing (Greenwood and Levin, 2007) in the problem-solving process. As a lead researcher, during the discussions I prompted participants to reflect on the issues and actions suggested by the team for depth and broad understanding, as opined by Schwarndt (2001) and Pillow (2010). Following Pillow (2010), position, I chose not to stifle differing perspectives nor silence voices, as such were the building blocks of the laboratory knowledge repository. Our working practices were core to problematization, action planning, and subsequent reflections. Ultimately, my choice of AR methodology assisted in the design and conduct of each of the action cycles considered and undertaken in this research.

Given the historical nature of the problem at NPHL in QI, the sole aim for a long time remained the attainment of regulatory compliance. However, given a social constructivist approach, other realities of QI exist (Erlingsson and Brysiewicz, 2013), which I as an insider researcher together with my colleagues needed to collaboratively explore in our shared experiences of the laboratory world. This research sought to identify micro-processes and knowledge development for quality improvement through participatory action research (PAR). My earlier positionality was that NPHL could achieve regulatory compliance by remaining objective. However, as an insider-researcher alongside the process of inquiry, and as participants and I interacted with data and reflected on subjectivity and vulnerability arising from contextual institutional order and organization-wide innovation. From an ontological perspective, this

research drew from critical realism philosophical approach (Lawani, 2020), depicting participants pursuing truths subject to error as contexts change. This position is cautionary and invites subjectivity to the research process, which may result in multiple perspectives (Levers, 2013). Moreover, the researchers made observations, focusing on possible multiple-social realities, placing the research permeable to a combination of ontology and objective epistemology.

This multi-method qualitative research (Roller and Lavrakas, 2015; Mik-Meyer, 2020) involved the integration of grounded theory approaches and participatory action research (PAR), informing participants to inform laboratory practices and, in the process, generate actionable knowledge (Teram et al., 2005). The choice of PAR is based on features that encourage criticality, pragmatism and collective reasoning, causal analysis, social innovation, and evidence-based learning (Sandra, 2016). Moreover, collaborative aspects of PAR enable systems thinking and process design making it suitable for this research and consistent with social learning. The chosen research methods bring into research space stakeholder value and fitness for context in real-time. The scope of changes and means for evaluating actions and actionable knowledge draw in rigor and relevance of the intervention. However, challenges are part of the PAR process, including a longer time for collaboration and networks to yield benefits. This owes to the technicality of balancing stakeholder interests, especially when there is a need for contributory funding of an action. Last is the relationship sensitivities between the powerless researchers and NPHL (a powerful government body), given that the parties might not receive the outcomes in mutuality. As a researcher, I was aware of these challenges before beginning this research and prepared to mitigate them.

In another vein, the research employed a search conference, a participatory model for community action planning, and organizational change in uncertain environments. The reason behind the choice of search conference was its features of robust democratic and collaborative space aiming at an adaptive and flexible organization transcending stagnation. The search conference's participatory values provide avenues for self-determination for eleven consenting participants to engage. In the process they develop a sense of belonging, ownership, and responsibility as participants collectively engage in decision-making and sensemaking (Gilson et al., 2021). Two search conference methods used in this research were nominal group techniques

(Manera et al., 2019) and consultative conferences (Halcomb et al., 2008), either in combination or stand-alone at any given time.

This research, therefore, gave the participants and I as an insider-researcher opportunities to deploy our knowledge, skills, and experiences in effecting change. The research emphasizes and prioritizes open inquiry, collaboration, and participant contributions which are pillars of action research. This is a deviation from the traditional practice mindset where laboratory personnel worked in silos towards regulatory compliance. Therefore, this thesis sought to realize quality improvement founded on the Kaizen principle of Plan-Do-Study-Act (PCDA). The model builds on team-based incremental changes and challenges the status quo.

The alternative paradigms to social constructivism as a genre of grounded theory employed by this research did not suffice. In any case, it risked returning the researchers to positivist approaches that edify regulatory compliance as unchanging truth in QI. This implies that although laboratories may use regulatory standards in QI, researchers could challenge this and seek to create and sustain alternative models through social constructivism, shared meaning, and language. Moreover, both the research and the participants had a pre-understanding of the laboratory, objective neutrality, and the rigor of applying the observed to create actionable knowledge is invalidity and thus rejected.

As action research informs both the thesis and addressing organizational challenges, I adopted Zuber-Skerritt and Perry, (2002) framework and drew from methods in qualitative research, giving rise to twin projects. Consequently, I undertook research data collection and analysis, through practice observations noted in field notes and the rest of the process through focus group discussions. I thus got deep and rich insights into laboratory quality issues. Figure 6 presents the relationship between the thesis and the core field project. This figure therefore explains how data collected in the thesis phase fits into the core laboratory projects at the NPHL.

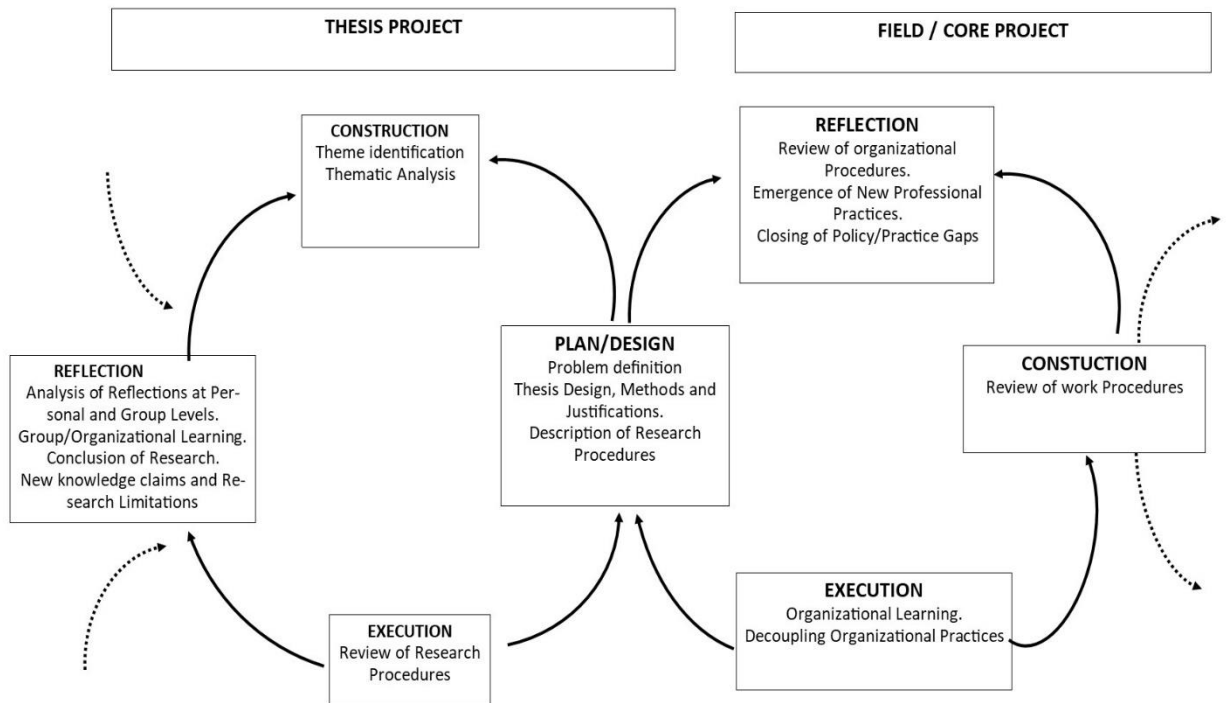


Figure 6: Relationships between core and action research Adopted from Zuber-Skerrit and Perry ,2002

3.4 Research Participants

This research employed a mix of convenience, and purposeful sampling (Andrade, 2021; Mize and Manago, 2022) as no other method was feasible given the sample size. In the alternative, I considered purposeful sampling, with the opportunity for the determine if they wanted to participate in the study or not, irrespective of the other requirements for participation, and this would have introduced a bias. Some aspects of participants’ demographics have however, not included, owing to the small number of participants, the risk of identity-exposure, and possible breach of confidentiality. The criteria for inclusion were simple, working in the laboratory for more than two years, with working knowledge on the phenomenon of

interest, available and willing to participate. First, the participants needed to have insider knowledge of the laboratory and demonstrate comfort with working with colleagues, at least in their assigned areas of work. The participants must have passed the trial or probationary period of work and confirmed as permanent or employees or placed on three-year contracts consistent with the traditions of the NPHL. This period was envisaged to allow the participants to make and sustain change, beyond the period of the DBA project. Second, they must have been willing to consent to take part in this research. Given the virtual data collection approach, I limited myself to working with Microbiology and Immuno-serology departments. The units had internet connectivity for ease of virtual meetings and data collection. After obtaining clearance from the Laboratory Director (who is the institutional head), in my capacity as the lead researcher, obtained employee profile from the administration and notified eligible participants and invited them to a search conference after two weeks. Such notice period allowed participants to consider the information given in the participant information sheet and consent forms (*Appendix 4*). At the beginning of the search conference, I made a presentation, providing the background information of the intended research and responding to concerns that could bring additional clarity to the participants. It included the lead researcher's commitment to protecting participant identities for safety and social reasons. Participation was purely voluntary, and individual participants were free to withdraw their participation at any point of the research without providing reasons for such action or decision. Out of the twelve invited participants, eleven voluntarily signed the consent forms and submitted them to the researcher. This turnout (91.6%) was a surprise to me but beneficial for the community of participants, and the project.

3.5. Ethical considerations and approval

I obtained ethical approvals from the University of Liverpool Ethics Office (*appendix 2*) and the NPHL through a support letter dated (*Appendix 3*). As the lead researcher, I recruited the participants and led the data collection process. I exhibited twin intentions in anonymizing research data. Primarily, I sought to mask the participants' identities to preserve their privacy. Secondly, I had to provide a good perspective and legitimate information fit for consumption at the tail end. The first stage was the pseudonymization of data. This study did not collect

participant demographics except for gender and suppressed age. These two attributes were deemed not to affect the participant's privacy. I assigned the participants Greek alphabet identifications, Alpha to Lambda. However, as an insider researcher, I noted the names of individual participants as linked to the Greek name identity in my reflective journal. I took this step to allow retrieval and mapping of information to the source in case I need to do a follow-up study or intervention beyond the DBA project. In the data capture and storage sources, the data was, thus, anonymized, and personal data was reliably protected and had no linkage to their real identity. The second stage was data clustering. For instance, some participants have been referred to as younger or senior without disclosing any experiences qualifying them to fit a cluster. Lastly, I generalized, referring to the participants as action researchers or thematic action groups when referring to researchers' interactive engagements and integrative position or ensuing knowledgebase.

Critical, however, was finding legitimacy and balance between my ideologies as an insider-researcher, and the inquiry into the NPHL problems, raising integrated sets of interest. To overcome the potential ethical implications, I invited a social structure through an action research approach (Bernandi et al., 2006; Atkinson and Heritage, 2010), with the most tangible meaning from reflection on the change and knowledge obtained in a community of practice. Given that AR forms the core of this thesis, I will demonstrate its utility and relevance in the subsequent sections of this chapter.

One residual issue of concern to me was my position as a long-term consultant from a different racial background. I was aware that such differences bore a likelihood to influence data, given the shared experiences with the participants. I now turn to elucidate how I juggled the challenges and dilemmas of an insider researcher into an opportunity to advance my research.

3.6 Role duality and ambiguity of being an insider-researcher.

I worked as a consultant at the NPHL and was equally a lead researcher during this period. My prior engagements were in different African countries before I became an advisor and then a consultant at the NPHL, Timor-Leste. These roles placed me as a member of the NPHL

with dotted reporting lines to the Executive Director (as reflected in the organizational organogram) but with no supervisory responsibilities over the employees. I had not only academic interests but also played a leading role in the development of the laboratory's new capabilities (Coghlan and Brannick, 2013). I was, therefore, an insider researcher and a member of the community in which the research took place (Fleming and Zeegward, 2018). These roles were interdependent, serving both purposes, conjoined to advance both scholarship and practice tenacities (Ellwood, 2015). In my case, I had served in the same laboratory in different advisory positions before my doctoral studies. However, during the research, I had to step back and look at the laboratory objectively. Besides, I was also a colleague and would occasionally have other social engagements with the same participants, beyond the work environment. Although it could be argued in scholarship that such relationships "contaminate research" (Mercer, 2007), I thought differently. For instance, I was already socialized in the team and would have an empathetic stance or 'understand' individual's arguments without participants feeling judged by their sentiments. Moreover, some trust already existed between the team and me. However, I had to learn to "put two different hats" (Roth et al., 2007), discerning when to engage as a consultant and as a researcher to make objective and persistent observations to enhance research credibility.

My familiarity with the context of research and the socio-political, historical, and cultural structure of the NPHL was a privilege. It leveraged depth in my understanding of the phenomena researched and data interpretation (Bonner and Tolhurst, 2002; Fleming, 2018; Saidin, 2016). This position could have equally presented opportunities for bias and loss of objectivity (Strobell, 2021), adding to the dilemma of multiple commonalities among participants. However, I overcame this by sustained vigilance in the benefits of reflexivity to enduring discomfort and confounding disruptions. To enrich research and transcend the lenses through which I viewed the world of practice. I, therefore, had to situate myself in the social space, accept vulnerability, by subjecting my thoughts to be shaped by research experience (Howard and Hammond, 2019), and interrogate my comments and questions during team discussions that could potentially influence participant narratives. During these debates, I would put my thoughts in a diagram in my journal thereby conceptualizing my participants' thoughts. In the end, I captured emerging

ideas, and this assisted me in being self-aware and enriching my subjectivity as the research progressed. This effort notwithstanding, I also recognized that my familiarity with the research context and organization could create a vicious cycle of a sense of hindsight bias or prejudice and stand in the way of academic rigor. Coghlan and Brannic (2007) challenge these thoughts, stating that familiarity brings to the insider-researcher benefits arising from knowledge of contextual nuances and aiding rigor in interpreting participant responses.

3.7. Managing biases

As an insider researcher with a pre-understanding of research context, conducting any studies without thinking of sources of bias constitutes obscurity in research (Vanderpool, 2002; Canella and Lincoln, 2007; MCLAughlin, 2011). I first acknowledged the potential sources of bias, starting with design, researcher actions, and researcher-participant relationships, setting aside pre-judice aside to permit data accuracy and transparency. If left unacknowledged, these could lead to inaccurate research conclusions, and potentially raise ethical concerns for the research (Simundić, 2013). Second, the philosophical underpinnings and methodological approaches I chose to advance this research enriched my experiences in managing prejudice in the research context. The participants co-designed and incubated actions by collective search for embodied meanings and wondering creating grounds for criticality. They also offered concurrent leadership, widening the research democratic space, with TAGs meeting at a mutually agreed time. My experiences indicate that open discussions manifested in team capacity for tolerance and transparency amongst actors amidst chaos and uncertainty in our laboratory, minimizing bias in this research. The steps outlined here promoted experiential learning, emergence, and shared conceptual frameworks, thereby limiting researcher overconfidence and the illusion of control. I have demonstrated the strategic bias limiting aspects in the rest of the body of this thesis. Finally, the researcher's position in the laboratory had no associated supervisory roles over the participants, thus, presenting no pressure or coercion for the respondents to behave in a particular fashion. To this end, I believe my experiences and historical engagement at the NPHL was pivotal for my insider-researcher role, as I have vividly demonstrated.

3.8. Data Collection

3.8.1. Data Collection Protocols

I used various data collection approaches in critical, self-reflection, and systematic to explore laboratory quality practices as the research team planned, observed, and reflected on interventions. The approaches were through interviews, focused group discussions, and observations and surveys.

3.8.2. Interviews

Data collection initially took the form of search conference “focus group” (Herrman, 2017) discussions, and virtual interviews. At these stages, a two-layered problematization was conducted by the researchers to dig into the laboratory problem. First, the participants broadly problematized together, eventually raising four themes for further review, reflections, and analysis, by small TAGs. The research cycles had dual integrated and underlying research elements. This initial problematization took place over two afternoons, in the form of a search conference (Levin, 2019) These were problem-solving and answering the research questions, although not necessarily clarifying how these elements work in tandem. At this stage of data collection, I administered a semi-structured questionnaire, complemented by open-ended questions that elicited responses from the participants. For instance, I asked: What is the overarching meaning of quality in your understanding considering the context of the NPHL? The open questions were meant to gain a richer in-depth answer to the question, but also to assist raise additional issues that the team needed to study to get to the root cause of the problem. It also assisted in gathering participants' real-time perceptions of the laboratory status, to enable reflections and capture emerging opinions. The outcomes of FGDs informed subsequent action planning.

3.8.3. Surveys

I engaged participants in surveys to evaluate the scope of implementation and whether the intervention fulfilled the participants' expectations and deployed between action cycles. The

survey had closed-ended items for the participants to answer (Yes, No) and open-ended items that required participants to provide brief responses. The survey questionnaires were shared with the participants by email. I administered a questionnaire to get responses on how well the action steps caused improvement in implementation both from individual and group perspectives. I asked the participants to indicate evidence in case there was an improvement. A semi-structured questionnaire was used to collect data between the cycles and the overall findings discussed in the focus group at the end of each AR cycle. For instance, *“Do you consider actions achieved? If so, what are some of the outcomes?”* The responses assisted in the team’s collective tailoring of subsequent action approaches to meet action shortfalls and gaps.

3.8.4. Secondary Data collection

In support of the data gathered during problematization, the AR team reviewed secondary data from laboratory resources and files and partnership agreements to locate gaps which were further evaluated in the light of stakeholder desires. Throughout the data collection, I noted comments both in my journal and across the computer entries to assist with personal reflection.

3.8.5. Integrated data collection methods

During the search conferences, I deployed integrated methods yielding a comprehensive understanding of the laboratory quality challenges and for participants to share lived experiences. These involved FGDs, interviews, ethnographic participant-observations, and reflective journaling

Two action cycles took 21 months, the long duration attributed to the challenges introduced into the research by COVID-19. This is in addition to actions associated with the research planning phase, which I did not consider as outstanding on their own merit as they were part of the research foundation. Information gathered from the problematization phase

was recorded on a voice recorder on a computer-based hand-held personal digital assistant (PDA). The use of voice recorders was explained to the participants and consent obtained. Secondly, I paused data collection just after the first problematization, planning, and implementation of a set of actions to allow reflection.

3.9 Data collection approaches and timelines

AR Stage	Data collection methods	Duration	Dates actualized
Determining the problem (Problematization phase I and II) through search conference and TAG activities.	Search conference	Two afternoons	August 6-7, 2020
	Focus Group Discussions	6 weeks	Sept 12 -November 19, 2020
Identifying potential solutions and action planning	FGDs/ ethnographic observations	One day	November 20, 2020
Implementing actions Phase I	FGDs, ethnographic observations	5 months	December 2, 2020- April 10, 2021
Evaluating Phase I implementation (Analyzing Action and reflecting on strategy effectiveness)	Survey and FGDs	One day	September 13, 2021
Implementing actions Phase II	FGDs, ethnographic observations	6 months	October 1, 2021- May 31, 2022
Evaluating Phase II implementation (Analyzing Action and reflecting on strategy effectiveness)	Survey and FGDs	2 days	May 14, 2022

3.10 Data analysis

The researchers collected and recorded in Personal Digital Assistant (PDA) and field notes in computer files in MS Word (1-3). To get information from the PDA, Kappa, and Delta assisted in verbatim transcription and provided me with a computer file (4). Given that the data resided in different places, the AR researchers and I engaged a Social Scientist knowledgeable in implementation sciences and unfamiliar with the study to assist with data integration. In this process, the Scientist used a triangulation protocol (O’Cathain et al., 2010), reducing limitations of either of the data sources and offering a complete picture of concepts in the conversations and interactions to enable analysis. This Scientist read the transcripts, followed threads, reflected on the information, evaluated places of agreement or disagreement, ambivalence, and silence, and interpreted and integrated the texts (Farmer et al., 2006; Bazeley and Jackson, 2013), and condensed them into five abstract meanings. The AR team assigned Eta and Alpha to narrow down the intermediate abstracted meanings by mapping similarities and differences to produce recurring meta-themes (codes). Thematic action groups problematized the themes further and decided on the critical actions with the potential to direct daily laboratory routines within a thematic area. These actions were reported, evaluated, and refined by the plenary as the need arose or during the action planning in the project implementation phase (See .

The manual coding was done based on inductive reasoning (Source and Matzel, 2017) and thinking of content, keywords, and richness of the language of textual data. This approach is based on predictability, consistency, and convergence of evidence, critical and algorithmic. Inductive reasoning functions contrary to the beliefs arising from logical certainty or rationality. Data files were systematically reviewed in relevance to the research questions, consequently eliminating non-corresponding codes.

In the same vein, connected codes were collapsed into themes by prototypical categorization, casual relations, and optimization of data from the discussions. I chose thematic analysis, based on its features which permitted identification of patterns in qualitative data, with reasonable flexibility to explore participant experiences inform data analysis (Braun and Clarke,

2006; Majumdar, 2022). Given that participants did not tell their narratives chronologically, so in data analysis, I had to reorganize and check overlaps to further assist in thematic analysis (See also section 4.3-*Problematization phase 1, p.75, para 1*).

As the principal researcher, I kept a reflective journal during data collection and analysis. I also took a reflective stance, recording what I considered personal values, feelings or beliefs that could influence data or interpretation (Ortlipp, 2008; Watt, 2007). Again, drawing from Watt (2007), keeping a journal was a step towards transparency in the research process. My position as a consultant had dual issues. First, coming from a different racial background could have influenced data interpretation validity (Ortlipp, 2008). Secondly, as an insider-researcher with shared experiences with participants, I considered that these encounters may have served to enhance validity of data interpretation.

At this point, I went back to the research team with the emerging themes and showed how they related to the codes and associated research questions. I then organized a second conference – action planning workshop. To aid transparency, at the beginning of the second conference, we mapped our path from acknowledgement of our laboratory problem to where we were at that point. The emerging themes were discussed, agreed upon, and pushed forward. The primary themes we arrived at were: (Theme 1) Re-engineering process control and managing patient outcomes; (Theme 2) Development of regulatory structures and mechanisms; and (Theme 3) Formation of cohesive actor engagement. These themes emerged central to the subsequent chapters with support of anonymized data extracts. Additionally, I subjected these themes to literature review for the purposes of enriching scholarship and practice. As a scholar-practitioner and research, it is my considered view that data analysis following problematization and a subsequent review in the light of extant literature would have strengthened this thesis further by assisting in reframing the themes. However, this approach was not tenable given the emergent nature of the research, and any opportunity to pre-determine the research direction by way of reframing would have stifled the co-researchers' debates. This direction can be taken in future research utilizing the findings in this thesis.

Figure 7 shows a thematic analysis arising from the data extracts comprising discussion notes, field notes that were entered into Microsoft excel combined with information extracted from the Personal Digital Assistant used during team discussions.

THEMATIC ANALYSIS

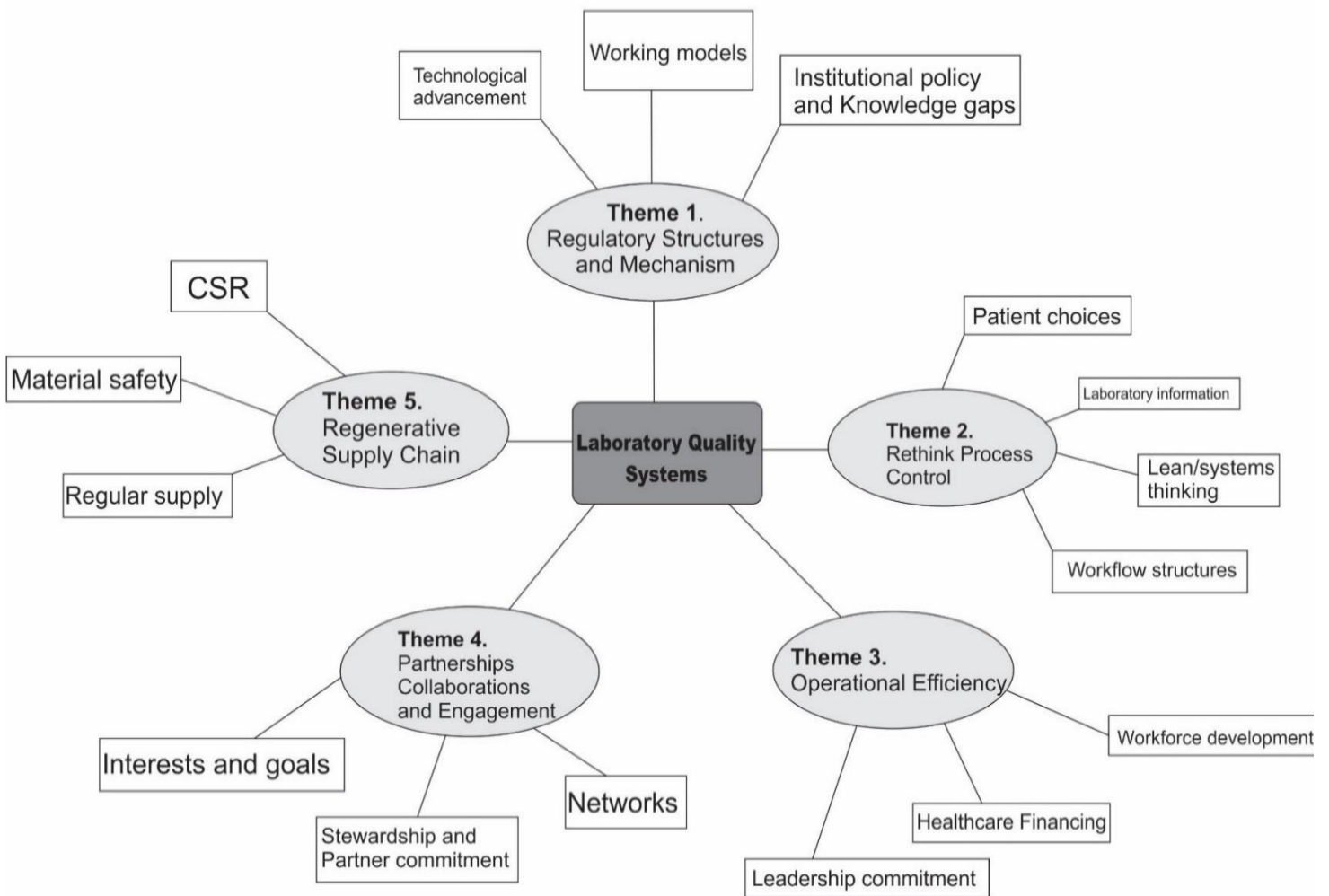


Figure 7: Thematic Analysis Diagram

3.11 Summary of Research Methodology

In this section, I provide a summary of the research methodology and strategies. First, I summarize the study design and then turn to recapitulate the methods. Researching an organization that one is part of has several challenges, and I strived to acknowledge them and minimize their impact as a researcher-practitioner. I take a cautious position and address role duality as an academic and a researcher, with potential for conflict, participant coercion and breach of confidentiality. Equally, I recognize that pre-existing understanding could engulf own ideologies and block pathways for significant organizational change. My reflection provides that I need to allow the emergence of a value system by entering the shared world of laboratory practice, underscored by social constructivism. Further, I recognize the role played by language power in building accounts as founded in the data texts. Following the constructivist approach and adoption of open inquiry, the methods employed depict realities as intertwined with discourse, with no single objective truth. Instead, it is painted as multiple realities, as a practice world is not describable with finality. Lastly, I acknowledge and demonstrate how I managed bias as a critical element with potential to raise criticisms on research rigor. Against these challenges, however, this research is an opportunity with a wide range of delivery driving on credibility and trustworthiness. I chose action research as the mode of delivery that enabled me to focus on objectivity, setting aside positivist arguments to generate knowledge, changing practice within our context. I draw from Lincoln and Guba's (1985)'s four criteria, that is, credibility, confirmability, dependability, and transferability, to validate our findings. First, by triangulating field notes with the Personal Digital Assistant (PDA), a digital audio-recorder content. I ensure the FGDs provide thick and rich descriptions of participants' lived practice experiences to enable transferability and external validity of the research findings. Each member checked with the other participants during the discussions, corroborating the information and ensuring credibility. Again, the field notes were documented, thereby ensuring confirmability. I have also demonstrated how the participants in their dynamics collaborate and coordinate, influence, and change the understanding of others to arrive at actions. Profoundly evident are the benefits of being an insider-researcher with knowledge of socio-historical and cultural

background; participants well known to the researcher; ease of understanding and interpreting nuances; and pre-understanding that aided data interpretation. Most importantly, the researcher is a professional laboratory practitioner and will directly benefit from the knowledge generated in this research.

