2022

Attitudes of State Public Health Laboratory Directors Towards ISO/IEC 17025 Accreditation

Christine Kilonzo
Walden University

Walden University

College of Health Professions

This is to certify that the doctoral dissertation by

Christine Kilonzo

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Raymond Panas, Committee Chairperson, Public Health Faculty
Dr. Zin Htway, Committee Member, Public Health Faculty
Dr. Thomas O'Grady, University Reviewer, Public Health Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2022

Abstract

Attitudes of State Public Health Laboratory Directors Towards ISO/IEC 17025 Accreditation

by

Christine Kilonzo

MS, University of Maryland, Baltimore County, 2010

BS, Sonoma State University, 2006

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

PhD Public Health – Epidemiology

Walden University

May 2022

Abstract

The impact of ISO/IEC 17025 accreditation in state public health laboratories (SPHLs) is understudied. There is a scarcity of research on SPHLs involving behavioral intent regarding ISO/IEC 17025 accreditation. The theory of planned behavior (TPB) was utilized to evaluate SPHL directors' attitudes towards and intent to seek or maintain ISO/IEC 17025 accreditation. To test the questions of whether the three constructs of the TPB, attitude, subjective norms and perceived behavioral control are significant predictors of intent to seek or maintain ISO/IEC 17025 accreditation, and whether there are significant differences in these constructs towards the accreditation between SPHL directors based on accreditation status, an online survey was distributed to SPHL directors across the United States. Responses were analyzed using simple linear regression and multiple linear regression (n=37) and, Multivariate Analysis of Variance (MANOVA) and Analysis of Variance (ANOVA) (n=36). Results showed that there are significant differences between SPHL directors based on their accreditation status which is supported by the three constructs of TPB. These findings suggest that TPB constructs can play a positive and significant role in terms of SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation, and SPHL directors who are involved in the accreditation have a favorable attitude toward it.

Attitudes of State Public Health Laboratory Directors Towards ISO/IEC 17025 Accreditation

by

Christine Kilonzo

MS, University of Maryland, Baltimore County, 2010

BS, Sonoma State University, 2006

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

PhD Public Health – Epidemiology

Walden University

May 2022

Dedication

I am dedicating this dissertation first and foremost to God almighty, without whom, none of this would have been possible and second, to my family. To my husband, Nabi, the love of my life, I cannot begin to express how grateful I am for your unwavering support, encouragement, and resilience throughout this process and so much more. I truly am in awe of your strength. You are my hero and I pray that I can be as much an inspiration to you as you are to me. To my sweet, amazing, brilliant children – Ibrahim, Noah, and Inara, words cannot express my gratitude to you. Thank you for cheering me on and for telling me it was okay to steal from your time on so many occasions. I love you all so very much and pray that this accomplishment inspires you all to strive for the very best in all that you do, and mostly that God bless us, your parents, to be able to provide you with all you need to succeed and accomplish your dreams.

Acknowledgments

I would like to acknowledge and express my deepest appreciation to my committee members, Dr Raymond Panas, Dr Zin Htway and Dr. Thomas O'Grady for their guidance, support, and encouragement throughout the process. I would also like to give a heartfelt thank you to Dr. David O. Anderson and Dr. Frederic J. Grant for their support during their roles as committee members earlier in my dissertation journey. Thank you to all participants who were gracious enough to take part in the study and made this research possible, I am deeply indebted to you.

I give a heartfelt thank you to my family: To dad, this accomplishment was inspired by you and I hope that it has made you proud. I miss you so much and would have loved for you to be here to see this. Keep resting in peace, till we meet again. To mom, I love you so much and I thank you for all the sacrifices you made in laying the foundation for me to get here, and for all the encouragement over the years. To my one and only sister, Mbithe, I love you and thank you for your support and sacrifices you made throughout my undergraduate years and for the encouragement through my doctoral journey. To Mbithi, I love you and miss you so very much. You were a part of the foundation that build me to who I am today and I thank you for that; keep resting in peace, till we meet again. To Chris and Kevin, thank you both for your encouragement throughout the years. And to all my friends and family, thank you for your support and encouragement, I'm forever grateful.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Introduction

State public health laboratories (SPHLs) are government not-for-profit entities whose mission is to uphold public health and safety across the United States (US) through laboratory analyses (Charlton et al., 2021). All 50 states, the District of Columbia, and the five major US territories have a central public health laboratory that performs laboratory services for their respective populations (Association of Public Health Laboratories [APHL], n.d.). SPHLs' mission entails capabilities beyond laboratory analysis that extend to communicating critical data to other public health agencies including epidemiologists and emergency preparedness and response groups (Centers for Disease Control and Prevention [CDC], 2014). Well known instances of SPHL involvement in identifying, diagnosing, and evaluating community health hazards include prevention and control of vector borne diseases such as the West Nile virus, and food and water borne outbreaks such as salmonella infections, and environmental testing including lead poisoning (Becker & Perlman, 2011). Therefore, it is imperative that SPHLs embed quality in their daily operations to support their ongoing mission to improve the health of communities they serve. To ensure that this quality is upheld, SPHLs in the US are overseen by both state and federal government systems. that specify quality standards that SPHLs should meet (APHL & CDC, 2014).

SPHLs abide by mandated national regulations governing public health safety requirements for tests they perform pertaining to environment, safety, and health. Examples of specific regulations include the Safe Drinking Water Act (SDWA), Food

Safety Modernization Act (FSMA), and Clinical Laboratory Improvement Act (CLIA). Meeting and maintaining these regulations ensures that SPHLs are in compliance with testing, safety, and quality requirements necessary to maintain public health. However, other quality improvement (QI) measures (i.e., systematic and continuous steps that result in measurable improvement) developed by non-governmental organizations such as the International Organization for Standardization (ISO) can be implemented by SPHLs.

Based in Geneva, Switzerland, the ISO is an independent nongovernmental organization with a global membership of 165 national standard bodies (ISO, 2019). The ISO develops international standards that have applications across multiple disciplines ranging from food safety and energy management to trade and manufacturing (ISO, 2019). To ensure that they are developing comprehensive international standards, the ISO collaborates with the International Electrotechnical Commission (IEC), a global not-for-profit organization that oversees four global Conformity Assessment (CA) systems. IEC CA systems provide a platform to support any activities such as effectiveness, safety, performance, and durability used to determinate whether parameters within the scope of an international standard are satisfactory.

The ISO and IEC through a collaborative effort develop and publish international standard series such as the ISO/IEC 17000 standard series. These international standard series specify how assessment bodies, which audit and provide certification of management systems, should perform a conformity assessment procedure to ensure specific standard requirements are being met. Within SPHLs, an ISO/IEC standard that has gained recognition is the ISO/IEC 17025.

The ISO (2017) defined ISO/IEC 17025 as an international quality standard that specifies general requirements for competence of testing, sampling, or calibration laboratories, which can be obtained by any laboratory performing these activities, including government, industry, and educational institutions regardless of the number of employees or scope of accreditation (i.e. number of tests within the laboratory that are accredited to the standard). According to the ISO, testing and calibration laboratories across the globe, which are accredited to the ISO/IEC 17025 standard, are reputed within the laboratory industry for being able to demonstrate technical competency and capacity to deliver reliable data. Regulatory and safety conformance is not a requirement of ISO/IEC 17025 accreditation, and as such, laboratories should pursue these through other means (ISO, n.d.-b).

Available literature suggest that ISO/IEC 17025 accreditation carries with it a promise to revolutionize laboratory processes through standardized procedures and quality improvement. SPHLs recognizing the need for high-quality performance, improved service delivery, workforce development, and better stakeholder satisfaction have been steadily implementing ISO/IEC 17025 accreditation. However, evidence-based data supporting purported benefits of ISO/IEC 17025 accreditation in SPHLs are lacking.

One of the critical factors in terms of implementing accreditation in healthcare settings is staff members' attitudes towards the program (Birken et al., 2012; Ellis et al., 2020; Pomey et al., 2010). Examining perspectives of SPHL directors towards ISO/IEC 17025 accreditation has the potential to provide crucial information in terms of the program's impact and need for modification. This information would be especially useful

to SPHLs which are already under budget constraints as it would offer clarity in terms of on whether accreditation is warranted. Furthermore, quality of services provided by SPHLs have the potential to greatly impact public health. Moreover, this evaluation would also contribute to evidence-based justification of SPHL engagement with ISO/IEC 17025 accreditation, thus providing a scientific rationale for decision-making regarding quality in SPHLs. This research may lead to social change by inspiring SPHL leaders to implement and promote quality-driven and effective programs that would ultimately improve the overall public health system.

Background

SPHLs are a collection of government public health, environmental, and agricultural laboratories, all of which are a crucial part of the US public health system. Functions carried out in SPHLs vary greatly due to differences in terms of scope of operations, size, resources, funding, and organizational structure (Inhorn et al., 2006). However, SPHLs main objective is protecting human populations from a multitude of adverse health outcomes, including foodborne illnesses, infectious diseases, environmental hazards, and public health emergencies (Desalegn et al., 2016; Kaml et al., 2014; Ned-Sykes et al., 2015; Whelen et al., 2013).

The ability to rapidly respond to public health threats such as disease outbreaks and bioterrorism, engage in population-based research and assessment such as bio surveillance, inform public health policies by providing the health status of a community, and support public health programs, further defines the role of the SPHL (CDC, 2014). Additionally, modern advances in molecular sciences, analytical chemistry, and

technology have progressed SPHLs' investigative competency, further emphasizing their importance to epidemiological research (Dowdle et al., 2011).

It has previously been noted that a large percentage (60% to 70%) of clinical decisions are derived from laboratory results (Alers, 2016). Data from public health laboratories are used to inform vital elements of population health including bio-monitoring efforts to assess human exposure to environmental pollutants, and epidemiological emergencies such as disease outbreaks (Abat et al., 2015; Birkhead et al., 2015; Gaines, 2015; Jang et al., 2017; Nsubuga et al., 2006; Smith et al., 2013). The importance of laboratory data integrity is further highlighted by the potential of SPHL data to potential to invoke regulatory authority, for example in the recall of consumer products or implementing quarantine measures (Institute of Medicine, 2000; Randolph et al., 2019).

Additionally, it has been noted that data collected for biomonitoring purposes can be valuable for instituting at-risk baselines for example, defining a known level of environmental exposure beyond which would be considered a population hazard, promoting epidemiological research on health effects, and risk evaluation and management (Aldous et al., 2012; Association of State and Territorial Health Officials [ASTHO] & APHL, n.d.). It is therefore imperative that any testing undertaken within SPHLs be accurate and reliable, allowing stakeholders such as epidemiologists and regulatory bodies to confidently rely on this data to inform policy (Chen et al., 2014).

To ensure quality data, SPHLs seek to implement quality measures such as accreditation despite limited evidence regarding its impact on laboratory quality

outcomes. Braithwaite et al. (2011) defined accreditation as an organizational improvement technique dependent upon on a certifying agency assessing performance against established standards. Karthiyayini and Rajendran (2017) further explained that the main goal of laboratory accreditation is to guarantee quality and competence. One such type of accreditation targeted to laboratories is ISO/IEC 17025 accreditation.

ISO/IEC 17025 is an accrediting standard formed by the ISO, an independent 165-member nongovernmental organization, which acts as a guide for general requirements for the competence of testing and calibration laboratories worldwide (ISO, 2019). In 2005, quality standards ISO 9001 and ISO GUIDE 25 were merged to form the ISO/IEC 17025 standard, which aims to engage collaboration between laboratories and other bodies such as APHL and Laboratory Response Network (LRN) via harmonization of laboratory standards and processes such as the ISO/IEC 17025 and data documentation, respectively (Karthiyayini & Rajendran, 2017). The standard was later revised in 2017 to align with evolving market and technology conditions including technical changes, vocabulary, and information technology innovations such as advances in testing techniques, term and acronym use , and simplified data processing, respectively (ISO, n.d.-a). The ability to have a universal standard for SPHL operations offers a potential promise to SPHLs for national and international recognition as competent, quality driven laboratories with valid results more readily accepted by stakeholders including regulatory bodies (ISO, 2017).

In the US, SPHL accreditation to ISO/IEC 17025 has been facilitated mainly through support from federally funded cooperative agreements (US federal government

accreditation financial assistance to SPHL) with the FDA which began in 2012; however, there are SPHLs that have funded their accreditation outside of these agreements. For example, the APHL noted that in 2017 they were able to offer assistance such as training to 10 unfunded laboratories including some SPHLs (APHL, 2016; 2017). The FDA's ability to fund SPHLs is a result of the FSMA that campaigns for a proactive rather than reactive strategy to food contamination. To support this strategy, FSMA required the formation of an Integrated Food Safety System (IFSS), a symbiotic system between federal, state, and local government agencies aimed at protecting public health.

Within the IFSS is Manufactured Food Regulatory Program Standards (MFRPS) for regulatory agencies overseeing food manufacturing plants. Since 2012, there have been multiple cooperative agreements, and according to the FDA (2020), in fiscal year 2020, there were 33 state laboratories awarded financial assistance to apply for ISO/IEC 17025 accreditation.

Cooperative funding agreements supported by the FDA are not indefinite; therefore, SPHLs relying on this financial assistance to sustain ISO/IEC 17025 accreditation in their laboratories are expected to financially support themselves unless the funding is renewed (Becker, 2017). Additionally, the ISO/IEC 17025 scope of accreditation covered by the cooperative agreements is for microbiological and chemical food analyses. By virtue of the ISO/IEC 17025 accreditation, data from these food analyses is competently derived and results are reliable and valid (ISO, 2019). However, other laboratory operations not covered in the scope of the ISO/IEC 17025 accreditation within these labs are still ongoing and producing data for public health use (APHL,

2019). Furthermore, not all SPHLs have been accredited to ISO/IEC 17025 accreditation and continue to operate and generate data pertinent to the health of their communities (APHL, 2019). This ability to continue operations despite not being ISO/IEC 17025 accredited is possible because of other laboratory quality programs such as the CLIA.

Furthermore, efforts are being made to make ISO/IEC 17025-like standards, which do not imply accreditation, available to these laboratories (APHL, 2019). One such measure to encourage processes that enhance data acceptability from such non-ISO accredited laboratories, is a white paper on best practices for submission of actionable human and animal food testing data generated in state and local laboratories that was released by the APHL (APHL, 2019).

In summary, a literature review of ISO/IEC 17025 accreditation shows that it is judged by many authorities to be an essential international reference standard for testing and calibration laboratories seeking to show their capability to deliver reliable data (Department of Health and Human Services, 2017; ISO, 2017; Randolph et al., 2019). However, evidence-based research regarding benefits of implementing ISO/IEC 17025 accreditation is lacking. Studying employee attitudes may facilitate understanding the effectiveness of accreditation (Ehlers et al., 2017). Therefore, to help understand the effectiveness of ISO/IEC 17025 accreditation in SPHLs, I aimed to evaluate the perspectives of SPHL directors towards ISO/IEC 17025 accreditation.

Problem Statement

SPHLs aim to use the core public health functions of assessment, assurance, and policy development with the ultimate focus of promoting health of the populations they

serve. As such, laboratory testing, being an integral part of the public health framework, should have reliable and actionable test results, and thus should conform to public health practitioner's commitment to high quality public health standards (Boulton et al., 2013; Peter et al., 2010).

Although multiple SPHLs have undergone or are considering ISO/IEC 17025 accreditation, there is limited research on its impact, and consequently, no concrete evidence that it ensures integrity, accuracy, and overall quality of services they provide (APHL, 2011; ASTHO & APHL, n.d.). Given this lack of evidence, further research regarding the impact of ISO/IEC 17025 accreditation in SPHLs is needed. SPHL directors are strategically placed in the operational hierarchy of the state laboratory, making them an ideal source of information on the intricacies of ISO/IEC 17025 accreditation in these laboratories and, the target population for this study.

Purpose

The purpose of this quantitative cross sectional survey study was to use the TPB as a guide to evaluate the perspectives of SPHL directors towards ISO/IEC 17025 accreditation. The TPB was developed by Icek Ajzen in 1985 and is an extension of the theory of reasoned action (TRA) developed in 1975 by Martin Fishbein and Icek Ajzen. Ajzen extended the TRA to provide a more holistic predictor of intention by accounting for behaviors that individuals have no control over; he achieved this in the TPB by adding to the TRA the construct of perceived behavioral control.

The central premise of the TPB is that behavioral intention to engage in a behavior is influenced by three core constructs: attitude, subjective norms, and perceived

behavioral control. Overall, the constructs allude to one's favorable or unfavorable evaluation of a behavior (attitude), the perceived social pressure to engage or not engage in the behavior (subjective norms) and one's perception of the ease or difficulty of engaging in the behavior (perceived behavioral control).

Drawing from the TPB, I evaluated the interaction of SPHL directors' attitudes, subjective norms and perceived behavioral control on intent to seek or maintain ISO/IEC 17025 accreditation. In the context of this study, seeking ISO/IEC 17025 accreditation relates to SPHLs that are actively applying for initial accreditation or expanding the scope of their accreditation to include processes not previously covered, while maintaining ISO/IEC 17025 accreditation relates to SPHLs that plan on renewing their accreditation coverage after its expiration period. Survey questions based on a study by Buhmann and Brønn (2018) were adapted for this study (see 0) . The study by Buhmann and Brønn (2018) used the TPB to predict practitioners' intentions to involve in a practice central to accountability of communication departments.

Research Questions and Hypotheses

In this study, the research questions guided by the TPB will assess SPHL director's attitudes, subjective norms, and perceived behavioral control towards behavioral intent concerning ISO/IEC 17025 accreditation. An analysis to determine whether there are significant differences between the mean scores of SPHL director attitudes, subjective norms and perceived behavioral control based on accreditation status will also be performed.

According to the TPB, more favorable views towards the three constructs tend to

result in a stronger tendency towards the behavioral intent. For example, within the framework of this study, SPHL directors are more willing to seek or maintain ISO/IEC 17025 accreditation if they have a positive attitude towards it and believe that the accreditation would promote quality driven practices and improve processes and procedures in their laboratories.

With regards to subjective norms, acquiescing with perceptions of those whose opinions they value would increase chances that SPHL directors would seek or maintain ISO/IEC 17025 accreditation, e.g., federal government collaborators and other SPHL directors encouraging them to implement ISO/IEC accreditation in their laboratories. As for perceived behavioral control, a greater confidence in their abilities and access to resources needed for seeking or maintaining ISO/IEC 17025 accreditation signals a greater perceived control and would most likely positively impact SPHL directors' intent towards ISO/IEC 17025 accreditation. Building from these TPB led expectations, the research questions (RQ) and corresponding null (H_0) and alternate (H_a) hypotheses are:

RQ1: Are SPHL directors' attitudes towards ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

$H_0$1: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

H_a1: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

RQ2: Are SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this

accreditation?

$H_0$2: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are not a significant predictor of intention to seek or maintain this accreditation.

H_a2: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are a significant predictor of intention to seek or maintain this accreditation.

RQ3: Are SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

$H_0$3: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

H_a3: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

RQ4: Are there significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories?

$H_0$4: There are no significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories.

H_a4: There are significant differences in the attitudes, subjective norms, and

perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories.

Theoretical Framework

The central role that SPHLs play in upholding public safety through testing and evaluation makes it evident that they play an important part in community disease epidemiology. The adoption of activities and methods by SPHLs (i.e., QI measures) aimed at improving the quality of work they perform should therefore be closely evaluated. QI measures can take different forms, including educational programs, policies, accreditations, and certificates (*Quality Improvement in Public Health: It Works! [Brochure]*, n.d.). Adoption of any QI measure is expected to invoke a behavioral change in recipients towards the measure's target outcomes.

As a QI measure, the ISO/IEC 17025 accreditation can be viewed as an intervention designed to improve laboratory procedures and processes through employee commitment to the changes prescribed by it (Randolph et al., 2019). As such, the TPB can be used to evaluate behavioral changes arising from how SPHL employees adapt to the ISO/IEC 17025 standard. As employees in SPHLs, SPHL directors have been identified as critical to laboratories' willingness to embrace change (U.S. Department of Health and Human Services Health Resources and Services Administration [HRSA], 2011).

Leadership's stance on QI measures trickles down to other employees and determines the success of these QI activities in their laboratories. This ultimately impacts work done in the laboratory and by extension the communities they serve. I used the TPB

to evaluate factors that contribute to SPHL directors' intention to seek and/or maintain ISO/IEC 17025 accreditation. Using the TPB to research SPHLs directors' behavioral intent towards ISO/IEC 17025 accreditation will offer insight into the status of this accreditation in SPHLs and the impact it has had on them.

The TPB is based on three constructs: attitude, subjective norms, and perceived behavioral control (Ajzen, 1991; Rimer & Glanz, 2005). The TPB posits that these three constructs influence behavioral intention (Ajzen, 1991). Azjen (1991) described attitude towards a behavior as an individual's favorable or unfavorable assessment of the behavior, subjective norm as the individual's perceived social pressure in terms of whether to perform the behavior, and perceived behavioral control as the individuals perceived level of effort when performing the behavior.

According to the TPB, the three constructs- attitude, subjective norms and perceived behavioral control, work in tandem to form a behavioral intention (Ajzen, 2011b). Behavioral intent relates to an individual's intention to engage in a particular behavior, and in this study, intention relates to seeking and/or maintaining ISO/IEC 17025 accreditation. By leveraging the TPB as the theoretical framework for this study, it was possible to elucidate some of the factors that influence SPHL directors' behavioral intentions to engage in ISO/IEC 17025 accreditation. Specifically, the theory aided in identifying the factors SPHL directors encounter that impede or facilitate seeking or maintaining ISO/IEC 17025 accreditation, as well as how they perceive or value it. Applying the TPB in this manner also showed support for the adequacy of TPB in predicting and understanding SPHL directors' intention towards quality measures.