In conclusion, participatory action provides an ecological approach to exploring an organizational problem and acting toward change. From ethnography and grounded theories, critical realism, and social constructivist philosophical paradigms, the language in contextual data injects equality and critique power relations in a qualitative study, thereby providing legitimacy. Thematic analysis in this thesis rests on the social constructivism framework as collaborative learning spaces enable amplifying voices, challenging and interrogating power and mainstream ideologies in building accounts. Social-constructionism, participatory action research (PAR) participatory models underlie the search conference providing a foundation for this thesis. Surveys conducted through interviews between action cycles provide opportunities for participants to evaluate the effectiveness of an action cycle.

Finally, given that this study is an exploration challenging the underlying quality issues at the NPHL to raise actionable knowledge for quality improvement, the methods deployed put pressure on the institution. The first challenge is resource limitation; however, it presents a significant opportunity for improvement for the NPHL to expand affiliations with partners and plan actions to find resources for action implementation. Second, innovations such as the one underlying this thesis are “disruptive and untimely” constraining the NPHL. Such disruptions are managed through AR team creativity and negotiation, especially with executive involvement. As a researcher, I find myself in a powerless position, as I stand the risks of justifying the actions, achievements, or lack thereof, and updating stakeholders on research progress. I am a learner, less familiar with AR approaches, only armed with negotiation tools such as advocacy. In the next chapter, I turn to problematization, where I provide details of focus group discussions among other participatory action research methodologies. In this chapter, the AR team identifies problems and outline desired outcomes.

Chapter Four: Problematization

4.1. Introduction

In the introductory chapter of this thesis, I presented laboratory service quality as a wicked challenge at the NPHL in the Democratic Republic of Timor-Leste. I explained the prevailing dominant practices emphasizing utility of regulatory guidelines or ISO standards. Subsequently, in the literature review chapter, I discussed how the regulatory guidelines, and the accompanying institutional mechanisms create tendencies for laboratories to imitate each other. The literature espoused the laboratory environment as painted with complexities, pressures, and contextual challenges against the backdrop of inflexibilities of regulatory guidelines. The scholarly body informs that actor engagement emphasizing the constructivist knowledge management is essential, with possibilities of raising an in-house framework for improving laboratory quality systems. The actors may find mutuality in their desire for an improved laboratory, approach challenges collectively, and plan actions accordingly. In chapter three, I presented Participatory Action Research (PAR) documenting how actor engagement assisted address quality problems at the laboratory.

In this chapter, I document the processes taken by laboratory practitioners at the laboratory in constructing the quality problem. The problematization process has dual-layer lenses and occurs in complementarity. The first layer reports broad areas of laboratory quality challenges as perceived by all research participants and raises certain themes for in-depth problematization by small teams. The second layer of problematization arises from the thematic analyses and involves a task-oriented small groups (TAGs) who are instrumental in building grounds for action points. I then provide a summary of action points and action plans and how they were executed at the project implementation phase and further evaluated in a plan-do-check-adjust (PDCA) cycle. To stay focused on the aims of this thesis, I coordinated the problematization phase as well as kept implementation lean to enable attainment of depth. At this earliest stage of the research, considered this a limitation, but also a gain for the advancement of this thesis.

4.2. Problem Construction Phase

I held a two half-day virtual search conference attended by 12 individuals drawn from Pathology and Clinical Microbiology and Immuno-Serology team on August 6-7, 2020. These individuals had received participant-specific information detailing the intended study and that they were selected to participate in the research based on their knowledge of the laboratory practices in NPHL. The research aims were outlined and consent for participation was obtained from 11 individuals, as one opted out as she was due to leave for overseas studies. This individual, therefore, did not participate in the study.

In chapter 1, I presented the laboratory audit report that was carried out at the National Laboratory in May 2019. I brought this audit report to the plenary, and it formed the basis of initial focus group discussions. Although I had intended to streamline the discussions to follow a certain structure, I was keen not to stifle some participants' perspectives. As such, I directed the discussions by asking questions related to the initial laboratory problems. Subsequently, I asked the participants to reflect on the report in relation to our quality practices and context of the laboratory. I then asked if any individual had an additional or different opinion. Zeta opined:

“The quality issues in this laboratory transcend the areas pointed out by the audit. Secondly, the audit report only provided a superficial image of the laboratory quality issues, as there are problems whose depths need to be better understood to enable search for solutions”.

The positive attitude with which the participants accepted the audit report notwithstanding, the session reincarnated some emotions individuals had the first time it was presented. The audit report was for our reference only, as participants dwelt in the depths of the challenges forming the core of quality to inform PAR cycles (planning, action, study, and evaluation). Before setting the research TAG's perceptions on the quality of laboratory services, I asked the participants: *“What is the overarching meaning of quality in your understanding considering the context of the NPHL?”* Key views, first, suggested that the laboratory should maintain its diagnostic mandate on timely and accuracy of identifying disease causing organisms. Second, the participants recognized that there is an authority mandated to issue and enforce policies. This was reinforced by Gamma's comment: *“It means compliance with the Ministry of*

Health's policies, internal laboratory mechanisms and regulatory guidelines". Third, quality in the perceptions of the participants suggested that there should be a mechanism for collecting and utilizing feedback to aid further improvement.

4.3 Problematization Phase I

This activity took place between August 19th to the end of October 2020. I asked that the TAG bear perceived quality characteristics in mind as we problematized laboratory challenges. Kappa (this is a pseudonym using the Greek alphabet that I used to identify individual participants) volunteered and co-led the problematization process and entered the data in spreadsheets. On the other hand, the information was entered into an excel spreadsheet and equally voice recorded using Personal Digital Assistant (PDA), a digital audio recorder that assists with data triangulation.

During the initial discussions, I gathered that the participants focused on issues detached from them. For instance, some equipment was not under any contractual maintenance. The participants thought the executive should be responsible for the failure. However, major equipment platforms underwent ad hoc maintenance courtesy of the World Health Organization and the Global Fund upon receiving a request for support from NPHL. To enrich the discussion, I asked that we take the next step to consult the equipment manuals on equipment use and adherence to maintenance guidelines. Alpha, however, responded:

"There are glaring disparities between policy and practice intra and inter-bench when it comes to equipment management".

This aspect drew us to how QA policy or the lack of it, affects areas other than equipment.

I asked whether we have other policies that guide laboratory quality. Critical to the discussion on policy was an evaluation of the laboratory's standpoint on the formation and adherence to basic internal policies. Different perceptions were evident, and so was the lack of trust among participants. Three participants had been with the laboratory since its inception, and they thought that that the problem was policy weakness. A different participant, Zeta,

however, thought there was a generalizable policy-making lethargy within the team, and everyone was responsible for the situation. She cited laboratory's strategies to downsize the resource, deployment of technology and offer quality services. She commented:

"The regulations aren't taken seriously. Look at our internal regulation, where is it? [...] Yes, we talk of the regulations, but how do they align with the adoption of lean thinking? Is there a way to make structural and technological adjustments to fit within the regulations and vice versa?"

4.4 Emerging Action Research Theme 1: Development of Regulatory Mechanisms

Equipment maintenance and organizational way of operation, consequences and desires were located in a single theme, that is "*policy and regulatory structures reforms*". However, participants called for caution that the laboratory gains some leverage with policy flexibility. Secondly, participants wanted partner program guidelines to be incorporated to strengthen policy initiatives. Other notable suggestions were to network the policies to give a simple meaning to the laboratory's work, or have integrated models into a super policy.

Beyond equipment maintenance, gaps identified by participants lay multiple opportunities which painted the participant desires in QA. With no effective policies on maintenance, gaps in knowledge and potential policy-practice gaps, Delta suggested that the laboratory expands laboratory information system should be modified to gather additional information. However, Eta commented:

"Can we then have systems-thinking, and document all our lab processes and gaps?"

4.5 Emerging Action Research Theme 2: Process Control

The team recognized that QA needs to be reengineered further as participants' comments suggested there are additional gaps to be filled in the laboratory system. The eventual decision was to *rethink process control*.

When asked to share their experiences on supply chain- that is, first, checking that bench areas continually got the right product at the right time. The TAG had mixed, but bitter feelings. Most of the time the laboratory did not perform tests requested, the participants identified the probable cause to be the lack of reagents rather than equipment breakdown. Gamma shared a bitter feeling concerning expiry of reagents.

“Reagents do expire on us, and it paints a bad image of the people working on the bench, as the end users are blamed by the executive for this. In reality, the people responsible for supply chain and not the product end users should be blamed for the expiry situation”.

For instance, First-In-First Out (FIFO) principle wasn't adhered to as noted by Beta:

“Its common knowledge that we have Irregular supply of reagents and consumables, and even when available the laboratory experience stock management challenges, ending with a significant number of expired reagents”.

Part of the discussion on the supply chain problem was the high number of tests and test combinations requested by medical officers once there was information that the requisite reagent was in stock. This ambivalence to change (Pederit, 2000) was evident when physicians required a full blood count, yet the main concern about the patient is hemoglobin as confirmed by Epsilon. Equally, participants agreed that irrational requests for laboratory tests overstretched the commodity forecasts, yet were not useful in decision-making regarding the patient. In such cases, often, the laboratory ends up with a commodity shortage. Further initiatives to correct the shortages in the experience of the participants result in overstock and expired products given the short shelf-lives.

The supply chain issue and the impending hazard led the group to discuss the management of unused products. I reminded the TAG that eventually non-attention to the expired chemical stocks might have a negative impact on the laboratory's ecosystem. Discussions revealed that there had not been substantial technical discussions on waste management. Another senior laboratory officer, Delta commented:

“The laboratory doesn't have an incinerator on-site, and rely on a tertiary-level hospital in the nearby compound to manage pathological and other wastes. Let alone waste segregation as a standard practice elsewhere”.

4.6 Emerging Action Research Theme 3: Regenerative Supply Chain

The supply chain and healthcare waste management are conjoined, and one cannot be addressed without the other. Analysis of the emerging theme depicted “*regenerative supply chain*”, to address both the excellent health of the communities served by the laboratory and the environment and bring profits. It draws from Elkington (1997) triple-bottom-line (TBL) reporting seeking sustainability, systems thinking, and acceleration of positive change. A recent laboratory graduate Zeta, a scientist employed a couple of years before this research elaborated on how deep engagement of the local laboratory personnel and surrounding communities in the laboratory value chain yield unprecedented benefits. For instance, this hybrid approach could repair the negative image of a lack of reagents and replenishment simultaneously. Moreover, it builds on “system thinking” (Cabrera et al., 2007) to address the complexity of health commodity supplies.

The NPHL has numerous loose partnerships with in-country and foreign entities. Each partner claims a different mandate and system, potentially spilling from their home offices and departments. Although partners contribute to strengthening diagnostic capacity, their missions and visions differ. Few of the participants have developed intercultural competence to interact with some of the foreign partners. Inter-ministerial or departmental communications or active engagement is a preserve of senior-level laboratory management staff. Further, our discussions revealed the staff with such capacity either obtained college degrees overseas or are in management positions. We considered partners as stakeholders in the laboratory development. One participant, Beta, reflecting on the kind of partners he has come across observed:

“Partnerships are good, but the partners have created another layer of problems for us. I don’t know all our partners, but those I have come across working with my unit have different managerial styles and goals which sometimes conflict”.

This observation shed light on the dark corners of the laboratory. I asked:

Does everyone participating in the research know all the NPHL stakeholders even if you had not interacted with them?

I was surprised that only four of the eleven participants had significant knowledge of the stakeholders, but even then, collectively, they could only name seventeen. Still, they were

unclear concerning the key mandates of each of the stakeholders they had knowledge of Iota said:

“It is unnecessary to reinvent the wheel when the institution has some of the remarkable achievements in history. For instance, we have had international partners playing a significant role in the development of the National Laboratory. There is one partner that has supported educational needs of our staff, who have subsequently injected stronger voices in our development path”.

These statements drew us to the organization’s vision and mission statement. The team particularly took interest in the mission *“to promote community and broad-based stakeholder participation”* as it had a close alignment with the design of this thesis research.

4.7 Emerging Action Research Theme 4: Laboratory Partnerships, Collaborations and Engagement

The themes arising from the plenary discussion was that problematizing partnerships should look have a broader view to include *creating partnerships, collaboration networks and engagement*. This session was interesting as participant concluded, that this approach will assist understand partner contributions to the laboratory and how these could be coordinated and harnessed for future benefits.

Alpha, referring to the confusion and scarce knowledge of the identity and forms of laboratory partnerships among the team was a concern. She injected critical remarks in the discussion pointing out that overall engagement mechanism is poor. Even leadership engagement within the workforce was thought to be weak as most information maintained top-down approach. The young laboratory officer thought that feedback should be prioritized, but it wasn’t. She commented:

“We often give feedback during staff meetings, but our recommendations are rarely acted upon by the executive. The leadership knot that is weak or uncommitted that’s why coordination is lacking”.

Theta, added:

“The truth is that workforce development isn’t prioritized, and career development pathways aren’t clear”.

This discussion was hot and threatening to fuel emotions in the team. First, there were participants who were in leadership positions and who felt the topic and related reference was targeting them. Second, as a small-sized organization, there were not as many leadership positions that could be shared, yet everyone desired career development. At this point, I reminded the participants of the objectives of the research and their own baseline recommendations raised earlier. The AR team and I considered that *operational efficiency* as a theme might not raise actionable realizable within the time frame of this thesis from a resource perspective (See also p.100-101).

I suggested that we break into homogeneous TAGs in whichever way the participants felt comfortable in handling issues around the identified themes, or within their usual work areas. Although originally belonging to one TAG, research members were free to collaborate with other TAGs at their convenience. Regenerative supply chain for instance was managed by membership drawn across the three original TAGs. This was significant participation and efforts for the two days of the search conference.

On October 5th, 2020, Kappa and I presented the emerging themes following the thematic analysis. Kappa summarized the recapped themes associated with the issues, as shown in figure 1 - to enable TAGs to follow with ease as individual TAGs went into working TAG sessions based on TAG internal arrangements. Here, I also recapped the aims of the research to enable participants to focus. During the period just before the working TAGs started meeting, there was a disruption from one TAG. This TAG thought that when discussing the problem area, the desired future, and actions, some space is permitted for the evolution of QI priorities going forward. The TAG wanted the potential nature of actions outlined as a guiding principle to all TAGs. Subsequently, in the second week of October 2020, I organized a 45-minute group meeting via skype attended by eight participants. It provided a collective and realistic view of the desired future. First, they wanted improvement and actions not to stifle other or existing QI efforts by any partner organization or individual bench team as this might create unnecessary

pressure and confusion. An example given by the TAG was QI efforts in the health sector strategic plan 2011 (MOH, 2011). Secondly, the TAG prioritizes the most important gaps in QI practices. Third, the proposed action be within the achievable capacity of the laboratory. Fourth, actions yield value to the people serving and being served by the laboratory. I circulated the group suggestion reports and suggested action points to all the TAGs.

The group problematization in table 1 assisted in understanding the weights the participants placed on each of the problem areas. This enabled prioritization of discussions and action development later, once the small TAGs handling key thematic areas met. Further, some problems were not discrete, but had connections to other issues raised on a different area, and raised ground for second-level problematizing of each theme.

Table 1: Preliminary Laboratory Quality System problematization and thematic classification

	<i>Laboratory system area</i>	<i>Intermediate issue</i>	<i>Future desires</i>	<i>Thematic classifications</i>
Laboratory Quality System	Equipment	Irregularly maintained. No Contracts Medical devices regulations	Technological advancement Point of Care testing	Regulatory structures
	QA practices	Regulatory Affairs Internal regulation lacking Knowledge practice gaps Institutional Pressures Collegial Pressures Lab Information Management Limited systems thinking Processes not clearly documented Expansive lab information	Workflow structures Lean/ Systems thinking Technology advancement	Process Control
	Supply Chain	Irregularly supplied reagents/ consumables Stock management challenges Material safety not documented	Socio-environmental management	Regenerative supply chain
		No on-site incineration Autoclaves irregularly placed	Infection prevention and control (IPC)	
	Partnerships	Different managerial styles, interests, and goals	Collaboration and engagement	Partnerships, Collaboration, and engagement
	Laboratory Administration	Inadequate leadership commitment No feedback utility Workforce development laboratory Financing	Workforce capacity building, career development, stewardship, commitment	Operational efficiency

A formal thematic analysis can be located in the research design section on figure 7.

4.8 Mop up of broad issues

In addition to the challenges already identified in the group problematization, and in the interest of time and keeping objective, during the search conference I asked the participants,

What kind of isomorphic pressures do the NPHL or staff experience at present or have had in the recent past?

I had planned to ask this question, to see what other issues and perspectives would come up that could add value to the initial problematization phase, enrich the second level or implementation process. Until this time, I had not realized this would open a Pandora's box. My surprise was every part and aspect of the laboratory process would be mentioned by the participants as indicated in the following comments.

"Key pressure is laboratory capacity to respond to emerging diseases consistent with demands of international health regulations e.g., Dengue fever, Japanese encephalitis, and now Covid-19. This is a challenge for laboratories in our category too". (Eta).

"The laboratory is expected to manage high work volume with corresponding human resources, though in our experience the NPHL is highly understaffed". (Epsilon)

"In reality, the entire healthcare capacity for the country is emerging, laboratory work is complex and the demand for highly skilled staff". (Delta)

"Management of laboratory errors arising from manual processing of samples prior to testing. This gives a bad reputation to this laboratory". (Gamma)

"For us to compare well with other laboratories, there is constant need for modern equipment and devices in the backdrop of limited financing". (Alpha)

"Heavy documentation is part of lab practice, and as is often said in lab practitioner circles, "if it is not documented, it is not done". (Eta)

These descriptions enriched the data gathered earlier, and served to uncover depths of challenges at the NPHL.

The thematic analysis done in first phase of problematization, and mop-up process provided a panoramic view of the depths of laboratory quality challenges, inasmuch as the laboratory endeavor to perform in the league of laboratories of similar caliber. They, additionally, acted as a guidance to participants in the second phase of problematization and decisions on actions in the subsequent stages of this thesis research.

4.9 Problematization phase II

thematic action groups (TAGs) that led the research aligned to a topic. The group had autonomy in deciding when to meet and to share their experiences with issues raised as thematic issues. The TAG membership was voluntary, and as an insider researcher, I encouraged the research team to choose which one they wanted to belong to, given their interests and expertise. I also urged them to ask questions, share strategies, and put their thoughts into action plans. The TAG members chose their leader, or one volunteered to lead the group as Kappa did in the earlier problematization phase. In this next section, I document the activities of each TAG, what they reported to the plenary (consisting of all participants), and, finally, highlight the suggested action points arising from the plenary.

4.10 Laboratory partnerships, collaborations, and engagements

The membership of the TAG handling this thematic area were Gamma, Eta, and Beta. The overall observation taken by TAG-1 from the plenary problematization was:

“Partnerships are good, but the partners have created another layer of problems for us. I don’t know all our partners, but those I have come across working with my unit have different managerial styles and goals which sometimes conflict”.

(Eta).

Gamma (Co-chair) and I engaged TAG one participants in an exercise to map existing entities that collaborated or had working relationships with the laboratory. From the exercise, the participants listed 29 different entities with their responsibilities as demonstrated in Figure 2. First, participants recognized that the NPHL has a vertical structural oversight over the lower-level laboratories (see figure 7). However, these were discrete entities with a voice on the

functional quality of services at the NPHL. Gamma, the TAG co-leader and I challenged the participants to locate the levels of collaboration with all other entities listed. A stakeholder map of lateral and vertical collaborations was eventually generated with lines of reporting and coordination.

The stakeholder map in figure 7 is read as follows: The NPHL (NPHL) is central, with its parent body the Ministry of Health at the top, while entities at the same administrative level, but supporting NPHL directly on the left. The entities who directly report to NPHL are at the lower level. Organizations that support the NPHL either in training, specimen analyses abroad, or providing material and technical support are on the right side of the laboratory. Lateral inter-ministerial collaboration is shown with the Ministry of Commerce, Industry, and Industrialization (MCI&I), and Ministry of Agriculture and Fisheries (MAF) shown at the same structural level.

The discussions revealed that although the laboratory collaborated with individual organizations within and outside the country, a panoramic view of the stakeholder landscape had not been in sight. Knowledge of the stakeholder landscape became an essential pillar as it also permitted discussions on barriers, challenges, or plans on capacity building and laboratory twinning. The stakeholder map also allowed the identification of communication processes, linkages, and opportunities that could eventually be improved. Further, the mapping allowed roles, interests, influence, and perspectives of stakeholders to be understood and for their engagement prioritization in directing quality system implementation.

Close to the final sessions of the mapping exercise and engagement, the session chair and I asked the participants that we collectively develop a rich overview of new possibilities and opportunities with a clear view of the stakeholder map. The discussion further determined that networks are an untapped resource that could be used to effectively respond to emerging diseases and support surveillance and database enrichment. These possibilities and potential challenges notwithstanding, the laboratory personnel found a new opportunity to champion diversity to yield social benefits to the NPHL. Given the participant partnership concerns, I introduced the question, “Does laboratory partnership, engagements and collaborations contribute to TQM?”

Considering the depth with which participants had explored partnerships, the question appeared as an opportunity for feedback. In Beta's opinion, partnerships are beneficial, and opportunities not fully utilized. In Beta's assertion:

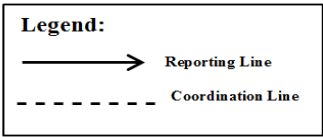
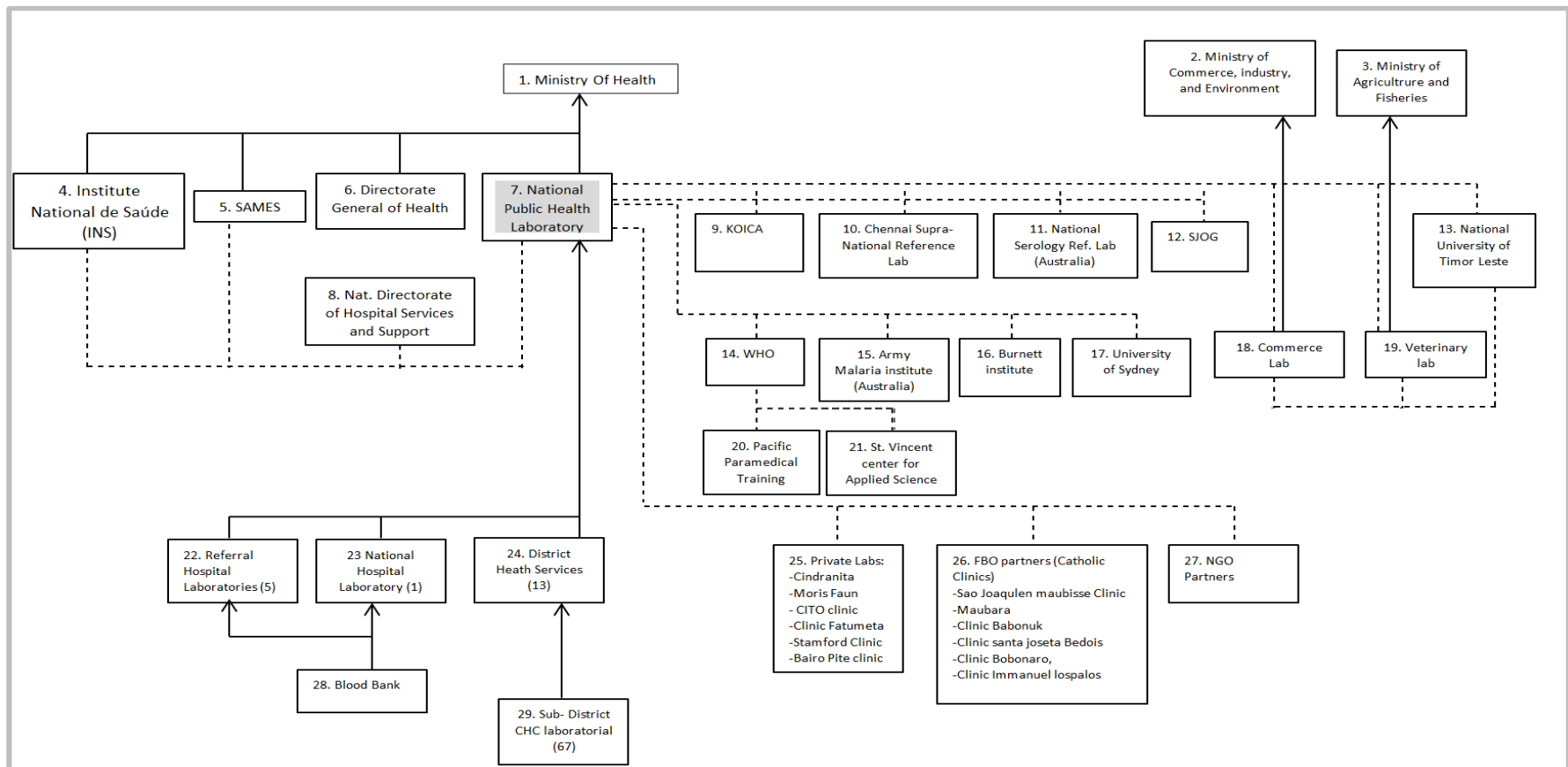
"Current partnership arrangement is a blur, although the laboratory leadership seem comfortable with the arrangement as it is. If partners had a common agenda, the outcomes of implementing TQM could be clearly evident".

Eta reflecting on Beta's comments, suggested,

"There could be a greater potential if partnerships were integrated and harmonized into a tool for TQM advancement, and placed at the heart of quality improvement.

Although there were several stakeholders as presented in Figure 7, to bring a focus to the aims of this thesis and prioritize actions, the participants suggested distillation of partners to engage in specific research interests. This will allow both discourse and evidence to be welcome and to aid action planning and execution. One of the immediate action plans was to work with the executive on convening and influencing the formation of cohesive engagement or actor alliance for the implementation of quality plans. The bottom line was that the actors be well nuanced and demonstrate substantive interest for engagement. At present each partner is collaborating with discrete units of the NPHL individually and in a silo.

Figure 7 summarizes the laboratory networks, collaborations, and engagements and shows working relationships with the NPHL.



- Key Role And Responsibilities**
- MOH: Overall authority for National Health Services.
 - MCIE: standardization and approval of chemical products.
 - MAF: livestock and crop laboratory services
 - INS: Training coordination and tradition.
 - SAMES: custom clearance warehousing and distribution of laboratory products.
 - DG: coordination among directorates and NPHL
 - NHL: provide oversight and coordination of laboratory services
 - NDHSS: coordination of procurement of Health Products
 - KOICA: infrastructure development and capacity building on TB
 - Chennai SRL: TB external quality assurance and MDR-TB culture
 - NRL: training and consultancy in Serology
 - SJOG: Provides capacity building
 - NUTL: training and delivery of new lab analyst graduates.
 - WHO: Infrastructure, equipment, capacity building and policy guidance.
 - AMI: QC of malaria microscopy and through PCR
 - Burnett Institute capacity building on molecular diagnostics.
 - University of Sydney: Laboratory training on parasitology.
 - Commerce lab: Testing standardization of chemical products
 - 19 Veterinary Lab: testing and of animals and plants samples
 - PPTC: Support external quality assurance of laboratory services
 - St. Vincent: Supports early Infant diagnostic of HIV.
 - RH Labs: provide diagnostic services at regional level
 - National Hospital Lab: Provide diagnostic services at National level
 - DHS: coordination and monitoring of lab activities in districts.
 - Private lab: provide diagnostic services in private clinics.
 - FBO Partners: provide selected diagnostic services in coordination with national disease specific programs.
 - NGO Partners: provide selected diagnostic services in coordination with national disease specific programs.
 - Blood Bank: Ensure blood safety
 - CHC Labs: provide diagnostic services at Sub-district level

Figure 8: Mapping of the Stakeholders of National Public Health Laboratory in Timor-Leste

4.11 Process control

This TAG was led by Alpha, and the other members were Zeta, Gamma, and Theta. The data leading to the process control theme considered equally the desires raised by the first problematization process which gave weight to “Lean/ systems thinking” in problematizing. In addition, the participants reflected on prevailing practices versus the desires, and consequently came to a consensus that the most appropriate way to think about process control was to have a picture of the “total testing process”² (TTP) and gaps thereof. The TTP is not only systemic thinking but also central to quality improvement. I wanted us to take notice of where we were as a lab, and note what was thought as our positive image. But participant Alpha requested to share his experience in a laboratory in a country in the region, where during internship, they used the “Swiss cheese model”³ to identify laboratory not only the weaknesses but also a platform for lab strengthening. The TAG was convinced of its benefits and accepted this offer. Alpha then co-led the process control TAG, to identify what we thought were our strengths in the practices, and the taken for granted issues that painted gaps in process control. These gaps were then harnessed to allow for configuration of quality improvement actions, seeing the beginning and the end of the failure loop concurrently. The TAG deployed Failure Mode Effects Analysis (FMEA) to evaluate our laboratory system's total testing processes (TTP) as shown in figure 9.

The conception of TTP enabled evaluation of what processes were prone to errors, how they could be avoided, or corrective actions planned and executed. The bottom-line was that a single gap does not cause overall system failure, but a trajectory of stick gaps do. From practice, this TAG of participants cited pre-analytical and post-analytical as the main processes that experience errors, and which would then be prioritized in systems re-designing in a QI initiative. Secondly, the participants identified the complexity of the laboratory testing processes, which contributed most to the organizational defensive mechanisms earlier deployed to support

² Total Testing Process is multiple coordinated steps in patient testing from a pre-analytic phase where the clinician asks the patient questions, the analytic where actual testing occurs to the post-analytic stage, where the physician receives the results to decide on the patient's treatment.

³ Swiss Cheese model is a risk management tool used to identify defects associated with any unit of an organization, and the cumulative effects that yield accident or failure.

prevailing practices. Reflecting on the team achievement in process control problematization, Theta opined,

“We have raised an evaluation tool that can be used in any contemporary laboratory, that challenges the status quo at any point, and purely based on systems thinking”.

Figure 9 is read from the defenses to the gaps sitting opposite of each cheese slice. The cheese slices have holes depicting defects or risks, otherwise they should be wholesome. The risk in the laboratory processes build up to yield failure trajectory.

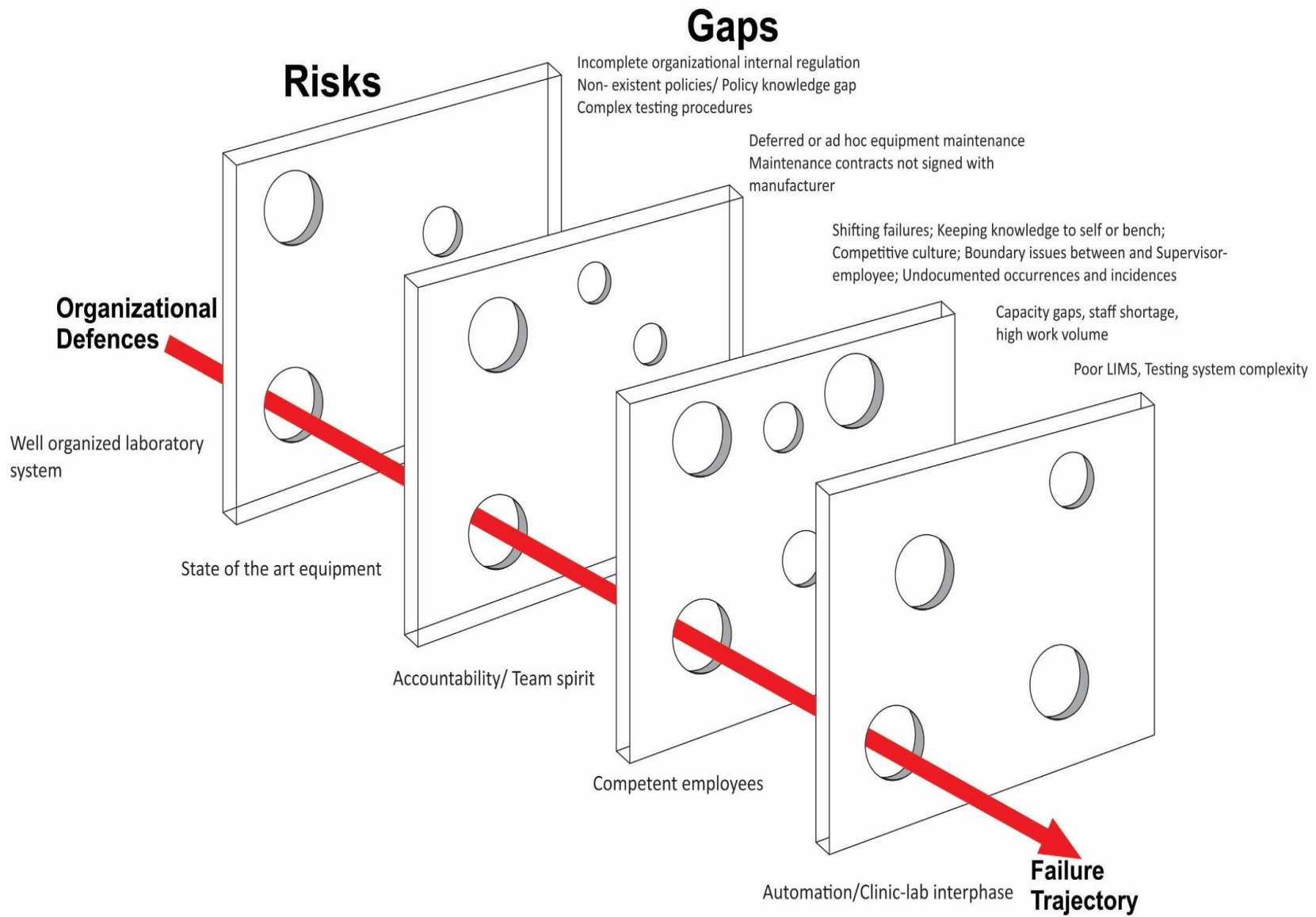


Figure 9: Swiss cheese Model deploying FMEA to evaluate Laboratory system adapted from Reason (2000)

Suggested immediate actions:

- a) Using technology to solve data management issues.
- b) Reporting adverse testing outcomes with immediacy, and evaluating near misses in testing outcomes by participating in Proficiency Testing programs.
- c) Sentinel reporting of laboratory occurrences.
- d) Developing standard operating procedures (SOPS) for every testing process.

4.12 Regulatory and Policy Guidelines Review

TAG 4 (Zeta, Kappa, Delta, and Epsilon) participants working on regulatory policy took a realist positivist interpretative approach reflecting on practice and existing medical laboratory regulations. As a consultant, it was important that I assist in revisiting the guidelines, but this aspect required courage as it could threaten my tenure for being overly critical. Although expected to follow the field regulatory guidelines, the participants' general interpretation was equally critical. I encouraged the TAG to act with the freedom to provide their interpretation of the guidelines in whatever form, negative or positive. The interpretations are represented by a hexagon in figure 10. Beta, however, expressed ambivalence with regulations.

“Regulatory processes are mediated by politics, often just plans that are not implemented”.

Epsilon, however, gave a distinct perspective. She had a firm belief that regulations are:

“Technocratic and complex in approach and represent some western ideology based on critical thinking”.

However, a shared belief among the participants was that any regulation flows from authority and it's a representation of legitimacy. The hexagon is read anti-clockwise from its top center and depicts the participants' approach in policy structure characterization. The other half of the hexagon read clockwise from mid-top, representing the participants' desires if they were to formulate regulations.

I had this question at hand but waited for an opportune time to pose it to the participants. At the time, hot items in the discussion arena were laboratory policies. Zeta opined:

“I want policies that mirror our culture and norms as the implementing agency”.

This suggestion portrayed misalignment of internal laboratory culture and existing policies at the irreducible minimum. Delta, however, wanted policies that the laboratory personnel could relate with. He observed:

“The current policies are silent. They just sit there, and some of us don’t even know anything about them. At a personal level, I would like to see more accountability in interaction with any policy. It’s got to be living”.

Although the participants had demonstrated knowledge gap in exiting policies in the first round of problematization, I asked them if they had a role in their formulation. This elicited a statement from Kappa

“Get any policy from the shelf, and you see it’s all wrong. I have hardly seen policies that recognize the presence and visibility of the actors”.

I understood Delta’s perspective in depth to mean policies need to reflect the opinions of the laboratory personnel such that policy making is painted with dialogue. Additionally, the actors are the street-level bureaucrats who promote policy, assist in knowledge brokerage and as I thought through this, pondered an empirical question on who are policy formulators?

Further discussion of participant observations and critical sensemaking yielded consensus on a constellation of desires on regulations, and raised four points:

- a) Policy instrumentalization
- b) Design for local context
- c) Construction of legitimacy
- d) Intra-institutional coordination mechanisms

This TAG first recognized that political mediation and legitimacy and authority are a critical part of regulatory isomorphic pressures. Second, that these features can be used to reinforce efficiencies, effectiveness, and instrumentalization of policy requirements, but a desire attached to this is that bureaucratic rigidities be relaxed.

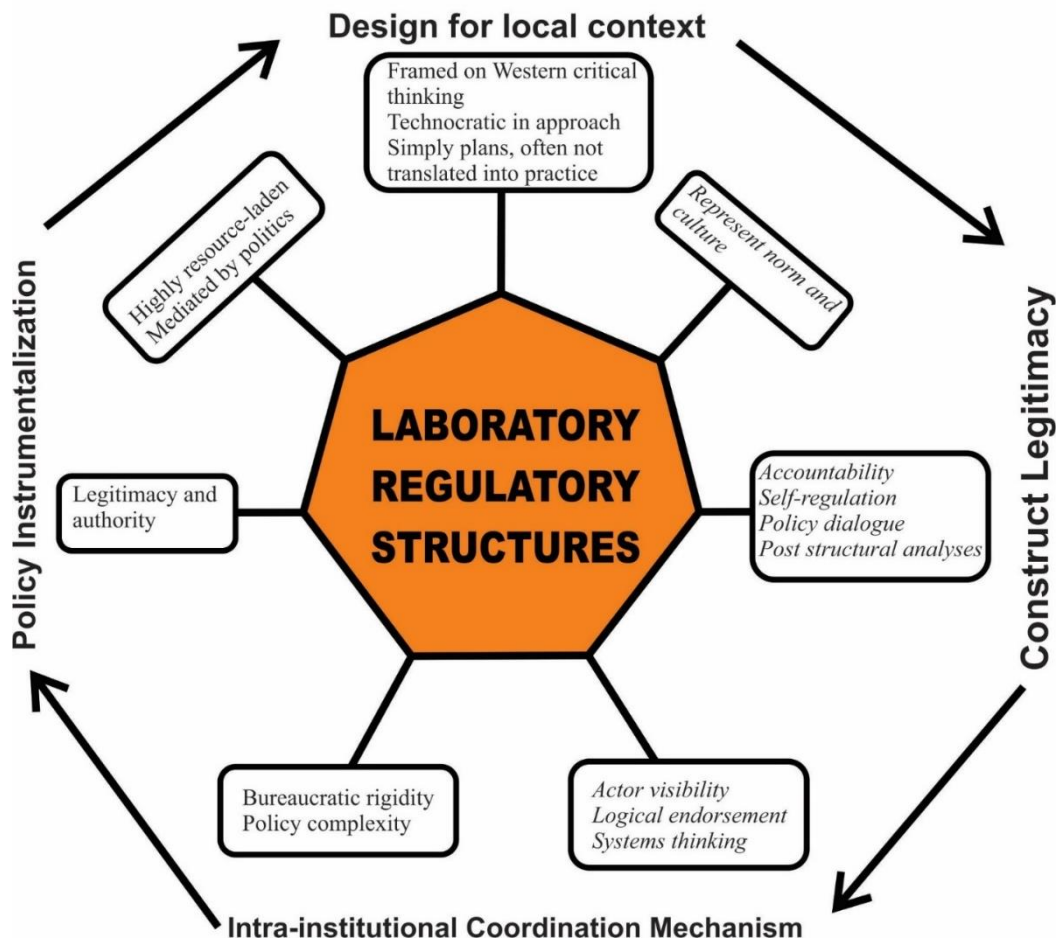


Figure 10: Regulatory guidelines problematization

The participants’ TAG suggests policy instrumentalization in laboratory TQM positioned and internalized into the organizational actors’ routine operations. The policy should inform a set of codes of behavior, rather than imposed. It then became evident that policies should be seen to complement cultures, paradigms, beliefs, and knowledge around TQM.

The features appearing in regulatory problematization (culture, accountability, legitimacy and authority, and actor visibility) extended a platform for me to ask the question regarding legitimacy, as it was the first time this arose during data collection. So, I framed the question:

Without the influence of pressures for isomorphic conformity, can laboratory staff create a legitimate organization, within the confines of institutional quality culture?

Kappa, opined,

“That has always been the case, butas we all see, the terrain and paths this laboratory has gone through, speaks for itself, and of course legitimate in my opinion, given the specific features”.

A section of the participants took this statement with ambivalence. This was evident in the in- Epsilon’s response:

“Those are the features we are contesting right now, as they have ambiguities that need to be unfolded, because largely, they tend to lean towards conformity, rather than our social values”.

Gamma suggested, *“A function or service of NPHL is legitimate as much as it represents our collective view as laboratory personnel, not in the form of consolidation, but entrepreneurship”.*

I tried to make sense of these participant narratives, and I found participants placing conceptualization of legitimacy in the cognitive domain and the influence of group values, norms, and culture. Overall, participants anchor legitimacy in the liberal sum of desirability, pragmatic actions, and instrumentality resulting in a morally appropriate institution. One aspect that came to my mind during the analysis of the narratives is the social pathology of aggregation in the group-wide approach, and I noted this in my reflective journal. I hoped, however, to evaluate how the community ecology of “our values” and “our collective view” might unfold in future activities of the AR team.

4.13 Regenerative Supply Chain

This TAG considering supply chain consisted of Eta, Gamma, Iota, and Beta. In here the team recognized that the supply chain in medical laboratory practice although critical to service provision has many aspects that are often taken-for-granted. Eta asked,

“How often do we care about the hard sciences that characterize the chemicals’ Material Safety Data Sheets (MSDS), and the precautionary discourse that it entails?”

The TAG also looked at the laboratory operations through the lenses of corporate social responsibility (CSR) in protecting the environment and the surrounding communities. Through CSR, the laboratory must transcend the narrow interests of profits to triple bottom line reporting (Elkington, 1997) as it manages hazardous wastes, thereby preserving environmental quality. We established a myriad of limitations both in the forms of unethical and unsustainable practices

creating a negative impact on the supply chain's environmental performance. First was the knowledge practice gap expressed by Gamma

"During the years that I have served here as a technician, it's only a few years ago that we got trained on simple training on biohazard waste management. We unfortunately cannot implement anything effectively from that training due to lack of material support."

This comment was further supported by views expressed by Zeta,

"At times we have biohazard bags supplied to us, nobody follows the color code, and wastes end up in either yellow or red bag even if it's the wrong bag. When you look around there is a lot of mess".

Discussions of these comments show that the diagnostic role of the laboratory is given preference to management of non-useful end products in the form of wastes. These concerns raised the need to prioritize consumer and supplier responsibilities, to the extent of catalyze innovative actions on products and wastes alike. In sum, the TAG determined the need for responsible supply chain, in which they also have a role to play, provided material as well as technical support made available.

Secondly, In the recent years the laboratory adopted a platform to assist manage a lean supply chain. This was deemed pivotal to organizational performance and quality initiatives became the second issue that the TAG dealt with. First, this team had immense delays in reaching conclusions due to ambivalences expressed at the initiatives meant to reach a lean supply chain system. For instance, an enterprise resource planning (ERP) tool called *m-supply*TM has been in use in assisting manage the supply chain but failed its premise. Gamma while leading the team reported that

"m-supply was so weak that we had to insist at the interdepartmental meeting that it be removed, after all, we have come across other related tools that did not see the light of the day".

Further, TAG discussions indicated that the tool's conceptualization was mechanistic, and did not include the people, cultural and environmental factors as critical nodes of the system. Comments obtained from Beta was that:

"It is time we develop a lean supply chain system whose center is the people, to enable understanding of the complexities, recognizing the multiplicity of actors in the supply chain".

I understood that several actors determine the whole laboratory supply chain, including information on test menus. Additionally, specific programs have peculiar needs that they need to bring to supply chain and should be present at the discussion table. However, I wanted to determine that usefulness of the system, at least when laboratory officers make efforts to effectively deploy it in their daily operations. Then Iota raised a point:

“Nobody is refuting the benefits premised on m-supply as its proven useful in New Zealand, but Timor-Leste has several contextual challenges that are not addressed in that tool”.

The positions taken by the research members depicted ambivalence or some resistance attitudes towards use of m-supply as a supply chain management tool as part of change process pioneered by the NPHL. My immediate thoughts were how the NPHL can engineer enthusiasm on the part of the supply chain stakeholders or employees to feel they are included, and their interests taken care of in the process.

To ensure implementation, the TAG wanted what works to ensure products are sourced, used and wastes managed effectively. The TAG suggested a prioritization of fundamental changes and practices towards improving the laboratory’s supply chains and environmental performance as twin action point. These actions to improve practices were thought would run parallel with developing and implementing key performance indicators and comprehensive monitoring and reporting. In this manner, the team sought to create mutual exclusivity between the diagnostic and environmental objectives of the laboratory, without constraining each other.

4.14 Conclusion of problematization process

At the end of the problematization, I shared the data gathered with the rest of the TAGs (with all participants) and held an online plenary session on 12th November 2020.

The TAG leaders presented the action points (recommendations) and explained the reasons behind their points, which were thus adopted by the plenary. In particular, TAG 1 took an empathetic approach with some emotional appeal to clarify why cohesive actor engagement

needed to be on the table. This action got the team thinking and resulted in prioritization as will be explained in the next chapter.

In sum, the problematization raised five main areas for action including convening and influencing formation of cohesive engagement or actor alliance for implementation of quality plans. Second, re-engineer process control by using technology to solve data management issues, reporting adverse testing outcomes with immediacy, and evaluation of near misses in testing outcomes by participating in Proficiency Testing programs. Third, sentinel reporting of laboratory occurrences, and developing standard operating procedures (SOPS) for every testing process. Fourth, developing internally or adopting regulatory mechanisms that permit policy instrumentalization, design for local context, construction of legitimacy, and intra-institutional coordination mechanisms. Fifth, bonding laboratory supply chain to environmental performance. In the next chapter, these proposed action areas are further evaluated and strategies for effecting actions considered.

Chapter Five: Laboratory Empirical Work Action Planning Phase

5.1. Introduction

The problematization phase of this thesis involved discussions by the multidisciplinary action research team on the laboratory quality challenges. This team consisted of technicians with skills in virology, hematology, biochemistry, Microbiology, and quality assurance consistent with skills required of a Public Health Laboratory. The team took both reflective and analytical perspectives, subsequently raising action research themes that we subjected to further review by small groups. In the TAGs, we maintained a sense of participatory community where all voices and suggestions discussed. The participatory community is an approach that empowers members, ensures equity, sharing in the decisions and knowledge integration across the community for the purposes of intervention for change. One approach for this was through constructive discourse, enabling members to think creatively to provide critical perspectives into the action research themes, each group focusing on a thematic area. In this planning phase, I reflected on the search conference data we had set then. In that search conference, the participants suggested actions arising from the problematization phase of the thesis should not stifle other improvements stemming from organizational and partner mechanisms. My intentions for bringing forward such reflections were to stir discussions to project quality improvement ideologies as boundary-spanning, often thought-provoking. It was the beginning of struggles, opening up organizational and partner silos confining elements of QI to self or specific projects, dealing with the blight of bureaucracies and inertia, impediment to innovation (Hamel and Zanini, 2017). Key elements raised during the workshop that provided grounds for sensemaking for this thesis were appreciative inquiry and democratic space. The participants took advantage of elements to evaluate our laboratory system yielding desires and raising action points (see in Chapter 4- section 4.6- *conclusion of problematization process*).

5.2. Defining Thematic Priority Areas

Thematic priority-setting was a socially driven, interactive process involving street-level bureaucrats (action researchers). These researchers ordinarily function at a low level of the organization, but their pragmatism, insights and actions are critical as key stakeholders. Overall, the thematic priority setting considered the feasibility of implementation (skill set and technology), population safety, and social and financial risk (resource impact). Also critical to the AR team were priority congruency, the political acceptability, and tensions thereof that facilitate implementation, the institutional culture, and the stakeholders' perspectives. The process exposed the effectiveness of the bottom-up approach, taking advantage of low-hanging fruits considering the variables involved, from a resource perspective to crises, uncertainties, and prevailing events underlying priority decisions. In sum, the decision to prioritize hinged on a multivariate contextual determinants crafted at the agency level, enabling governance of the emerging knowledgebase depending on whether a theme yielded new discoveries, got discarded, or retained. Although the data yielded five themes, translating these themes into implementable projects, meeting stakeholder desired outcomes needed emergent operationalization from the aggregate effects of researcher actions beyond prioritization. Weighing these variables functioning in complementarity, the AR team prioritized the following themes:

1. Convene and influence the formation of cohesive engagement or actor alliance for implementation of quality plans.
2. Reengineer process control through technology, laboratory results monitoring, occurrence management, and documentation.
3. Develop internally or adopt regulatory mechanisms that permit policy instrumentalization, design for local context, construction of legitimacy, and intra-institutional coordination mechanisms.