A more detailed discussion of the theory as it relates to this study is presented in Chapter 2.

Nature of the Study

I used the positivist approach to answer the research questions. The positivist approach is a strategy of inquiry associated with quantitative research where the researcher seeks to study causes that inspire outcomes by developing numeric measures of observations and examining people's behavior (Park et al., 2020). According to Creswell (2014), quantitative research involves gathering data so that information can be quantified and used in statistical tests.

In this study, I sought to evaluate the influence of the independent variables of attitude, subjective norms, and perceived behavioral control on intention to seek or maintain ISO/IEC 17025 accreditation, which is the dependent variable. To evaluate the relationship between these variables, a descriptive cross-sectional survey design was used. Cross-sectional studies involve using data from either the entire population or a sample of it to help answer research questions by measuring outcomes at the same point in time (Setia, 2016).

Mertler (2018) further noted that cross-sectional study design are is suited to evaluating the prevalence of a phenomenon, problem, situation, or attitude by addressing a cross section of a population. As such, the descriptive cross-sectional survey was best to address the present research questions as they seek to determine outcomes based on attitude.

Definition of Terms

Accreditation: Accreditation is a system by which an organization is periodically reviewed by a third party accrediting agency through a performance assessment weighed against pre-established standards (Karthiyayini & Rajendran, 2017).

Laboratory quality: Based upon international standard, accuracy of laboratory results coupled with reliable laboratory operations and timely data reporting to guarantee useful information in a public health setting (World Health Organization, 2011).

SPHLs: Government public health, environmental, and agricultural laboratories that focus on diseases and the health status of population groups and perform limited diagnostic and reference testing, disease surveillance, emergency response support, applied research, and training for laboratory personnel (CDC, 2014).

SPHL director: A person responsible for the overall operation and administration of SPHLs, including personnel, performance, finances and quality assurance (Office of the Federal Register, National Archives and Records Administration, 2011).

Assumptions

Study assumptions are underlying truths or beliefs beyond the researcher's control that they declare for their study (Tavakol & Sandars, 2014). In this study, I made assumptions on different elements of the study including the theoretical framework, the methodology, and the study participants. The study was built upon the theoretical framework of the TPB which stipulates that the constructs of attitude, subjective norms, and perceived behavioral control are directly related to intention to perform a behavior (Ajzen, 2011a). Extrapolating from the TPB, I assumed that SPHL director's attitudes, subjective norms, and perceived behavioral controls affect their intentions to seek or

maintain ISO/IEC 17025 accreditation.

As relates to the methodology, I assumed that the quantitative cross-sectional survey design methodology would adequately address the research questions. Cross-sectional study designs are suited to evaluating the prevalence of a phenomenon, problem, situation, or attitude by taking a cross-section of a population (Mertler, 2018).

I assumed public contact information was up to date and was a direct line of contact to them. I also assumed that participant responses were honest, accurate, and unbiased. Furthermore, I assumed that respondents were qualified and had the skills and knowledge to answer the survey questions.

Scope and Delimitations

Delimitations are study constraints which are defined by the researcher define a study's bounds; they are informed by the research questions (Newman et al., 2015; Theofanidis & Fountouki, 2019). This study was limited in scope to SPHLs across the US and only focused on laboratory directors. Other employees who work within these laboratories were not included in the study and neither were persons who work in other public health departments

Limitations

Study limitations are weaknesses or shortcomings which could be a result of factors including inadequate sample size, research design, and lack of resources that are outside of the researcher's control that may influence results of the research (Ross & Bibler Zaidi, 2019). There were several limitations to this study that revolved around the phenomenon under study, participants, the study methodology, and the data collection

instrument. I relied on the general public health practice, e.g., public health departments and hospitals to gain context and support data trends relating to public health accreditation due to limited information on employee attitudes towards accreditation in SPHLs.

The study was limited to laboratory directors whose role and interactions with the ISO/IEC 17025 standard differs greatly to that of other employees in the laboratory. This means that the results of the study would not necessarily be generalized to employees throughout the organization given the differences in its exposure to the various end users. Furthermore, this study was limited to evaluating laboratory directors' intent to seek or maintain ISO/IEC 17025 accreditation as opposed to the actual enrolment in the program.

The methodology I used was an additional limitation in the study, as cross-sectional surveys do not account for time differences between variables. This static nature of the study methodology limited its capacity to attribute direction to variable associations. I used a survey instrument comprised of closed ended questions, thereby limiting respondents' ability to clarify, elaborate, or comment further on the topic under study. This may have led to omission of information with potential to offer more insight into SPHL directors' attitudes towards ISO/IEC 17025 accreditation.

Significance

This research may help fill a gap in understanding uptake of ISO/IEC 17025 accreditation in SPHLs by focusing specifically on perceptions of leadership in public health laboratories towards ISO/IEC 17025 accreditation. This study is unique because I addressed an under researched area of SPHLs with regards to accreditation. Results of

this study will lead to evidence justifying the impact of ISO/IEC 17025 accreditation on SPHLs and whether these laboratories should engage in the accreditation. This information is especially useful to SPHLs which are already under budget constraints, as this would lead to more clarity in terms of whether the accreditation is warranted. Furthermore, quality of services provided by SPHLs has the potential to greatly impact the health of their state's population. This research may lead to social change by inspiring laboratory public health leaders in the US to implement and promote quality driven and cost-effective programs that would ultimately improve the overall public health system in the US.

Summary

SPHLs play a vital role in promoting the health of the communities they serve through services such as population biomonitoring and diagnostic disease epidemiology services. SPHLs have implemented ISO/IEC 17025 accreditation, despite a lack of evidence based research regarding the benefits of this accreditation to their laboratories.

The purpose of this study was to use the TPB to explore perspectives of SPHL directors towards ISO/IEC 17025 accreditation to identify factors that they encounter that impede or facilitate seeking or maintaining ISO/IEC 17025 accreditation, as well as how they perceive or value accreditation programs. A cross-sectional quantitative design was used to collect data from SPHL directors across the US. Chapter 2 includes an evaluation of significant literature on SPHLs and accreditation. I discuss the role of SPHL leaders, laboratory quality, and ISO/IEC 17025 accreditation.

Chapter 2: Literature Review

Introduction

There is a paucity of research regarding QI programs in SPHLs specifically concerning ISO/IEC 17025 accreditation, despite SPHLs' significance to public health. The importance of the SPHL to communities has been examined within the literature, for example, SPHL testing encompasses a plethora of scientific fields including chemistry, biology, and pharmacology, all with real implications for public health, including medical, environmental, agricultural, and food analyses, along with forensic and toxicological testing (Fox & Latshaw, 2013; Olsen et al., 2000). Timely, credible, and reliable data is critical for recognizing, surveilling, preventing, and limiting public health threats, thereby reducing rates of preventable injury and death (Jenkins, 2010; Taverniers et al., 2004; Witt-Kushner et al., 2002).

Poor laboratory data can lead to incorrect identification of disease causative agents which can lead to failure to provide patients with necessary treatment, and in some cases death due to delayed diagnosis and therapy (Albert et al., 2017; Kitchen et al., 2013). The potential damaging impact on public health, and a diminished confidence in the public health laboratory system due to such indiscretions cannot be overlooked (Ratseou & Ramphal, 2014).

Public health departments have the duty to uphold public health by advancing and maintaining healthy populations (National Association of County and City Health Officials, 2005). Public health departments operate under federal government mandates such as the CLIA and FSMA to ensure public safety however, there has been a push for

additional quality measures. A key strategy to fortifying the public health infrastructure identified by public health officials is accreditation (Riley et al., 2012). Accreditation is a system by which an organization is periodically reviewed by a third party accrediting agency through a performance assessment weighed against pre-established standards (Karthiyayini & Rajendran, 2017).

Public health laboratory authorities such as CDC, FDA, APHL, and WHO emphasize the importance for the implementation of quality in all aspects of the SPHL's activities and see accreditation as a viable means to move towards this goal (Inhorn et al., 2010a; Wangsness et al., 2017b; Wilcke et al., 2010). A standard currently seeing greater implementation in the SPHLs arena is the ISO/IEC 17025 an international accrediting standard dictating the general requirements for demonstrating the competence of testing and calibrating laboratories.

However, studies evaluating the impact of ISO/IEC 17025 accreditation on SPHLs are lacking, and literature is mainly normative, involving reports from individual institutions, unverified and subjective information, or reporting project-specific data (Gerundino et al., 2014; Ratseou & Ramphal, 2014; Riley et al., 2012). Investigations of quality systems user behavior therefore becomes especially important when behaviors like accreditation adoption affect laboratory testing quality, but accreditation adoption antecedents remain elusive. Little is known about attitudes or opinions of laboratory directors responsible for ensuring implementation, integration, and functioning of ISO/IEC 17025 accreditation in their SPHLs.

Implementing and achieving the ISO/IEC 17025 accreditation requires a

significant investment of time, resources, and organizational commitment from the top down (Wangsness et al., 2017a). This raises the question as to whether ISO/IEC 17025 accreditation is worth the cost and effort- which is particularly true in the SPHLs where financial constraints are pervasive, which further reinforces the need for evidence based research (Astles et al., 2010; Hsieh et al., 2013; Inhorn et al., 2010a; Ridderhof et al., 2013; Somsel & Warnock, 2004; Su & Vagnone, 2013; Wilcke, 2007).

In this chapter, I review relevant literature on SPHLs, SPHL directors, and quality in laboratories. I describe the TPB and discuss the ISO/IEC 17025 standard. Discovering perspectives held by SPHL directors regarding the impact of ISO/IEC 17025 accreditation on their laboratories is the purpose of this descriptive cross-sectional survey study.

Literature Search Strategy

In this study, I used the following electronic databases: Emerald Insight, Science Direct, Academic Search Complete, CINAHL Plus with Full Text, MEDLINE with Full Text, and Google Scholar. The search was limited to peer-reviewed research journals published after 2012, with a focus on SPHLs and ISO/IEC 17025 accreditation.

In this study, I used the following key terms: *ISO/IEC 17025 accreditation*, *public health laboratory quality standards*, *laboratory epidemiology*, *regulations*, *quality control*, *theory of planned behavior*, *laboratory testing*, *performance measures*, and *leadership*. These terms were searched individually and in various combinations to identify appropriate literature.

Where information was lacking, search dates were expanded to include sources

published between 2000 and 2021. Additionally, dissertations and accreditation and government agency websites were also examined to investigate relevant documents and reports.

SPHLs

It has been noted that the first application to communal level laboratory practice of public health service was based on a study of water sanitary conditions in Massachusetts in 1870 (American Medical Association, 2016). As such, the history of SPHLs in the U.S. dates back over a century ago, when populations in the US transitioned to an urban-centered society. This urbanization brought with it a surge in the population complemented by unsanitary conditions that led to a spike in diseases such as cholera, plague, measles, mumps, whooping cough, and diphtheria (Ryan, 2013). Death from these diseases was common and prompted governments to evolve with the changing times in a race to prevent fatalities. It was during this period that public health departments arose, and with them, SPHLs which played a crucial role in diagnosing the causative agents of diseases; this contributed to the government's efforts to protect its citizens.

Reduced cases of the aforementioned diseases can be partially attributed to work performed in SPHLs which are now in every state (Dowdle et al., 2011; Ridderhof & Wilcke, 2013). Distribution of these laboratories across the country created opportunities to further strengthen capabilities and capacities of SPHLs where collaborative efforts between them has led to networks of public health laboratory systems (Inhorn et al., 2010; Ridderhof & Wilcke, 2013). All 50 states, the District of Columbia, and five

inhabited US territories all have a central SPHL (APHL, n.d.).

Even as diseases such as cholera and diphtheria were demystified, new and reemerging public health threats in recent years have propelled SPHLs and public health departments back into the purview of public safety and security (Azadbakht, 2015). Risks posed by emerging and reemerging infectious diseases such as COVID-19, multidrug-resistant bacteria, West Nile Virus, SARS, tuberculosis, HIV/AIDS, Measles, Ebola, and the Zika Virus along with bioterrorism, foodborne illnesses, and environmental pollutants are some of the challenges that public health faces today (Holshue et al., 2020; Jones et al., 2017; Nii-Trebi, 2017; Poland & Jacobson, 2012; Siani, 2019; Tognotti, 2013; Toney et al., 2021). These challenges fortify the need for a more robust and accountable SPHL system that is able to safely and confidently produce quality, reliable, and reproducible data in support of public health.

Efforts have been made to ensure a continued growth and strengthening of the SPHL. Terrorist attacks in the United States in 2001 including the anthrax and September 11, 2001, attacks were defining moments in the United States and public health history. These events renewed emphasis on public health preparedness and security. An urgent need to strengthen SPHL capacity to rapidly screen, identify, and efficiently report biological and environmental threats arose. Murthy et al. (2017) said there was a significant increase in public health preparedness when comparing before September 11, 2001 to 2016. The researchers reported a recorded increase of 150% in jurisdictions able to engage in electronic lab reporting that supported public health surveillance and epidemiological investigation was reported (Murthy et al., 2017).

Funding and collaborative efforts in the SPHL are crucial to SPHLs. Fox and Latshaw (2013) supported this observation in their study which indicated funding as the biggest priority for SPHLs they investigated while quality assurance and quality control ranked highest from a technical aspect. Wahnich et al. (2018) conducted surveillance for locally acquired mosquito-borne Zika virus infections in 2016 and their study consisted of collaborative efforts with multiple stakeholders. These stakeholders included 24 sentinel clinical sites, hospitals, epidemiologists, and the New York SPHL. The extensive engagement of public health departments and crucial confirmatory role played by the SPHL highlighted the critical role that SPHLs play in supporting the health of the public. These studies underscore some of the critical activities carried out in SPHLs, however, they do not fully encompass vast repository of SPHLs functions.

To better define its role as a critical part of the public health system, it was imperative that a clear outline of the basic functions of the public health laboratory be defined. To achieve this goal, in 2000 the APHL published a white paper expounding on the 11 core functions of the public health laboratory (hereafter, Core Functions) (Inhorn et al., 2010a). These 11 core functions (see Figure 1) succinctly summarize the role of the SPHLs and how it supports the essential public health services by contributing laboratory-based scientific data.

Figure 1

Core Functions of the Public Health Laboratory

SPHL Directors

As evidenced by the 11 core functions, the SPHL's director deals with issues that are far reaching and complex, affecting multiple stakeholders, and each presenting with unique circumstances and challenges that require equally unique solutions (Carlton et al., 2015; Inhorn et al., 2010). From supporting clinical diagnostics by performing confirmatory tests (e.g. for venereal disease), and food regulatory and outbreak response,

to newborn screening, toxicology, and environmental protection, the scientific disciplines within the SPHLs highlight the crucial activities they perform to protect the health of the communities they serve (APHL, 2017, 2018a; Salfinger, 2016).

Additionally, SPHL directors are charged with not only having an understanding of the repertoire of scientific fields encompassed within the SPHLs but a knowledge of the multitudes of state and federal policies overarching their laboratories (APHL, 2018a). The ability to collaborate with fellow public health leaders is another skill shown to benefit the SPHLs director. Umble et al. (2005) evaluated the National Public Health Leadership Institute's (NPHLI) efforts towards creating collaborations between public health leaders. It was revealed that team building in the public health community can result in improved programs and services (Umble et al., 2005).

Furthermore, SPHL directors are required to be able to improve laboratory efficiency while operating under tight budgets (Salfinger, 2016). A list of 15 core competency areas (see 0) that identify the skills, knowledge, and abilities necessary for delivering effective and efficient laboratory services were developed for leadership professionals in public health laboratories (Ned-Sykes et al., 2015). Laboratory quality improvement systems and processes were identified as competencies of most relevance to public health leaders serving as directors and managers within the public health laboratory (Jadhav et al., 2017).

A review of the expectations, duties, and responsibilities of a public health laboratory director shows that they are strategically poised as the key decision makers on QI activities in the laboratory. Such laboratory QI activities include accreditation

procedures and processes and are further discussed later in this chapter. In addition to their leadership stature, top management commitment has been identified as a critical factor in the successful implementation and management of ISO/IEC 17025 accreditation (Karthiyayini & Rajendran, 2017).

Laboratory Quality

The subjective nature of the term quality arises from the most basic definition of the word which relates to the current status, condition, or being of tangible materials or processes (Kitchen et al., 2013). One's view of the state of an object or process therefore defines whether they accept it as is, or demand alterations to it, to change it to their definition of quality. A handbook published by the WHO explains laboratory quality as, "accuracy, reliability, and timeliness of reported test results" (WHO, 2011, p. 8). For most testing laboratories, quality is a dynamic concept injected into various workings within the laboratory from sample collection and analysis, to the data reporting stage (Aarsand & Sandberg, 2014; Carraro & Plebani, 2007; Ned-Sykes et al., 2015; Plebani et al., 2014).

Each of these levels further present with multiple variables such as multiple clients, samples, testing equipment, reporting technologies, and technicians that can all be seen as potential points of error (Ratseou & Ramphal, 2014). These variables drive the need for comprehensive quality implementation through processes such as standardization, quality controls, laboratory information management systems (LIMS), and reference materials (Ratseou & Ramphal, 2014). Carraro and Plebani (2007) conducted a study to monitor laboratory testing error rates in a stat laboratory. Their

research revealed that the pre- and post-analytical testing steps presented with the highest error rates in the laboratory. This data highlights the significance of evaluating for and practicing quality measures in various steps in laboratory operations.

The ultimate goal for testing laboratories is the production of timely, high-quality results that are accurate, reproducible, and reliable (Su & Vagnone, 2013). The evolving nature of laboratory testing, attributed to occurrences such as the introduction of new analytical equipment, and method development and optimization, showcases the need for laboratories to synchronize quality to these fluctuations in technologies as they strive to improve products and services while observing safety and error reduction (Inhorn et al., 2010; Kitchen et al., 2013). Quality in the laboratory can therefore be viewed as a fluid concept whose definition has to be continually reviewed by means such as continuous quality improvement.

QI

QI in an organization pertains to the systematic and continuous steps that result in measurable improvement (HRSA, 2011; McLees et al., 2015). QI in public health can be defined as the use of an integrative process focused on activities centered around community needs and population health improvement while deliberately evaluating for quality indicators throughout these activities (American Public Health Association, 2013; Duong et al., 2017; Riley et al., 2010).

In the public health laboratory arena, the Quality Management System (QMS) was identified as one of 15 domain areas developed in 2012 by a workforce project sponsored by the CDC and the APHL to prepare competency guidelines for public health

laboratory professionals (Ned-Sykes et al., 2015). Significant emphasis was placed on the QMS as the bedrock for all other activities identified by the workforce, highlighting the need for quality testing and services to support public health (Ned-Sykes et al., 2015).

Chen et al. (2015) discussed involvement in QI as a strong prerequisite for local health department's smooth transition to accreditation. The purpose of the Chen et al. (2015) study was to examine the relationship between established QI systems in local health departments and accreditation. The researchers were able to associate attitudes and beliefs about accreditation readiness by analyzing the level of QI integration throughout the local health departments; higher levels of QI diffusion showed stronger acceptance of accreditation (Chen et al., 2015).

ISO

The ISO is a global conglomerate of 165 national standards bodies that are regarded as experts in their fields (ISO, 2019). The ISO Committee on Conformity Assessment (ISO/CASCO) develops and publishes international standards. These documents are comprised of practical information and best practice i.e., they highlight agreed ways of accomplishing tasks or solutions to world-wide problems (ISO, 2016; Ratseou & Ramphal, 2014). Additionally, these standards and guides aim to demonstrate that specified requirements relating to a product, process, system, person, or body are achieved. Prior to achieving standard status, a rigorous process is applied where ISO members review, discuss and come to a full consensus vote on standard drafts that they receive. Standard development ultimately relies on four key concepts: market need, global expert opinion, multi-stakeholder contribution and committee consensus (ISO,

n.d.b).

ISO limits the reach of their work to developing standards and are not involved with conferring accreditation to those seeking it (ISO, n.d.a). For a body to become accredited to a specific ISO standard, they would have to engage in the process through a third-party organization. These third party organizations operate under various organizational capacities and ownerships ranging from commercial to not-for-profit businesses such as government agencies, national standards bodies, trade associations, consumer organizations, and private or publicly owned companies (ISO/CASCO , 2014). As such, accreditation is defined by ISO as the process by which a recognized authoritative body-an accreditation body- formally recognizes that a person or an organization is competent to perform specific tasks (ISO, 2014).

ISO/IEC 17025 Accreditation

ISO/IEC 17025 was birthed from the need for an internationally accepted standard for laboratory quality systems and was published in 1999 (United Nations Industrial Development Organization, 2009). The standard was revised in 2005 and later in 2017 (ISO, 2017; Karthiyayini & Rajendran, 2017). ISO describes ISO/IEC 17025 as a guide for general requirements for the competence of testing and calibration laboratories. It is conformance to these requirements that external accreditation organizations assess to confirm that the system they are auditing meets the ISO/IEC 17025 requirements.

The ISO/IEC 17025 standard evolved from the ISO Guide 25 with additional inclusions from the management standard ISO 9001 (Karthiyayini & Rajendran, 2017; United Nations Industrial Development Organization, 2009). Convergence of ISO/IEC

17025 and the already established ISO 9001 ensured an overarching standard for quality management systems (i.e., ISO 9001) and one specific to testing and calibration laboratories (i.e. , ISO/IEC 17025) (United Nations Industrial Development Organization, 2009). The scope of accreditation defines what methods a laboratory chooses to have accredited and these are the focus of assessments (United Nations Industrial Development Organization, 2009). By virtue of scope of accreditation, not all methods performed within the laboratory are accredited and choice of what methods to accredit lie on the laboratory. Strategies to select qualifying methods include their frequency of use, objectivity of use, commerciality, and compulsory accreditation (United Nations Industrial Development Organization, 2009)

The inability to show data consistency with regards to infrequently used methods makes them a poor choice for scope inclusion as do methods that are not profitable (United Nations Industrial Development Organization, 2009). Additionally, poorly performing methods that have a track record of inconsistency are typically not included in the scope of accreditation (United Nations Industrial Development Organization, 2009). There are instances where laboratories are obligated to include methods under the ISO/IEC 17025 scope of accreditation such as data generated for public safety and legal issues (United Nations Industrial Development Organization, 2009).