While theme prioritization is the epitome of action research, conversely, as researchers, we deprioritized and displaced the themes “bonding laboratory supply chain to environmental performance” and “operational efficiency” from a resource perspective. We established to

operationalize supply chain as a priority action area, we needed to engage laboratory commodity vendors, a constituency whose commitment the researchers could not secure, thus an impregnable project unable reach new organizational capability as an aspiration of the current research. Again, the financial resources that the laboratory required to attain an efficient, scalable, and resilient supply chain and to achieve operational efficiency were enormous, and envisaged to be unavailable during the period of the research. However, I have placed these deprioritized and unsupported themes in the appendix of actions areas earlier suggested by the research team, but which were not implemented, first, as a limitation and then as an opportunity that future research would potentially benefit.

Given my position in the research as TAG co-leader and insider-researcher, I presented these action points in the second conference. We conducted the workshop on 30th November 2020 involving the multi-disciplinary research team. The aim was to build consensus on the action points and evaluate how they align the thesis. This conference also provided an opportunity for participants across TAGs to discuss challenges and tensions that emerged. Despite all the four identified vicious cycles, a backbone of laboratory quality problems, we had to set priorities based on the feasibility of resolving them.

With the first question arising from prioritizing and focusing on the actions that would shape the thesis ahead, the steps made almost rendered the team susceptible to division and conflict. A cross-section of participants sought to remind me of the vital role the laboratory environmental performance could bring to the laboratory quality improvement endeavor. Indeed, Gamma observed:

“Now, are we focusing on profits, lives of the customers served by this laboratory, but forgetting the wellbeing of the immediate community by neglecting environmental performance?”

It appeared that a section of the participants thought their contributions to the research from inception would be lost, with environmental issues abandoned. I tactfully handled the question, employing advocacy, and explained that we were bound to choose between four rights

and competing priorities. In the next section of the planning phase, I discuss the tensions, their origins and give an account of how we managed them.

Revisiting the problematization data, the National Laboratory partner landscape was not clear at the outset of this research. A critical platform for engagement was lacking, despite each partner running projects in the facility. One of such large projects is managed virtually from outside the country but implemented locally. Yet, still, participants cited the financial muscle of partners or source of financing was associated with hierarchical influence within the laboratory. These prevailing actor characteristics were not likely to shift but could be harnessed and embraced for increasing value creation. Alpha reflecting on partnerships arrangements made this comment:

“Although there were many partners, each of them has an entity-based (specific) relationship with the laboratory. On the part of the laboratory leadership such relationships worked, at least in achieving the immediate goals. But we should look for the big picture with a systemic outlook rather than dyadic forms of relationships with the laboratory...”

An emerging panoramic view of the web of networks and partnerships led the participants to a collective decision. They thought that there was greater potential obtainable from the partnerships, in authentic systemic model that appreciate multilateralism.

Eta stated:

“This is a compelling crucial juncture to rethink agreements in the interest of all partners, without any taking predominant influence”.

To manage the tension, the participants agreed to an architecture that enable all the actor’s institutional ecosystem and partnerships. In this proposed relationship model, the participants sought to open up strengths and accelerate innovation and aiding choices between deals origination from partners. This model enables each actor to orchestrate and facilitate engagement, exchange, and learning. As Delta suggested

“The systemic approach enables institutionalization and emergence of linked resources, a key strategic priority for the laboratory”.

In here, participants' suggested action-points reflect the aspiration to such an ecosystem through steering committees and other knowledge sharing opportunities as discussed in the next section.

The plurality of actors with various origins and divergent work cultures provided a ground for conflict. One participant from the serology unit commented,

"In practice, guidelines introduced to the laboratory from outside are prioritized during project implementation".

This comment raised concerns among participants regarding the dissemination of guidelines and future active implementation. During the workshop, it emerged that some of the protocols for studies conducted by the laboratory were written overseas and not reviewed locally. Long-term utility of partner guidelines and sustainability were the central issues on which key questions oscillated. To reconcile these challenges, participants advocated the complementarity of local and international guidelines to create sustainable value across partners.

A cross-section of the participants expressed that the adoption of international guidelines alongside locally developed ones will not solve the challenge of sustainability and direction envisaged for change. To inform practice, participants agreed there has to be a will to review every patient result for consistency, and to pick any alarming issues within. This would be done irrespective of the protocol used for studies and regular laboratory specimen runs. The participants sought a process that vibrantly identifies irregularities and flattens bottlenecks in process control as a priority action. In doing so, participants gained consensus that the bottom line is that a guideline should maintain rigor and also be feasible to aid implementation.

At the outset of the research, I observed that it appeared to the participants that the researcher was setting up a conflict between the laboratory and the international regulatory bodies. Micro-elements of these perceptions persisted into the planning workshop. The elements raised tensions, supported by difficulties among some participants in discerning regulatory and internal driven TQM quality approaches. These thoughts notwithstanding, we had to develop a shared understanding, thinking about how to meet the collective desires. This

introduced a third voice in the research, whose role was moral imagination. Again, I reflected on the goals of this thesis, knowing that I had to achieve the goals with these participants. These thoughts, therefore, were not unfortunate but contributed to widening the research democratic space, enabling participants to remain reflexive, and interactive consistent with action research (Reason and Bradbury, 2008).

Alpha, who was consistent with the research approach explained the complementarity offered by TQM. Her sentiments were:

“This process isn’t dictated by a document from somewhere else, we just need to get to know what’s working, and see how it enables quality improvement...., how do we fit in...., what are our strengths...or the lessons in it. Again, if that process leads to improvement similar, or parallel to internal regulatory standards, the bottom-line is, we will have made a difference”.

With support from World Health Organization, the laboratory had previously allocated funds for training in regulatory standards by a third party overseas. However, the laboratory retained the sole responsibility of implementation, which had not yet borne premised benefits. The findings here first, brought to question the sustainability of the approach when the focus is regulatory compliance. Secondly, it was an opportunity for participants to revisit the problematization data including actor involvement (belongingness), and context-dependency (relevance). In reconciling these emerging issues, Beta suggested:

“We can take on [actions such as] co-development of the laboratory quality manual reflective of the laboratory context”.

This was reinforced by Delta’s additional suggestion, and a pivot of the session,

“The centrality of planning actions ought to be informed by laboratory community engagement, with partners and staff, aiding learning from within the institution and across institutions”.

Although ISO certification remains the dominant paradigm and aspiration of the laboratory, there is a concerted effort to an alternative pathway through a TQM approach as a new paradigm. In table 2, I summarize the PAR action themes, outcomes and ensuing accounts of workshop discussions. The research team tasked Delta, Alpha, and me to collaborate with the Director of Pathology to ensure action plans and outcomes followed up, resources mapped or generated to fund activities, and link with partners and the laboratory executive. Most of the

suggested actions were, however, low-hanging fruits, which required limited resources, adherent approach, and political will to implement. The subsequent section provides details of the action points.

Table 2: Summary of PAR action Planning workshop outcomes

Action themes	Residual challenges/ tensions	Agreed and planned actions
Formation of cohesive actor engagement	Actor engagement platform, yet some of the partners only run projects in the lab periodically.	<p>Develop an innovative approach to guide laboratory-wide actor engagement (steering committee) and scope for observed gaps.</p> <p>Create a forum for knowledge sharing among partners through webinars and other peer learning opportunities.</p> <p>Identify quality champions to assist in knowledge sharing and learning.</p> <p>Locate and curate an accessible location for sharing laboratory content to aid knowledge or success factors among partners.</p>
Reengineering process control	Contradictions between laboratory guidelines for individual partner projects versus the long-term process control goals	<p>Rigorous reporting of adverse testing outcomes with immediacy. Design laboratory processes that identify innovative prospects.</p> <p>Correct irregularities, and bottlenecks - a system optimization model, strengthened through cross-border learning visits.</p> <p>Document and manage laboratory incidences and occurrences</p>
Development of internal regulatory mechanisms	Discernment of the conventional regulatory standards and the internally driven regulations in a TQM	<p>Develop and operationalize laboratory quality manual.</p> <p>Create laboratory quality policy.</p> <p>Initiate and sustain community participation-an interactive process in policy making and implementation.</p> <p>Initiate intra- institutional coordination in policy implementation</p>

5.3. Details of Action Themes

5.3.1 Formation of Cohesive actor engagement

The participants kept the action themes, reflected on critical notes from the consecutive problematization phases and proposed action points, which we brought into the planning conference. Gaining momentum, the participants thought these actions would directly lead to laboratory quality improvement. However, from an insider researcher perspective, I considered these action themes as emerging theoretical streams for repeated reflections and cyclic planning towards quality improvement. I hoped and waited for the imminent PDSA cycles, but allowed these subsequent phases to unfold, only retaining the role of an advocate and “casting my lot with the devil” and questioning the dark corners of practice in the implementation. For this I remained anticipatory, but prepared to cope with realities and practicalities that come with implementation, measure outcomes through feedback and to see how the knowledge learned could transform into a culture. With immediacy, first, the participants suggested that the loose collaborations between the laboratory partners, and partner to partner were an area that needed review and action taken. In reality, there existed many partners, but actual engagement platform was lacking. In addressing the problem, participants agreed to form a mainstream boundary-spanning steering committee and oversight (Karimi, 2000), and need-based section-specific steering committees formed. The argument placed forward and summarized by Theta was:

“Laboratory is a complex, dynamic and multifunctional in structure, and not a single entity can synchronize, synthesize and utilize information arising from laboratory operations and outcomes”.

The term “capacity” here portrayed some uncertainties in the knowledge that an individual partner working alone would hold. Reflecting on the problematization data, much information exists held in silos by partners and individuals. Opportunities afforded by the steering committees provide an alternative approach in managing such information.

The basic principle was not only to share knowledge through the community of practice, that is between partners and staff, but also to generate a sustainable organizational memory. The participants were intentional in what they wanted was to create interdependence and generate a system that is pervasive. One technician, [Delta] commented:

“We need to break those silos, and whatever exists we share in a common pool, and the aggregate is greater than any of us as individuals and partners really own” as an individual I do not know much, but I seek someone else with a different knowledge, who wants a trusted person to share it. Look at the knowledge repository that we can build...”.

Actions arising from partner collaboration and involvement of the workforce build capacity for collective information presentation and synthesis. The proposed opportunities were through virtual engagement and information sharing in portals and specific curated locations accessible to laboratory staff and partners. For the participants, these would be virtual workspaces that facilitate both engagement and collaboration for knowledge consumers and users. Participants reflecting on some of the successful knowledge sharing opportunities in the past, and which were often taken for granted suggested use of webinars and seminars. Gamma suggested:

“In our ordinary laboratory meetings, we often have someone asked to share their experiences, whether using a modern technology or an equipment platform, for instance in data management”. For our research, these persons could be ‘champions’, and they may be adopted to quality improvement course”.

An individual had been sent out for training in the Indo-pacific region slightly over seven months preceding this research, and when she returned, she organized activities that saw her pass the knowledge learned to their counterparts. That model enabled that person to be champion in inducting new practice, and so participants agreed to adapt the model for quality “champions” in our TQM initiative.

5.3.2 Process Control reengineering

The centrality of process control was another agreed action plan. The first step is to recognize the uncertainties with which testing processes may present. The laboratory officers would be required to rigorously review any anomalies in the results and make immediate efforts to report outlier values back to the clinic. A plan is to identify these outlier patient outcomes and revise them based on the need to ensure sustained conformity. One underlying problem emerged out of a comment by Beta as she observed:

“There are values instance in hematology and clinical chemistry that are already input with outlier values flagged. It offers an excellent way for interpreting results”.

Although I noticed cynicism regarding the source of data used to inform test parameter values inbuilt in the laboratory equipment platforms, I waited for the participants to make their interpretation and to suggest actions.

During the planning session, I recognized two areas that drew my concern. First, the action points identified by the research team were not only convenient but interpreted as hinged on task completion. Second, to complete the tasks, laboratory devices and instruments could be based on programmable mathematical configurations or simulations meant to reach specific outcomes. Were these conventional approaches influenced the team, they could hinder the cognitive, collaborative, and innovative dimensions that this thesis sought to advance. Therefore, I advocated that the research team keep the actions permeable to the feedback dynamics for nested interactions between the active processes, intermediate outcomes, the laboratory personnel involved, and the field.

The ambivalences and cynicisms of equipment inbuilt test references catalyzed team thinking on a system optimization model as an action priority. The proposed action suggested laboratory processes identify the innovative channel to correct irregularities and flatten bottlenecks in the sustained process. Again, this proposal came with additional tension arising from contradictions between laboratory test guidelines for individual partner projects versus the long-term process control goals championed by the research group. Participants, however, saw the tension as a learning opportunity for all. The group agreed to cross-border learning visits to

Indonesia and to New Zealand to share practices as an additional action as resources might permit. However, this did not occur, given the “no entry restrictions” put in place by these countries at the time.

5.3.3 Development of internal regulatory mechanisms

The conference discussions established that some sporadic documents on quality in various locations and bookshelves in the laboratory, with the potential to raise some grounds for quality documentation. However, participants suggested the development of a quality manual as a priority action. Further, participants suggested that they should design a laboratory manual that depicts the context of the NPHL, include the internal regulation, and associated checklists. Additionally, and, attached to the quality manual is quality policy development as a key action. Participants equally suggested that conformity would be achieved if, and, when their involvement is prioritized from the start of quality policy implementation. Given this position, participants planned the third action as sustained community participation in policymaking, and involvement in management reviews. A critical issue that the research team had to be aware of was the discernment of the conventional regulatory standards and the internally driven regulations in a TQM. Theta, however, gave an interesting dimension in managing the potential tension arising from established regulatory standards and the TQM approach, which provided a solid advantage in moving the research forward.

“This group isn’t necessarily concerned on reversing any gains from observation of regulatory standards. What we should be doing is exploring our laboratory challenges, make some decisions, monitor to see if the issues are exhausted, or new problems emerge”.

A window for benchmarking was, therefore, left by the research group to enable NPHL staff benchmark considering that the two approaches are not parallel. This collegial decision notwithstanding, the staff already had some knowledge of regulatory standards, but their actual implementation was riddled with challenges.

5.4 Summary of action planning Phase of PAR

The chapter on PAR action planning provides the step-by-step summary of events at the PAR planning workshop, and an epitome of the effects of problematization shown in the previous chapter. First, it also demonstrates the democratic approach and communicative actions taken by this thesis. Second, the conference enabled collaborative strategy and planning for the future of our laboratory. Discussions and planning gave a wider stakeholder involvement, as everyone actively participated in reaching the planned actions. Reflecting on the previous steps, I was already thriving, but I now had to learn to survive. My view then, was that I had surmounted the hiccups of establishing action research. First, I had succeeded in maneuvering politics, bureaucracies, and power to have the laboratory scrutinized through the lenses of employees. The participants that ordinarily potentially felt undervalued and disposable essentially pragmatically dealt with issues through open conversations and actions. These conversations were deliberate and brought in community accountability and responsibility. Equally, I opened up for criticism, for instance, when participants thought I was thawing trouble with regulatory authorities. I questioned myself deeply, as this threatened the continuity of the research. However, the participant's reflections and mine triggered a significant position for the research, standing on the conversations and the emergence of the “moral imagination” as a third voice in the action research. I now turn to document the accounts taken by planned actions in the implementation phase in the next chapter.

Chapter Six: Project Implementation Action Cycle One:

6.1. Introduction

This chapter discusses and brings into perspective the action points selected by PAR team for implementation, and evaluation thereof of how interventions raised value in practice. The chapter appreciates post positivist epistemology through critical realism, characterizing policy implementation as a rationality in solving organizational problems. Such rationality is conveyed in actor involvement and communicative action as dual elements that assisted in the project implementation. This chapter demonstrates how organizational politics and power dynamics extended into the project implementation. Through reflections and mapping back and forth, the problems through the PDSA cycles were defined, solutions and new frames of meaning were constructed, while inquiry and data collection went on between and within cycles. Thus, the gaps between the initial laboratory practices and desires got blurred in implementation process praxeology, and finally I show results from the implementation. The research team decided to work in self-organized sub-groups (by participants themselves) each focusing on a thematic area. Subsequently, daily, or weekly activities were agreed with the Laboratory Director, based on the informal networks created by the participants given participants' mutual engagements and thematic interests at that time. The evolution of the groupings notwithstanding, some tasks were led by individuals, then reviewed and implemented at thematic action group level. Throughout the implementation phase the action groups socially explored the laboratory practices and put their thoughts and collective strategies into specific actions based on the group's priority and available resource. In this chapter the labels "thematic action group (TAG)" and "Researchers" are used interchangeably to convey similar meaning.

I envisaged the study to take nine months, with seven of these accounting for the implementation phase. However, it took 21 months, with delays associated with participants paying attention to COVID-19 surveillance activities. Although participants arrived at several action points at the planning phase, to maintain clarity I have kept discussions and actions within three major action themes. The origins of these themes can be traced from problematization

phase and subsequent empirical work planning in “*summary of PAR action planning workshop outcomes*”.

In Table 3 below, I provide a summary of the thematic actions and the immediate results obtained during implementation. The dynamics of these actions are further discussed theme by theme in the subsequent subsections of this chapter.

Table 3: Summary of thematic actions and their immediate outcomes

<i>Thematic area proposed actions</i>	<i>Expected Immediate outcomes</i>	<i>Resource implications</i>	<i>Who is responsible/ lead</i>
<p>1. (A) Re-engineering process control (B) Managing adverse patient outcomes</p>	<p>Mapping and documenting the depths and dynamics of testing process.</p> <p>Generated the laboratory workflow. Developed laboratory SOPs. Retrospective review of blinded patient data to detect adverse testing outcomes.</p> <p>Development of systems for sharing knowledge and social- networking.</p> <p>Establishment of surveillance systems for warning that provide data on adverse patient outcomes.</p>	<p>All lab units and benches (No financial implication) Database</p> <p>Intranet, boards</p> <p>Re-programming and testing of lab computer systems- IT engineer</p>	<p>Lambda Delta and Alpha</p>
<p>2. Development of Regulatory Mechanisms</p>	<p>Networking and partnerships for policymaking</p> <p>Development and adoption of laboratory policy manual at institutional level</p>	<p>Policy documents and materials, laboratory staff, and data</p>	<p>Eta</p>
<p>3. Formation of cohesive actor engagement</p>	<p>Establishment of diagnostic expert forum for knowledge sharing</p> <p>Curation of place(s) for sharing information</p> <p>Emergence of communities of practice</p>	<p>Network analysis/ map</p>	<p>Epsilon</p>

6.2. Thematic action 1: Re-engineering process control

Whilst this thesis embraced the priorities set in the planning, this changed the reason being that the researchers adopted an exploratory orientation in the implementation, defined and directed by their pragmatic considerations. The AR team also remained cultivating in their approach, addressing issues and challenges as they arose throughout the implementation. I struggled to restrain myself from interfering with the order and means of reaching team actions, often taking a back seat to permit open discussions within the thematic action group. These struggles notwithstanding, I could not sustain a passive observer position, as my reflections and inquiry stimulated participants into providing additional perspectives and stay reflexive. The primary group target focused on improving testing outcomes by enhancing the processes involved and to make it easy to detect and correct irregularities. Epsilon argued that... “to get off the ground the team needed to identify tasks and primary needs and requirements of any testing process. The existing processes are an imagined picture, but this should be made real, clear, and well understood across the team”. In the view of Iota, knowledge of the process exists, but it is only imagined, and not documented. Emerging thinking was that the thematic group needed to go beyond basic knowledge of the testing process, and document how the system elements assist depicts the rich picture of a testing process.

The response in the room was that these statements were a shocker, amusement, and embarrassment. However, stepping aside as a researcher, I noticed the team was not only willing to accept weaknesses, but equally confront their own practices and assumptions. While discussing the emerging task of documenting what they know, participants mapped out the testing process and workflow in figure 11.

These meetings have since translated to last Friday of the month morning meetings (0730-0830 hours), once -COVID-19 restrictions eased and attended by between 28-40 people, and open to laboratory units not participating in this study.

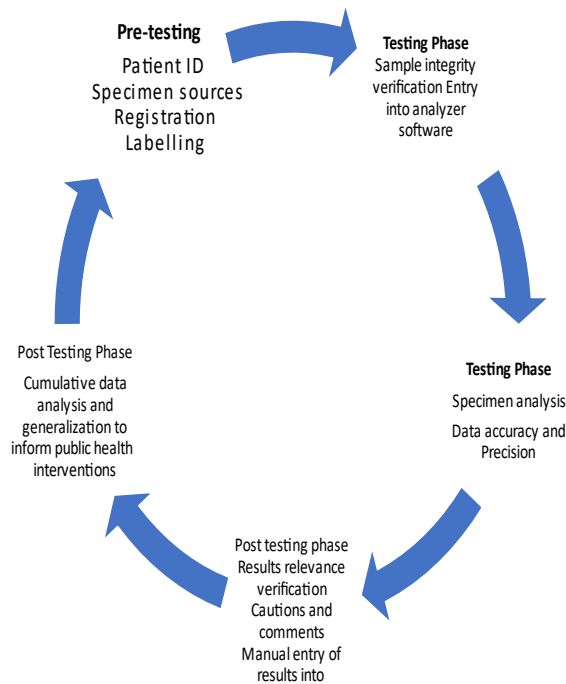


Figure 11: Existing laboratory workflow as constructed by participants

What the participants came up with is an extensive workflow schematic, but the mood in the room suggested a non-uniform understanding on processes. Given the complexity of laboratory tests from the pre-testing activities to the time the results are delivered to the physician in the clinic, documentation should include a form of an SOP. The conversations here supported the initial decision at the action planning phase for thematic group to undertake the task to developing SOPs. Eta highlighted some of the historical challenges with non- documented techniques and procedures in testing processes, and how in some cases the individuals conducting the test ended up with using a reagent in wrong stage causing the whole testing process to be discarded. This wastes reagents and human resource. One of the primary actions thus agreed was for individual participants to write SOPs laboratory procedures.

These once written, the SOPs were then introduced to the bench by the writers for implementation at the bench-level with a note on the last page, with a note that read *“document any non-conformities, variations, omissions or areas that need to be restructured”*.

In the weeks following the SOPs introduction, implementers identified several gaps and issues which included missing supportive documentation. These gaps pointed to a historical and connectedness, perspectives, and orientation feature of an SOP. First, Lambda, who often prefers to offer alternative view in regular laboratory operations raised a suggestion, which was adopted by the TAG.

“We need to include test references and worksheets to support these SOPS”.

Lastly, when it comes to releasing results, Delta suggested,

“There is need to add peer review and reporting to detect and correct any errors before final determination and sign-off”.

The feedback and review outcomes were documented on the comments section on the last-page of the SOPs by a team of implementers at the bench-level. The comments were reported alongside progress and concerns in the implementation of other themes, and subsequently presented at the first evaluation. This evaluation doubled up as a second conference for the thesis research [will be shown at a later stage].

To realize the intentions of reporting critical or adverse testing outcomes required that background, historic orientations, and systems for patient laboratory values be known. For this reason, the AR team conducted a micro-problematization embedded in a retrospective review of data for blood serum and associated pathologies. In subsequent weeks, individuals with dengue fever disease were followed up from diagnosis through the disease progression, picking warning signs in real-time. The follow-up earnestly encouraged team engagement, prioritizing the well-being of the patient over individual departmental responsibilities. The participants kept constant communication between the laboratory and the clinic, with a collegial decision-making regarding the direction of treatment of every dengue case. Thus, the researchers in a short time put in place a surveillance system that collects events and warning signs for dengue fever

management. First, the effect of this action suggested possibilities of higher organizational capacities when actors engage beyond their present jurisdictional assignments. The actor engagement elements are further demonstrated in the policy making as shown in sub-section thematic action three of the present chapter.

In biochemistry, universally, the interpretation of life-threatening values or hepatotoxicity levels are defined internationally. Given this reality, however, Beta suggested:

“This is an island country with people of small frames, and often a significant number of adults smoke cigarettes or use alcoholic beverages...the levels of liver-toxicity are likely to be high and reflected in blood chemistry parameters..”.

In the implementation, the participants randomly picked data from 100 individuals and delinked the demographics. The TAG judged the prospective patient data by identifying and reporting critical values and shared these values with the head of pathology and assisted run a query on a cross-section of the results. I had the privilege to present the outcomes of the data query at the routine bi-weekly ‘Grand-Round’ meeting. In the room were the doctors, laboratory officers, nurses and administrators, and other paramedics. In addition, was the data on laboratory and clinical monitoring of the dengue patients. The collective expectation of the TAG was that this would be an eye-opener for everyone involved in handling the patients. The now expanded team assessed the gravity of the near misses, misdiagnoses, and omissions, which we extensively discussed. At the end of the meeting, we concluded to open call lines and contact persons at the patient or specimen sources both for the hospitals and clinics.

From an insider researcher perspective, I drew different lessons from the thematic actions, which benefited both the laboratory and the clinical settings in institutionalizing change. First, the participants built flexible and adaptable organization structures towards a shared purpose, which in the current case is reducing mortality. Second, the participants set up an internal audit system which enabled the identification of problems that require action to support change and effectiveness of adaptability to new challenges. In the end, this is an evolutionary system for self-renewal, presenting opportunities not only for motivation to share but also a culture of team sharing and knowledge management consistent with TQM.

The TAG presented the 'grand-round' discussion notes at the first project evaluation workshop.

6.3. Thematic Action 2: Development of Regulatory Mechanisms

The participants deemed development of laboratory quality policy and manual as action points at this point of implementation to be tightly coupled, thus were combined as a broader action. First, the TAG permitted one of them Eta to coordinate the process, with an initial invitation sent to all the laboratory actors. These actors were requested to make a note on what they each thought should be in the quality manual and policy document. The researchers considered whatever the actors desired as planning models to direct policy making and implementation were: -

“Policy to reflect Good Laboratory and Clinical Practices (GCLP)”.