To attain accreditation status, there are two main components to ISO/IEC 17025 that must be met by laboratories i.e., management and technical requirements (Sadikoglu & Temur, 2012; United Nations Industrial Development Organization, 2009). Additionally, a financial component must be met to attain accreditation status. Several

fees are assessed that factor into the overall cost of initiating and maintaining ISO/IEC 17025 accreditation. Various fees include trainings, assessment fees, consultation costs, preventative maintenance, and salaries (APHL, 2018b). A survey of 18 laboratories carried out by APHL found that median total annual cost of ISO/IEC 17025 accreditation was $311,485 (APHL, 2018b).

Despite the daunting costs and involving requirements, the ISO states that ISO/IEC 17025 accreditation has several benefits to laboratories including promoting national and international confidence, universal acceptance of their results, and improved international trade (ISO, 2017). Furthermore, the ISO notes that the ISO/IEC 17025 accreditation presents additional benefits to use of their international standards including, having a competitive advantage, increased profits and reduced costs, and access to subject matter experts (ISO, 2016). Evidence based research backing these claims and research on the impact of ISO/IEC 17025 accreditation in SPHLs is lacking.

There is limited literature on studies assessing the impact of ISO/IEC 17025 accreditation in laboratories with various articles both critical and accepting of the purported benefits of accreditation (Brook, 2010; Cortez, 1999; Honsa & McIntyre, 2003; Verstraete et al., 1998; Wilson et al., 2016). Wilson et al. (2016) performed a retrospective meta-audit of laboratory audits in a public health laboratory that checked compliance with ISO/IEC 17025 accreditation where they found that standards were not an efficient means to assure quality (Wilson et al., 2016). This conclusion came from the realization that majority of the noncompliance's reported did not affect the validity of results or service quality in the laboratory (Wilson et al., 2016). It was noted that findings

from the audits were specific to clauses in the standard and had no bearing on users (Wilson et al., 2016).

Conversely, it has been reported that implementing ISO/IEC 17025 accreditation translates into quality in daily laboratory practices (Randolph et al., 2019). Okezue et al. (2020) evaluated the impact of ISO/IEC 17025 accreditation in a quality control laboratory in the National Agency for Food and Drug Administration and Control (NAFDAC), located in Nigeria, West Africa. Data from their pre- and post-accreditation descriptive and comparative study showed a reduction in the number and severity of nonconformities as well as a reduction in major observations (Okezue et al., 2020). The researchers concluded that as a result of ISO/IEC 17025 accreditation, the laboratory had improved the reliability of their test reports and strengthened their laboratory quality system (Okezue et al., 2020). Additionally, faster problem resolution pertaining to methods and personnel or equipment was observed as well as better customer satisfaction, passing product quality expectations, and increased business (Randolph et al., 2019).

TPB

The TPB traces its roots to the TRA first developed by Ajzen and Fishbein, and is founded on the idea that performing a particular behavior is rooted in an individual's intentions and perceived behavioral control (Ajzen, 2011a). The theory, proposed in 1985, identifies three constructs as predictive elements of behavioral intention that differ with individuals, the constructs are: attitude towards the behavior or action (one's overall evaluation or assessment of the behavior or action); subjective norms (one's perceptions

of societal pressures to engage or not engage in the behavior or action); and perceived behavioral control (one's perception of the ease or difficulty of engaging in the behavior or action) (Ajzen, 1991; 2011). Behavioral intention relates to the amount of dedication individuals have towards engaging in a specific behavior in that, with greater dedication they will more likely perform the behavior (Ajzen, 2011b).

The TPB has been used to predict and explain various behavioral intentions and actual behaviors in an array of research areas including marketing, psychology, data collection, and information system adoption (Chen et al., 2007; Fukukawa, 2002; Millar & Shevlin, 2003; Murphy, 2009; Shim et al., 2001). In the healthcare arena, intention has been identified as a legitimate proxy measure for behavior among health care professionals. For example, Eccles et al. (2007) concluded, based on a review of ten prospective studies, that there was an association between intent and behavior among healthcare professionals. Similarly, in a review of ten studies by Perkins et al. (2007), the researchers concluded that TPB constructs predict intention and behavior among healthcare practitioners. The explanatory nature of TPB renders it a useful framework for understanding laboratory directors' attitudes towards ISO/IEC 17025 accreditation.

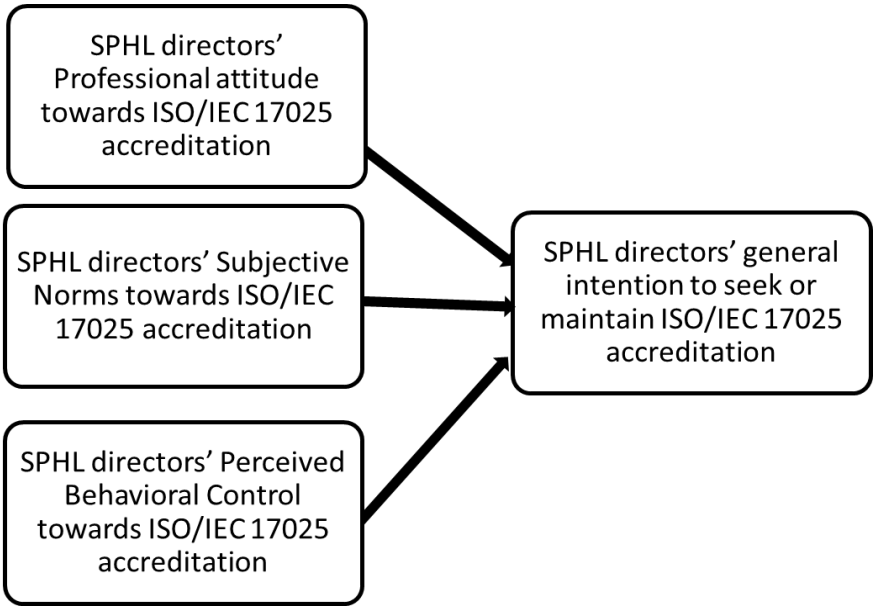
The objective of implementing and maintaining a voluntary accreditation program is to ensure organizational improvement, quality, and competence (Braithwaite et al., 2011; Karthiyayini & Rajendran, 2017). A higher level of transparency to this claim of guaranteed quality and competence could be achieved by examining attitudes of SPHL directors towards the ISO/IEC 17025 accreditation program and their intent to implement and maintain the program. Previous studies have shown that attitudes and beliefs about

accreditation can be critical to the extent to which accreditation is accepted (Chen et al., 2015; Ehlers et al., 2017; Petrusevska et al., 2016).

Additionally, research on attitudes towards accreditation has shown varying sentiment towards the practice based on participant title, however, a constant theme throughout is the importance of leadership involvement and commitment to its successful implementation (Karthiyayini & Rajendran, 2017). SPHL directors' attitudes toward accreditation are particularly important because laboratory leaders have been identified as a predictor of successful implementation of accreditation and other quality improvement initiatives. Consequently, studying SPHLs directors' attitude using the TPB as a framework for the study would potentially reveal how well ISO/IEC 17025 accreditation is embraced in SPHLs. A conceptual model (see Figure 2) based on the TPB will be used to measure and explain the formation of SPHL directors' intentions to seek or maintain implementing and maintaining ISO/IEC 17025 accreditation.

Figure 2

Conceptual Model Based on the TPB



The conceptual model graphically illustrates the dependent variable of behavioral intent that is derived from multiple independent variables – intentions from attitude, subjective norms, and perceived behavioral control.

Summary

This chapter evaluated the literature on the major topics of inquiry provoked by the research questions and relevant to evaluating the interaction of SPHL director's attitudes, subjective norms and perceived behavioral control on intent to seek or maintain ISO/IEC 17025 accreditation. The reviewed literature provided foundational knowledge on various topics including the workings of the public health laboratory with emphasis on quality measures such as accreditation. Additionally, the literature review provided evidence for the importance of leadership in believing in and implementing quality measures and how attitudes affect behavior.

There is a scarcity of research on SPHLs with regards to behavioral intent towards quality interventions, specifically, with regards to ISO/IEC 17025 accreditation. A literature review of attitude and SPHL directors showed a knowledge gap on the attitudes and beliefs of state public laboratory directors responsible for ensuring implementation, integration, and functioning of the system in their laboratories towards ISO/IEC 17025 accreditation. This gap offers justification for this research study. The literature review helped concentrate the research-on-research questions driven by the TPB. The literature review will provide a template for the study and research design as discussed in Chapter 3.

Chapter 3: Research Method

Introduction

The purpose of this study was to use the TPB as a guide to evaluate perspectives of SPHL directors towards ISO/IEC 17025 accreditation. To address this gap in the literature, this study used a quantitative cross-sectional survey approach to collect data from directors managing public health laboratories. The following topics will be addressed in this chapter: research questions, research design, target population, sampling frame, instrumentation, data collection procedures, data analysis plan and ethical considerations.

Research Questions

Three research questions were addressed in this study in an attempt identify the TPB factors SPHL directors encounter that impede or facilitate seeking or maintaining ISO/IEC 17025 accreditation. An additional question will evaluate for significant differences between the mean scores of SPHL attitudes, subjective norms and perceived behavioral control on the basis of accreditation status. The four research questions and corresponding null (Ho) and alternate (Ha) hypotheses were:

RQ1: Are SPHL directors' attitudes towards ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

$H_0 1$: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

$H_a 1$: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

RQ2: Are SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

$H_0$2: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are not a significant predictor of intention to seek or maintain this accreditation.

H_a2: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are a significant predictor of intention to seek or maintain this accreditation.

RQ3: Are SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

$H_0$3: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

H_a3: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

RQ4: Are there significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories?

$H_0$4: There are no significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL

directors of accredited, non-accredited, and working towards accreditation laboratories.

H_a4: There are significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories.

Research Design

A cross-sectional survey design was used in this study to establish a quantitative description of SPHL directors' attitudes, subjective norms, and perceived behavioral control towards ISO/IEC 17025 accreditation and their influence on intent to seek or maintain this accreditation. Creswell (2013) said cross-sectional survey designs are suitable for studies evaluating constructs such as attitudes and behaviors. Rudestam and Newton (2015) noted that when using a quantitative approach, the researcher makes assumptions regarding relationships between a set of variables before collecting data.

I investigated SPHLs directors' attitudes and other factors that contribute to their intentions regarding implementing and maintaining ISO/IEC 17025 accreditation. Frankfort-Nachmias and Nachmias (2008) recognize the use of surveys as a data collection tool for participant information on areas including attitude. I used survey monkey, a web-based self-administered survey questionnaire, to collect data on attitudes, subjective norms, perceived behavioral controls and intent towards ISO/IEC 17025 accreditation from SPHL directors during a 6-week period. A web-based survey was used to reach participants over a vast geographical area within a short period of time compared to other methods such as mail or in-person interviews.

Target Population

This research involved focusing on identifying specific determinants that drive SPHL directors to implement or maintain ISO/IEC 17025 accreditation in their laboratories. Laboratory directors from public health laboratories across the US and its territories are the target population for this study. Laboratory directors are key resources as they make adoption decisions in the operational hierarchy of the state laboratory.

Sampling Frame

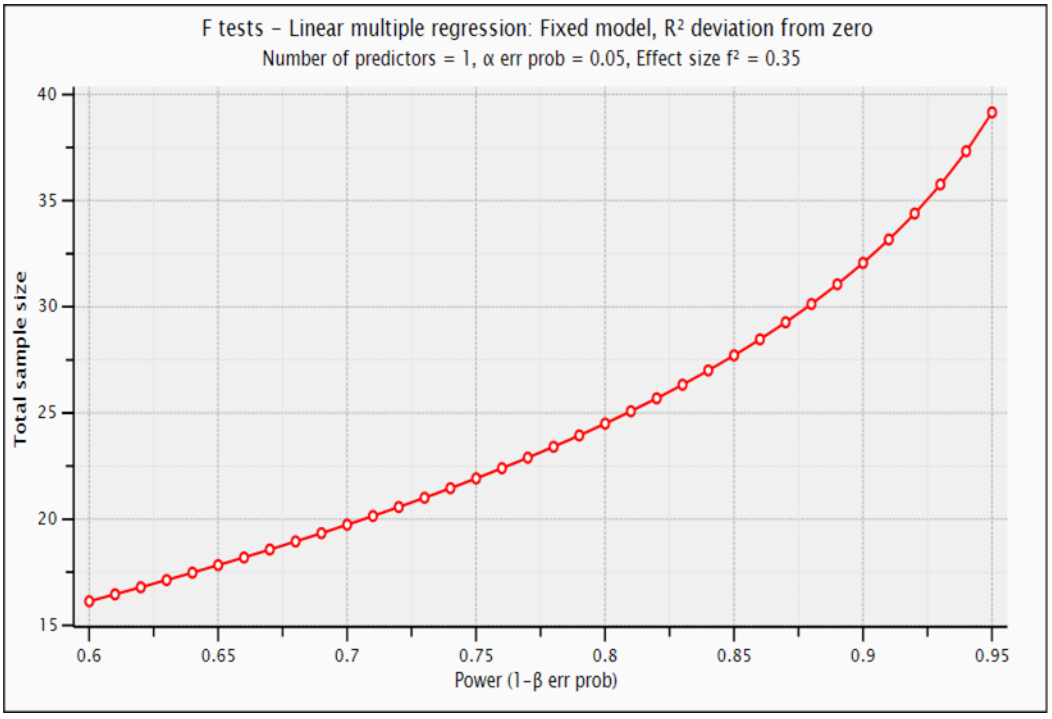
A sampling frame can be defined as a listing of all possible sampling units (individual members of the target population) (Crosby et al., 2006; Frankfort-Nachmias & Nachmias, 2008). Due to the small total population of interest and uncommon characteristics held by the SPHLs directors, a total population sampling strategy will be applied for this study. The United States has 50 states, one federal district (Washington, D.C.) and 5 inhabited territories; each with a central laboratory. Being government entities, contact information on laboratory directors in these labs is public and readily available online. It is from this public data that compiled the SPHLs director contact information contact information and emailed them the link to the web-based survey.

To determine the minimum sample size for simple linear regression analysis, an a priori sample size calculation using the statistical software package G*Power version 3.1.9.6 (Faul et al., 2009) was used. The a priori sample size calculation requires inputs values for probability of error, effect size (Cohen's f^2), and number of predictors. Probability of error was set at $\alpha = 0.05$ and power set at .80 as is convention. Cohen's f^2 is a standard measure of effect size applied to multivariate regression analysis in an effort to determine one variable's effect size within the analysis (Selya et al., 2012). Three effect

sizes- .02, .15, and .35 corresponding to small, medium, and large are presented in the software. These effect size conventions are reflective of a proposition by (Cohen, 1992) that the values are approximately consistent across different effect size indexes. An effect size of .35 was inputted into the software and one predictor representing each research question (RQ1, RQ2, and RQ3) was inputted as well (Ajzen, 1991). To achieve a power of .80, the resulting sample size is 25 (see Figure 3).

Figure 3

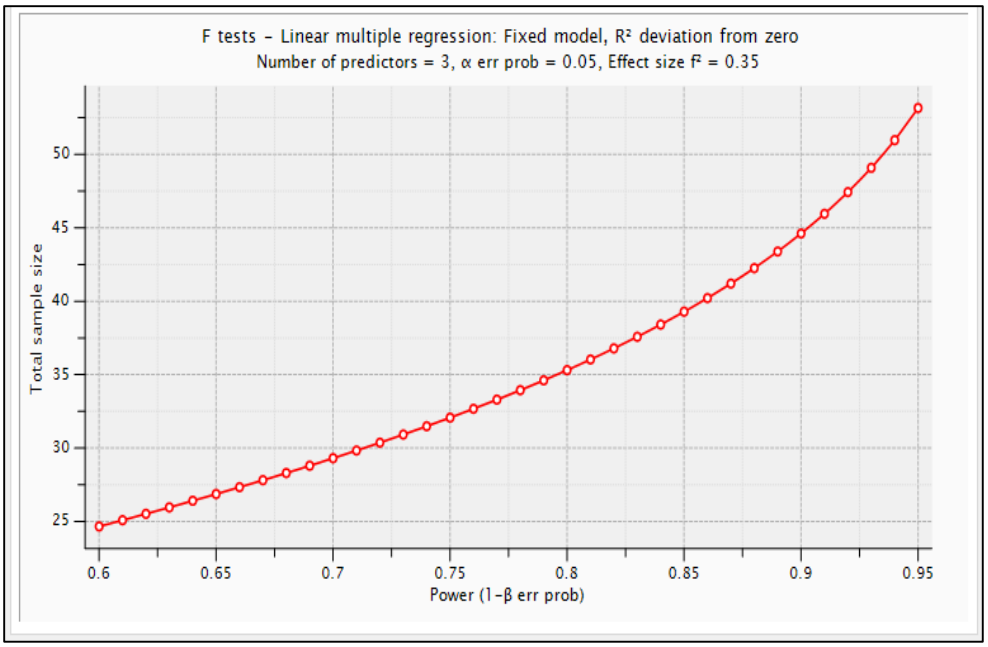
Simple Linear Regression Calculated Sample Size



A multiple linear regression was also performed to observe for interaction effects of the independent variables on the dependent variable. The calculated sample size necessary to perform a multiple linear regression analysis was found to be 36 (see Figure 4). All values except the number of predictors, which changed from 1 to 3, remained the same.

Figure 4

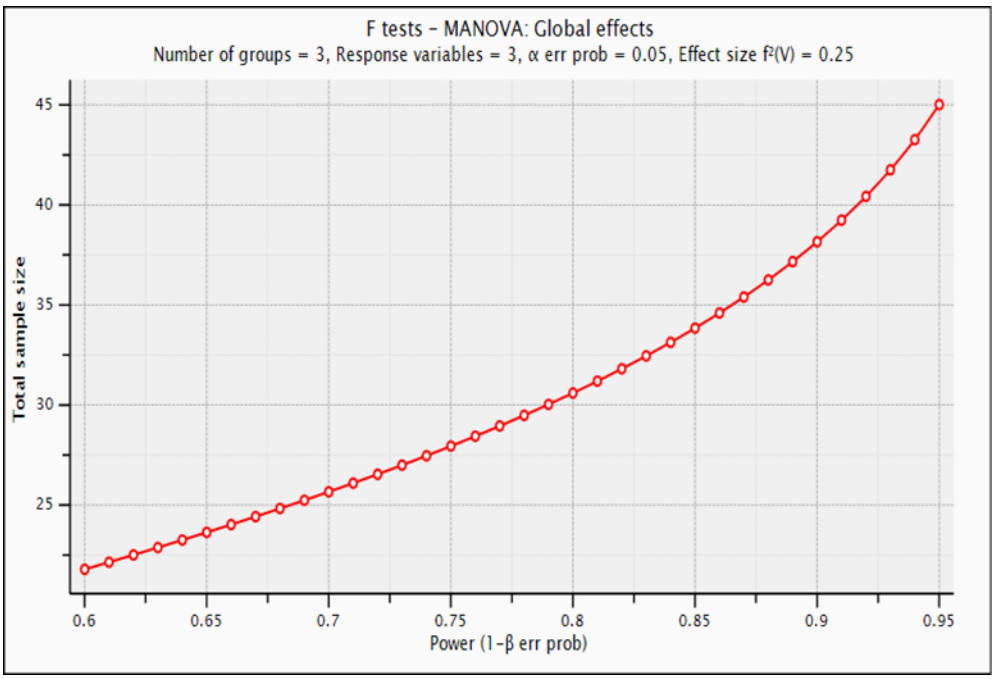
Multiple Linear Regression Calculated Sample Size



The minimum sample size required to perform the MANOVA analysis to answer RQ4 was determined to be 33 (see Figure 5). This was calculated using G*Power version 3.1.9.6 (Faul et al., 2009). The a priori sample size calculation requires inputs values for probability of error, power, and number of groups and response variables. The effect size ($f^2(V)$) was calculated to be 0.25 based on the number of groups (3) and response variables (3). Probability of error was set at $\alpha = 0.05$ and power set at .80 as is convention.

Figure 5

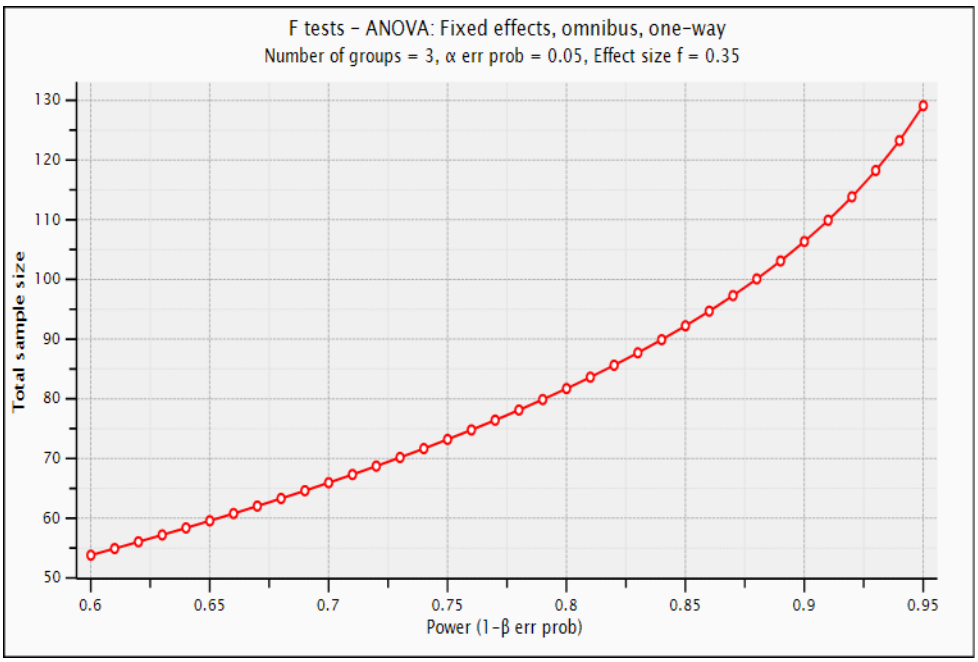
MANOVA Calculated Sample Size



Any differences revealed in the MANOVA were then evaluated using a one-way analysis of variance (ANOVA). The calculated minimum sample size needed for the ANOVA was 84. G*Power version 3.1.9.6 was used to calculate this minimum sample size. (Faul et al., 2009). Fixed effects, omnibus, one-way parameters were used with an effect size, alpha and power values of .10, .05 and .80 respectively, entered into the program. The number of groups entered was three (see Figure 6).

Figure 6

ANOVA Calculated Sample Size



Instrumentation

A survey by Buhmann and Brønn was the data collection tool with a Likert scale, which was adapted for this study. The survey instrument is an online survey questionnaire with five indicator items for all independent variables and three indicator variables for the dependent variable used in the TPB (Buhmann & Brønn, 2018). The Buhmann and Brønn survey is based on the TPB and was guided by research by Kinsky et al. (2015) and Warmerdam et al. (2015). Additionally, research using surveys of the same practice being evaluated by Buhmann and Brønn were used to inform the format and wording of for the study's survey items. Answers to all categories were measured on a 7-point Likert scale with anchors ranging from 1= strongly disagree to 7 = strongly agree.

Construct reliability was evaluated using Cronbach's alpha where construct alpha values ranged from 0.83-0.88 (Buhmann & Brønn, 2018). Reliability is the capacity for an instrument to consistently measure the values it targets (Tavakol & Dennick, 2011). Cronbach's alpha is a popular method used by researchers to assess instrument reliability (Lakshmi & Mohideen, 2013). Cronbach's alpha values range from 0 to 1 where higher values confer greater confidence in the measured value and to be acceptable, alpha reliabilities should be greater than 0.70 (Lakshmi & Mohideen, 2013).

Additional validity measures performed on the instrument included discriminant validity and convergent validity (Buhmann & Brønn, 2018). Permission to use the instrument was requested from the authors. Buhmann and Brønn (2018) created the survey to evaluate practitioners' perceptions of barriers to and drivers for measurement and evaluation of communication outcomes.

The survey by Buhmann and Brønn (2018) was appropriate for this study as it revolves around intention to engage in a process geared towards internal accountability, similar to the premise behind ISO/IEC 17025 accreditation. Furthermore, like the objective of my study, the survey was based on the theory of planed behavior to evaluate employee individual-level attitudes towards involvement in a quality system.

The target population of the study by Buhmann and Brønn (2018) was members of a national association for communication practitioners. For my study, the survey was modified to account for the change in the respondent group (see Appendix A) . The title practitioner, used in the Buhmann and Brønn (2018) study, was changed to state public health laboratory director. The original survey applied the TPB to predict practitioner

intent to measure and evaluate communication outcomes while this study applies the TPB to predict SPHL director intent to seek or maintain ISO/IEC 17025 accreditation. Both studies are therefore based on the same theory and evaluate behavioral intent towards processes geared at internal accountability, showing the instrument's applicability to this study. Changes reflecting this evaluation parameter will be made to the questionnaire.

Data Analysis Plan

The statistical software, IBM SPSS Statistics 27, was used for data analysis. The questionnaires were reviewed for completeness, for example, completion of all information seeking questions on the survey. Demographic information such as respondent gender, education, years as a director, and accreditation status were collected with simple descriptive statistics being used to summarize various characteristics of the sample.

Simple linear regression analysis was used to regress each of the three independent variables (relating to RQ1, RQ2 and RQ3) on the dependent variable. The interaction of each of the independent variables with the dependent variable was hypothesized to influence intent to implement and maintain ISO/IEC 17025 accreditation. Specifically, independent variables were determined to be the SPHLs director's attitude, subjective norms, and perceived behavioral control while their intention to involve is the dependent variable. Multivariate analysis of variance (MANOVA) was be used to evaluate for significant differences between the mean scores of SPHL director attitudes, subjective norms and perceived behavioral control on the basis of accreditation status represented by three levels: accredited, non-accredited and working towards

accreditation.

Threats to Validity and Reliability

The validity of a data collection method is concerned with whether the research presented is believable and valid, and whether it truly is evaluating what it claims to be evaluating; it deals with the quality and acceptability of the research (Zohrabi, 2013). Two parts to validity measurements are internal and external validity where internal validity relates to the legitimacy of the study results and external validity the generalizability of the study data (Lakshmi & Mohideen, 2013). As such, threats to the validity and reliability of the measurement instrument, and data collection, analysis and reporting should be controlled. Control measures applied included use of an instrument previously tested for validity and reliability, using an anonymous self-administered questionnaire to control for potential bias at data collection and for data analysis and reporting, the use of closed-ended questions to assist with the coding process thus reducing error.

Ethical Procedures

Institutional Review Board

Creswell (2014) said researchers should actively design any anticipated ethical issues that may arise during their research study into their research proposal. This method of integrating measures to counter ethical issues during the study would help the researchers to remain objective and ethical. Utilizing an Institutional Review Board (IRB) is one such way that the researcher can protect themselves from ethical pitfalls. IRBs are put in place to ensure that studies have a favorable balance of potential benefits and risks,

that participants are selected equitably, and that procedures for obtaining informed consent are adequate (Coughlin, 2006). Walden University's IRB is responsible for ensuring that research at the university is conducted according to the school's ethical standards and complies with federal regulations. IRB approval is therefore required prior to any data collection and as such, an IRB application was completed for this study prior to data collection. IRB approval to proceed with the study was received on July 1, 2021. The approval number is 07-01-21-0399710.

Informed Consent

Any research that involves human participants needs to be conducted with their informed consent (Frankfort-Nachmias & Nachmias, 2008). Informed consent is comprised of four elements: competence, voluntarism, full information and comprehension (Frankfort-Nachmias & Nachmias, 2008). Including these four elements ensures that each participant voluntarily chooses whether to participate in the study. An informed consent form was the first page of the web-based survey; participants were given the choice to agree or not agree to participating in the study. Those who chose to consent were directed to the survey while those who chose not to consent were thanked and exited from the survey. The informed consent clearly explained the purpose of the study and the procedures to be followed in data collection. Participants were made aware that participation was voluntary and that they could decline participation and withdraw at any time. The informed consent communicated to potential participants that the study would not pose any risk or violation of their rights and of the fact that no compensation would be provided for participation in the study. Disclosure on guaranteeing anonymity,

confidentiality and clarity was also stipulated on the informed consent.

Positive Social Change

Positive social change can be thought of as the transformational processes that address various challenges faced by communities in areas such as public health and social inequality (Stephan et al., 2016). These transformational processes promote positive change by enhancing societal well-being. Data from SPHLs are utilized for disease surveillance, control, and prevention activities and have the potential to impact public health. It is therefore imperative that this data promotes consistent, reliable, and reproducible results. Investigating SPHL director attitudes to ISO/IEC 17025 accreditation will offer evidence-based data on the ISO/IEC 17025 accreditation program in the SPHL.

This study promotes positive social change by potentially inspiring public health laboratories to research, implement, and promote transformational processes such as quality driven, effective programs that would ultimately improve the overall public health system.

Summary

In this chapter, I described the study design, instrumentation, and methodology used to examine SPHLs directors' attitudes towards ISO/IEC 17025 accreditation. Chapter 3 concluded with a discussion of potential ethical considerations in the study. Chapter 4 includes an examination of research questions, data analysis, and findings.

Chapter 4: Results

Introduction

The purpose of this study was to use the TPB as the conceptual framework guiding the evaluation of the perspectives of SPHL directors towards ISO/IEC 17025 accreditation. To address this, I used a quantitative cross-sectional survey approach to collect data measuring attitudes, subjective norms, perceived behavioral control and intent from directors managing SPHLs. In Chapter 4, I summarize the data collection steps, results of the study, and participants.

Data Collection

Survey data were collected over a 6-week period between July and August 2021. Poor response from SPHL lab directors led to an expansion of the sampling frame to include directors from environmental, agricultural, and local public health laboratories. These public environmental and agricultural laboratories are annexes to state laboratories and perform various tests at the state level, while local public health laboratories report results from their specific regions to the state, thereby functioning as extensions of the state program.

Directors from these laboratories were therefore invited to participate in the study; their contact information is public, and emails were sent to them. A total of 164 emails were successfully sent out. Additionally, a link to the web-based survey was posted on the APHL's lab director online community. Potential participants received a total of three emails, one introductory and two reminders. The total number of potential participants was unclear to me since I did not know the number of individuals in the online

community and how many of them also received email invitations.

A total of 46 individuals participated in the survey, representing a 28% participation rate based on the number of emails sent out. The minimum calculated number of required responses for the survey was 36; out of 46 responses, 37 met the criteria for inclusion in data analysis, 35 individuals met all participation criteria and responded to all 18 items in the information-seeking section of the survey as well as all five items in the demographics section of the survey. Additionally, data were reviewed to ensure correct representation of each scale measure. Response choices from one question in the attitude scale did not represent the appropriate direction of intent as the others and were therefore inverted. Inversion ensured that each scale point was labeled according to agreement level and positive directionality. Values were inverted from: 1 = Strongly agree to 7 = Strongly Disagree, to 1 = Strongly Disagree to 7 = Strongly Agree.

One participant responded to all 18 items in the information section of the survey and three items in the demographics section. The participant skipped questions regarding age and years in position. A second respondent skipped all questions in the demographics section; however, they answered all items in the information-seeking portion of the survey. Because both respondents answered all questions in the information-seeking section, their responses were included in data analysis for RQ 1-3. There were 36 individuals who responded to the question regarding accreditation status and all 18 questions in the information-seeking portion of the survey. These 36 responses were used in data analysis for RQ4.

My measurement instrument (see Appendix A) was adopted from Buhmann and

Brønn where respondents were asked to record their scores on a Likert scale with anchors from 1 (strongly disagree) to 7 (strongly agree). The instrument consisted of five indicator items for each of the three independent variables (attitudes, subjective norms, and perceived behavioral control) and three for the dependent variable (intent).

Data Analysis

Data from the web-based survey were downloaded via an Excel spreadsheet and imported into SPSS Statistics 27 for analysis.

Descriptive Statistics

The survey questionnaire had a demographics section that asked participants to answer questions regarding their gender, age, education, years in position, and ISO/IEC 17025 accreditation status of their laboratories. One respondent did not reveal their age and years in position, while another did respond to any of the demographic questions. The sample consisted of 18 (48.6%) male and 18 (48.6%) female respondents. Most participants were over 50 years with only one between 31 and 40 years, and 64.9% of participants had doctoral degrees. There were an equal number of participants with Bachelor's and Master's degrees.

The years in position category was approximately evenly distributed. 27% had held their position for 5-10 years. 24.3% of respondents had been at their position for over 10 years, and 24.3% for less than 5 years. 48.6% (n = 18) of respondents were accredited while 35.1% (n = 13) were not accredited. 13.5% (n = 5) of respondents indicated that they were working towards accreditation (see Table 1).

Table 1

Demographic Variable Frequency Table

Variable	Frequency	Percent
Gender		
Male	18	48.6%
Female	18	48.6%
Age		
31-40	1	2.7%
41-50	9	24.3%
51-60	12	32.4%
>61	13	35.1%
Education		
Bachelors	6	16.2%
Masters	6	16.2%
Doctoral	24	64.9%
Years in Position		
<5	9	24.3%
5-10	10	27.0%
11-20	9	24.3%
>20	7	18.9%
ISO/IEC 17025 Accreditation Status		
Accredited	18	48.6%
Not Accredited	13	35.1%
Working Towards Accreditation	5	13.5%

Item-Wise Descriptive Statistics of TPB Constructs

I calculated descriptive statistics for individual items by construct. Individual item descriptive statistics were recorded as either positive (somewhat agree to strongly agree) neutral, or negative (somewhat disagree to strongly disagree) (see Table 2).

Table 2

Survey Items and Descriptive Statistics by Construct (n= 37)

Construct	Item	Mean[a] (SD)	Percent Strongly agree [b]	Somewhat agree	Percent Neutral	Somewhat Disagree	Percent Strongly Disagree [c]
Attitude (ATT)	Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is smart (ATT1)	5.68 (1.49)	62.2%	16.2%	13.5%	5.40%	2.70%
	Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is valuable (ATT2)	5.62 (1.55)	62.2%	13.5%	13.5%	8.11%	2.70%

	Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency has many benefits (ATT3)	5.49 (1.41)	56.8%	18.9%	13.5%	8.11%	2.70%
	Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is interesting (ATT4)	5.14 (1.27)	45.9%	13.5%	32.4%	8.11%	0.00%
	Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is a good thing to do (ATT5)	5.76 (1.23)	64.9%	16.2%	13.5%	5.41%	0.00%
Subjective Norms (SN)	Most people who are important to me in my line of work think that I should seek or maintain ISO/IEC 17025 accreditation related to technical competency (SN1)	4.54 (1.73)	37.8%	10.8%	24.3%	10.8%	16.2%
	Most people like me in my line of work have sought or are maintaining ISO/IEC 17025 accreditation related to technical competency (SN2)	4.84 (1.39)	32.4%	32.4%	18.9%	8.11%	8.11%
	Most people who influence my decisions in my line of work think I should seek or maintain ISO/IEC 17025 accreditation related to technical competency (SN3)	4.57 (1.41)	29.7%	27.0%	24.3%	8.11%	10.8%
	People whose opinion I value in my line of work would prefer that I seek or maintain ISO/IEC 17025 accreditation related to technical competency (SN4)	4.84 (1.52)	37.8%	24.3%	18.9%	8.11%	10.8%
	Most people who are important to me in my line of work want me to be seek or maintain ISO/IEC 17025 accreditation related to technical competency (SN5)	4.65 (1.57)	35.1%	24.3%	18.9%	8.11%	13.5%

Construct	Item	Mean[a] (SD)	Percent Strongly agree [b]	Somewhat agree	Percent Neutral	Somewhat Disagree	Percent Strongly Disagree [c]
Perceived Behavioral Control (PBC)	Whether I seek or maintain ISO/IEC 17025 accreditation related to technical competency completely up to me (PBC1)	4.43 (2.04)	43.2%	18.9%	0.00%	5.41%	32.4%
	I am confident that if I want to I can seek or maintain ISO/IEC 17025 accreditation related to technical competency (PBC2)	5.81 (1.43)	75.7%	8.11%	5.41%	5.41%	5.41%
	I have the skills to seek or maintain ISO/IEC 17025 accreditation related to technical competency	6.08 (0.98)	81.1%	10.8%	5.41%	2.70%	0.00%

	(PBC3)						
	I generally have management support to seek or maintain ISO/IEC 17025 accreditation related to technical competency (PBC4)	5.78 (1.25)	70.3%	8.11%	16.2%	5.41%	0.00%
	I have the resources and time to seek or maintain ISO/IEC 17025 accreditation related to technical competency (PBC5)	4.51 (1.66)	29.7%	35.1%	10.8%	8.11%	16.2%
Intention (IN)	I am willing to seek or maintain ISO/IEC 17025 accreditation related to technical competency (IN1)	5.32 (1.62)	62.2%	13.5%	10.8%	2.70%	10.8%
	I plan to seek or maintain ISO/IEC 17025 accreditation related to technical competency (IN2)	5.41 (1.80)	67.6%	10.8%	5.41%	2.70%	13.5%
	I will make an effort to seek or maintain ISO/IEC 17025 accreditation related to technical competency (IN3)	5.38 (1.85)	67.6%	5.41%	10.8%	2.70%	16.2%

Note. SD = standard deviation. [a] Coded as 1 = strongly disagree, 2 = disagree, 3 = somewhat disagree, 4 = neither agree nor disagree, 5 = somewhat agree, 6 = agree, 7 = strongly agree. [b] Percent agree to strongly agree. [c] Percent disagree to strongly disagree.

Of the five factors measuring the attitude variable, ATT5, Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is a good thing to do, was selected by the most participants (see Table 2). Responses to subjective norms was the widest spread with most items scoring evenly from neutral to strongly agree. There was a small distinction between the percentage of participants selecting the five items measuring the subjective norms with SN4 having the most at 37.8% of strongly agree and SN2 with 29.7% selecting strongly agree (see Table 2).

For perceived behavioral control, the results show that the most important item when measuring perceived behavioral control was PBC2 where 81.1% of participants strongly agreed that they have the skills to seek or maintaining ISO/IEC 17025 accreditation. Participant selection of whether they intent to seek or maintain ISO/IEC 17025 accreditation was evenly spread across the three items. Both IN2 and IN3 had the same percentage of respondents (67.6%) selecting that they strongly agree however, IN2 had 10.8% selected they agree compared to 5.41% for IN3, indicating that item IN2 had the greatest impact on the measure for intent to seek or maintain ISO/IEC 17025 accreditation.

Summary Statistics

I calculated summary statistics for the variables of interest in the study. Summary scores of the variables were determined by averaging participants' responses related to each variable. On average out of a possible 7.00, participants scored 5.54 (*SD* = 1.16) and 4.69 (*SD* = 1.38) for ATT and SN, respectively while for PBC and IN, they scored 5.32 (*SD* = 0.95) and 5.37 (*SD* = 1.71) respectively. To get a general overview of variable

distribution, I also calculated skewness and kurtosis (see Table 3).

Due to the small sample size of n<50, a z-test was applied for normality test using skewness and kurtosis. The z score for skewness and kurtosis were defined as z = skewness/ SEskewness and z = kurtosis/ SEkurtosis. z values ± 1.96 are used to establish normality of the data (Mishra et al., 2019). Reported scores for both values are within these parameters (see Table 3). Scale reliability was evaluated using Cronbach's Alpha. All scales had an initial Cronbach's alpha value greater than 0.7 except PBC.

The inter-item correlation matrix revealed that one item, PBC1 correlated poorly with the other items on the perceived behavioral control scale, further supported by the Cronbach's Alpha if the item was deleted. As such I deleted item PBC1 from the perceived behavioral control scale. The Cronbach's Alpha after deletion was 0.71, indicating that the scale was reliable.

Table 3

Variable Summary Statistics Table

	Min	Max	Mean	Std. Deviation	Skewness	Kurtosis	Cronbach's Alpha
ATT	3.20	7.00	5.54	1.16	-0.735	-1.052	0.89
SN	1.80	6.80	4.69	1.38	-0.979	-0.641	0.95
PBC	3.00	7.00	5.55	0.99	-1.683	0.829	0.71
IN	1.00	7.00	5.37	1.71	-1.283	0.555	0.98

Simple Linear Regression

Simple linear regression is a statistical test used in research to define and quantify the relationship between two variables – a dependent and independent variable (Khushubu & Yadav, 2018). In this study, I conducted three simple linear regression

models in support of the three research questions (RQ1-RQ3) where I sought to predict the dependent variable, intent to seek or maintain ISO 17025 accreditation, based on each of the independent variables (attitude, subjective norms or perceived behavioral control). The simple linear regression models (RQ1-RQ3) will help in understanding whether attitude, subjective norms and perceived behavioral controls may be good surrogate markers for SPHL director's intent to seek or maintain ISO/IEC 17025 accreditation and whether each construct explains some of the variability in intent. The simple linear regression analysis is discussed below.

Data Assumptions

Ensuring that the assumptions of linear regression have been met is the first step to performing the analytical method. Violating the assumptions of the model prevents generalization to the population from which the sample was obtained. The assumptions that must be met for performing simple linear regression require that – there is one dependent variable measured at the continuous level, one independent variable measured at the continuous level, a linear relationship exists between the two variables, that there is an independence of observations, a lack of significant outliers, homoscedasticity is met and that the residuals are approximately normally distributed (Kim, 2018). The first two assumptions, one dependent variable and one independent variable were met for research question 1-3. Further analysis was performed below to determine whether the remaining assumptions were met for each of the research questions (RQ1, RQ2 and RQ3).

Linearity

To meet the linearity assumption for simple linear regression, linear relationships

must be observed between the dependent variable and the independent variables (Kim, 2018; Olsen et al., 2020). The following sections provide discussion regarding the linearity condition for each of the research questions (RQ1-RQ3). I tested the relationship between the dependent variable and the independent variables together using a scatterplot of the dependent variable against the independent variable (see Figures 7-9).