“Focused on accuracy and reliability principles”.

“Consider all aspects of sample collection and chain of custody, quality of test reagents, test procedures, calibration and maintenance of laboratory equipment, documentation lastly, capacity development and competence assessment”.

These elements informed the policy and manual evaluation.

Given the broad nature of the assignment to develop the quality policy and manual, Eta distributed the policy manual components to the rest of the participants. For quality assurance and engagement in policy making, the document once the components were drafted was shared with the earlier identified partners for their input and review. Of the 29 partners, the participant TAG received feedback from 17 (58%) only. Some of the partners had no ongoing project or program at this time and this might have resulted in low response rate. This outstanding, policy adjustments were made, and revised version sent shared with partners. In structure, this emerged as a complete innovative planning model of what needed to happen and translated into practice. Through the leadership of Eta and I undertook advocacy with the laboratory executive and partners for the purposes of building coalition on resource allocation for policy implementation, beyond the DBA thesis period. The researchers agreed that Eta, would continue

this role in the foreseeable future for the purposes of sustaining change. Admittedly, finding flexibilities was difficult and messy. First, some partners wanted more time to translate the policies into their programs and to weigh alternatives. Second, implementation meant a critical and logical focus into investing resources for better outcomes. It meant fragmentation of existing programs, raising tensions as sub-beliefs, cultures and priorities are shifted, and a dilemma of joint action settled in. Participants experienced resource limitations, but it was left until the third conference, for the available resources to be mapped in directing implementation.

Although the need of having a quality manual arose from the problematization phase of this thesis, its development brought to the forefront learning opportunities. First, documentation is key component of quality manual, and includes laboratory forms, SOPs, and entire testing process, all strategic to a quality management system. The earlier developed documents were, thus, embedded into the quality manual.

6.4. Thematic Action 3: Formation of cohesive actor engagement

The AR team selected Epsilon as the champion for quality to work with various bench units. The AR team deemed she had a good working relationship with everyone in the team, and acted as boundary spanner, between microbiology, serology, molecular and quality control units of the larger pathology laboratory. In her role she led as a vehicle for spill-over of knowledge, and in effecting change-actions at the bench level as TAG repertory competencies improved. Historically, and prior to the DBA research one of the knowledge-sharing forums was the bi-weekly “Grand Round” often happening at the National Hospital. This hospital and the National Laboratory twin institutions located side by side, thus, the main source of specimen for laboratory investigations. Routinely, nevertheless, the presentations were case studies involving patients or for international medical experts or local medical consultants to showcase what works in clinical fields. The TAG team challenged this forum by their initial presentation of near misses or complete misses mainly from the lab data. However, this discussion was an eye opener to the laboratory to have its own forums for knowledge sharing. Friday 1600-1700 hours local time was chosen for the ‘diagnostic expert’ meetings both physical and streaming live for

individuals to join electronically. This plan was significantly affected by the deployment of laboratory staff at the devolved health units and border posts in supporting covid-19 surveillance. The challenge for those joining through these applications was, however, poor quality of internet outside of the capital city and major towns. These meetings have since translated to last Friday of the month morning meetings (0730-0830 hours), once -COVID-19 restrictions eased and attended by between 28-40 people, and open to laboratory units not participating in this study.

In nurturing knowledge and securing organizational commitment, the participants advocated for and secured from laboratory leadership a shelf, which they requested be moved from the main library to the tea/ reception area. Recent publications which the quality champion, Epsilon, had access to, with permission to print, were made available here. Secondly, with the list of partners in place the researchers sent out an invitation through the Director, for partners to nominate a representative to the laboratory steering committee forum. The first steering meeting via skype happened on 21March 2021 attended by 15 members (earlier identified in the “laboratory stakeholders mapping”). Three key staff in the laboratory executive, and six of the study participants also joined the stakeholders’ forum. I, although an insider researcher, took the role of an ethnographic observer (Easterby-Smith et al., 1993) on this occasion with permission of the laboratory director. The aim of the steering committee was to guide the overall direction of the laboratory operations as an umbrella body. This first meeting had protocols of inducting a new body including introduction of members and their organization portfolios. The main agenda was the introduction of the final version laboratory quality manual and policy, which they had co-developed with the participants. The DBA research part was presented as a sub-agenda to wade through potential emerging politics as the overall aim of the exercise was to develop new organizational capacity. This approach was for me to maintain politicalF savviness, and to negotiate power imbalances between the executive, the powerful laboratory partner agencies, and participants for the relationship to thrive and benefit the organization and this research. The other reason was to control managerial tendencies and bureaucracies and instead of operating at “arm’s length”, deliberately integrate these skills into the action research.

One step towards realization of the actionable quality manual was cost-sharing and resource mobilization towards implementation of the manual. One outcome was maintenance contracts signed with Ortho-clinical diagnostics followed by an annual maintenance three weeks later for all the laboratory equipment. Second action was utilization the opportunity afforded by the equipment to interphase them with Labtrack™ a platform for efficient data management. The laboratory benefited from this function supplementarily as the Orthoclinical diagnostic service team had the knowledge to complete the task. The residual challenge is that the maintenance vendor (with offices in Singapore and Indonesia) had no local biomedical engineer.

In the next section, I explore how the TAGs together with the rest of the researchers evaluated thematic actions. The primary aim was to provide a view of how the actions met the desires of the participants expressed in the problematization and subsequent action planning. The evaluation also provided a new opportunity to rethink or strengthen the initial actions going into the second AR cycle, and deployment of other TQM tools and thoughts as organizational and researchers' capacity improved.

6.5. Evaluating Action Research Cycle One

This chapter details PAR cycle one, specifically evaluating actions undertaken in reaching not only new organizational capacity but also informs how these contributed to the DBA thesis journey. This section demonstrates the engagement of the participants during the second conference. I end this chapter by providing a summary of the conference outcomes. I highlight any identified problems, the basis of the second phase of PAR.

6.6. Action Research cycle one evaluation conference

We experienced significant delays between the action implementation in cycle one following the deployment of the majority of the participants to the Covid-19 testing sites from the NPHL, which was their regular work site. Some of the participants felt somewhat discouraged, and I noticed this, considering the level of engagement during AR cycle one evaluation planning. In my view, this could have risen from increasing work pressures and, therefore, the need to juggle priorities. The challenges notwithstanding, we held the workshop with eight of the original eleven participants, the rest staying in remote sites with no internet

connection. My role during this session was to facilitate the participants to evaluate their actions, reflect on their personal and collective experiences while providing any supporting emerging evidence. I stayed kept an open mind, and remained respectful and neutral recognizing group dynamics in lived experiences. This competency permitted accommodative and dialogic space in the team. Even when I had a divergent opinion or disagreed, I was flexible and did not refute participant ideas. When I recognized sources of tension, I responded by advocating for the participants to focus on the goal, understand and connect the past, current status in implementation, and futuristic desires. This session offered the TAGs and the entire research team grounds for reflecting on footsteps in the research. We traced our steps from problem identification through action implementation. Participants completed the laboratory quality improvement survey questionnaire in *appendix 3*, and we used the information gathered as the basis of discussions during the conference.

The evaluation process involved tracing the effects of actions to the initial problems at the laboratory. If and when the change was sub-optimal, participants recommended additional steps consistent with the PDCA cycle model (Deming, 2000). During PAR cycle one, participants collected field notes, which were entered into MS word and combined it with additional workshop notes arising from participant ideas. We collected data from the conference discussions using audio-visual, and notes on flipcharts, to identify the steps taken improvement. The data provided a rich picture of the process. Table 4 is a matrix providing a panoramic view of initial laboratory challenges, QI steps, and participant decisions on the improvement.

Table 4: Matrix of PAR cycle one evaluation of laboratory quality improvement

Thematic Priority	Planned actions	Actions taken	Period/ Duration	Action outcomes	Did the actions result in improvement? (yes/No: evidence)	Planned modifications	Suggested action priorities (for the next cycle)
Reengineering process control and patient outcomes	Improve documentation including capturing and response to laboratory occurrence and incidences.	Retrospective review of blinded patient data to detect adverse testing outcomes	July 11, 2020, to February 8, 2021	"Near misses" in patient results identified.	Yes, outlier results	Case-based peer review of patient results.	Review patient results turn-around-time (TAT).
		Development of systems for sharing knowledge and social- networking.		SOPs developed	Yes, SOPs developed	Procedure indexing Introduce charts and matrixes for reagent preparations.	Develop SOP Masterfile and institutionalize the SOPs
	Rigorous reporting of adverse patient outcomes in a process that enable system optimization	Establishment of surveillance systems for warning that provide data on adverse patient		Laboratory technical team established. Critical values data capture	No, prospective data review needed	Real-time reporting of patient data. Introduce telephone-based result reporting support	Electronic laboratory-tracking of results
Development of regulatory mechanisms	Develop and operationalize laboratory quality manual. Create laboratory quality policy	Networking and partnerships for policymaking	May 18, 2020, to September 30, 2021	System-wide network for engagement towards laboratory quality improvement.	Yes, collegial decisions	Micro and Macro- level evaluation of laboratory processes	Patient feedback Develop a framework for policy practice, systems evaluation, and networking
	Initiate and sustain community participation- an interactive process in policy making and implementation.	Development and adoption of laboratory policy manual at institutional level					
Formation of cohesive actor engagement	Create opportunities for laboratory sector-wide actor engagement	Establishment of diagnostic expert forum for knowledge sharing	August 5 to December 23, 2021	Laboratory personnel operate in a sphere of communities of practice	Yes, team cohesion observed	Sustain cohesive laboratory team. Leadership and Infrastructure for supporting knowledge creation	Value co-creation and knowledge sharing via mentorship circles and storyboards Laboratory share-point
	Create forums for knowledge sharing.	Curation of place(s) for sharing information					
	Identify quality champion.	Emergence of communities of practice					

6.6.1. Action Cycle One: Process Control

While the planned actions and the outcomes proved difficult in arriving at an immediate decision that there was a complete improvement, the participants saw each action as a steppingstone towards improvement. For Delta, this was a testament to what laboratory improvement should be in her comments,

“You think of laboratory processes and their complexity, and immediately you know, you’re not going to arrive at the answer easily..., but we’ve made a mark. While we thought of working on patient outcomes to capture all adverse results, little did we know we were creating a surveillance system for this laboratory”.

Another technician, Eta, added,

“When I look at the developments in reporting, I may consider it an improvement against what we set out to do, ... after all the discussions here, it is clear that the collective view in this room says it’s not an explicit improvement, since such surveillance is informed by data continuously generated here. We’ll have to scale-up this to something new and better each time”.

This technician referred to the decision by the whole team of AR researchers, that there was no substantive evidence to suggest identifying critical patient testing values was itself an improvement. For the AR researchers, sustainable improvement abides in continuous data capture and review in real-time, and, therefore, agreed to research laboratory data capture by electronic means in the second cycle of PAR.

Since in practice, the laboratory had to return the results for the patient to be reviewed and treatment or prescription offered in the afternoons, the participants appreciated the efforts made by the TAGs on identifying near misses. Alpha in support of notes by the TAG on peer review of the results by a colleague working on the same bench, and thereafter the supervisor, and lastly the Director of Pathology. She commented,

“While it is appreciable that we have put in place these checkpoints for the accuracy of the results, we are missing on criticality with which the results need to be delivered to treating

physician or clinic. In any case, we may be losing a patient due to unnecessary delay of the results when the laboratory test parameter is severely out of normal range”.

This comment assisted the participants at the conference to reflect on few occasions when the results would linger on the laboratory results release desk or even at the physician’s desk just to be informed later that the patient already passed on. Planning jointly, the participants suggested turn-around time (TAT) that is sensitive to the patient needs, e.g., urgency with which the tests are ordered (Hawkins, 2007; Stotler and Kratz, 2012). Additionally, the conference discussed possibilities of the technicians to quickly respond to the pathologies associated with the results, even when there are no suggestive clinical notes accompanying the test orders. Summarizing the discussions, Zeta commented

“Patient results is reviewed on case-by-case basis and there is not a standard turn-around-time for a specific test”.

Participants planned review of the patient test results turn-around-time in the second cycle of PAR.

Laboratory documentation was enhanced with SOPs developed by the one of the TAGs, and in my view, there was an entire research team concurrence that this was a definite improvement. I challenged the team to find a place for not only the notes from the TAG accompanying the SOPs, but also how the other thematic groups not initially involved in this action could share in the same knowledge. Eta while reflecting on my challenge to the group asked,

“What if we developed method for storing all the documents, we have developed for those not initially directly involved to read?”

Delta in accepting my challenge and thinking through the question aided by Eta led the team in planning for development of SOP master file in the second research cycle.

6.6.2. Action Cycle One: Developments in regulatory mechanisms

The second TAG set out to develop and operationalize laboratory quality policy and manual. Here, the outcomes were a system-wide network of laboratory partners and section-

wide engagement of laboratory practitioners. Although the action resulted in collegial decision-making and in the views, of Eta:

“This is not just a model for optimizing a diagnostic organization like ours, I think it is also a more realistic framework for decision support system any organization might want to rival. Notable benefits arising from this is a better-informed laboratory policy that serves the interest of every laboratory partner”.

Zeta, however, sounded reserved as to whether this was actually a complete improvement, only detailing that there are macro and micro laboratory process factors that would need to be involved in sustaining networks. These concerns directed the PAR to consider framework for practice and system evaluation that identifies key gaps, in optimizing networks. In addition, a challenge was posed by Alpha regarding the outcome of the collegial decisions or even networks, and whether they would result in patient satisfaction. In her view, the networks ought to be patient centered. These issues were planned to be researched further in PAR cycle two.

6.6.3. Action Cycle One: Formation of cohesive actor engagement

The TAG that researched this area suggested actions on sector-wide actor engagement and opportunities for sharing knowledge among practitioners and laboratory partners. This action resulted in laboratory personnel functioning as a community of practice. In reality, the team observed that they were more collaborative and consultative than they were prior to this thesis research. The PAR was cognizant of the dynamic nature of members that has not only led to collective learning, but also personal learning among members as they share knowledge. As Theta observed,

“Look at the way my colleagues from the quality control unit and immune- serology have engaged with us in microbiology and the knowledge we have each gained from working with everyone. Personally, I have had to break from what I thought was a virtue, ‘working independently without supervision’, to allow point gaps in my work or even practice. Everyone is kind of friendly and I hope this will continue in the future”.

Taking a step to observe the proceedings from the sides of the workshop, I noticed ambivalence regarding infrastructure for the laboratory community of practice (CoPs) such as the prevailing ones to thrive. Key aspects in supporting knowledge creation could be an assurance by the laboratory leadership that support for the CoPs will continue. I did not conceive these CoPs at the beginning of the research, but were products of emergence and team innovation. Although the practitioners could look for bigger and tangible evidence of such leadership support, Eta was quick in figuring out that,

“We have managed to secure a shelf for sharing what works at the tea area. We will continue the same advocacy, just not tiring just yet”.

Again, Delta observed

“In the previous thematic actions, we saw how laboratory network is a critical instrument for learning...., what we need to do then, is to make it a culture of learning within the network and outside of it. We must hold firm such culture and values”.

At the end of the discussions around formation of cohesive actor engagement, participants put emphasis on value co-creation and knowledge sharing as key areas for them to research further as part of laboratory quality improvement. In here, the PAR would be looking for opportunities for laboratory practitioners to share their experiences as they implement changes and the actual impact in the organization.

6.7. Summary of cycle one evaluation conference

This chapter is the culmination of a significant part of the DBA research, and demonstrates how the participants were able to construct the problem, plan, prioritize, implement, and evaluate actions. I have also detailed my role as an insider-researcher, a facilitator, engaging the participants in discussions and knitted the narratives (in character and function) that reflected the DBA journey. I enacted an attitude that assisted take the narratives from empathetic stances, opening research democratic spaces and enabling the participants to stay participative and reflective. Further, I identified tensions within the research community and had to bear the burden of participant expectations and occasional emotions. I documented the tensions and emotions in the personal journal (a reflective memo) to aid analytic objectivity. My

participation as an insider researcher enabled me to mitigate insider researcher challenges, for instance, I acknowledged participant expectations. I periodically debriefed the participants to clarify the research objectives and peer-analyzed the research findings. The most challenging part of my insider researcher position reflected role ambiguity, as I felt psychological detachment during data collection and got a self- persuasion that my performance had significantly reduced. My close collaboration with the participants occasionally raised political problems but traversed these with political acumen, alignment, negotiation, and overall political savviness. I also acknowledge the dilemma and ethical concerns that participating in this research got the participant into as they integrated the findings into their practice to create change. The critical part of this section is the milestones achieved in laboratory quality improvement, while areas participants identified for further research are explored in the next chapter consistent with continuous quality improvement.

Chapter Seven: Project Implementation Action Cycle Two

7.1. Introduction

This chapter builds on the developments in chapter six, which detail the implementation of thematic actions at the NPHL. The researchers retrospectively traced and reflected on our footprints in the quality improvement and our current position. Presumably, there was already a knowledge repository that the research team could potentially reference. The participants were liberative as they opened the knowledge silos (Hamel and Zanini, 2017), both in behavior and emerging knowledge sharing culture. It is critical to note that contrary to the planning workshop in chapter four, planning for the current phase was part of the PAR cycle one evaluation conference. We subjected the plans to team reflections concurrently with further problematization based on context and stages of research or present organizational capacity. The data collection method deployed in this stage of research consisted of focus group discussion and eventually a survey in evaluation of achievements of actions and formulating next stage.

I voiced a concern that the team had brought forward from the previous cycle too many areas suggested for action. (*Refer to Table 4. Matrix of PAR cycle one evaluation of laboratory quality improvement-the column suggested action priorities*). However, the researchers needed to re-prioritize actions for depth and content. Although my desire was to get all team desired actions implemented, I had to advocate for the depth of coverage of every agreed priority area and theme, but also manage my biases and assumptions, even as an insider researcher. Although I knew the context of my organization well, I had to immerse these pre-understanding biases and assumptions in the ongoing discourse to permit constructive change (Kemmis, 2008; Coughlan, 2011).

7.2 Development of Regulatory mechanisms: a framework for policy-practice review, systems evaluation, and networking

The second action cycle took five months (October 21, 2021, to March 30, 2022) subsequent to the first action cycle evaluation workshop. Setting the wheels in motion towards a framework for policy practice, the mood in the room suggested that while it is generalizable that in medical laboratory sciences policy is a common daily terminology, policy practices in our setting were loose. This thesis granted an opportunity for the practitioners not only to deploy their skills during action implementation but also a powerful avenue to propose and implement change. Theta recognized that:

“While faced with challenges within the complexity of laboratory practice, the first item that comes to mind is a change in policy practice to re-orient the system to one that is permeable to the pursuit of efficiency, flexibility, and growth”.

However, for Beta the idea of systems only comes as a second thought.

“First I think of what I can do to change my own behavior or just my thinking to meet the objectives of laboratory practice, then what others can do to effect change”.

Group discussions brought out that scoping for policy change need, direct involvement of all in policy assessments, interaction with environmental and systems approaches, policymaking, and more brutally, accepting that once organizational policies are in place, they will determine the latitude of practice. Here, participants revealed that they have learned that the determination of policy practices cannot be left to consultants as had been the practice earlier. These practitioners had taken it as normal for someone else to do the policies as that took the yoke off their shoulders to concentrate on the heavy tasks they run on a daily basis.

Alpha raised awareness among the team that the current laboratory quality policy, for instance, wasn't rich in elements that the group advocated. In response to this challenge, first, the team sought to understand the historical background of existing policies. The historical weaknesses included the lack of involvement in policymaking and poor skills in policymaking. To counteract these policy weaknesses, we divided ourselves into policy task teams (akin to TAGs in chapter six) to enable us to cover significant ground on policy. My role during this period was to coordinate the task teams. The team met six times between January and March 2022. The first

action was to review the laboratory quality policy. Conversely, during team discussions, I identified that majority of the participants focused on policy prescriptions or the purposes of “playing by the rules of the game,” and not policy governance and other angles for holistic accountability. However, in my interpretation as a researcher, these weaknesses pointed to issues with engagement, dedication, and commitment, all core elements of core policy governance. These issues could have been responsible for policy misalignments or even gaps in implementation. Nonetheless, I did not want to hold onto this assumption but allowed the discourse to take its path as there could have been multifaceted micro and meso institutional policy mechanisms (Serpa and Ferreira, 2019; Vlado and Chatzinikolaou, 2020) responsible for these. Eta, however, raised weighty concerns,

“For me the questions on policy have to do with high level political involvement in policy implementation and resource allocation for operationalizing polices”.

In implementing actions on quality policy, the team, first, indicated actors likely to be affected by a policy and brought them to the discussion forum or network (refer to laboratory stakeholder mapping in Chapter three). The team being frontline staff of the NPHL, strategized to have the right individuals represent their organizations or actors. Working with these actors wasn't easy as they had conflicting interests, ideas, varying levels of commitment, power, and even policy beliefs. Although most of the work is documented in consecutive parts of this section of the thesis, in here I detail the network, collaboration and political aspects that characterized policy discussions. Primarily reflecting on the strategies, the AR team involved in policymaking, as a researcher, I learned at this stage that in a multiplayer context, the political consensus remains elusive, and this infiltrates implementation. I accredited this elusiveness to partner freedoms and plurality of ideas, but still found it profoundly moral. Our experiences and learning in building consensus came from trade-offs between sustainability and benefits to the customers. Team discussions brought out that decision-making on policy required that we hold on to the actor engagement, reflect on what programs existed, and a broader policy roadmap as critical policy building blocks, likely to lend acceptability and legitimacy to the process. Reflecting on the foundations on which the researchers proposed policy networking, as an action plan, Theta posited:

“Peer networks and coalitions that characterized policy implementation, must be the same one informing accountability and future policy repository”.

Some actors thought that implementing the quality policy in its entirety could be a source of lethargy, as there were underlying historical hindrances. Thus, actors discussed and obtained consensus that the policy is vast, and we should direct efforts to a few elements that are implementable at the time. Actors then identified implementation gaps in equipment and test calibration, quality control, and specimen processing. Subsequently, the team got into micro-planning within known resource limitations, although with support from the Global Fund, WHO and Abbott laboratories. In collaborating with partners, the AR team considered the benefits and the costs of laboratory service optimization by participating in External Quality Assurance (EQA) and reviewing Internal Quality Assurance (IQA) aimed at changing practice. In the following months, NPH took part in EQA programs for HIV, Hepatitis B, Malaria and Syphilis, with results.

At the point of enrollment into the EQA programs, Beta observed,

“Reputable laboratories in other jurisdictions maintain participation in EQA to cross check their results, and I think we should take the same path”.

Beta’s commented further *“Does this mean these laboratories behave the same? What could be the effects institutions wanting to imitate one another?”*

In the next section, I discuss development of SOPs and their institutionalization in the laboratory as an emerging sub-theme, under the theme- process control.

7.3 Process Control: Develop SOP Masterfile and Institutionalize SOPs

In the previous cycle of this research, we had focused on SOP development and other documentation that detail laboratory procedures. In the current AR cycle, the team discussions suggested changes, including procedure indexing usage of charts to give direction during testing. An analysis of the accounts of the group discussions pointed to development of a master file of these procedures followed by institutionalization. To guide the research, I suggested that we take notes and examine the SOPs based on notes provided from the previous cycle before

embarking on further steps. The purpose of my suggestion was to ensure we built a cohesive knowledge base from previous to successive PAR cycles. Gamma supported my view but suggested that after incorporating the notes in the SOPs, the team consider developing an SOP that would explain their writing with homogeneity to close a void in the documentation. We gained consensus on the concerns and suggestions and developed the SOP of SOPs (Gitonga et al., 2016; Barbosa et al., 2011). Besides testing procedure, an SOP has a background, material supplies, equipment, quality control, and testing procedure. The interpretation of results against expected values, reporting and archiving, and specimen management (See Annexure 2). The document assigns responsibility to the laboratory personnel and management. The SOP has a version control table that details revisions and references. Alpha opined that the laboratory maintains these SOPs in electronic and print forms.

The team then brought together the SOPs to form a Masterfile as a source of knowledge and an innovation arising from team creativity, yielding value for us practitioners and our laboratory. Zeta, reflecting on the process, asked:

“Now the NPHL has a tremendous cultural shift breaking professional barriers experienced before with the SOPs, and even better the SOP Masterfile. How are we going to ensure Alpha and Theta have the same understanding of these documents? How about employees coming in tomorrow or even when the current colleagues are gone?”.

This question was disruptive and provoked “collective sensemaking⁴” (Weick, 2005) and a critical debate. One opportunity for collective sensemaking, was researcher’s demonstrated distributive recognition of the gaps in SOPs and collectively paid attention to the gaps, by interactively dealing with them considering our laboratory context. Our laboratory personnel, thus, found a grounding for institutionalizing laboratory evolutive innovations. Through discussions and inquiry, the team revised individual SOPs and supporting documents. These include version control and training to ensure everyone had a similar understanding. The revised SOP versions on the SOP Masterfile documented names and signatures of personnel who commit to understanding the SOP. Other steps were training and socialization of the SOPs to

⁴ Sensemaking -A sustained retrospective view of plausible options arising from rational insights of what people do.

enable personnel to use them with assurance. As an insider-researcher, stepping aside, I got an insight that the tendencies of the laboratory personnel to document laboratory practices and implement the prescribed actions in the SOPs birthed an accountability framework and enhanced entrepreneurship. Similarly, the SOPs turned into divers for organizational change and institutionalization of practice. SOPs and other developments in documentation embodied the conventional approach giving distinction to inquiry and participant self-reflection on what else needed to be done instead of settlement.