Figure 7

Scatterplot of Intent vs. Attitude (RQ1)

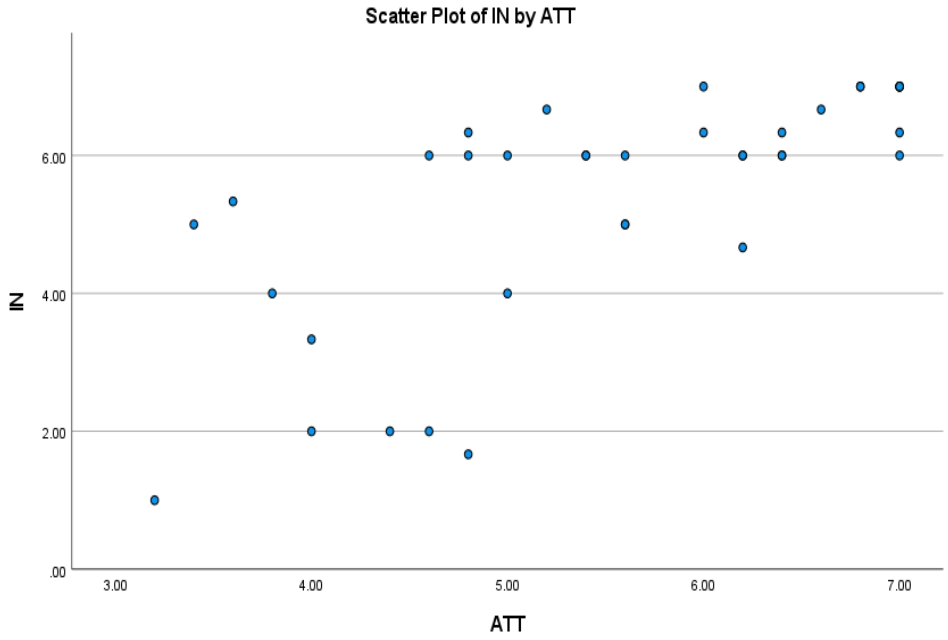


Figure 8

Scatterplot of Intent vs. Subjective Norms (RQ2)

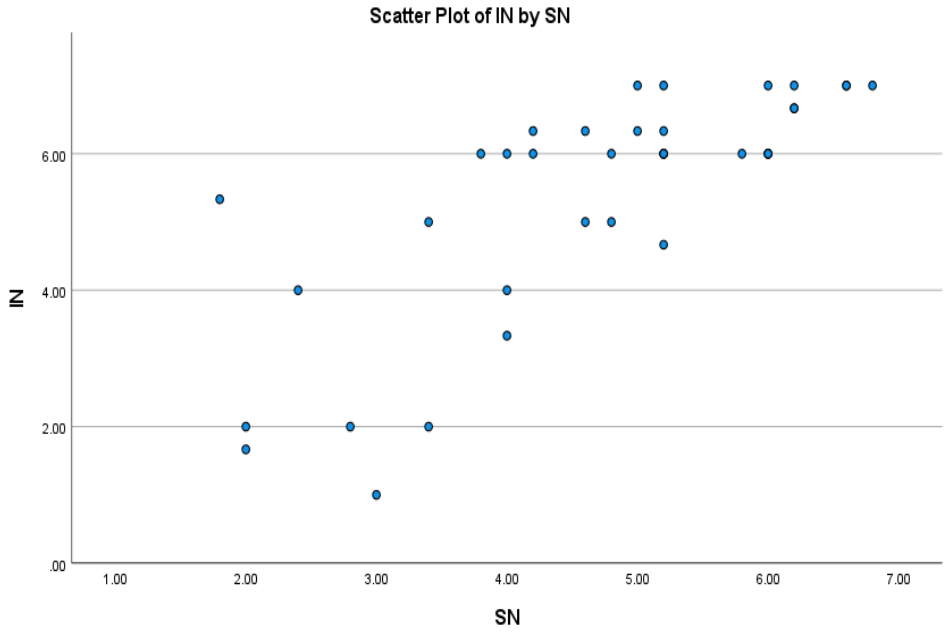
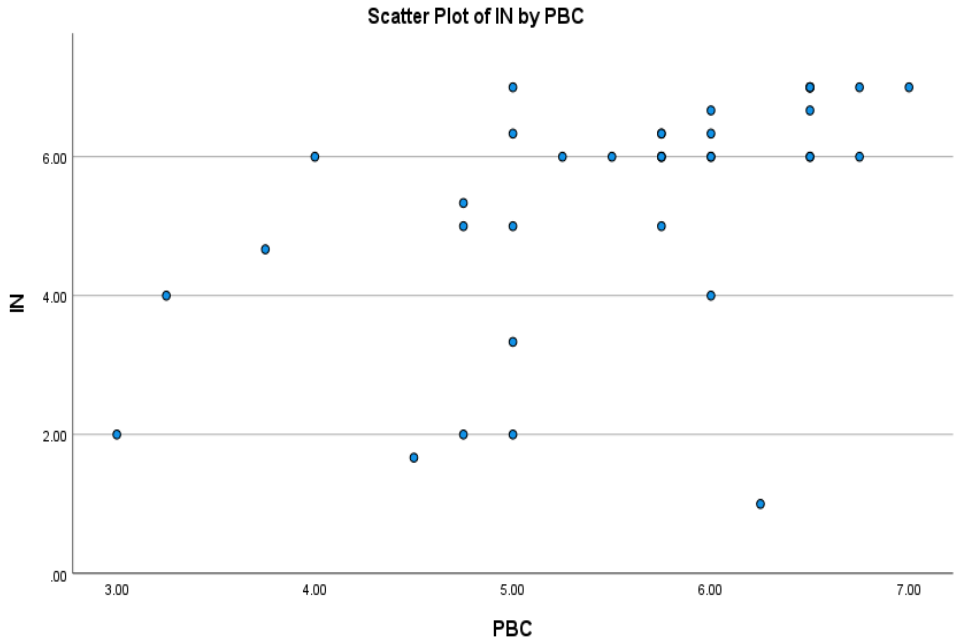


Figure 9

Scatterplot of Intent vs. Perceived Behavioral Norms (RQ3)



Visual inspection of the scatterplots between the dependent and each of the independent

variables shows a linear trend, indicating a linear relationship between the variables. The assumption of linearity has been met for all variables.

Independence of Observations

Simple linear regression requires that observations under study not be related (Kim, 2019). The assumption of independence of observations in a simple linear regression test for 1st-order autocorrelation, meaning that the values of successive residuals are correlated (Zuur & Ieno, 2016). I evaluated for independence of observations using the Durbin-Watson statistic. The following section discusses the independence of observations condition for each of the research questions (RQ1-RQ3).

Table 4

Simple Linear Regression Assumption of Independence of Observation: Durbin-Watson Statistic

	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
ATT	.706	.499	.484	1.23057	1.901
SN	.767	.588	.576	1.11591	1.787
	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
PBC	.538	.289	.269	1.46520	1.610

For each of the variables, there was independence of residuals, as assessed by a Durbin-Watson statistic of 1.90, 1.79, and 1.61 for attitude, subjective norms, and perceived behavioral control, respectively (see Table 4).

Outliers

A casewise diagnostics was run to evaluate the simple linear regressions for outliers. I set the standardized residuals at ±3 standard deviations for each of the three conditions (RQ1-RQ3). Values above or below three standard deviations for a specific case would then be identified as an outlier.

Table 5

Casewise Diagnostics for outliers

Case Number	Std. Residual	IN	Predicted Value	Residual
1	-3.430	1.00	6.0253	-5.02534

For ATT and SN, no outliers were identified, therefore the data met the assumption. There was one case (case number 1) that was identified as an outlier in the casewise diagnostics for perceived behavioral control. The case presented with a standardized residual of -3.43, which was less than the -3 cutoff standard deviation (see Table 5). The actual intent value was 1.00 which differed from the predicted value, 6.03 by -5.03. A review of the data found that this was a genuine outlier; there was no indication that it was a result of data entry or measurement error and therefore will be used in the analysis.

Homoscedasticity

Homoscedasticity tests for equivalent variance for all values of the predicted dependent variable (Bangdiwala, 2018). Homoscedasticity can be evaluated using the scatterplot of the studentized residuals against the unstandardized predicted values by observing the spread of residuals across the predicted values. To pass the assumption of homoscedasticity, the residuals should be evenly spread (Olsen et al., 2020). I created scatterplots of the studentized residuals against the unstandardized predicted values for all three conditions as shown below (see Figures 10- 12).

Figure 10

Assumption of Homoscedasticity: Attitude Residuals Plot

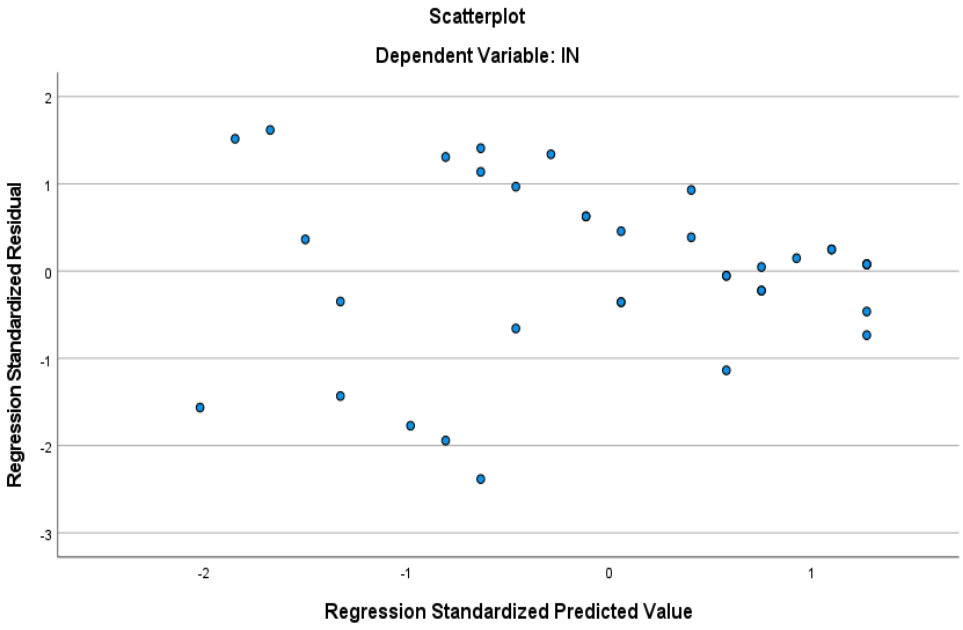


Figure 11

Assumption of Homoscedasticity: Subjective Norms Residuals Plot

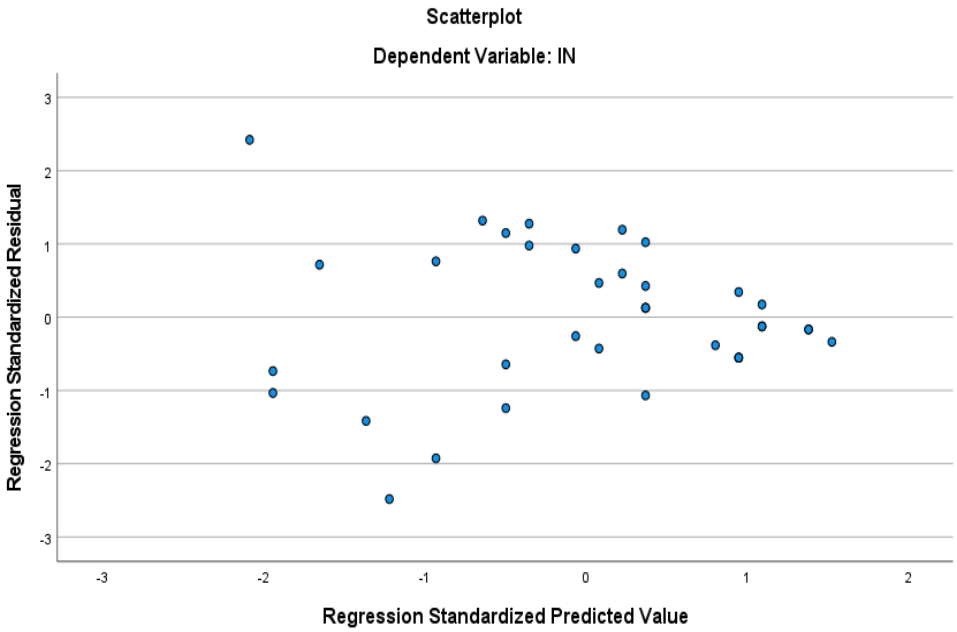
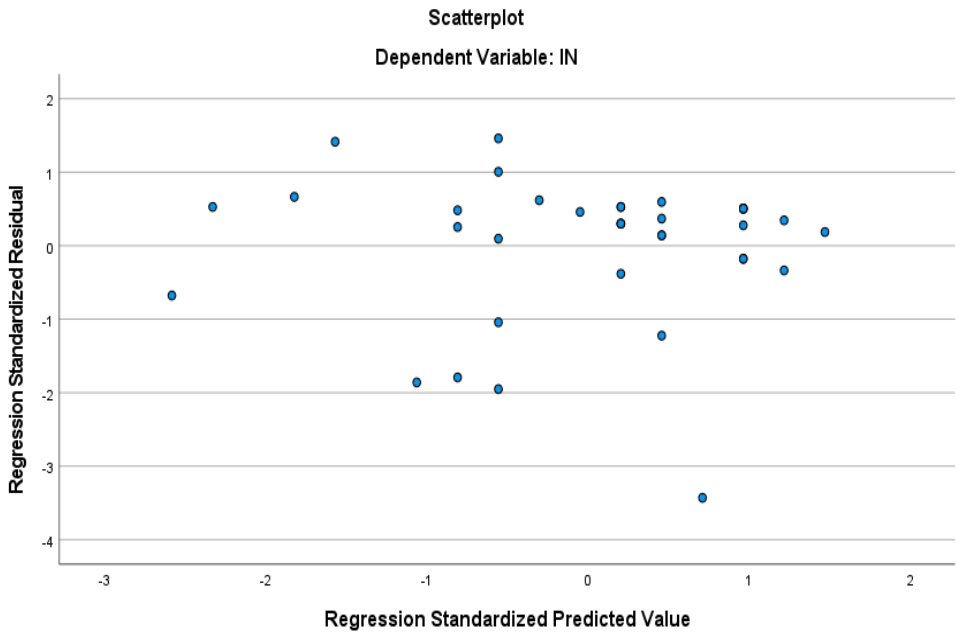


Figure 12

Assumption of Homoscedasticity: Perceived Behavioral Controls Residuals Plot



The plots indicate that aside from some minor deviations, the variation around the predictive values is constant, indicating that the data for all three conditions meets the assumption of homoscedasticity.

Normality

To test for the assumption of normality, for each condition, I performed an evaluation to determine whether the errors were normally distributed (Araiza-Aguilar et al., 2020). The generated histograms (see Figures 13-15) indicate that the data distribution is generally normal. The values on the normal P-P plot (see Figures 16-18) appear to generally follow the diagonal line, therefore a visual inspection of the histogram and normal P-P plot indicate that the residuals are normally distributed, indicating that the data meets the normality assumption.

Figure 13

Normality Histogram for Attitude

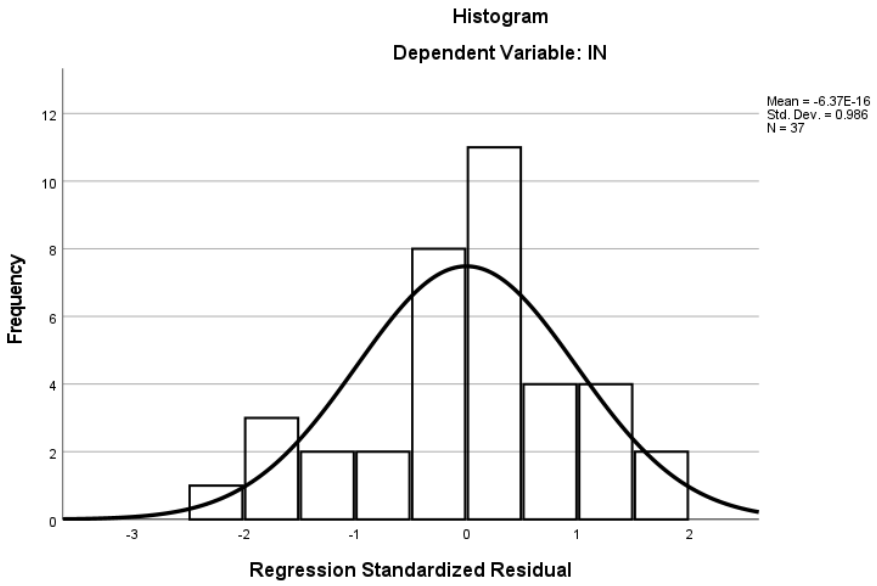


Figure 14

Normality Histogram for Subjective Norms

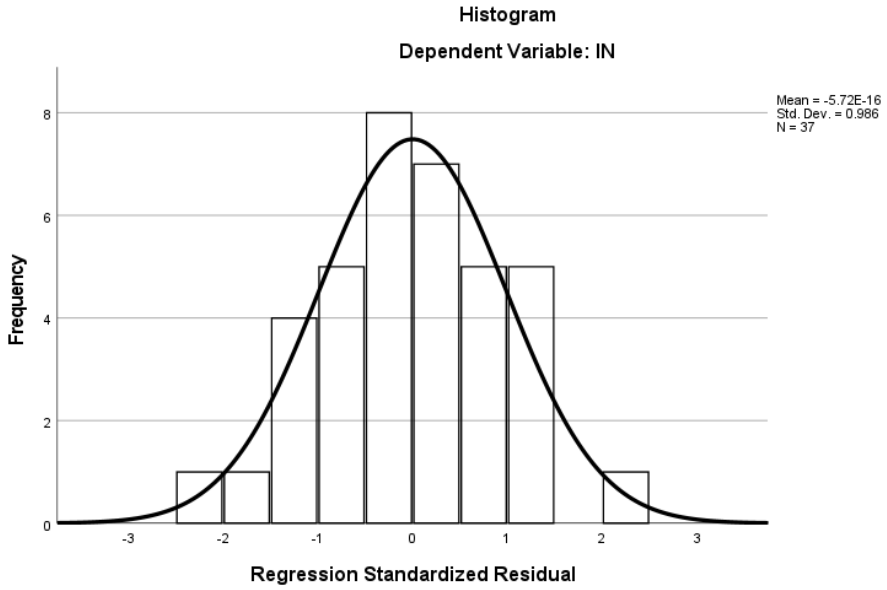


Figure 15

Normality Histogram for Perceived Behavioral Control

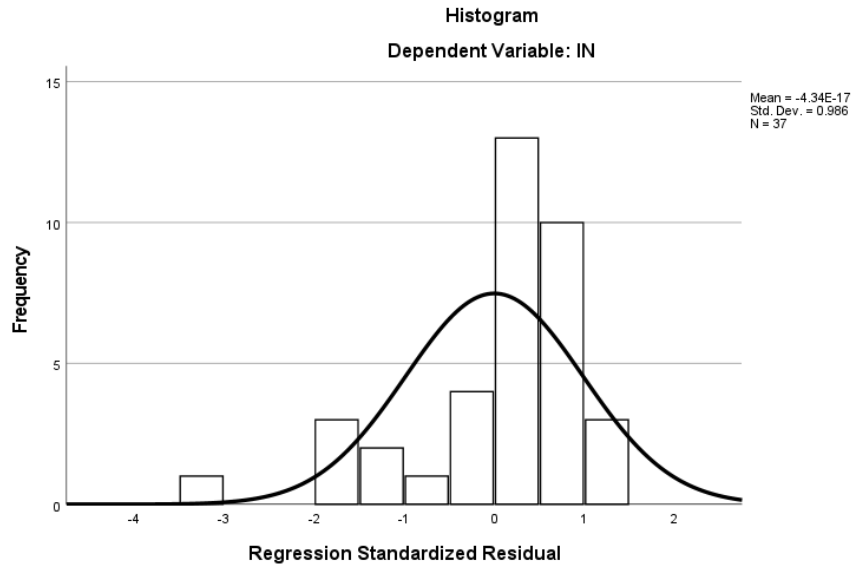


Figure 16

Normality P-P plot for Attitude

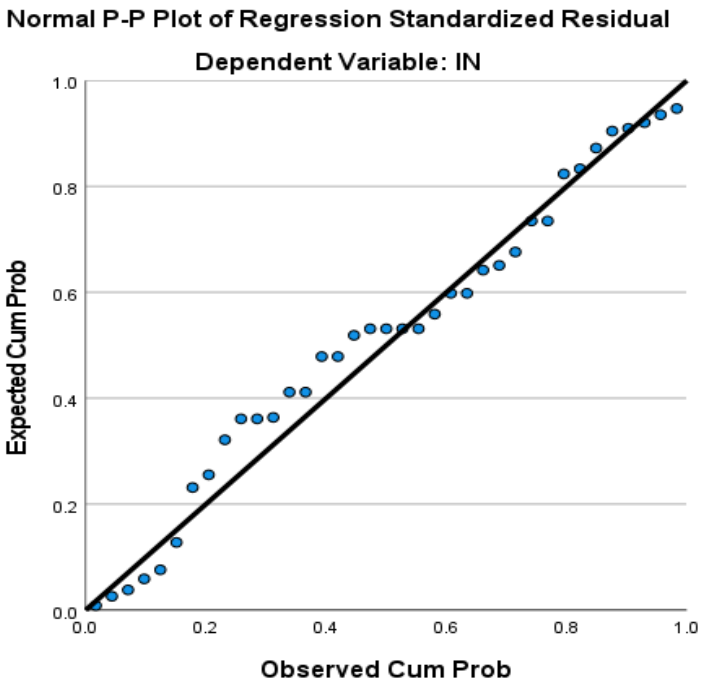


Figure 17

Normality Histogram for Subjective Norms

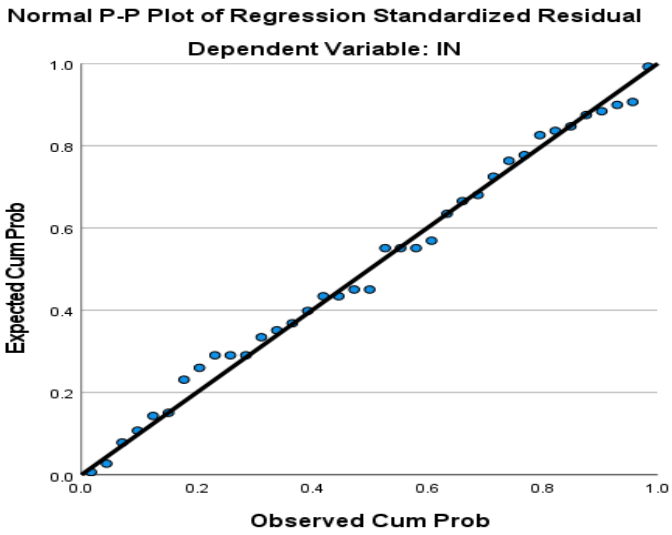
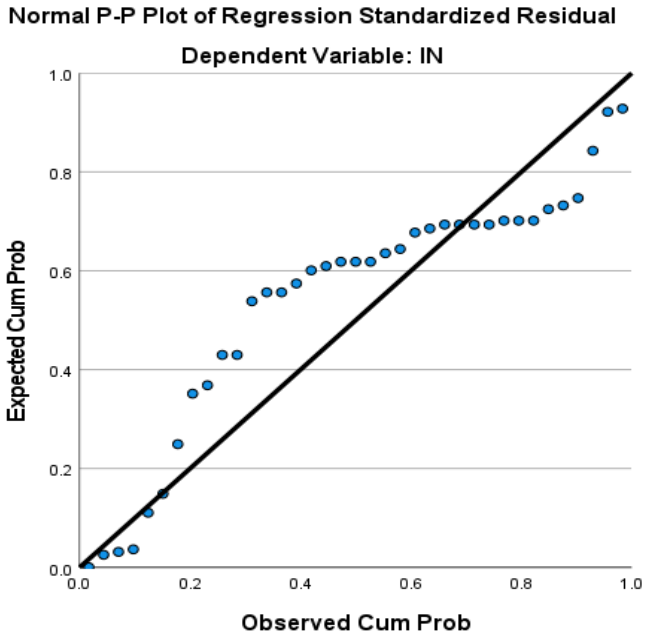


Figure 18

Normality Histogram for Perceived Behavioral Controls



Data evaluating the linear relationship between each of the independent variables of attitude, subjective norms, and perceived behavioral control and dependent variable of intent met the assumptions of simple linear regression therefore I proceeded to determine whether the simple linear regression model is a good fit for the data. For each of the research questions (RQ1-RQ3), a simple linear regression model was used to determine the amount of variation in dependent variable (intent to seek or maintain ISO/IEC 17025 accreditation) that is as a result of each the independent variables.

Model Fit

Various strategies can be applied to determine whether the simple linear regression model is a good fit for the data including the multiple correlation coefficient, percentage of explained variance, and the models overall statistical significance (Bazdaric et al., 2021). I applied these strategies in this study.

Multiple Correlation Coefficient (R)

The multiple correlation coefficient is a value that measures the degree of linear relationship between the independent variables and the dependent variable. The value of R can range from 0 to 1 where the strength of linear association increases from 0 (no linear association) to 1 (perfect linear association) (Olsen et al., 2020). For attitude, subjective norms and perceived behavioral control, values of .706, .767, and .538, respectively (see Table 6) were obtained indicating a moderate to strong level of association.

Table 6

Simple Linear Regression Model Fit Values for R, R^2, and Adjusted R^2

	R	R Square	Adjusted R Square	Std. Error of the Estimate
ATT → IN	.706	.499	.484	1.23057
SN → IN	.767	.588	.576	1.11591
PBC → IN	.538	.289	.269	1.46520

Total Variance (R^2 and adjusted R^2)

R^2 is a measure of the amount of variance in the dependent variable arising from the independent variable and was used as the effect size from the linear regression analysis. From the results in Table 6, the R^2 values for attitude, subjective norms and perceived behavioral control are .499, .588, and .289, respectively. This means that for RQ1, 49.9% of the variance in intention was explained by attitude. For RQ2 and RQ3, 58.8% and 28.9 % of variance in intention was explained by subjective norms and perceived behavioral controls, respectively. This R^2 value is based on the sample ($n = 37$) and therefore would be a biased estimate of the dependent variable accounted for by the regression model. To correct for this positive bias, the adjusted R^2 values (48.4%, 57.6% and 26.9%), which are the expected population values, were evaluated. In summary, with regards to attitude, the R^2 for the overall model was 49.9% with an adjusted R^2 value of 48.4%, which has been identified as a large effect size (Olsen et al., 2020). Subjective norms had an overall R^2 of 58.8% for the model with an adjusted R^2 value of 57.6%, also a large effect size. Perceived behavioral control had a small effect size of 26.9% as observed with by the adjusted R^2 value. The overall R^2 value for perceived behavioral control was 28.9%.

Model Statistical Significance

Statistical significance of the model relates to the significance value when the model contains the independent variable. The statistical significance of all three models

was assessed in table 7. Statistical significance is achieved if $p < .05$; all models representing the three research questions were statistically significant (see Table 7). Therefore, attitude, subjective norms, and perceived behavioral control statistically significantly predicted SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation, F (1, 35) = 34.82, p < .001 (attitude); F (1, 35) = 49.90, $p < .001$ (subjective norms); F (1, 35) = 14.25, $p < .001$(perceived behavioral control).

Table 7

Statistical Significance of the Simple Linear Regression Models

		Sum of Squares	df	Mean Square	F	Sig.
ATT → IN	Regression	52.729	1	52.729	34.821	.000
	Residual	53.001	35	1.514		
	Total	105.730	36			
SN → IN	Regression	62.146	1	62.146	49.906	.000
	Residual	43.584	35	1.245		
	Total	105.730	36			
PBC → IN	Regression	30.591	1	30.591	14.249	.001
	Residual	75.139	35	2.147		
	Total	105.730	36			

I concluded that simple linear regression was a good overall model fit to the data. The next step I took was to determine whether I would accept or reject my null hypothesis.

Research Questions

RQ1

RQ1 involved assessing the influence of SPHL directors' attitudes on their intention to seek or maintain ISO/IEC 17025 accreditation. The research question and corresponding null and alternate hypotheses were:

RQ1: Are SPHL directors' attitudes towards ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

H01: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

Ha1: SPHL directors' attitudes towards ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

The hypothesis sought to answer the question of whether SPHL directors' attitudes towards ISO/IEC 17025 would be a significant predictor of their intention to seek or maintain ISO/IEC 17025 accreditation. The dependent variable, intent was regressed on the predicting variable, attitude, to test the hypothesis Ha1. The results indicate that attitude can play a positive and significant role in SPHL directors' intent to seek or maintain the accreditation $\beta = 1.05$, $t = 5.90$, $p<.001$; as such, the null hypothesis was rejected. Further, the results showed that for every one unit in the attitude subscale score, attitude towards ISO/IEC 17025 accreditation increased by approximately 1.05 units. This indicated that there was a positive correlation between attitude and intent to seek or maintain ISO 17025 accreditation (i.e., the higher score on the attitude scale the more positive the attitude towards ISO/IEC 17025 accreditation). Furthermore, the $R^2 = .499$ shows that the model explains 49.9% of the variance in intention to seek or maintain ISO/IEC 17025 accreditation. Table 8 below shows a summary of the findings.

RQ2

RQ2 was about assessing the influence of SPHL directors' subjective norms on their intention to seek or maintain ISO/IEC 17025 accreditation. The research question and its corresponding null and alternate hypotheses were:

RQ2: Are SPHL directors' subjective norms associated with ISO/IEC 17025

accreditation a significant predictor of their intention to seek or maintain this accreditation?

H_02: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are not a significant predictor of intention to seek or maintain this accreditation.

H_a2: SPHL directors' subjective norms associated with ISO/IEC 17025 accreditation are a significant predictor of intention to seek or maintain this accreditation. The simple linear regression analysis found that subjective norms was statistically significant, $\beta = 0.95$, $t = 7.06$, $p<.001$ as shown in table 8 below. The null hypothesis was therefore rejected. The results showed that for every one unit in the subjective norms subscale score, SPHL directors' intention to seek or maintain ISO/IEC 17025 accreditation increased by almost 0.95 units. This indicated that there was a positive correlation between subjective norms and intent to seek or maintain ISO 17025 accreditation (i.e., a higher score on the subjective norms scale correlated with a greater perceived social pressure to seek or maintain ISO 17025 accreditation).

RQ3

RQ3 involved assessing the influence of SPHL directors' perceived behavioral control on their intention to seek or maintain ISO/IEC 17025 accreditation. The research question and its corresponding null and alternate hypotheses were:

RQ3: Are SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation a significant predictor of their intention to seek or maintain this accreditation?

H_03: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain this accreditation.

H_a3: SPHL directors' perceived behavioral controls associated with ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain this accreditation.

RQ3 asked if SPHL directors' perceived behavioral control towards ISO/IEC 17025 would be a significant predictor of their intention to seek or maintain ISO/IEC 17025 accreditation. The dependent variable, intent was regressed on the predicting variable, perceived behavioral control, to test the hypothesis Ha3. Based on the results in table 8, perceived behavioral control can play a positive and significant role in SPHL directors' intent to seek or maintain the accreditation $\beta = .93$, $t = 3.78$, $p<.001$; the null hypothesis was therefore rejected. Additionally, the results showed that for each unit in the perceived behavioral control subscale score, SPHL directors' intention to seek or maintain ISO/IEC 17025 accreditation increased by approximately 0.934 units. This means that perceived behavioral control and intent to seek or maintain ISO 17025 accreditation were positively associated, in that, SPHL directors' who scored higher on the perceived behavioral control scale felt greater control over their decision to seek or maintain ISO 17025 accreditation.

Table 8

Summary of Hypotheses Results Based on Simple Linear Regression Analysis

RQ	Hypothesis	Regression Weights	Beta Coefficient	R^2	t	p-value	Hypotheses Supported

RQ1	Ha1	ATT→IN	1.047	.499	5.901	.000	Yes
RQ2	Ha2	SN → IN	.949	.588	7.064	.000	Yes
RQ3	Ha3	PBC → IN	.934	.289	3.775	.001	Yes

Note: p*<0.05, ATT: Attitude, SN: Subjective Norms, PBC: Perceived Behavioral Control

The simple linear regression models evaluating RQ1-RQ3 do not however account for the two other TPB constructs in the predictive model. As such, the results from each of the simple linear regressions assumes that the other two predictors of intent identified in the theory of planned behavior are absent and therefore do not confound the analysis. A multiple linear regression analysis was therefore performed to estimate the simultaneous effect of the three independent constructs of the theory of planned behavior, ATT, SN, and PBC, on IN. The multiple linear regression analysis also defined the direct relationship between each of the variables by canceling out the linear effects of other the other two explanatory variables. The multiple linear regression analysis is discussed below.

Multiple Linear Regression

Multiple linear regression, like simple linear regression, is a statistical test used to predict the value of one variable from another, only, multiple linear regression uses more than one independent variable (Bazdaric et al., 2021). This statistical analysis allows researchers to evaluate the contribution of the independent variables to predict the dependent variable

Data Assumptions

The assumptions that must be met for performing multiple linear regression requires that the assumptions of independence of observations, linearity, homoscedasticity, multicollinearity and normality, are met (Chung et al., 2020; Daoud,

2017; Olsen et al., 2020; Syazali et al., 2019). The dependent variable must be continuous, interval or ratio. I treated the dependent variable (IN) as an interval variable after computing the dependent variable Likert items into scale domain scores, providing a numeric representation of respondents overall IN.

Independence of Observations

Similar to simple linear regression, to evaluate for the assumption of the independence of observations for multiple linear regression analysis, I used the Durbin-Watson statistic (see Table 9).

Table 9

Multiple Linear Regression Assumption of Independence of Observation: Durbin-Watson Statistic

R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
.789	.623	.589	1.09895	1.895

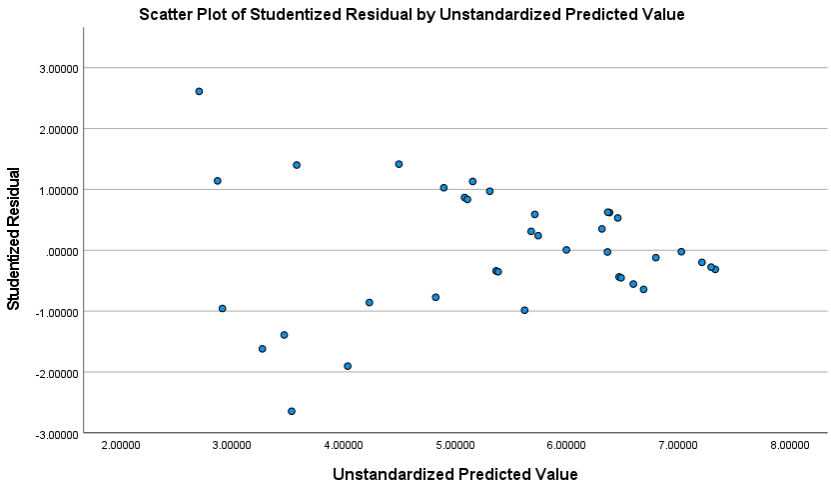
There was independence of residuals, as assessed by a Durbin-Watson statistic of 1.895.

Linearity

Linear relationships in multiple linear regression analysis must be observed between the dependent variable and each of the independent variables as well as between the dependent variable and the independent variables collectively (Zuur & Ieno, 2016). As such, both relationships should be tested to establish linearity. I first tested the relationship between the dependent variable and the independent variables together using a scatterplot of the studentized residuals against the unstandardized predicted values (see Figure 19).

Figure 19

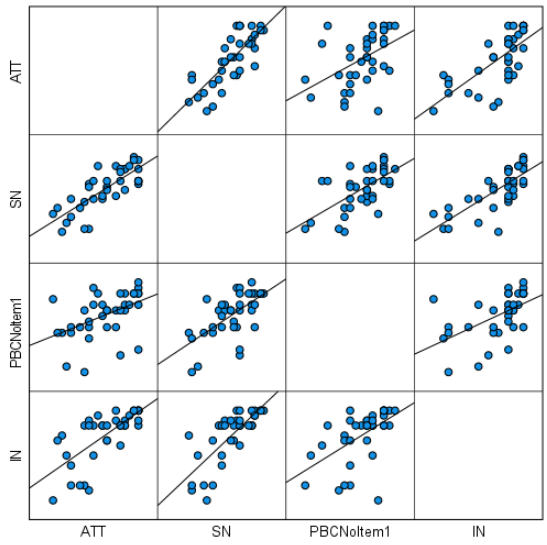
Multiple Linear Regression Assumption of Linearity Residuals Plot



The residuals form a somewhat horizontal band, indicating that the relationship between the dependent variable (IN) and the independent variables (ATT, SN, PBC) is likely to be linear. To establish whether a linear relationship existed between the dependent variable and each of the independent variables, I used a matrix scatterplot (see Figure 20) below as a simple way to check for linearity. I reviewed the scatterplots to see if the dependent variable is linearly related to three independent variables. The plots between the independent and dependent variables show a somewhat linear trend.

Figure 20

Multiple Linear Regression Assumption of Linearity Variables Matrix Scatterplot

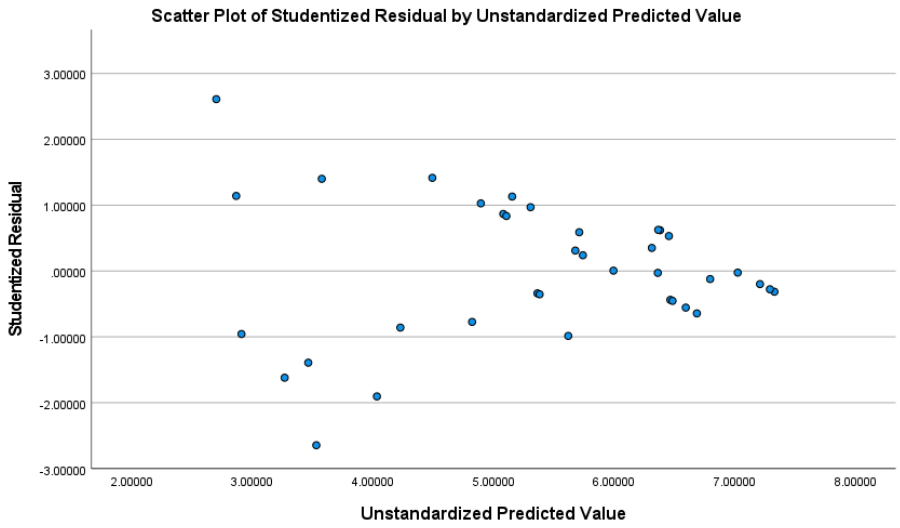


Homoscedasticity

As with simple linear regression, one of the assumptions that must be met for multiple linear regression is the assumption of homoscedasticity. Based on the scatterplot of studentized residuals against unstandardized predicted values (Figure 21) the variation around the predictive values is constant, therefore the data meets the assumption of homoscedasticity.

Figure 21

Scatterplot of Studentized Residuals Against Unstandardized Predicted Values



Multicollinearity

Multicollinearity involves ensuring there are no instances where two or more independent variables are highly correlated to each other (Bangdiwala, 2018). This is an important test as it clarifies independent variable contributions to the variance explained in the dependent variable. Multicollinearity detection is a two-step process entailing the inspection of correlation coefficients and Tolerance/VIF values as summarized below.

Correlation Coefficients

The collinearity test is performed to test the linear association between two explanatory variable e.g. ATT and SN (Vatcheva et al., 2016). To test for collinearity, I reviewed the correlation between the independent variables. The highest correlation was between ATT and SN with a Pearson correlation value of .785 (see Table 10). This value was below typical 0.8 threshold level therefore the data met the assumption of

collinearity (Vatcheva et al., 2016).

Table 10

Correlation Coefficients of the Independent Variables

		ATT	SN	PBC
ATT	Pearson Correlation	1	.785	.471
	Sig. (2-tailed)		.000	.003
	N	37	37	37
SN	Pearson Correlation	.785	1	.624
	Sig. (2-tailed)	.000		.000
	N	37	37	37
PBC	Pearson Correlation	.471	.624	1
	Sig. (2-tailed)	.003	.000	
	N	37	37	37

Tolerance/VIF

VIF and tolerance values are used to determine whether a predictor has a strong linear relationship with the other predictors (Vatcheva et al., 2016). For each variable, both values associated with collinearity statistics were in the acceptable range of tolerance i.e. (>0.1) and VIF (<10), which demonstrated a lack of multicollinearity (see Table 11); the data does not violate the assumption of multicollinearity (Thompson et al., 2017).

Table 11

Multicollinearity - Tolerance/VIF

	Collinearity Statistics	
	Tolerance	VIF
ATT	.384	2.608
SN	.301	3.320
PBC	.610	1.639

Normality

To test for the assumption of normality, the errors were observed to determine whether they were normally distributed (Araiza-Aguilar et al., 2020). The generated

histogram (see Figure 22) indicated a generally normal data distribution pattern. The values on the normal P-P plot (see Figure 23) appear to generally follow the diagonal line, therefore a preliminary review of the charts indicate that the residuals are normally distributed therefore, the data meets the normality assumption.

Figure 22

Normality Histogram of Standardized Residuals

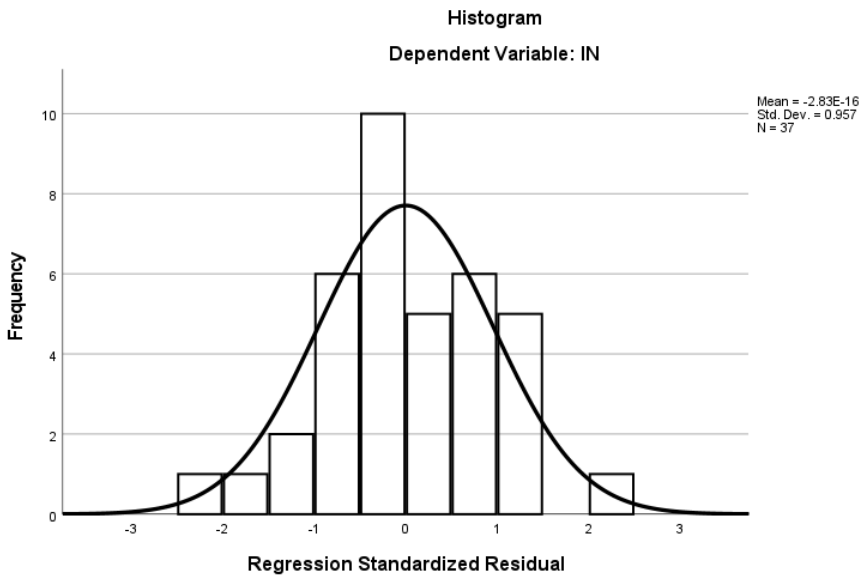
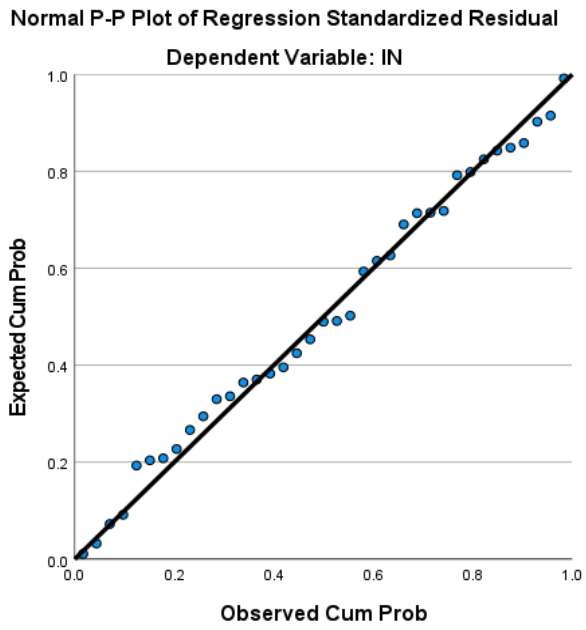


Figure 23

Normality P-P Plot of Standardized Residuals



Multiple Linear Regression Analysis

The data met the assumptions of multiple linear regression therefore the next step was to confirm whether the statistical model is a good fit for the data. The multiple linear regression model is used to determine the amount of variation in dependent variable (intent to seek or maintain ISO/IEC 17025 accreditation) that is as a result combining the independent variables (attitude, subjective norms and perceived behavioral control).