7.4 Formation of Actor Engagement: Value co-creation, knowledge sharing via mentorship circles and storyboards

As inquiry went through the previous phases of research, the participants seemed, in my view, to already recognize that they operate in an atmosphere of an ecosystem, even though they worked on various benches with varied objectives. The practitioners became more self-aware, engaging in critical self-reflection, gaining new insights into practice, learning from inquiry, and lived experiences (Schon, 1983). The participants had a persistent endeavor for continuous improvement. As a result, team achievements evolved because of resource integration and engagement features and platforms created by a collective strive for improvement. On collective reflection, the most prominent concepts evident in our inquiry were the shared intentionality, researcher-participant⁵ agency roles, and taking responsibility among the team members. Occasionally, individual participants had different interpretations as the laboratory was at the constant edge of chaos. For instance, whenever we dealt with actor relationships, demanding ethical explanations or organizational rigidities, a cross section of staff had the courage to stand-out and voice concerns, while others did not. I now turn to recollection of birth and advancement of the ideology of mentorship in advancing knowledge sharing and value co-creation.

⁵ Researcher-participant “is a terminology used to denote research methods where a study participant offers and includes self-as-subject.

The element of mutuality was evident in the interactive, dialogical, and collaborative manner in which the participants and actors inquired of their laboratory and practice. The actors sought to influence each other creating a platform for emergence of value co-creation. This did not necessarily mean convergence, but merging different opinions to yield value for us, our laboratory and ultimately for the patients we serve. Drawing from the “diagnostic expert” forum earlier created in PAR cycle one, the team expressed their desire to work with a seasoned laboratory expert more closely as there were emerging trends in dengue and respiratory tract infections including Tuberculosis and now COVID-19. Theta, nevertheless, cautioned that relying on an individual expert could risk *“design for ‘groupthink’ and potentially catastrophic”*. However, the team proposed short-term technical assistance organized between our laboratory and its partners. The NPHL then asked partners to identify and commit a budget line for capacity building. At this time, one of the most pressing needs was enhancing the testing of COVID-19. The WHO revealed it still had funds meant to assist in the capacity building of the Ministry of Health in surveillance and improving the country’s diagnostic capacity. The COVID-19 activities were already ongoing, using the same funds, although at various stages. While collaborating with public health laboratory network for South- East Asia and regional subject matter experts, the WHO designed a program to assist the laboratory towards accreditation as National Influenza Center (WHO, 2010), consequently deploying a Technical Assistant. The WHO asked the Technical Assistant to train and handhold the laboratory staff on influenza, COVID-19, and other priority areas over nine months. This individual arrived in November 2021 and organized fortnightly roundtable meetings with the staff to assess gaps and plan actions.

Earlier, in September 2021, JICA sponsored two of our laboratory staff for training in Tokyo, Japan for three months as an initiative for global health security. The nominated trainees were participants in the DBA research (participants Alpha and Delta) not by design but utter chance. The purpose of the training was “to strengthen disease surveillance and capacity for low- and middle-income countries to respond to emerging infectious diseases of global concern”. Alpha and Delta returned from Tokyo in mid-December, and, on December 22, 2021, we had a discussion, where the Laboratory Director introduced them to the mentor being part of the NPHL staff. On this occasion, I also introduced the mentor to the DBA research and obtained his

consent, as his role, although planned to follow a trajectory, was consistent with the intent of the DBA research. We agreed to split the group into two co-led by the mentor and the two staff, who now assumed the role of internal mentors to make roundtables discussions, hereafter called mentorship circles, more robust and to startup actions on gaps earlier identified.

In the first mentorship meeting on January 3, 2022, we set our own goals based on the gaps in our laboratory and drew out comprehensive personalized and team action plans, and agreed on collaborative problem-solving. These was followed by actionable gap evaluations using telephone and video conferencing support with regional subject experts at the WHO South-East Asia office in Delhi, India, resulting in strong communities of practice. Giving an example from what they learned in Japan and how it's applicable in our context, Alpha said:

“We saw presentations how group-led laboratory strategic initiatives in some countries yielded value in stopping the transmission for HIV, dengue, malaria, Japanese encephalitis, and COVID-19 a Singapore case study, and many more diseases. I urge all of us to be ready to lead in particular subjects in the coming days to make this initiative worthwhile”.

One of the agreed circle goals was to improve internal quality assurance in HIV testing. Delta led, training the rest of us on introducing the ‘Dry Tube Specimen’ (DTS) technique for HIV testing evaluation. Delta prepared the samples, and the following week, each circle member got a chance to do the testing, and the qualitative results when compared were concordant. The most noteworthy part of using DTS emerged with the suggestion of Gamma that *“we could as well use it for quality monitoring in Hepatitis and syphilis testing”*. The mentorship circle discussions suggested that Gamma make it a personal goal to process the tubes on an automated analyzer and obtained values for the diseases. Each circle member ran a rapid test on the quality samples and reproduced values earlier obtained by Gamma, except for Theta whose test appeared inconclusive. In malaria, the mentorship circle set a goal to peer review slides for microscopy by core group microscopists, who were only three in the circles. Among these microscopists, we agreed that a circle member who was not an expert in malaria microscopy is attached for two weeks, one at a time to polish their proficiency as well. After eight weeks of mentorship, all circle members realized the vision of expertise in malaria microscopy as there was qualitative consistency of results for malaria slides between circle members.

The culmination of malaria microscopy is reflected in Beta's aspirations,

"My dream is to train someone, who will train another....and another, and make our lab known for pool of experts in malaria microscopy, who can be sent, and partner with local officers in any malaria endemic country to realize the global vision of malaria elimination".

In the early months of 2022, the pacific island country experienced a wet season with rains and a drop in regional average temperatures resulting in the rise in acute respiratory infections or febrile illnesses such as pneumonia and bronchitis. These challenges became worse with COVID-19, whose symptoms mirror the other febrile illnesses. The circle discussions suggested a need to support the laboratory in surveillance of COVID-19 by detecting and monitoring disease progression. Discussions led to setting an objective of timely detection and reporting and advising on the value of abnormal laboratory findings, which could lead to unfavorable outcomes for the patient. The mentor conducted a refresher training for the team on the use of polymerase chain reaction (PCR) in the detection of COVID-19. The circle also reviewed most taken-for-granted biomarkers such as blood indices and biochemical parameters and determined how they predict patient outcomes.

In one of the periodic video conference calls, Delta observed, *"The height of learning between circle members and even you regional experts is that the pandemic knows no boundaries nor nationality, and we owe this to the experiences shared and learning from one another".*

Finally, the circle shared their stories starting with the HIV testing evaluation and monitoring, expansion of assessment towards the quality of blood-borne infections, and malaria diagnosis. We employed storyboards, facilitating members sharing their stories, encouraging, and supporting one another across the laboratory and beyond.

7.5 Summary of cycle two actions implementation

In this section, I have demonstrated the linkage between AR cycles one and two, managing my biases as an insider researcher while permitting and encouraging subjective team reflections in planning and action implementation. Although the team planned many actions for

implementation in the current AR cycle, through discussions and my advocacy, researchers prioritized only three, which included the development of a framework for policy-practice review, systems evaluation, and networking; development of SOP Masterfile and their institutionalization; and, value co-creation, knowledge sharing via mentorship circles and storyboards. Finally, in the next section of this chapter, I provide details of PAR team evaluation of the outcomes of AR cycle two and, subsequently, collective scaffolding for cycle three.

In managing my personal biases, for instance, I construed policy misalignments to mean weakness in policy governance, the policies and any other documents were considered secondary data and were blindly analyzed. However, these thoughts might have been applicable in my previous organizations than at the NPHL as organizational dynamics were different. I shared this assumption, though with Eta for the purposes of gatekeeping. The researchers were already out to explore this in the current study in context and practicality consistent with the foundations of AR. Further, my background could introduce a bias, as an African who has spent years in healthcare development I the work at NPHL was inefficient, in my understanding. I was cognizant that introducing lessons I have learned elsewhere alone could not bring a lasting change to the laboratory except by involvement of laboratory practitioners. I shared this with both the executive, and Delta, who confirmed this bias, keeping me reminded that my thoughts and way of doing is not universal. These positions were key in my decision to employ AR to fulfil the DBA project needs, and organizational change, because it offered a chance for exploring organizational issue in depth. The AR choice enabled me as an insider researcher to keep asking, why and how throughout the research process.

7.6 Evaluating Action Research cycle two

This evaluation employed interviews and FGD to gather data. Researchers drew from the previous action research evaluation- cycle one to inform subsequent cycle action evaluations. We agreed on this approach to keep consistency and a cohesive trajectory that builds action implementation around themes earlier identified in this research. For us to evaluate actions in the second action cycle, we kept a focus on:

- a) The gaps identified in the previous cycle.
- b) Actions planned and undertaken.
- c) Evidence for achievement
- d) Whether the actions resulted in laboratory improvement; and
- e) Additional gaps, and, or priorities for action adjustments

Table 5 summarizes the evaluation of PAR action cycle two, from actions to outcomes. These actions emerged as suggestions from the previous PAR cycle, and it was up to the team to review and reflect upon them while implementing actions. As detailed, we mapped the actions onto the parent themes. The evaluation took the form of semi-structured interviews and open-ended questions with a focus group consisting of eight participants who fully participated in planning the second action research cycle and its implementation. Focus group discussions (FGD), although evident throughout the research, its choice at this stage was due to cascading effect it brings to the conversation (Krueger and Mary, 2010; Tracey, 2013) as respondents add their voices to the discourse.

I sent the five-item survey questions (See Appendix 6: Laboratory Quality improvement Survey Questionnaire) to the participants two weeks earlier for them to acquaint themselves before the evaluation conference. The purpose of sharing these survey questions was for the participant to feel encouraged to independent thinking and creatively and have some commitment to individual perspectives that they would eventually bring to the focus group discussions (FGD). The combination of interviews and FGD was to enrich and triangulate data, and to ensure comprehensive understanding, with exploration of accounts and contexts (Stewart et al., 2008; Lambert and Loiselle, 2008). I already knew my participants' traits, and some of them being dominant in conversation than others, and probed the rather quiet participants for alternative thoughts. Under a social influence, the less assertive individuals risked being swayed into certain beliefs, thus negating collaborative inquiry. For this reason, I used examples like *"Theta, you have made your point, and I sincerely appreciate it, but for us to move on as a team, I need to hear what others think too"*.

While table six matrix provides an overview of the quality improvement evaluation outcomes, I have captured the excerpts from the evaluation workshop in the text following the table. The text organized in the sequence of the discussion enriches the understanding of the table and offers feedback on the implementation of PAR cycle two.

Table 5: Matrix for evaluation of PAR cycle two for laboratory quality improvement

Thematic Priority	Planned actions	Actions taken	Action outcomes	Did the actions result in improvement? (yes/No: evidence)	Planned modifications	Suggested action priorities (for the next cycle)
Reengineering process control and patient outcomes	Develop a framework for policy - practice review, action, system evaluation, and networks	Conducted laboratory policy processes review	Partner coalescence on policy formulation, implementation, and evaluation. Procurement and Supply plan with short- order placement to supply duration (lead-time) Quality policy framework established detailing internal IQA and EQA	Yes, policy footprints traced, and lessons learned deployed in policy decisions. Partner-led supply chain assistance The laboratory participated in EQA proficiency panel testing with other laboratories and obtained satisfactory outcomes	None	Address tensions in collaboration e.g., power struggles, shared- leadership and authority. Develop an analytical surveillance, through Integration of IQA and EQA into laboratory routines to raise quality improvement
Development of regulatory mechanisms	Develop Masterfile and Institutionalize SOPS	Establishment of SOP of SOPS	Creation of laboratory Masterfile. The development of SOP of SOPS provided a guideline and a framework for writing SOPs for tests that may be added to the current laboratory services	Yes, Efficiencies in referencing and provided a holistic composition of all the services the laboratory provides	Work on schematic drawing of the layout of laboratory work area; electrical water and gas channels and signs. Include annexures for reference.	Cultivate ownership and discourse around SOPS Plan for new employee onboarding (induction and training) on the SOPS
Formation of cohesive actor engagement	Value creation, knowledge sharing via mentorships and storyboards	Professional educator (mentor); Collaborative engagements; and emancipatory leadership	Leadership without formal authority, Engagement, and support from partners. Telephone and video support by experts	Yes, Improved HIV quality assurance. Emergence of malaria microscopy experts	Prioritize professional education and development of independent thinking.	Build a quality culture, skills, knowledge, attitudes and beliefs through handholding and stories that colleagues buy into, to effect transformation. Explore role of technology in knowledge sharing

At the start of the evaluation the researchers considered policy-practice review as a sub-theme of process control. Although there was evidence of actor collaboration and support to the National Laboratory, interagency policy collaboration, shared vision, negotiated approach, and competing interests for a sustainable quality improvement were weak. In Delta's observation,

"The most outright difficulty with policy review is tailoring policy to fit the aspirations of all partners".

This led me to ask the TAG if an objective that brings partner interests together for the purposes of TQM. In participants view, this objective was already achieved. Moreover, despite what appears as a collaborative platform, differing actor priorities reinforced by differing strategic approaches and organizational cultures, internal power inequalities (Dowling et al., 2004) presented both a dilemma and an opportunity. For instance, Alpha argued that:

"We've experienced some coalescence around policy change, and even in the implementation process, but it risked oversimplifying the complex nature of quality improvement processes, which every partner on board should openly acknowledge".

Stepping aside to reading the mood among the research team, I learned that what they advocated for is a framework for policy collaboration inviting a structural plan that shares quality challenges, responsibilities in quality action implementations, potential incentives, and leadership between actors.

Alongside the collaborative policy desires arose issues that actors often overlooked, which the research team wanted to explore in the next cycle of this research. These were tensions and politics in both policymaking and implementation and the layer of disruption that come with it to create an environment for role-distribution, collaborative learning, harmony, and interdependence (Voupala et al., 2019; Thees et al., 2020). Further, the study team suggested a total testing process, thus strengthening the analytical surveillance system to check out potential areas for patients' test outcomes and pick outlier events. I now turn to illuminate the evaluation of SOP Masterfile and the institutionalization thereof as a sub-theme of development of regulatory mechanisms.

Delta outlined the processes that led to the development of the Masterfile, which the research team concurred was a good document that the laboratory workforce, supervisors, or external parties could rely on for efficient planning. The Masterfile provided a rich overview of the laboratory operations, which our team found a significant milestone for quality improvement during the evaluation workshop.

Despite the benefits that came with the Masterfile, a cross-section of the participants referring to the processes they followed in the SOPs development immediately identified gaps. Gamma observed”

“I am happy with this achievement, and I want [to encourage us] to assign responsibility for the overall management of the Masterfile. For this I would propose that the Pathology Director takes responsibility including custody and amendments”.

This idea aimed to avert voids and ensure overarching ownership of the Masterfile and give additional energy to the leadership role of the Pathology Director. SOPs, although implemented individually, referencing other related procedures in other SOPs as necessary, there was an overall team concurrence that the bench supervisor is responsible. However, there were mixed opinions on what to do to ensure a sense of ownership across the laboratory benches. For example, Zeta commented:

“If we don’t take it upon ourselves to socialize or induct a new employee on the Masterfile as well as the SOPs, and ensure it forms the backbone of what our operations look like, getting that culture once they become insiders, would be hard”.

(Zeta)

Another interesting approach was to use a positive orientation to reinforce the culture of reading and understanding all SOPs in the Masterfile in managing knowledge. A statement such as this could follow:

“Clinical chemistry bench has maintained good results even in the proficiency testing, but I [bench supervisor] realize the readings for iron have twice come out in different units rather than the standard units (SI)... although the Director says we have such a brilliant bench team.... Try to investigate where this minor error could have come from”.

(Beta)

The two excerpts sought to reinforce both ownership and responsibility to prevent a negative feeling individually or collectively at the bench level. Similarly, the research team thought leadership had a role in enhancing the building of knowledge repositories by cultivating opportunities and incentives for the workforce to tap into the knowledge repository as an enabler for learning. Finally, I turn to the evaluation of actions on value creation, knowledge sharing and mentorships as an emerging sub-theme under the original theme of formation of cohesive actor engagement.

Value creation in the team operational context arose from the desire and a mindset for integrating knowledge rather than an obligation. In this excerpt, for instance, Alpha opined:

“While each of us had or became an expert [in specific laboratory discipline] what enabled our learning is our willingness and a culture of wanting to share what we know with colleagues”.

Similarly, the research team thought leadership had a role in enhancing the building of knowledge repositories by cultivating opportunities and incentives for the workforce to tap into it as an enabler for learning.

The mentorship followed pathways that the participants did not initially expect. Nonetheless, it brought benefits of positive change and some concerns to the mentors.

“I [find myself] occupy[ing] a different space with challenges on how to [manage time] to attend to professional demands on my bench without any workload release, while at the same time finding a fair share of time as a critical support system for my colleagues.... I don’t know, but only hope I will keep managing the competing priorities”.

(Delta)

“You initially think you’re just a mentor, [and]as you start the role, but soon you realize you put the hat of a counsellor, a role model, a friend, and a coach to many that engage in such workplace learning opportunity”.

(Kappa)

As a scholar practitioner, one encompassing phrase from a mentor was:

“Learning so as to know, and to teach others that will in turn teach others.... Ooh (sic), the sense of pride, the confidence and satisfaction one feels inwardly given the influence on others”

(Beta)

The team found that the cycle of PAR saw peer educators both from outside and within the organization emerge. These individuals provided leadership to laboratory colleagues, ignoring the formal leadership and supervisory structures, thus improving knowledge flow. Participants attributed the cycle achievements to joint and collaborative planning. However, Alpha opined that:

“What we have gained even with the mentorship would one day become common practice knowledge, but [what may be] more lasting, is to have colleagues whose actions demonstrate passion to ‘living’ quality”.

Six of the eight participants at the evaluation workshop suggested that the third action cycle seeks supportive leadership. Secondly, the group sought to explore credible, believable messages in hand-holding sessions with professional educators. Lastly, the team should invite cultural dimensions that solidify quality accountabilities and peer-driven quality approaches. Participants planned to work on projects they are enthusiastic about with freedom of discovery and choice and get messages pinned on the notice boards at the tea area towards the end of the laboratory hallway. Reviewing the outcomes of the evaluation, the research team mutually agreed to prioritize projects that would address:

- a) Tensions in laboratory partnerships
- b) The role of technology in advancing knowledge sharing practices

7.7 Summary of cycle two evaluation

This PAR cycle evaluation elicited a large amount of data, going by the notes I took as a co-moderator (the other co-moderator was Eta), and we used mobile phone as Personal Digital Assistant (PDA) for recording for data triangulation. Key to guidance of which data was useful was the focus on theory of change and the open-ended, and semi structured questions our

moderator (Eta) and I had at hand. We asked broad questions first, then got more specific to stir debate and generate qualitative data for decision making on planning and implementation.

Chapter Eight: Discussion and conclusions

8.1 Introduction

The aims of this thesis were three-fold and sought (a) to build a contextualized and evidence-based integrated framework for laboratory systems quality improvement. I desired to (b) understand macro-processes for institutionalizing quality improvement and, lastly, to (c) explore the role of knowledge management within a research community in realizing TQM. Chapter two of the thesis consists of literature review on quality management, predominantly within the medical laboratory practices, but also drew in lessons from other sectors, securing both scholarship and practice orientations. In chapter three, I provide details of how we problematized the laboratory quality challenge in consideration of the NPHL context and, consequently, planned the empirical work in chapter four. I used the opportunity in chapters five and six to demonstrate how the participants of collaborative action research worked collaboratively to address quality challenges within the NPHL. For consistency, each action implementation phase had a corresponding evaluation attached.

Considering the aims of this thesis, this chapter is organized as follows: First, I present an emerging integrated framework from the thematic analysis and participant ethnographic accounts and take a systems approach. I discuss critical quality components and then turn to answer the research questions starting with the sub-research questions and subsequently the main question in this thesis, in relation to the AR findings in view of the literature. Subsequently, I illuminate how action research group created for themselves a democratic discourse space sharing their lived experiences, knowledge, influencing, and learning from one another in the process. Given the significance of collaborative inquiry and collegial decision-making in action research, I elaborate on their utility in the personal reflection section. A significant part of the chapter is a reflection as an insider researcher. I kept a personal reflective journal during data collection and analysis, as I had contextual preunderstanding and needed to keep an open mind. The reason for reflections was to minimize my influence on the study both from scholarship and practice, to ensure the findings were credible, rigorous, transparent, and transferable. Finally, I document the practice, policy, and theoretical implications. I then reflect on what went well in

the study, its limitations, the approaches that prospective studies could take, building on this research, and my development as a scholar-practitioner.

8.2 Integrated Quality Framework

Chapter three provides a precursor for this thesis with problematization of quality challenges in context, raising themes upon which actionable points informing planning, implementation, and evaluation from the participants ensued. The thematic analysis yielded five themes. Due to the need for depth, the AR team covered three of them, as presented in the laboratory-integrated quality framework (see Figure 12).

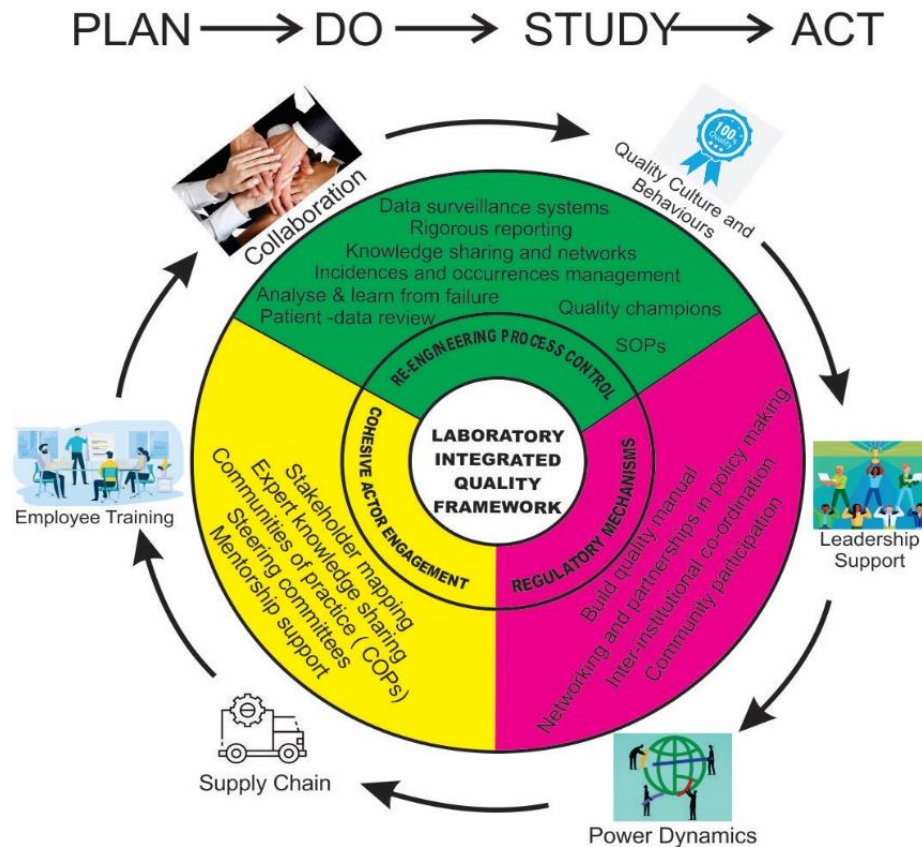


Figure 12: Laboratory Integrated Quality Framework

The main themes are: Reengineering process control and managing patient outcomes (In green); developments in regulatory mechanisms (in pink). Last is the formation of cohesive actor engagements (in yellow). Primarily, this chapter presents an opportunity for me to return to the

objectives of this thesis by introducing and explaining a contextual evidence-based integrated framework for laboratory systems quality improvement from the data. Laboratory practice traditionally leans on hard science, but the findings depict a significant portion of it lies in social constructs in the real world. These constructs include quality culture, leadership support, and power dynamics whose functions cannot be argued scientifically, but are part of micro-processes in quality improvement. The framework is context-based, temporal, flexible and adaptable for use in other laboratories, given that TQM approach builds on individual laboratory capability.

From the literature review, the emerging framework consists of some features of the quality systems essentials (CLSI/NCCS, 2014) and the ISO 17025:2012 (Burnett, 2013). This proximity raises the visibility of the framework, not only supplementing other existing laboratory quality management systems but also standing out as an enriched alternative system. I drew this conclusion because *Process control towards patient outcomes and cohesive actor engagement* are pillars for optimal TQM performance and thematically featured strongly in this research. The framework draws from Edward Deming's seminal work (Demings, 2013) and depicts a systems approach where all parts function together to produce an optimal outcome. Equally, the framework espouses the sustainability of the TQM with thematic actions revealing acts of knowledge sharing and value for communities of practice. These findings reinforce the Silimperi model (Silimperi et al., 2003), paying attention to structure, leadership, communication, training, policy, and activation of core values through quality culture and behaviors. This research has, therefore, raised a context-based integrated framework for laboratory quality improvement. The emergence of the framework notwithstanding, the problematization phase revealed other areas depicting the complexity of the laboratory with opportunities to raise additional themes, which future researchers could explore.

Contrary to the debates on accreditation (Plebani, 2003; Yao et al., 2010; Gachuki et al., 2014) and its role in quality improvement, the findings of this research locate critical drivers for QI in collective cognition and the desire to break from the past. The research findings show the precursor for QI in change readiness, where actors exhibit cognitions and behaviors that support change. I locate this in the caption:

“First I think of what I can do to change my own behavior or just my thinking to meet the objectives of laboratory practice, then what others can do to effect change”.

(Beta-cf cycle two implementation)

The improvement process features interactive and recursive inspirations that birth legitimacy, expressed through consentaneous institutional experimental steps and eventually securing organizational change. This research espouses the role of individual laboratory actors, whose actions are likely to influence the overall change effectiveness, contrary to the leader-centric models that paint straightforward prescriptions. For this reason, participants permit sharing of expert knowledge, engage in community participation, analyze, learn from failure, and encourage inter-institutional coordination and networks. These steps are critical for institutionalizing any QI initiatives such as TQM and are expressed in the integrated laboratory quality framework raised by this research. Looking through the intentionality of actors and the reflexive approaches they deploy in undertaking these steps explains how institutional frames are destroyed and new ones raised. The findings edify the work of Meyer and Rowan (1977) in response to organizational needs the work being taken for granted (Lawrence and Suddaby, 2006), at any point in time due to institutionalization notwithstanding. The participants and I were surprised at the emerging integrated quality framework but elated regarding its structure, which brings emerging components together. This was evident during the debriefing with the participants. The framework presents similar components to existing quality frameworks, which include SOPs, LIMS, incidences and occurrences, supply chain, and employee training. However, its other components (power dynamics, knowledge sharing, communities of practice (CoPs), and inter-institutional coordination) are novel to the existing frameworks. The integrated quality framework is adaptable, and exploration of these novel areas may bring additional benefits for laboratories keen to apply alternative quality improvement frameworks.