Multiple Linear Regression Model Fit

Various strategies can be applied to determine whether the multiple linear regression model is a good fit for the data including multiple correlation coefficient, percentage of explained variance, the models overall statistical significance and the precision of the predictions from the regression model; All these strategies were applied

in this study.

Multiple Correlation Coefficient (R) and Total Variance

The strength of the linear association between the independent variables and the dependent variable was reported to be .789 (see Table 12), indicating a moderate to strong level of association. From the results in table 12, the R^2 value is equal to 62.3%. This means that 62.3% of the variance in intention was explained by the independent variables. This R^2 value is based on the sample ($n = 37$) and therefore would be a biased estimate of the dependent variable accounted for by the regression model. To correct for this positive bias, the adjusted R^2 value (58.9%), which is the expected population value is evaluated. In summary, the R^2 for the overall model was 62.3% with an adjusted R^2 value of 58.9%, typically accepted as a large effect size (Burgueño & Medina-Casaubón, 2020; Olsen et al., 2020).

Table 12

Multiple Linear Regression Model Fit Values for R, R2, and adjusted R2

R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
.789	.623	.589	1.09895	1.895

Model Statistical Significance

Statistical significance of the model relates to the significance value when the model contains all the independent variables. Statistical significance is achieved if $p < .05$; which based on Table 13 is $p = .001$. Therefore, combined, attitude, subjective norms and perceived behavioral control statistically significantly predicted SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation, F (3, 33) = 18.18, $p < .001$.

Table 13

Statistical Significance of Multiple Linear Regression Model

	Sum of Squares	Df	Mean Square	F	Sig.
Regression	65.876	3	21.959	18.183	.000
Residual	39.853	33	1.208		
Total	105.730	36			

I concluded that there was a good overall model fit to the data. The results of the influence of each construct on intent as evaluated by multiple linear regression are discussed next.

Multiple Linear Regression: Influence of Attitude on Intention (RQ1)

RQ1 involved assessing the influence of SPHL directors' attitude on their intention to seek or maintain ISO/IEC 17025 accreditation. Based on the results of the level of significance for attitude, $p = .118$, I fail to reject the null hypothesis for RQ1 (see Table 14). Therefore, I conclude that the result of the regression analysis, $\beta = 0.41$, $t = 1.61$, $p = .118$ show that SPHL directors' attitudes towards ISO/IEC 17025 are not a significant predictor of their intention to seek or maintain ISO/IEC 17025 accreditation.

Table 14

Variable Estimates from Multiple Linear Regression Analysis

	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
(Constant)	-.728	1.237		-.588	.560	-3.244	1.789
ATT	.411	.256	.277	1.606	.118	-.110	.932
SN	.598	.241	.483	2.481	.018	.108	1.088
PBC	.184	.237	.106	.775	.444	-.299	.667

Multiple Linear Regression: Influence of Subjective Norms on Intention (RQ2)

RQ2 involved assessing the influence of SPHL directors' subjective norms on their intention to seek or maintain ISO/IEC 17025 accreditation. The regression analysis found that subjective norms was statistically significant, $\beta = 0.60$, $t = 2.48$, $p = .018$, and that for each unit the subjective norms subscale score, SPHL directors' intention to seek or maintain ISO/IEC 17025 accreditation increased by almost 0.60 units (i.e. a higher score on the subjective norms scale correlated with a greater perceived social pressure to seek or maintain ISO 17025 accreditation) (see Table 14). Subjective norms were found to be significant ($p < .05$). The null hypothesis in this case was rejected and therefore I concluded that SPHL directors' subjective norms (organizational culture) associated with ISO/IEC 17025 accreditation are a significant predictor of their intention to seek or maintain ISO/IEC 17025 accreditation

Multiple Linear Regression: Influence of Perceived Behavioral Control on Intention (RQ3)

RQ3 involved assessing the influence of SPHL directors' perceived behavioral control on their intention to seek or maintain ISO/IEC 17025 accreditation. The regression analysis found that perceived behavioral control was not statistically significant $\beta = 0.18$, $t = 0.76$, $p = .444$ as shown in Table 14. I therefore failed to reject the null hypothesis and concluded that SPHL directors' perceived behavioral control associated with ISO/IEC 17025 accreditation are not a significant predictor of their intention to seek or maintain ISO/IEC 17025 accreditation.

Linear Regression Summary

Three simple linear regression models were run to define and quantify the

relationship between the three dependent variables from RQ1-RQ3 and the independent variable of intent. Assumption testing revealed that data was normally distributed as assessed by visual inspection of histograms and normal P-P plots; one outlier was identified in the casewise diagnostics for perceived behavioral control; linear relationships were observed as assessed by scatterplots; there was homoscedasticity as assessed by scatterplot of the studentized residuals against the unstandardized predicted values and there was independence of observation for all three regressions as assessed by the Durbin-Watson statistic (ATT - 1.90, SN - 1.79, and PBC - 1.61). Results from the three simple linear regression analyses revealed that all three constructs, attitude, subjective norms, and perceived behavioral control, statistically significantly predicted SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation, $\beta = 1.05$, $t = 5.90$, $p < .001$ (attitude); $\beta = 0.95$, $t=7.06$, $p < .001$ (subjective norms); $\beta = .93$, $t = 3.78$, $p < .001$(perceived behavioral control). However, this was not the case in the multivariate analysis.

A multiple linear regression analysis that included all three independent variables was conducted. Preliminary independence of observation assumption testing was met as observed with the Durbin-Watson statistic (1.895); linearity was observed as assessed with a scatterplot of the studentized residuals against the unstandardized predicted values and a linearity matrix plot; there was homoscedasticity as assessed by scatterplot of the studentized residuals against the unstandardized predicted values; multicollinearity was met as assessed by correlation coefficients and tolerance/VIF where each variable was within acceptable values; and normality was met as assessed by a histogram and normal

P-P plot. The multiple linear model results showed that 58.9% of the variance in intention was explained by the independent variables.

Additionally, the simultaneous effect of the three independent constructs on intent were apparent in the multiple linear regression model, which defined the direct relationship between each of the variables by canceling out the linear effects of other two explanatory variables (see Table 15). The multiple linear regression showed that subjective norms were a statistically significant $\beta = 0.60$, $t = 2.48$, $p = .018$ predictor of SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation while attitude ($\beta = 0.41$, $t = 1.61$, $p = .118$) and perceived behavioral control ($\beta = 0.18$, $t = 0.78$, $p = .444$) were not. The results showed that attitudes and perceived behavioral control towards ISO/IEC 17025 had a positive effect their intention to seek or maintain ISO/IEC 17025 accreditation it was not enough to be a significant predictor of intention. The effect sizes for all three variables were greatly reduced from the observed effect sizes in the simple linear regression models, confirming the interactive effects the constructs of the TPB have on each other.

Table 15

Interaction Effects of Independent Variables

	Simple Linear Regression				Multiple Linear Regression			
	β	*t*	*p*	R^2	*β*	*t*	*P*	R^2
ATT	1.047	5.901	.001	.499	.411	1.606	.118	
SN	.949	7.064	.001	.588	.598	2.481	.018	.623
PBC	.934	3.775	.001	.289	.184	.775	.444	

MANOVA

The MANOVA is a statistical test used to evaluate group differences based on different outcomes (Smith et al., 2020). A MANOVA was used to determine whether there were any differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited and working towards accreditation laboratories. To obtain a valid result, data must meet different assumptions of the one-way MANOVA.

Data Assumptions

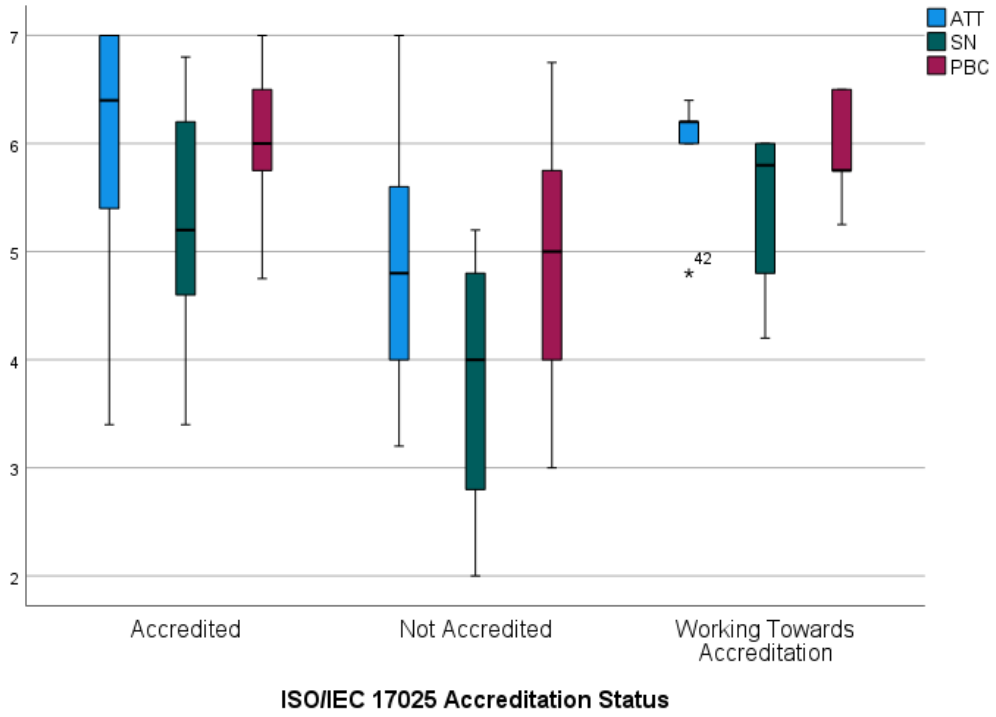
The statistical assumptions that must be met include: two or more dependent variables measured at the interval or ratio level; independent variable with two or more categorical, independent groups; independence of observations, adequate sample size; lack of univariate or multivariate outliers; multivariate normality; a linear relationship between each pair of independent variables for each group of the dependent variable; homogeneity of variance-covariance matrices; and no multicollinearity. The data set meets the first three assumptions which relate to the study design. The sections that follow below evaluate the data to identify any violations to the remaining assumptions.

No Univariate or Multivariate Outliers.

Outliers are identified as values in any group of the independent variable that greatly differ from the general scores of the sample within the group.

Figure 24

Multivariate Outlier Summary



A boxplot was generated as a simple way to scan for outliers (Figure 24). Based on the output, one data point in the working towards accreditation category was identified as an outlier. The dependent variable, ATT had an outlier present. The outlier was determined to be a genuinely unusual value and were therefore kept for the analysis.

Multivariate Normality

The Shapiro-Wilk test for normality was used to test if the data was normally distributed within each of the independent variable groups for all of the dependent variables. This test is also suitable for use with small sample sizes. To pass the normality test, the Shapiro-Wilks significance results should be greater than .05 (see Table 16).

Table 16

MANOVA Shapiro-Wilk Test for Normality

		Shapiro-Wilk		
	Accreditation Status	Statistic	Df	Sig.
ATT	Accredited	.866	18	.016
	Not Accredited	.975	13	.946
	Working Towards Accreditation	.750	5	.030
SN	Accredited	.938	18	.268
	Not Accredited	.901	13	.138
	Working Towards Accreditation	.826	5	.131
PBC	Accredited	.937	18	.255
	Not Accredited	.970	13	.893
	Working Towards Accreditation	.871	5	.272

SN and PBC were normally distributed as assessed by Shapiro-Wilk's test (p>.05). The Shapiro-Wilk's test however indicated that ATT within the accredited and working towards accreditation status was not normally distributed. Even though there was a violation to the assumption of normality, the MANOVA is known to be robust to deviations from normality (Yun et al., 2020), therefore I proceeded with assessing the next assumption.

Multicollinearity

For MANOVA, the collinearity test is performed to determine the correlation between the dependent variables. A moderate correlation indicates that the assumption of multicollinearity has been met. Pearson correlations was used to detect multicollinearity (see Table 17). The highest correlation was between ATT and SN with a Pearson correlation value of .79, which was below typical .80 threshold level. Therefore, there was no multicollinearity as assessed by Pearson correlation (r = .785, p = .000; r = .471, p

= .003; r = .624, *p* =.000; see Table 17).

Table 17

MANOVA Pearson Correlations Test for Multicollinearity

		ATT	SN	PBC
ATT	Pearson Correlation	1	.785	.471
	Sig. (2-tailed)		.000	.003
	N	37	37	37
SN	Pearson Correlation	.785	1	.624
	Sig. (2-tailed)	.000		.000
	N	37	37	37
PBC	Pearson Correlation	.471	.624	1
	Sig. (2-tailed)	.003	.000	
	N	37	37	37

Assumption of Linearity

The assumption of linearity test seeks to determine whether there is a linear relationship between each pair of dependent variables for each group of the independent variables. The assumption was tested by plotting a scatterplot matrix of each group of the independent variable, ISO/IEC 17025 accreditation status (see Figures 25 to 27).

Figure 25

Scatterplot of Accredited Status

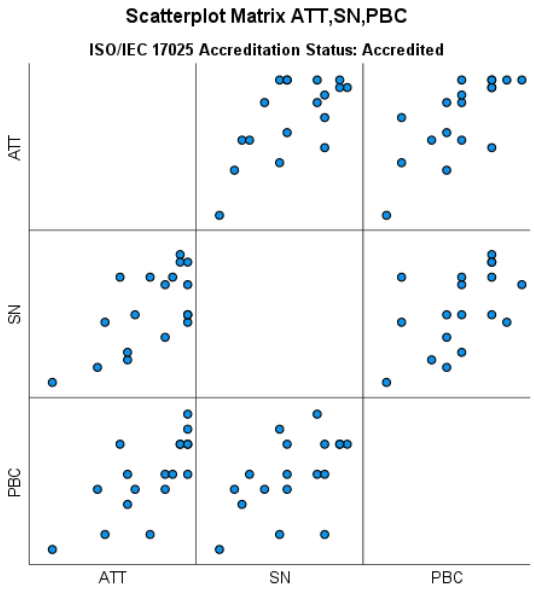


Figure 26

Scatterplot of Non Accredited Status

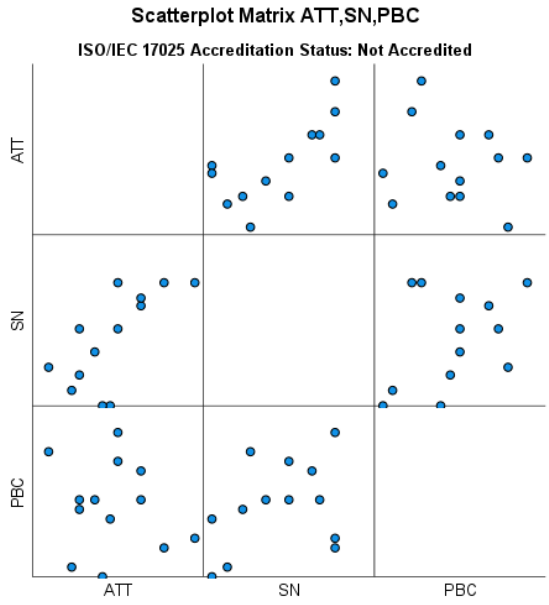
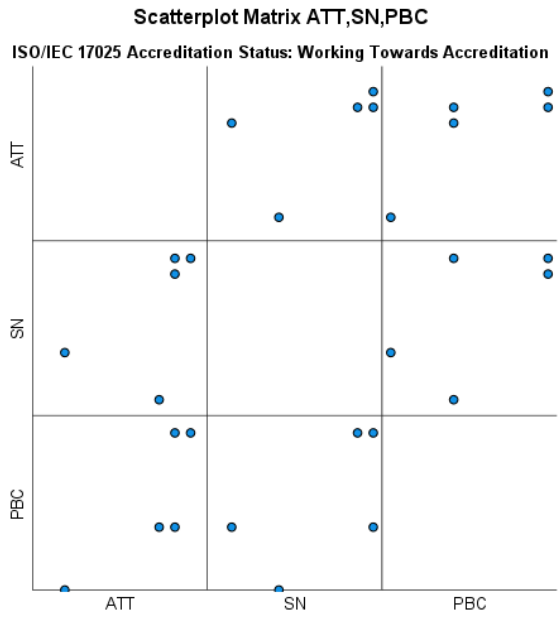


Figure 27

Scatterplot of Working Towards Accreditation Status



For two accreditation statuses, accredited and working towards accreditation, the plotted data followed a linear pattern for the assessed combinations of dependent variables. However, this was not the case for the working towards accreditation group. The non-linear pattern observed for this group could be attributed to the very small sample size (n = 5).

Multivariate Outliers

Multivariate outliers are data points that present with unusual combinations of values on the dependent variables and can be identified using the statistic measure, Mahalanobis distance. Mahalanobis distance is a statistical technique applied in the detections of multivariate outliers (Bulut, 2020). SPSS was used to generate the Mahalanobis distance for each participant as calculated within their specific group of

independent variables, i.e., accredited, non-accredited and working towards accreditation. The Mahalanobis distance values generated in SPSS were then compared against a chi-square (χ^2) distribution with degrees of freedom equivalent to the number of dependent variables (four) and an alpha of .001 (El-Masri et al., 2021). The critical value for 4 dependent variables is 18.47. The largest Mahalanobis distance value reported was 9.66. Therefore, as assessed by Mahalanobis distance, there were no multivariate outliers in the data.

Sample Size Assumption

A generally accepted rule for MANOVA sample sizes is that, at a bare minimum, there are as many respondents in each group of independent variables (different accreditation statuses) as there are the number of dependent variables, (three in this case). Based on this rule, the data has met the assumption of sample size (see Table 18).

Table 18

MANOVA Sample Sizes

	Groups	N
ISO/IEC 17025 Accreditation Status	Accredited	18
	Not Accredited	13
	Working Towards Accreditation	5

Homogeneity of Variance-Covariance Matrices

MANOVA also requires that the assumption of equality of variance-covariance matrices is met. Box's test was used to determine whether the assumption was met where a non-significant Box's test indicates that the data has met the assumption of homogeneity of variance-covariance matrices.

Table 19

Equality of Covariance Matrices

Box's Test of Equality of Covariance Matrices	
Box's M	27.163
F	1.778
df1	12
df2	649.019
Sig.	.048

Therefore, as assessed by Box's test of equality of covariance matrices, there was homogeneity of variance-covariance matrices (p = .048) (see Table 19). The MANOVA assumptions were met, therefore I conducted the MANOVA on the data set. The results of the MANOVA are presented next.

MANOVA Descriptive Statistics

A descriptive summary of the MANOVA results is presented in Table 20. Data are presented as mean ± standard deviation. SPHL directors from accredited and working towards accreditation laboratories had higher mean scores for all three dependent variables compared to those from non-accredited laboratories. The higher mean ATT score observed with SPHL directors from accredited and working towards accreditation laboratories indicated that these respondents had a more positive attitude towards ISO/IEC 17025 accreditation. As relates to ATT between respondents from accredited and working towards accreditation laboratories, those from accredited laboratories scored higher (6.02) compared to those from working towards accreditation laboratories (5.92). Those from non-accredited laboratories had a mean score of 4.86.

The SN score related to SPHL director perceptions of societal pressure towards

ISO/IEC 17025 accreditation, where a higher mean score indicated greater perceived pressure to seek or maintain ISO/IEC 17025 accreditation. As mentioned, SPHL directors from accredited and working towards accreditation laboratories had higher SN mean scores compared to those from non-accredited laboratories (3.74), however, there was a slight difference between the two, with those from working towards accreditation laboratories scoring slightly higher (5.36) than those from accredited laboratories (5.34).

The PBC scale sought to evaluate SPHL directors' perception of their control over the decision to seek or maintain ISO/IEC 17025 accreditation for their laboratories. A higher PBC score was indicative of respondents feeling more strongly that they had control over their laboratories decision to seek or maintain ISO/IEC 17025 accreditation. Mean scores for SPHL directors from accredited (5.99) and working towards accreditation laboratories (5.95) differed slightly from each other and were both higher than those for SPHL directors from non-accredited laboratories (4.85).

Table 20

MANOVA Descriptive Summary

	Accreditation Status	Mean	Std. Deviation	n
ATT	Accredited	6.0222	1.04688	18
	Not Accredited	4.8615	1.04685	13
	Working Towards Accreditation	5.9200	.64187	5
SN	Accredited	5.3444	1.04218	18
	Not Accredited	3.7385	1.21761	13
	Working Towards Accreditation	5.3600	.81731	5
	Accreditation Status	Mean	Std. Deviation	N
PBC	Accredited	5.9861	.63288	18
	Not Accredited	4.8462	1.14809	13
	Working Towards Accreditation	5.9500	.54199	5

Statistical Significance Analysis

Multiple multivariate statistics that can be used to test the statistical significance of the differences between groups are presented in the SPSS MANOVA output table including: Pillai's Trace, Wilks' Lambda, Hotelling's Trace and Roy's Largest Root (Ateş et al., 2019). Due to the unequal sample sizes in my data as well as a statistically significant Box's M, I used Pillai's trace statistic (Ateş et al., 2019).