Having explored the framework, I now turn to the other aims of the thesis as they emerge in later sections of this chapter. Moving forward, I explore the research questions and by extension research sub-questions and occasionally refer back to the framework. At this stage, this framework prompts reflection and planning, and action research in laboratories, especially if a laboratory is inherent in a dialectic landscape. This thesis resists descriptive scenarios of

laboratory quality improvement, as these were already part of the assertive improvement methods associated with accreditation pathways (Plebani, 2003; Yao et al., 2010; Gachuki et al., 2014).

8.3 Research Questions

I kept the overarching research question broad, supported by research sub-questions to permit exploration to enable rich qualitative inquiry. I envisaged this approach would facilitate the capture of novel insights and experiences of an inadequately researched area of laboratory medicine. In the end, I intend to answer the empirical question underlying this thesis, and to support it from literature bearing.

Question 1: **What exists between TQM knowledge and its implementation in real context of action?**

I will return to this main question later in this chapter, but to answer it, the empirical work, I was guided by these research sub-questions:

- a) **What are the effects of institutional isomorphism in TQM implementation? If there are, how do laboratory actors respond to these effects?**

In the following section, I refer to the evidence in the data to discuss the effects of institutional isomorphism, first, at a macro-level in search of efficiency in reaction to government policies or international regulations, then at the micro-level using laboratory-level data. This research hinges on the role of institutional pressures on TQM implementation and the effect thereof. Empirical data demonstrate the influence of three forms of isomorphic pressures (coercive, mimetic, and normative) on TQM implementation and obtaining legitimacy. This is consistent with literature revelations (DiMaggio and Powell, 1991) on the origins of institutions and struggles for self-definition. Coercive pressures bear the burden of influence on TQM adoption as it relates to regulatory demands. The MOH determines the functional structure of the NPHL, which includes financing and has a significant voice in the decisions of the laboratory. The coercive nature of the government is consistent with that of partners such as the WHO, as they exert influence on the laboratory on TQM adoption and implementation by financing the laboratory TQM activities. These coercive pressures, however, decline as the level of TQM

implementation increases. Without the adoption of coercive pressures, the NPHL risks isolation, and low investments. The empirical data, however, suggest that the actors at the NPHL, in professional practices, acted in differentiation while implementing quality activities internally, employing various strategies and techniques. These staff deployed institutional logic and played active roles as laboratory actors and an internal driving force. I find the responses consistent with Greenwood et al. (2011) proposition on plausible differentiated responses to organizational pressures, given organizational structural fragmentation and differentiated institutional logic.

Data analysis shows sociological effects such as internationalization and acquaintance with “standards”. The NPHL participated in the proficiency panel testing, in which the laboratory performances compared to others in the field were the basis of ranking. In these engagements, the other laboratories defined the behaviors of the NPHL in conformity to the expected results outcomes and potentially systems of beliefs informing guidelines and procedures for sample testing and reporting. The participating laboratories moved towards standard practices and structures, gaining “legitimacy” (Lowndes and Wilson, 2003) and social acceptance. Although this legitimacy is attained, the efficiencies and effectiveness that it premises on TQM is lost (Barreto and Baden-Fuller, 2006) if the intention is to imitate “best practice” of other participating laboratories or adopt standards. In connection van Kemenade and Hardjono (2019) postulate that the benefits should go beyond quality management to impact continuous institutional transformation. Eventually, the laboratories mimic each other in a competitive environment, thus, invoking institutional-isomorphic rationale (DiMaggio and Powell, 1983; Rhoades and Sporn, 2002; Hassels and Terjesen, 2010). Further, participation in the external quality assurance (EQA) did not pay fidelity to the laboratory peculiarities but the need for conformity to the norms of the field of practice, driven by institutional pressures. The data identifies two overlapping institutional isomorphism pressures associated with EQA, that is, coercive and mimetic pressures that push for legitimacy. These responses to coercive or mimetic institutional pressures are not substantive to aid meaningful change in laboratories as their enactment remains symbolic (Meyer and Rowan, 1977; DiMaggio and Powell, 1983; Westphal and Zajac, 2001; Perezts and Picard, 2014). However, the findings demonstrate mimetic pressures positively impacted the expansion of managerial networks, particularly given the communication between the NPHL and

CDC, WHO, and other partners in addressing constraints such as EQA and equipment management. Conversely, normative pressures emerge in this context through the professional laboratory practice arena, where a landscape of shared understanding emerged (Scott, 2001). The normative pressures thwart both the coercive and mimetic ones as laboratory practitioners try to free themselves from the mimetic and coercive pressures suggesting deregulation and raising a dilemma.

Participants expressed neoliberalism in TQM policy formulation and exploration of technical rationality for institutional change, exploring realities of change from sociological perspective, capturing different participant aspirations. For instance, during problematization, participants argued for policy instrumentalization and rooting in context (cf. diagram 12). These participants enact their agency to influence the laboratory's social structure over time, demanding their involvement in determining laboratory operations including policymaking, and challenge historical policy pathways. These efforts constrain and enable laboratory structure in distinctive and innovative ways (Giddens, 1991; Battilana et al., 2009; Nichols, 2010). The findings show participants raising alternative ideological values, with preference for policy models that align with pluralism. Further, participants engage in deliberate and conscious efforts to influence change with distributed and empathetic policy decisions. Given these empathetic stances, the team sought to explore possibilities in quality improvement following realities of the laboratory practice field despite regulations and coercive or normative pressures. These findings support Giddens reasoning on time and space are critical contextual features in construction of social reality.

b) In what forms does institutional entrepreneurship function towards quality management system (QMS) change effectiveness?

In literature, scholars define institutional entrepreneurship as actor actions demonstrating interest in an institutional order which the entrepreneurs leverage resources to transform (Maguire et al., 2004; Pacheco et al., 2010). The entrepreneurs demonstrate their ability, will and resourcefulness in engendering change within the laboratory. The

resourcefulness and pragmatic approaches employed by laboratory actors functioning contrary to Seyfried (2019) scholarship arguing that institutional environment influence actors. Therefore, institutional entrepreneurship is the main driver and force behind the implementation and sustainability of TQM and against the tendency to the simple need for quality conformity. These findings establish the primacy of institutional entrepreneurship in the forms of *agency* and *sociology* and the interplay between them. On one hand, the agency is backed by entrepreneurs' resourcefulness and rent-seeking behaviors that pursue an organizational occupation. On the other hand, sociological form invokes struggles to influence the organizational structural constraints culturally, politically, or economically in context from a constructivist perspective to one that new organization entrepreneurs can defend. I, therefore, explain these forms shortly based on the empirical data.

The data demonstrate laboratory actors concerted and conscious efforts and interests in leveraging resources for TQM implementation. In other instances, the actors requested and positively influenced those in leadership to seek external assistance to implement quality improvement initiatives. Overall, the actor-agency in driving institutional change (Greenwood and Suddaby, 2006) embedded in laboratory officers' collaborative actions wading through the organizational politics and hierarchical structures. The actors made their collective desires and vision for the future laboratory known throughout the action research cycle. These action researchers exercised their entrepreneurial and actor-hood functions in the forms discussed in the next section.

Participants navigated conventional organizational structures that constrain new organizational capabilities by purposeful creativity (Loomba and Spencer, 1997), openly experimenting while avoiding optimism. The action researchers engage their social positions and mobilize social, behavioral, and cultural resources in skillful framing organizational problems and opportunities for crafting solutions in the institutional arena. From a strategic perspective, this engagement is the origin of a coalescence of agency interests, values, and beliefs at an institutional level. This evidenced in the engagement dynamics at play in the problematization, planning, and collaborative implementation of actions. In these steps, the AR team passionately engaged in their dynamics and cross disciplines in trying home-grown solutions to learn from

failure, critical dynamics, and principles in organizing for innovation. The team does try the candidate innovations in a climate of psychological safety, unafraid of the risks and consequences of the outcome. First, a component in failure analysis cited in the cheese model for evaluating laboratory systems (*see figure 9*). Second, the empirical data demonstrate decentralized decision making, as participants flatten hierarchical organizational structures and break organizational silos to create knowledge in action (Reason and Bradbury, 2008). These AR steps birth the emergence of socially defined entrepreneurial forms that seek to redefine institutional framework based on the midpoint of regulations and informal contextual organizational norms. Thus, I find this the epitome of innovation, given the opportunities for casual agency-structure interaction (Giddens, 1984; Battilana et al., 2009) and the foundations upon which actors craft interventions. I will come back to the primacy of structuration and debates at a later stage.

The participants demonstrate the importance of securing a managerial commitment (Westgard and Westgard,2014).

“For me the questions on policy have to do with high level political involvement in policy implementation and resource allocation for operationalizing polices”.

(Eta).

Here, the researchers respect the authority of the ministry of health on enforcing policies, presenting coercive institutional isomorphism (DiMaggio and Powell, 1983; Enjolras et al., 2021).

“It means compliance with the Ministry of Health’s policies, internal laboratory mechanisms and regulatory guidelines”.

(Gamma).

Second, the participants got the leadership support in allocating resources required for implementing QA activities. Further, participants developed cultural systems orientation in their work approaches for long-term QI. An example is the mapping of the laboratory workflow (cf p.97 - Figure 10). A further systems approach is in design thinking.

“Can we then have systems-thinking, and document all our lab processes and gaps?”

(Eta).

Engagement of laboratory personnel and the communities concerning the work to reinforce the image of the laboratory is yet another way of systems thinking and triple-bottom-line reporting (Elkington, 1997). Some participants were pragmatic in challenging the directions taken by the research group. For example, they provided alternative thoughts when they felt they had had not dealt with important systemic actions.

“Now, are we focusing on profits, lives of the customers served by this laboratory, but forgetting the wellbeing of the immediate community by neglecting environmental performance?”

(Gamma).

Although it may seem the laboratory is functioning efficiently, a systems approach opens up a collaborative and dialogic space with opportunities for feedback to improve the laboratory systems. There is a sense of pluralistic understanding, cross-laboratory systemic intervention within the purview of action cycles, and the construction of realities. In-process control, I found gap analysis a rich avenue for systems thinking as participants analyzed failure trajectories (p.75,). Participants equally sought platforms for sharing knowledge among themselves (page 119). These findings contradict Øgland (2018) suggestion that actors can secure quality without management commitment upon deploying a critical thinking approach.

The actors foster and cultivate an entrepreneurial culture mindset, ensuring continuity in an environment where colleagues empower and learn from one another. Participants take the lead and also inspire others to lead voluntarily. The empirical findings demonstrate that given the opportunity in leadership, laboratory entrepreneurs can influence their institutional world towards change (Hardy and Maguire, 2008).

- c) **In what ways can laboratory members create a legitimate organization, within the confines of institutional quality culture without pressures for isomorphic conformity?**

In scholarship, legitimacy in the lenses of institutional theorists is the degree to which an organizational socio-cultural and legal structures and values are consistent with its environment, to the extent that it empowers peoples' behaviors to enact strategic choices (Meyer and Rowan 1977; Zucker, 1988; Song and Zeng, 2011; Tang, 2017). For this group of laboratory practitioners, legitimacy is built or created and stems from the cognition and desire for constructive contribution. In pursuit of institutional reform, the participants expressed contestations in institutional features (DiMaggio and Powell, 1983; Charlton and Andras, 2002; Wilson et al., 2016) and made efforts for an analytical room to redefine and cultivate beliefs around these features. The research data demonstrate contestations in organizational behavior with participants on inspirational mission seeking values, meaning, and creating a purpose-driven laboratory. This is reflected in Theta's statement: *"We have raised an evaluation tool that can be used in any contemporary laboratory, that challenges the status quo at any point, and purely based on systems thinking"*.

In another vein, participants contest the exercise of authority and formal organizational structures, assigning duties to those in higher hierarchies against the norm in duty arrangements. In addition, the participants advocated for those in authority to allocate resources for quality improvement activities.

The data shows a strand of contestation of institutional democratic deficit (Charlton and Andras, 2002). Adding a paradox, however, the AR researchers also seek to enrich participatory governance. One contestation is evidenced in two ways, first questioning the policy pathways taken in the past, which gave rise to policy misconceptions and lack of understanding. Secondly, participants seek involvement in policymaking (cf -evaluating research cycle two) to improve accountability and generate legitimacy. In response to policy gaps, the researchers refine consultative links to aid their constructive policy assessment and improve their effectiveness. The data also illuminate casual advancements by the researchers towards policy foundations and directions in a dichotomous fashion. While the participants maintain conscious pragmatism with laboratory policies, they enact them from a practitioner rationale, and diverse perspectives raise grounds for loose decoupling (Bromley et al., 2012). This pragmatic policy enactment, therefore, does not pay allegiance to policy structures, although it effectively permits policy legitimization

and may explain the post-adoption heterogeneity (Westphal et al., 1997), closing the policy-practice gap. The empirical data reveal legitimacy stems from feedback loops in the form of lessons learned in the experiences of implementing continuous quality improvement. Critical to the use of feedback loops is failure typologization and the subsequent efforts by the practitioners to develop strategies for dismantling failure horizontally and vertically. Examples of failure typology is located in conceptualizing change, planning and executing it in context. In leadership failure, for instance, a community of practitioners worked with those in the executive to allocate resources (cf. PAR cycle two implementation) for QI, which they invested strategically to add value to TQM implementation (cf. *thematic actions*). The laboratory officers used feedback loops between themselves and also with the clinic by being bold enough to utilize negative feedback to improve patient outcomes and laboratory system efficiency. In other instances, the laboratory officers positively used the link between themselves and the executive to tap into opportunities that widen a collective view of dark organizational corners.

My laboratory colleagues attach their role as entrepreneurs to resources and build synergies in the stewardship of the core organizational ideology. Finally, the actors reconcile the core ideology with values, efforts that depict both pragmatic and cognitive legitimacy. The findings support previous research suggesting marrying the ideologies into a dynamic framework tolerable (Brook, 2010; Heras-Saizarbitoria, and Boiral, 2013; Seddon, 2014) and represents entrepreneur values. In sum, the laboratory officers' actions were instrumental in initiating, attaining, restoring, and maintaining institutional legitimacy.

d) To what extent do partnerships and networks contribute to TQM implementation processes?

The empirical data shows the laboratory actors create social networks that succeed in accessing organizational resources, building synergies, and culture and flair for stewardship of an organizational core ideology. The networks help in customizing the TQM or change initiative to organizational-specific needs and integration for philosophical flexibility (Thelen, 2017) and maturity of work practices (Graafland and Smid, 2009). From the implementation perspective, partners reconcile the core ideology with values, efforts that not only espouse processual

pragmatism and cognitive legitimacy (Bowen, 2019), but also extend a window for questioning (Greenwood and Levin, 2007). Consequently, within the partnership, the group produced systematic procedures, methodologies, and goals out of a shared vision, understood organizational-wide (Senge, 1990). For example, the actors jointly engage in critical inquiry into laboratory practices (Coghlan, 2009) and subsequently, mobilize resources to effect change. Following Creswell (2013)'s social constructivism anecdotal opinion, participants attain consensus on a range of action points, institutionalize policies and SOPs, and make strategic adjustments when the immediate change was conceptualized as sub-optimal. The laboratory team was instrumental in initiating, restoring, attaining, and maintaining new institutional working practices. This is evidenced in this caption:

"In the previous thematic actions, we saw how laboratory network is a critical instrument for learning...., what we need to do then, is to make it a culture of learning within the network and outside of it. We must hold firm such culture and values".

(Delta).

Partnerships and networks facilitate deep critical action learning within a team, with new insights enabling conceptualization and realization of desired change bringing forth reflective practitioners capable of articulating the change. The participants networked and worked closely with partners, taking radical innovation breaking from the existing norms and challenging the institutional foundations and structure out of rational actions despite the forces for conformity. Some networks and partnership effects were the formations of steering committees and interinstitutional coordination mechanisms (Loomba and Spenser, 1997; Karimi, 2000). The committees were instrumental in reviewing and operationalizing the quality manual, appointing a quality champion who acted as a boundary spanner (Ansett, 2005) between laboratory benches. Other observable effects were the formation of the diagnostic expert forum, the emergence of communities of practice, and mentorship cycles. The mentorship cycles enabled thinking at the team level (Barrick et al., 2013) and knowledge diffusion or exchange (Nonaka and Takeuchi, 1995; Raelin, 1997). In addition, are spillovers such as the curation of information-sharing spaces within the laboratory. Entrepreneurial actionable activities and achievements such as mentorship cycles are contagious and result in executive and staff buy-in without a top-

down push, with everyone acting as a vehicle for change. Illumination of initial laboratory problems caused the group to recognize the urgency to mobilize commitment through internal coalitions. In their networks, actors made some short-term QI gains, subsequently consolidating the gains into an integrated quality framework. In sum, the networks and partnerships raised a social change platform, with new habits, beliefs, and culture upon which they anchored change. These habits have a propensity for enhancement by commitment, collaboration, consummation, and a culture ingrained into the fabric and architecture of a TQM program.

e) How (if at all) do responses to environmental pressures experienced by a field-level laboratory and internal ambitions support quality improvement?

The interaction and supplemental effects of environmental pressures (regulatory or field-level entities) and the search for legitimacy (internal ambitions) function as a critical mid-point for quality improvement in laboratory practice. This position notwithstanding, the thematic analysis suggested practitioners should rethink regulatory frameworks to address three interior aspirations. First, the AR team wanted to address legitimacy through policy dialogue, ensuring actor visibility with stakeholder voices included. They also wanted to consider local contextual design, building on information symmetries, and inject inter-institutional/ partner coordination mechanisms. These internal desires offer incentives for a laboratory to determine its path for quality improvement, which the existing environmental pressures presented by the regulatory framework fail to do. Again, I find evidence of domestic ambitions in process control, and internal quality control (IQC), a mechanism implemented based on an assurance that the organization is working towards quality improvement objectives. This study, thus, suggest that it is plausible that laboratory practitioners' decisions or judgments change with a more responsive regulatory framework.

Finally, research findings suggest that response to external demands from the patients and other stakeholders' desires could have resulted in or even superseded compliance. As a result, there are enhanced engagement practices, increased accountability, insider-ownership, and governance practices to which practitioners are voluntarily willing to conform. Participants

navigate a positivist culture to that of constructivism through voluntary sharing of lived experiences. As a result, these behaviors and responses enable new organizational capabilities.

Having explored the research sub-questions, I now turn to the main question:

8.4 What exists between TQM knowledge and its implementation in real context of action?

Although this question may have differing answers depending on the ontological orientation action research takes, I limit myself to the most observable effects and events we experienced in the research journey's PDCA. This study found *organizational learning* (Senge, 1990), as a fundamental factor in TQM knowledge extension, given team experiential learning, critical reflection, experimenting within the daily routines, and taking corrective actions. As I have noted in the thesis's research limitations, given the panoramic view of the implementation of the project, the learning was situational. Therefore, a future opportunity for scholars and practitioners to pursue generalizable learning across laboratories is required. Through this research, the laboratory practitioners created for themselves knowledge-sharing spaces from which they generated and shared, described as a "knowledge spiral process" (Nonaka and Takeuchi, 1995). Additional learning spaces are in the participant interactions and engagement in the form of communities of practice (Wenger, 1998).

Preceding organizational learning, however, was the *acknowledgment of a wicked organizational problem* to be tackled. The problem is wicked because quality is clumsy and cannot be solved suddenly, except by maintaining curiosity, immersion in collaboration and co-creation, systemic innovation mindset, design thinking, and implementing coherent solutions. The data show practitioner attunement to a laboratory quality challenge was critical in facilitating collaborative inquiry on quality. Collectively, the practitioners' made themselves permeable to paradigmatic shifts in mindset, resonating with the realities of co-practicing with others with similar experiences. Additionally, their descriptions suggested that the laboratory problems were beyond the issues captured in the "May 2019" audit report. However, some laboratory staff had pragmatically started corrective actions in response.

I also find a crux in the evidential nature of the Plan-Do-Check-Action (PDCA) elements. The PDCA steps are essential in picking out what brings success through pedagogical-oriented approaches to quality improvement. Here, the precursor and basis for incremental development are opportunities to reflect, identify and respond to challenges and eventually make small cyclical interventions bringing us to *Knowledge institutionalization*. These practices served to extend knowledge management and linked it to the kaizen practices as well. I locate participant attributes for knowledge institutionalization in the collaborative forums in which they exercised tolerance to each other's contributions, and collegial decision platforms supported by evidence. Our findings align with suggestions in the literature on knowledge spiraling, Nonaka, and Takeuchi (1995), knowledge exchange, Raelin (1997), experiential learning, Reason (2001), and integrated learning between incongruent constituencies Mendes (2007). The action researchers position themselves to benefit from both embedded and differentiated knowledge by choosing a quality champion who acts as a boundary spanner (Ansett, 2005) between thematic action groups, thus extending knowledge institutionalization.

The action researchers create a structure that springs from their visibility to *search for legitimacy* due to environmental and regulatory pressures. The researchers' decision for a laboratory to participate in external quality assurance (EQA) contributes to conformation to the "mimetic institutional order" (DiMaggio and Powell, 1983; Kennedy and Fiss, 2009).

8.5 Research implications, future directions, and Limitations

8.5.1 Practical and policy implications

This research raises four practical implications, that is future deployment of communicative institutionalism in laboratory practice, modeling the QI confounding factors, QI sustainability, and consequences of hot groups. Primarily, maintaining temporal benevolence and knowledge of the institutional contextual settings in which a search for a collective understanding of QI occur is critical. Despite possible fragmentation at an institutional level, as laboratory actors engage, search within their organization and take corrective measures, QI

evolves. First, I find proverbial phrases (casting the lot with the devil), idioms (problematization, entrepreneurship), and language (institutional logic) to be cognitive building blocks for the quality improvement program. How AR works to deploy these rhetoric and messages to wade through potential resistance, ambivalence, power dynamics, conflicts, or partnership interests to realize a change needs further illumination in practice. Organizations should, thus, prioritize linguistics and cognitive tools that premise change.

Secondly, our data collection process found no QI unifying model for laboratory practice, save for latent key dimensions for which QI could be evaluated. There is need for TQM research to model and adjust confounding factors or key dimensions (such as laboratory workflow structure, leadership commitment, institutional policy, patient choices, stewardship, networks, partner commitments and engagements, and community participation) to enhance generalizability of the findings.

Third, laboratories have restricted budgets, as demonstrated in our research data. The cost effectiveness of QI interventions may not be sustained, against the growing call for practitioners to engage in evidence-based practices underscored by TQM. The effect of context on QI intervention need to be answered by longitudinal research that gather data routinely to make correct judgement on deployment of resources for future QI interventions. A practical framework that integrate QI the confounding factors, financial resources, contextual, processual and outcome measures should be a focus of prospective studies.

Finally, isomorphic dynamics notwithstanding innovation diffusion between laboratory benches, and networks, spillover effects may occur as hot groups break and members join other laboratories. As researchers, we were woven together in pursuit of change, with researcher forming informal networks, which the executive already saw as a channel for institutional change. Up until the end of this DBA project, the participants remained engaged. However, the AR team being organizational architects, in the way they maintained creativity and innovativeness, could experience unprecedented network breakage. Future studies should provide a guide for high-level organization management on how to challenge or adjust the demography of these networks to stay innovative and for the evolution of additional hot groups.

Drawing from practical implications, this thesis also offers implications for policymakers. The research data demonstrate a drift from traditions of solution-focused approaches, which could render quick fixes for laboratory challenges while disregarding the change process. It drew values from the increased use of feedback loops and could explain the levels of intensity of peer learning in response to environmental pressures. The feedback came in the form of evaluation and discoveries-in-action, thus informing definite steps in problematization. This research, therefore, advocates for policymakers to explore full-PDSA cycles in quality improvement as a consequence of a holistic scoping review. Scoping policy reviews can also take the form of root cause analyses searching laboratory dark corners or criticisms from stakeholders as a basis for formulating appropriate action-based policy interventions.

8.5.2 Theoretical implications

This research explicitly contributes to the literature on institutional entrepreneurship with actors' innovations providing insights and concepts for change at micro-level, while macro-level change are located at the institutional level, working in complementarity and in respect of contextual characteristics. The study builds on the lacunae in laboratory QI approaches, where reliance on existing regulatory frameworks and individualistic interpretations fail to account for social interaction factors in the improvement process. While the importance of quality management systems (QMS) is acknowledged in medical laboratory practice, the manner in which laboratory personnel engage, create value, and learn from QMS processes is poorly understood. If quality improvement is a function of sensemaking and cognitions, then behaviors that promote efforts at a group level and a shared meaning might better prepare the organization for change. Secondly, variance analyses traditionally advocated for in QI are both ahistorical and acontextual and contribute to the shortcomings of quality improvement approaches. This research brings in an institutional lens to understand the interactions of laboratory personnel between themselves, the laboratory structure, and the environment from an institutional perspective to quality improvement as a change. Improving practitioner understanding of dynamical influences on the developments of QMS, considering how their choices influence attainment of quality, manifest the value practitioners place on collegial

approaches . With enhanced understanding, laboratory practitioners communicate openly, constructively review their practices and remain consistently curious and pragmatic in their work. Data from the AR discussions suggest that laboratory practitioners are keen to voice their desires for a future laboratory, and are placed strategically to engage. Explorations in laboratories scoping for future accreditation, and where practitioners are keen to influence their laboratory structure and systems is critical. Studies taking that route are likely to find resources and an environment for psychological safety of the actors and shortening time taken in QI

Maintaining the gains and ensuring sustainability of quality improvement will require concerted action by all stakeholders with strong leadership and funding. Although some scholars identify leadership as a pillar in quality improvement initiatives, how leadership function to facilitate quality improvement in a wholistic perspective is a function of debate. The debate notwithstanding, the significance of leadership role in this research appeared limited to provision of resources in the process of implementation of TQM. Conversely, literature demonstrate ambivalences and espouse triviality of leadership engagement suggest that when action group is engaged in critical thinking, they can achieve quality objectives devoid of leadership support. This research in its scope did not look into supervisory and other support aspects of leadership in depth raising a chance for future researchers to explore these avenues in laboratory quality improvement.

Given the outcomes of this research, and its integration of ontological engineering and knowledge management, it presents actors agency in change process from a positivistic front. However, this is superficial as entrepreneurs had different strengths. This research, therefore, presents the question: Could prospective action research employing critical realism, and that dwells on persona and contextual dimensions reveal artifacts missed by contemporary entrepreneurship scholarship?

8.5.3. Research Limitations

This research involved eleven participants of the NPHL co-participating together with me as an insider-researcher. I noticed that the participants operated in the informal networks influenced one another while exercising power dynamics, impacting the collective whole. The case could have been different with an outsider researcher or with participants drawn from various laboratories and unknown to one another. Furthermore, the basis of these findings is a single laboratory experience in implementing and managing quality improvement in a Southeast Asian country's context. These findings may not support the “western ideological frames,” and should potentially be branded, ‘NPHL framework for quality improvement’, given the differences. The NPHL adopted an approach allied to an internally driven QI mechanism, the prescriptions of regulatory standards notwithstanding.

The second limitation is the multi-method approach I adopted in this research, owing to the resources and time taken to conduct and conclude a study. I would suggest that prospective studies on TQM adopt a multi-method approach given its robustness, potentially tapping into the strengths, and correcting the weaknesses. This research could have taken less time with more cycles where a single research paradigmatic approach used. However, it is my delight that the research in its design yielded knowledge to the researchers that would otherwise be inaccessible.

Coverage of all themes and sub-themes, for example, bonding of laboratory supply chain to environmental performance, and operational efficiency came to the light of discussions as themes. However, based on participants’ consensus, these themes were deprioritized to allow us to explore others in depth. I have placed these at the *appendix 3-supplementary themes*- for easy identification by future researchers. I believe that a similar study in a different laboratory in a different context could yield outcomes different from the current research with additional themes considered drawing from the seminal work of (Coglan 2011), who argues that practical knowledge is context dependent. I, therefore, suggest that researchers explore this opportunity in future studies.

Finally, the country's coordination and response to Covid-19 mechanisms presented challenges for this research. Seven of the original eleven research participants were temporarily

assigned duties at the ports of entry to assist with surveillance, including specimen collection, testing, and reporting. This temporary redeployment significantly slowed the progress of this research. I also had to do with the poor network at the field sites where individuals were working to hold the first virtual action cycle evaluation conference.

8.6 Conclusions

I raised this thesis on a foundation challenging a wicked laboratory quality problem in a Southeast Asian country. Together with my work colleagues, we not only subsequently built an evidence-based quality framework but also institutional social mechanisms functioning on incremental approaches to reach laboratory quality solutions. Although the framework differs from the prevailing frameworks traditionally relied on by laboratories for quality improvement, it does incorporate the social and technical aspects, thus building synergy for quality improvement. The emergence of this framework is in no way a pointer to an abandonment of checklist-based frameworks but a starting point for a comparative and pragmatic laboratory assessment tool that applies the laboratory's dynamic and unique data for systems quality improvement. The action researchers prioritized actions designed to enhance process control analytical quality and patient health outcomes with active cohesive actor involvement. These are equally critical ingredients at all stages of quality improvement implementation and work simultaneously in an orchestra. The data also demonstrate that successful quality improvement routinely demands the deployment of innovative strategies and unconventional thinking around fundamental questions and ensuing actions. At the forefront is the value of free reign of participants, who collaboratively contributed significantly to achievements in quality improvement and organization-wide learning through emerging spaces for collaborative inquiry. In doing so, the participants exercise power and authority in co-crafting the study design. For instance, participants chose participatory approach, and the pace of this research, enriching reflexivity and praxis. However, given the storms of COVID-19 and varying depths of commitment, three participants only managed to complete the first action cycle. Further, I have argued for moral cognition contextual considerations in support of internal legitimacy. These elements combined

with external institutional pressures could enrich laboratory practice to attain compliance and even transcend regulatory demands, emphasizing the effectiveness of the institutional theory.

This research, thus, advocates for a paradigmatic shift in the thinking management of healthcare laboratories from rational systems to open systems, with flexibilities characterized by robust evidence-based quality structures. Laboratory quality evaluation, thus, links the structures, process, and outcomes. Consequently, the laboratory can incorporate a biological model where structures and actors function simultaneously, paying allegiance to emergence due to collective agential actions and personnel interactions with the laboratory structure. The goal is to ensure the laboratory personnel grows into a culture that appreciates evidence and courts cross-cutting themes. This research adds to the growing call on evidence-based learning for organizational growth. In sum, the changes the NPHL experienced understood in the auspices and frames of neoliberalism influenced organizational reforms, applicable beyond the laboratory, extending to the health systems into the emergence of new governance structures. The workforce symbolically respects rules but relies upon them less. From a wider perspective, this research has produced a laboratory systems renewal in pursuit of TQM. Overall, this thesis contributes to the Giddens-agency structure theory (Giddens, 1991) by combining organization structure with practitioner cognitions, interactions, and actions, resulting in consequences that transform the QI structure presently and in the future. The symbiotic relationship between structure and agency is evidenced by practitioner entrepreneurial competencies that permit the emergence of COPs, steering committees, and value-laden partnerships that generate structuralism of a new quality system.

Before the final conclusion of this work, I proceed to reflect on the DBA research journey, enumerating the fruits of the DBA vine and the weeds, remaining authentic while taking the experiences with pride and acknowledging my failures.

8.7 Reflections, development and learning in scholarship and practice

The reflections are products of what I captured in my research / reflective journal throughout the period of data collection. It is easy to identify an organizational problem superficially and formulate a simple solution. On the contrary, conceptualizing, designing, and

conducting a study that simultaneously addresses research objectives and organizational challenges require pragmatism and curiosity. These are rare but core competencies and skills in qualitative research, in addition to formulating and evaluating ideas to strengthen discourse (e.g., language, cognitions, and place of emotions) in TQM research. As a researcher these competencies enabled me to recognize the best time to intervene, asking questions or seeking clarification. Examples of reflexivity consisted of recognizing in the participant utterances a dialogue (meaningful engagement) or just monologue (delineating contrary interests), stimulating thoughts to strategize for an inclusive discussion. I also distilled the intention of the addresser against my personal biases and group behavior. Similarly, I consistently evaluated informational content to adjust, discover meanings or re-check data. I did these things to assist in self-examination, awareness, critical thinking, and my own growth. This study did not follow the plan I envisaged, and I attributed this to participants traits, reflecting and acting as “free molecules, able to react with one another” altering research dynamics. However, given the interactions employing critical reflexivity, as collaborators, we improved on what we had each time. I found the process both reflexive and recursive, and even though we made certain decisions at different points during the research, we revised them whenever we had new insights. The processes we undertook revealed the nature of integration and circularity of action research. Adopting these changes was not easy either, but it was a way to keep referring to the methodology to check for research quality indicators (reliability, confirmability, transferability, dependability and credibility) (Guba, 1988). The steps assisted in keeping us on a tempo of pragmatic curiosity. At the initial stage of this research, I thought the problem lay in the unmet stakeholder needs, which researchers could identify and take corrective measures through action plans. I also thought the participants could stay tuned to the boundaries of research. Transformation, however, is credited to the power of entrepreneurship of hot groups/ TAGs as they integrated data and inquiry into their work, checked for contextual fit, and gained knowledge in the process. The other participant attributes to my surprise was that the epitome of transformation is their ability to build networks, reflect on the action, and take responsibility.

I learned lessons in the process of conducting this research. Interestingly, I collaborated with participants with treasures of knowledge and experiences who reigned free from rules and

assumptions. Given these attributes, participants recognized neither the boundaries of research methodology nor the paradigmatic viewpoints. In response to these attributes, I did not consider these research limitations but opportunities to share their understanding and lived experiences. I had spent nine years with these participants working on various laboratory-based work, but the DBA project engagement and plans led to a new dimension in understanding their personalities. This eventually assisted in my understanding of change in mindsets and future quality improvement ownership. In the next section, I elaborate the utility of collaboration in opening research democratic space and show how it facilitated this research. I spent seven of these years as an objective advisor, offering business solutions and recommendations, defending every achievement, and maintaining a passive relationship with the laboratory staff. The difference is that in the later years, I stayed consultancy but took the hat of an insider researcher, jointly identifying the laboratory's wicked problems and dilemmas (Fitzgerald et al., 2013).

I began this thesis project by conceptualizing what the problem at NPHL was. At that time, I thought that after inviting and enrolling colleagues as participants in the study, I could take a back seat and allow the research to continue on an auto-pilot mechanism. I equally thought of the need to maintain minimal influence, and indeed, I strived to keep this strategy. Nevertheless, I soon realized I took the role of co-coordinator, alternative moderator, and collaborator having to “walk the talk” through the research journey with the participants, as I was one of them. I also ‘wore the shoes of a data collector’ and an insider critical “friend” since this research was part of my DBA program. In the entire research process, however, I was keen not to impose my views on the participants. My eminent involvement was evident immediately after I presented the May 2019 quality audit report (cf. chapter three, pp.) and persisted during the PAR cycles, where I propped the growth of ideas on context-rich laboratory practice. The roles I played were novel, given that the literature search did not provide an iota of understanding of how best I could confront the awaiting challenges in my position. Similarly, my colleagues facilitating the research at various stages did so based on emergence. Even as thematic action groups (TAGs) emerged through self-appointment (by the voluntary choice of interest and association), I remained a full member, often taking an observer space but asking questions when there was an opportunity and need to do so.

Each TAGs coordinator or facilitator organized meetings at their convenience, took responsibility for the data, and freed the other spaces to be taken over by the rest of the participants. Since the research looked at existing laboratory professional practices, it took courage for the participants to agree to be partakers. They had to learn to open up and accept vulnerabilities as the research provided avenues for feedback. Occasionally there were bits of discomfort, as being critical to colleagues with whom one works every day had the potential to change perceptions and invite risks and vulnerabilities to criticism. The other annoying experience was that the participants functioned as though they were magnifying lenses on the vulnerabilities. These potential challenges notwithstanding, the dialogic space and trial of agreed actions, the outcomes notwithstanding, permitted participants to stay innovative. The participants in the PAR cycle prepared the materials and laboratory procedures and allowed dialogue as part of the review and through a longitudinal test in the real world of practice. A participant led and occasionally stepped back to allow others to lead without formal authority (Gottwald, 2008). In sum, we found balance in our interactions and used the opportunity to extend communication action (Carvalho, 2017). As noble and meaningful the research process proved to be, the dark side of doing research arrived. The work almost stalled, suffering a setback going by the degree of progress I made in previously. I can only phrase the challenge as “Expat dilemma and unforeseen Covid-19 pandemic casting a doubt on success of health-based action research”. The scope of this thesis does not allow me to express this in detail.

SARS-CoV-2/COVID-19 came with austerity measures with unprecedented impact on myriad of studies worldwide (Weiner et al., 2020) where the NPHL had to redirect its resources amidst reduced donor funding. From healthcare sustainability lens, COVID-19 highlight vulnerability laboratory, already significantly underfunded, and in dire need of a strong financing policy. My position as a consultant and advisor to the NPHL executive became untenable due to these changes. I, therefore, had to face reality, shrug off the tempting coat of an escapist, and accept that it was time to pack my bags and leave for my country, Kenya. My role and engagement mode changed to the technical advisor working on viral Hepatitis, Hepatitis B, and Influenza. I stayed remote, with synchronized weekly or bi-weekly video conferences with the laboratory team, providing inputs towards laboratory progress and drafting the reports. These

changes came after I had done the groundwork for the DBA, but I had to change the design into virtual action research (Stowell and Cooray, 2016) to adapt to the changes. These changes necessitated a revision of ethics application and subsequent approval from the University of Liverpool Ethics Committee. In sum, my decision to reflectively journal the trail of activities (Ruiz-Lopez, 2015), and researchers' efforts stayed is one of the best decisions I made in the DBA journey, the vehicle through which I realized the thesis.

It is the grasp of the challenges of doing action research that I found the precursors of my learning and research anchorage. First, the emerging discourse structure in the DBA project presented a web of quality arguments that were difficult to assume as the counterarguments ensued. I found that collaborative inquiry practices advance peer learning within a social structure afforded by the communities of practice (COPs) we had in the project. Secondly, the collaborative dialogues assisted my attainment of interactional competence and rediscovering personal and professional identity through understanding of present-day practices. Perhaps this could be judged by my ability to use intersubjective language and communal resources mutually constructed across the laboratory. These resources emerged as a constellation and a trajectory of cultural and institutional scripts aiding the apprenticeship of new laboratory employees and engagements during in-house training. The peak of professional development is, therefore, in acquiring an instrument adaptable to sustainable quality improvement arising from a help-seeking transformation process. Lastly, my awareness of the benefits of professional identity-transformation may enhance my future engagement beyond the existing consultancy. This is hinged on my ability to guide manage team social relationships, reflections, concurrent moral leadership, support growth of communities of practice and skilled mentorship. These elements form the most tangible benefits of my professional persona in the DBA journey.

8.7.1 What went well

At a personal and professional level, I have grown significantly, and I can ascribe most of these developments to the challenges of doing action research. This research has been acknowledged in other forums, especially given that our laboratory is a referral facility. I have since received invitations to make presentations in lower-level facilities at the district level, given

that I have shared experiences with laboratory practitioners in the country. The shared experiences provided credibility for the research findings as participants related to the data.

Searching literature relevant to my area of research proved difficult, especially when the electronic search engines failed to return a reasonable number of articles for consideration given my search strategy. It requires a significant time investment to augment the traditional search approaches with other sources such as bibliography listings. I avoided an extremist interpretivist approach, rather choosing a subjective epistemology enabling me to reflect and generate multiple interpretations from the literature.

I liked the problematization process, and the emotions (bitterness) it raised when the audit report was presented. At that stage, I thought emotions might intrude on actions, but this only brought a sense of responsibility and rationality among the AR team. For instance,

“The truth is that workforce development isn’t prioritized, and career development pathways aren’t clear”. (Zeta)

“The quality issues in this laboratory transcend the areas pointed out by the audit. Secondly, the audit report only provided a superficial image of the laboratory quality issues, as there are problems whose depths need to be better understood to enable search for solutions”.

(Theta)

The bulk of data arising from the problematization process aided coding, with contextualized evaluation going into the detailed planning phase (action generation readiness). Similarly, emotions were the foundations upon which the team recognized the concerns/difficulties in QI and a basis for the urgency of actions.

This thesis development was opportunistic, intervening in the outcomes of an audit report at the NPHL. It was an opportunity for laboratory practitioners doubling as researcher subjects to identify problems as they occurred in real-time and reflect on their practices and situation to plan each intervention cyclically. As an insider, I was immersed in the work at the laboratory and had a fairly good pre-understanding of the context studied. However, I did not allow my pre-understanding to obscure my assumptions and biases, as I remained open to the

reframing of thinking structure and for my feelings to be probed as though I was an outsider (Coghlan and Casey, 2001). Again, staying open allowed me to understand the potential effects of pre-understanding the study. My bubble burst into the challenges of being an action researcher. I had to find out to combine the responsibilities of a consultant and an insider researcher and ensure the tactical coexistence of the roles. Besides the prior knowledge as an insider researcher, I navigated political dynamics, projecting how the DBA project would contribute to knowledge creation and creating new organizational capabilities (Coghlan, 2001; Greenwood and Levin, 2006). Nevertheless, I knew that for the project to succeed, I had to have constant and purpose-driven relationships with the AR team as an insider researcher. I documented my biases and assumptions vividly in the research design and discussed my flexibility.

Finally, the multi-method approach provided a robust platform for exploring the real world. The data collection started with FGDs, then augmented with ethnographic observations and evaluative surveys, enabling immersion into the laboratory's researched phenomena (McDonnell et al., 2017). The integrated study methods assisted the researchers to attain knowledge of what is at stake in a complex multi-layered laboratory social world. My reason for this approach was to allow participants to engage and bring their reflections on board.

8.7.2 What could be improved

This research faced difficulties given the austerities arising from COVID-19, resulting in a reduction in funding. The regular laboratory services comprising internal quality-driven approaches to generate evidence are under threat. However, researchers could navigate this by integrating applied research into routine laboratory practice, yielding evidence advocating for funding allocation. I am more than ready to take a leading role in an initiative that takes this approach.

I am an African male working in South-East Asia, and there are significant cultural differences between the participants and me. These differences create a distance between the researcher and the participants (Mays and Pope, 2000). Although my positioning as an insider - researcher helped develop skills among participants to be future researchers, I may have misinterpreted some of their culturally alienated statements, or they might have withheld some

information. However, during the FGDs, members checked each other's statements providing validity, and I also shared my interpretations with participants or asked additional questions to seek clarity. A prospective study relinquishing the role dichotomy and maintaining an outsider positionality could potentially bring new insights with closely related research, thus enriching our findings.

8.7.3 Generating actionable knowledge.

This research emerged from a slate of failure analysis supported by an audit report detailing quality drawbacks. Participants enthusiastically deconstructed failure, unpacking the dark corners of laboratory practice at the NPHL, against desires to meet regulatory standards requirements. In the process, the participants in their dynamics (in perspectives, backgrounds, expertise) engaged in a mixed-method data collection, thereby improving collective understanding, and discovering ways to solve the problem. This became possible due to research democratic space allowing rich dialogue for participants to confront failure, culminating in practice change and organizational transformation. This research, therefore, presents failure as an opportunity for participants to engage in innovative behaviors (Grama, 2016). Between the cycles, participants detect failure, embrace feedback, strategize, and prioritize responses, freely experimenting and learning from the process. Lastly, participants leap into the organizational future, placing uncertainty at the center of quality improvement to enable courting critical conversations and higher order thinking as a foundation for change.

From a researcher, position actionable knowledge is advanced under the participant diversities enabling social learning. The diversities are evident in participants co-create knowledge through participation, collaboration, and engagement. This result in multiple approaches, consensus, and ultimate decision-making. Researchers discovered the process and design gaps in the existing laboratory structure and actions that influence TQM. Knowledge and actions are co-constructed in a process that involves critical reflection by participants leading to triple-loop learning and enriching knowledge credibility (Wall et al., 2017). The continued involvement and engagement of participants give them a sense of satisfaction and legitimate

representation through planning, implementation, reflection, and evaluation such that the research findings are transferable for the benefit of the community (Lawson et al., 2017).

Reflecting on the research process and actionable knowledge generation, my experiences during the DBA journey provide that too much focus on knowledge co-production may create a lapse or burden to the research project due to the multiple stages involved. As there is the

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Appendices

Appendix 1: Supplementary Themes

	<i>Laboratory system area</i>	<i>Intermediate issue</i>	<i>Future desires</i>	<i>Thematic classifications for small group problematization</i>
Laboratory Quality System	Supply Chain	Irregularly supplied reagents/ consumables Stock management challenges Material safety not documented	Socio-environmental management	Regenerative supply chain
	Pathological Waste Management	No on-site incineration Autoclaves irregularly placed	Infection prevention and control (IPC)	
	Laboratory Administration	Inadequate leadership commitment No feedback utility Workforce	Workforce capacity building, career development, stewardship, commitment	Operational efficiency

		development laboratory Financing		
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Appendix 2: University of Liverpool Ethics Committee Approval Letter



Management School
Chatham Street,
Liverpool
L69 7ZH

Dear Benard Owino

I am pleased to inform you that the DBA Ethics Committee has approved your application for ethical approval for your study. Details and conditions of the approval can be found below:

Committee Name: DBA Ethics Committee

Title of Study: Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement approach

Student Investigator: Benard Owino

School/Institute: School of Management Approval

Date: 15th May 2020

The application was APPROVED subject to the following conditions:

1. The researchers must obtain ethical approval from a local research ethics committee if this is an international study
2. University of Liverpool approval is subject to compliance with all relevant national legislative requirements if this is an international study.
3. All serious adverse events must be reported to the Sub-Committee within 24 hours of their occurrence, via the Research Integrity and Governance Officer (ethics@liv.ac.uk)
4. If it is proposed to make an amendment to the research, you should notify the Committee of the amendment.

This approval applies to the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

Kind regards

A handwritten signature in blue ink, appearing to read "Sue Greener".

Dr Sue Greener

DBA Ethics Committee University of Liverpool On-line Programmes

Appendix 3: Institutional Support Letter



MINISTÉRIO DA
SAÚDE

LABORATÓRIO NACIONAL DE SAÚDE
(LNS)

Dili, 8th of April 2020
MS/LNS/DE/IV/2020/ 81

To The Chairperson
The Research Ethics Committee
University of Liverpool,
Foundation Building, Brownlow Hill,
Liverpool, L69 7ZX
United Kingdom

Ref: Institutional Support for Bernard Ouma Owino's Doctoral Research

This is to inform you that the above-mentioned individual has been a long-term consultant in the National Health Laboratory, Timor-Leste. As an institution, we are aware that he is also a student of the University of Liverpool. He has duly indicated intentions of undertaking a research titled: *"Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement approach"* as part of his doctoral studies.

On behalf of the National Health Laboratory, I would like to inform the committee that our institution is ready to grant him necessary enabling environment and related support during his research within the confines of research guidelines of the Instituto Nacional de Saude (INS), Democratic Republic of Timor-Leste.

Kind regards,

Endang Soares da Silva
Executive Director

National Health Laboratory Timor - Leste

Cc:
Executive Director, Instituto Nacional da Saude, RDTL
Director Gabinete Quality Control and Research, Ministry of Health, RDTL



Rua Belau Tolo Bata
Dhí Timór-Leste
Caixa Postal 574
Tel : (+670) 3330151

Appendix 4: Participant Consent Form



Participant consent form

Version number & date: V6-06022020

Research ethics approval number:

Title of the research project: *“Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement approach”*

Name of researcher(s): Benard Ouma Owino

Please initial box

1. I confirm that I have read and have understood the information sheet dated [--/--/----
(**dd/mm/yyyy**) for the above study, or it has been read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that taking part in the study **involves virtual conferences and email discussions** understand that my participation is voluntary and that I am free to stop taking part and can withdraw from the study at any time without giving any reason and without my rights being affected. In addition, I understand that I am free to decline to answer any particular question or questions.
3. I understand that I can ask for access to the information I provide and I can request the destruction of that information if I wish at any time prior to anonymization. I understand that following anonymization I will no longer be able to request access to or withdrawal of the information I provide.
4. I understand that the information I provide will be held securely and in line with data protection requirements at the University of Liverpool until it is fully anonymised and then deposited in the archive for sharing and use by other authorised researchers to support other research in the future.
5. I understand that signed consent forms questionnaires will be retained in secure electronic storage until 5 years.
6. I agree to take part in the above study.

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting:

Participant name

Date

Signature

Name of person taking consent

Date

Signature

Principal Investigator

Dr. Paul Elwood
University of Liverpool
Management School
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Student Investigator

Bernard Owino
Consultant
National Health Laboratory
+67077977808
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Appendix 5: Participant Information Sheet

#5



Participant Information Sheet

1. Title of Study

"Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement approach"

2. Version Number and Date

V6_06022019

3. Invitation Paragraph

I Benard Ouma Owino, a student of the University of Liverpool School of Management undertaking a degree of Doctor of Business Administration, also a researcher in the proposed study do invite you to participate in the study entitled *"Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement approach"*. This study builds on action research approach, whereby areas found deficient in the National Health Laboratory quality approaches are strengthened through actions that you and fellow participants will suggest in a Plan-Do-Study-Act Cycle. The research envisages that through your participation in the study, you will gain immense insights into good laboratory practices, enrich your knowledge in the field of laboratory and learn some new things in your field which may be beneficial to you at a personal level. You have been proposed by virtue of being a technical staff of the National Health Laboratory in **Microbiology and Immuno-serology department** and being knowledgeable of the laboratory practices forming the foundations of the NHL as an institution. Your participation is purely on voluntary basis as there are no direct financial benefits to you. It is envisaged that the study **will involve four bi-monthly virtual conferences and continuous thematic email discussions for a period of nine months**. Please note that the frequency and timing of thematic discussions may differ depending on time availability of a group or individuals.

You are invited to read the participant information provided here carefully and ask any questions prior to giving your consent to participation in the study or choosing not to participate. If you so agree to participation, kindly sign the attached consent form and return to the researcher as provided in the below contact details.

Benard Ouma Owino

Pathology and Clinical Microbiology Unit

National Health Laboratory

Rua Bidau Toko Baru

Dili, Timor-Leste

Email: benard.owino@online.liverpool.ac.uk

Appendix 6: Laboratory Quality Improvement Evaluation-Survey Questionnaire

Laboratory Quality Improvement Evaluation- Survey Questionnaire

Participant Study ID__

Instructions (Check an appropriate box and note your comments)

- (I) What were the problems identified in the problematization phase related to the current cycle?
.....
.....
.....

- (II) What were the planned actions?
Comments
.....
.....
.....

- (III) Do you consider the actions achieved, and, if so, list some of the outcomes? Yes No
Comments
.....
.....
.....

- (IV) Did these actions result in improvements in the laboratory? Yes No
Comments
.....
.....
.....

- (V) (In your opinion) Were there additional gaps or problems identified during the action implementation by the thematic action groups (TAGs), and, if so, what are the planned modifications? (Only relevant post cycle one) Yes No
Comments
.....
.....
.....

- (VI) Any suggestions on action priorities, (to inform next cycle) Yes No
Comments
.....
.....
.....