Table 21

Analysis of Statistical Significance

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Accreditation Status	Pillai's Trace	.420	2.832	6.000	64.000	.017	.210

There was a statistically significant difference between the laboratories on the combined dependent variables, F (6,64) = 2.83, p<0.05; Pillai's Trace = .420; partial η2 = .21 (see Table 21). The effect for group differences as assessed by the partial η2 (.21) indicated that the effect for the three groups in the MANOVA accounted for 21% of the group differences.

RQ4

RQ4 involved whether there were there were significant differences in the three constructs between SPHL directors based on accreditation status of their laboratories. The research question and corresponding null and alternate hypotheses were:

RQ4: Are there significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL

directors of accredited, non-accredited, and working towards accreditation laboratories?

$H_0$4: There are no significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories.

H_a4: There are significant differences in the attitudes, subjective norms, and perceived behavioral controls towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories.

Results from the MANOVA found that there was a statistically significant difference between the laboratories based on accreditation status, $F(6,64) = 2.83$, $p<0.05$; Pillai's Trace = .420; partial $\eta 2 = .21$; the null hypothesis was therefore rejected.

A one-way ANOVA result for each dependent variable was run to further isolate the exact dependent variables that contributed to the statistically significant MANOVA. The ANOVA is discussed next.

ANOVA

To determine which of the three dependent variables contributed to the statistically significant MANOVA an ANOVA statistic was run on the dependent variables of ATT, SN, and PBC (see Table 22). Results show that there were significant differences in the attitudes ($F(2,33) = 5.33$, $p<.05$; partial $\eta 2 = .24$), subjective norms ($F(2,33) = 9.12$, $p<.05$; partial $\eta 2 = .36$), and perceived behavioral controls ($F(2,33) = 7.38$, $p<.05$; partial $\eta 2 = .31$) for SPHL directors from all three accreditation statuses. The partial $\eta 2$ values indicate that subjective norms had the strongest effect, followed by attitude then perceived behavioral control. These results showed that there were

significant differences in the ATT, SN and PBC (with an effect of 27.4%, 35.6% and 30.9% respectively) between SPHL directors in accredited, non-accredited and working towards accreditation.

Table 22

ANOVA Test of Between-Subjects Effects

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Accreditation Status	ATT	10.806	2	5.403	5.333	.010	.244
	SN	21.513	2	10.756	9.119	.001	.356
	PBC	10.650	2	5.325	7.383	.002	.309
Error	ATT	33.430	33	1.013			
	SN	38.927	33	1.180			
	PBC	23.801	33	.721			

Attitude

I first evaluated for significant differences in the attitudes towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited and working towards accreditation laboratories. Of the 36 participants that responded to the question on accreditation status, 18 were accredited, 13 were not accredited and 5 were working towards accreditation. ANOVA results suggest that the attitude scores of the groups differ significantly ($F_{2, 33} = 5.33$, $p = .010$).

The Levine's test of variance was used to determine whether the variance in the scores is the same for each of the three groups being observed. A non-significance Levine's test indicates that equality of variance is assumed which was the case for this data set ($p = 0.354$). As such, post-hoc comparisons were assessed using Tukey's range

test. The test indicated that the mean score for being accredited (M = 6.02, *SD* = 1.05) was significantly higher from being non-accredited (M = 4.86, *SD* = 1.05). No significant difference was assessed between the mean score for working towards accreditation (M = 5.92, *SD* = 0.64) and the other two groups. Table 23 summarizes ANOVA attitude results.

Table 23

ANOVA Attitude Results

			Test of Homogeneity of Variances		ANOVA	
Status	Mean	Std. Dev (SD)	Levene's Statistic	Sig.	F	Sig.
Accredited	6.0222	1.04688	1.071	.354	5.333	.010
Not Accredited	4.8615	1.04685				
Working to Accreditation	5.9200	0.64187				
Group Differences						
Accreditation Status	Mean Difference		Sig	95% Confidence Interval [LL-UL]		
Accredited- Not Accredited	1.607		0.009	0.2618	2.0596	

Subjective Norms

Differences in the subjective norms towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited and working towards accreditation laboratories were assessed next. The ANOVA results suggest that the subjective norm scores of the groups differ significantly ($F_{2, 33} = 9.12$, $p = .001$). The Levine's test of variance was used to determine whether the variance in the scores is the same for each of the three groups being observed.

A non-significance Levine's test indicates that equality of variance is assumed which was the case for this data set ($p = .369$). Therefore, post-hoc comparisons were

assessed using Tukey's range test. The test indicated that the mean score for being accredited (M = 5.34, *SD* = 1.04) was significantly different from being not-accredited (M = 3.73, *SD* = 1.21). The mean score for working towards accreditation (M = 5.36, *SD* 0.82) differed significantly from not accredited. The mean differences were significant at the 0.05 level. However, no significant difference was assessed between the mean score for working towards accreditation and the accredited groups. Table 24 summarizes ANOVA subjective norms results.

Table 24

ANOVA Subjective Norms Results

			Test of Homogeneity of Variances		ANOVA	
Status	Mean	Std. Dev (SD)	Levene's Statistic	Sig.	F	Sig.
Accredited	5.3444	1.04218	1.027	.369	9.119	.001
Not Accredited	3.7385	1.21761				
Working to Accreditation	5.3600	0.81731				
Group Differences						
Accreditation Status		Mean Difference	Sig	95% Confidence Interval [LL-UL]		
Accredited- Not Accredited		1.606	0.001	0.6360	2.5760	
Working to Accreditation- Not Accredited		1.622	0.021	0.2191	3.0240	

Perceived Behavioral Control

The next difference explored was perceived behavioral control towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited, and working towards accreditation laboratories. ANOVA results suggest that perceived behavioral control scores of the groups differ significantly ($F_{2, 33} = 7.38$, $p = .002$). A non-significance Levine's test indicates that equality of variance is assumed which was the case for this data set (p = .064). Therefore, post-hoc comparisons were assessed using Tukey's range test. The test indicated that the mean score for being accredited (M =

5.99, SD = 0.633) was significantly different from being not-accredited (M = 4.85, SD = 1.15). The mean score for working towards accreditation (M = 5.95, SD 0.542) differed significantly from not accredited. The mean differences were significant at the 0.05 level. However, no significant difference was assessed between the mean score for working towards accreditation and the accredited groups. Table 25 summarizes the One-Way ANOVA subjective norms results.

Table 25

ANOVA Perceived Behavioral Control Results

			Test of Homogeneity of Variances		ANOVA	
			Levene's		F	Sig.
Status	Mean	Std. Dev (SD)	Statistic	Sig.		
Accredited	5.9861	0.63288	2.983	0.064	7.383	.002
Not Accredited	4.8462	1.14809				
Working to Accreditation	5.9500	0.54199				
		Group Differences				
Accreditation Status		Mean Difference	Sig	95% Confidence Interval [LL-UL]		
Accredited - Not Accredited		1.140	0.002	0.3815	1.8985	
Working to Accreditation - Not Accredited		1.10385	0.048	0.0072	2.2005	

MANOVA and ANOVA Summary

A one-way multivariate analysis of variance was run to determine the effect of SPHL director accreditation status on attitude, subjective norms and perceived behavioral control. The different accreditation statuses were accredited, not accredited, and working towards accreditation. Preliminary assumption checking revealed that data was normally distributed, as assessed by Shapiro-Wilk test ($p > .05$); one univariate outlier was identified as assessed by boxplot and there were no multivariate outliers per Mahalanobis distance ($p > .001$) evaluation; there were linear relationships, as assessed by scatterplot; no multicollinearity (r = .785, p= .000; r = .471, p = .003; r = .624, p =.000); and there

was homogeneity of variance-covariance matrices, as assessed by Box's M test (p = .048). SPHL directors from accredited and working towards accreditation laboratories had higher mean scores for all three dependent variables compared to those from non-accredited laboratories. The differences between accreditation status on the combined dependent variables was statistically significant, F (6,64) = 2.83, $p < 0.05$; Pillai's Trace = .420; partial η2 = .21.

A separate ANOVA was conducted for each dependent variable, where each ANOVA was evaluated at an alpha level of .05. The ANOVA results showed a statistically significant difference in ATT between SPHL directors with different accreditation status F (2,33) = 5.33, $p < .05$; partial η2 = .24. Similarly, for the other two dependent variables, there was a statistically significant difference in SN and PBC between SPHL directors with different accreditation status, F (2,33) = 9.12, $p < .05$; partial η2 = .36 and F (2,33) = 7.38, $p < .05$; partial η2 = .31, respectively. Tukey post-hoc tests showed that for attitude scores, SPHL directors from accredited laboratories (M = 6.02, *SD* = 1.05, p = .009) had statistically significantly higher mean scores than SPHL directors from non-accredited laboratories (M = 4.86, *SD* = 1.04).

For subjective norm scores, Tukey post-hoc tests showed that SPHL directors from accredited (M = 5.34, *SD* = 1.04, p = .001) and working towards accreditation laboratories (M = 5.36, *SD* 0.82, p = .021) had statistically significantly higher mean scores from non-accredited laboratories (M = 3.73, *SD* = 1.21). Dunnett's test showed that for perceived behavioral control, the mean score for SPHL directors from accredited laboratories (M = 5.99, *SD* = 0.63, p = .014) scored statistically higher than those from

non-accredited laboratories (M = 4.85, *SD* = 1.15). Similarly, SPHL directors from working towards accredited laboratories (M = 5.95, *SD* = 0.54, *p* = .042) scored statistically higher than those from non-accredited laboratories (M = 4.85, *SD* = 1.15) on the PBC variable.

Chapter 5 includes interpretations of findings from data analyses, limitations of the study, recommendations for future study, and implications for social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this quantitative, cross-sectional survey study was to use the TPB as a guide to examine SPHL directors' attitudes, subjective norms, and perceived behavioral control towards ISO/IEC 17025 accreditation and their influence on intent to seek or maintain ISO/IEC 17025 accreditation. Understanding these relationships can be helpful in terms of understanding the predictors of SPHL directors' intentions to become ISO/IEC 17025 accredited.

There is a paucity of research regarding quality improvement programs in SPHLs specifically concerning ISO/IEC 17025 accreditation despite SPHLs' significance to public health. Therefore, researching how SPHL directors perceive or value ISO/IEC 17025 accreditation is important because laboratory leaders have been identified as a predictor of successful implementation of accreditation and other QI initiatives.

Interpretation of the Findings

Three simple linear regression models were performed to address the first three research questions involving associations between independent variables of attitude, subjective norms, and perceived behavioral control with intention seek or maintain ISO 17025 accreditation at a 95% confidence interval. Variables that were significant in the simple linear regression models were then analyzed using multiple linear regression for further statistical significance while adjusting for interference effects. Results indicated that independently, each of the variables can play a positive and significant role in SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation, with β =1.05, t = 5.90,

$p < .001$ (attitude); $\beta = 0.95$, $t = 7.06$, $p < .001$ (subjective norms); $\beta = .93$, $t = 3.78$, and $p < .001$ (perceived behavioral control).

All three variables due to their statistical significance in the simple linear regression, were analyzed via a multiple linear regression analysis. The multiple linear regression model defined the direct relationship between each of the independent variables and the dependent variable by canceling out the linear effects of other two explanatory variables in the model. The multiple linear regression model confirmed the interactive effects of the constructs of the TPB on each other. Results from the multiple linear regression showed that the perceived impact for every one unit in the construct subscales was greatly reduced compared to simple linear regression models. Attitude, subjective norms, and perceived behavioral control perceived impact went from $\beta = 1.05$, $\beta = .95$, and $\beta = .93$ to $\beta = .41$, $\beta = .60$, and $\beta = .18$, respectively.

Positive attitudes towards a specific behavior generally translates into intent to partake in that behavior or action. The construct of attitude sought to evaluate SPHL directors' favorable or unfavorable view of the ISO/IEC 17025 accreditation. Simple linear regression data from the attitude scale showed that attitude towards ISO 17025 accreditation increased by approximately 1.04 units for every one unit in the attitude subscale score. There was a positive correlation between attitude and intent to seek or maintain ISO 17025 accreditation from the simple linear regression where, as the independent variable increased, the dependent variable increased as well. Essentially, participants who scored higher on the attitude subscale had a more favorable evaluation of ISO 17025 accreditation. Results from the multiple linear regression model showed

attitude as having a positive effect (β = 0.41) on SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation; however, it was not a statistically significant predictor of intention (p =.118). These findings are consistent with findings in the literature.

Data involving attitudes towards accreditation in the US overall healthcare setting have been inconsistent including data on favorable and unfavorable attitude (Alkhenizan & Shaw, 2012; Chen et al., 2015; Greenfield et al., 2011; Kakemam et al., 2020; Lapić et al., 2021; Zamboni et al., 2020). A study by Kakemam et al., (2020) found low support for accreditation amongst managers, nurses, and para-clinical staff. In contrast the simple linear regression in this study showed an overwhelmingly positive attitude towards ISO/17025 accreditation by SPHL directors and though not statistically significant in the multiple linear regression model, attitude had a positive effect on SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation.

Chen et al., (2015) found that local health departments (LHD) with leaders expressing greater commitment to QI and working in LHD's that engaged in QI longer, showed the greatest desire to seek accreditation. This assessment is reflected in the explorative MANOVA analysis of the current study of the differences in the attitudes towards ISO/IEC 17025 accreditation between SPHL directors of accredited, non-accredited and working towards accreditation laboratories. Data from this analysis showed a significant difference between the groups with those from accredited laboratories (M = 6.02, SD = 1.05) and working towards accreditation laboratories (M = 5.92, SD = 0.64) having a higher means score than those from non-accredited laboratories

(M = 4.86, SD = 1.05).

Overall, higher mean attitude scores observed among SPHL directors from accredited and working towards accreditation laboratories indicated that these respondents had a more positive attitude towards ISO/IEC 17025 accreditation than those from non-accredited laboratories. This shows that SPHL directors who have interacted with or are involved in ISO/IEC 17025 accreditation acknowledge the standard as being valuable and beneficial to their laboratories. This finding implies that it is not until involvement with the standard that its value is recognized by SPHL directors.

Subjective norms relate to societal pressures, which are beliefs that a person or group of people, are important to those who approve or support a specific behavior (Abufarsakh & Okoli, 2021; Aschwanden et al., 2021). In this study, subjective norms referred to a public health director's belief that most people who are important to them, are of similar standing, influence their decisions, and have opinions they value, think they should seek or maintain ISO/IEC 17025 accreditation. Essentially, with subjective norms I sought to evaluate how work-related networks and relationships that public health directors have impact their intent to seek or maintain ISO/IEC 17025 accreditation.

Results of the simple linear regression showed that for every one unit in the subjective norms subscale score, SPHL directors' intention to seek or maintain ISO/IEC 17025 accreditation increased by almost 0.95 units, meaning that respondents who scored higher on the subjective norms scale perceived greater social pressure involving ISO/IEC 17025 accreditation and were more likely to seek or maintain the accreditation. Of the three independent variables in the multiple linear regression analysis, subjective norms

were identified as the only statistically significant variable ($\beta = 0.60$, $t = 2.48$, $p = .018$).

Therefore, results of both linear regression models revealed that subjective norms played a significant role in terms of public health directors' intent to seek or maintain ISO/17025 accreditation. This was especially evident amongst SPHL directors from accredited and working towards accreditation laboratories as observed from the MANOVA analysis. The MANOVA revealed that those from working towards accreditation laboratories ($M = 5.36$, $S = 1.04$) and accredited laboratories ($M = 5.34$, $S = 0.82$) scored significantly higher than those from non-accredited laboratories ($M = 3.74$, $S = 1.22$). This finding suggests that those in their networks who are important to SPHL directors from accredited and working towards accreditation laboratories played a significant role in terms of their intent to seek or maintain ISO/17025 accreditation. This conclusion is in line with literature involving the progression of public health initiatives and collaborative efforts between public health entities.

Collaborations and networks are important to the advancement of public health agendas and initiatives such as standardization of processes and surveillance and disease control efforts (McLaughlin et al., 2021; Ned-Sykes et al., 2021). Furthermore, there has been an increased trend towards collaborations among public health laboratories in the form of various laboratory networks and partnerships between public health labs such as the Association of Public Health Laboratories (APHL), ASTHO, and Laboratory Response Network (LRN) (Horney et al., 2017; Hsieh et al., 2013).

These networks go beyond the laboratories regional localities and expand across the nation with some being supported by federal funding (Erwin et al., 2019; Hsieh et al.,

2013; Randolph et al., 2019; Ridderhof & Wilcke, 2013; St. George et al., 2019). Emphasis on the core functions and responsibilities of public health laboratories by the association of public health laboratories highlights the value of partnerships in the public health laboratory arena (Inhorn et al., 2010).

Horney et al. (2017) identified partnerships as being critical to public health preparedness, with health departments that had more partnerships being more likely to engage in the public health preparedness capabilities. Kubota et al., (2019) reported on public health lab collaborations supported by a network of standardized laboratory and data methodologies and a dynamic communication, that aided in the annual prevention of approximately 270,000 foodborne illnesses. This disease prevention led to an increased disease awareness and reduced reaction time with financial benefits from saved medical costs and increased productivity. Findings from a qualitative study by Yeager et al., (2021) local health department affiliate state health departments encouraged and/or facilitated accreditation. Further, one of the benefits reported among accredited state health agencies as reported by Kittle & Liss-Levinson, (2018) was greater collaboration across departments within the agency- highlighting the importance of subjective norms to the promotion of quality measures within the public health framework. Data from this research showed that the subjective norms component of the theory of planned behavior is supported by the research provided in the literature review.

The perceived behavioral control instrument sought to elucidate SPHL directors' perceptions of their ability to seek or maintain ISO/IEC 17025 accreditation. In this study, perceived behavioral control was statistically significant in the simple linear

regression ($p < .001$) but was not significant in the multiple linear regression analysis (p = .444). Results from both analyses indicate that the construct had a positive effect on SPHL director's intent to seek or maintain ISO/IEC 17025 accreditation ($\beta = .93$ for simple linear regression and $\beta = 0.18$ for multiple linear regression). As relates to perceived behavioral control, participants who scored higher on the perceived behavioral control scale felt greater control over their decision to seek or maintain ISO 17025 accreditation and were more likely to seek or maintain the accreditation. In the simple linear regression, every one unit in the perceived behavioral control subscale score, SPHL directors' intention to seek or maintain ISO/IEC 17025 accreditation increased by almost 0.93 units. The perceived impact for every one unit in the perceived behavioral control subscale score, $\beta = .93$, from the simple linear regression was greatly reduced to $\beta = 0.18$ after performing the multiple linear regression.

Of the three constructs evaluated in the multiple linear regression, perceived behavioral control reported the lowest positive effect ($\beta = 0.18$) on the SPHL director's intent to seek or maintain ISO/IEC 17025 accreditation. Similar to other studies, perceived behavioral control towards accreditation in the public health framework has revolved around perceived competence, individual level skills, and decision-making capacity. For example, Jadhav et al., (2017) performed a cross-sectional study to characterize leadership competency structure in local health departments and to identify the relevance of existing competencies for public health leadership; they found that for program directors/managers or administrators, the competency most relevant to them was ensuring continuous improvement. This is in line with the results from the descriptive

statistics of the current study where the most important item when measuring perceived behavioral control was PBC2 where 81.1% of participants strongly agreed that they have the skills to seek or maintaining ISO/IEC 17025 accreditation.

Similarly, Erwin et al. (2020) measured individual and organizational level skills, as well as external factors, each with items relating to perceived behavioral control and found no differences between participants in regards to knowledge about evidence based public process, being skilled in modifying evidence-based interventions and capacity to lead their work units in evidence based public health. These results were contrary to my study where the data from the one-way ANOVA analysis of the differences in perceived behavioral control towards ISO/IEC 17025 accreditation between SPHL directors of accredited and working towards accreditation laboratories differed from those from non-accredited laboratories. Furthermore, data from the simple linear regression analysis showed perceived behavioral control as being statistically significant; implying that the construct plays a role in intent to seek or maintain accreditation.

Results from the one-way ANOVA showed significant differences observed in the mean scores of perceived behavioral control between directors from accredited and working towards accreditation laboratories compared to those from non-accredited laboratories; the mean score for SPHL directors from accredited ($M = 5.99$, $SD = 0.63$) and working towards accreditation ($M = 5.95$, $SD = 0.54$) laboratories was higher than those from non-accredited laboratories ($M = 4.85$, $SD= 1.15$).

The effect size, partial $\eta 2$, represents the amount of variance in the dependent variable that can be attributed to the variance in the independent variable groups (Allen,

2017). Interpreting partial η2, values of .01, .09 and .25 represent a small, medium and large effect size, respectively (Allen, 2017). The effect sizes from the post hoc analysis showed that despite having a lower sample size than calculated for ANOVA (n = 84) the sample size used in the study (n = 36) was sufficient to produce a large effect size (ATT-partial η2 = .24; SN- partial η2 = .36; PBC-partial η2 = .31) on all measured constructs.

There were significant differences observed between those from accredited laboratories compared to those from non-accredited laboratories across all constructs; with the mean scores for directors from accredited laboratories being significantly higher than those from non-accredited laboratories. Study results indicated that among different accredited groups, SPHL directors from accredited and working towards ISO/IEC 17025 accreditation had a more positive attitude compared with those from non-accredited laboratories. Furthermore, a higher level of perceived behavioral control toward ISO/IEC 17025 accreditation was associated with being a SPHL director from accredited and working towards ISO/IEC 17025 accreditation laboratory and subjective norm influence towards seeking or maintaining the accreditation was also associated with these two groups.

Limitations of the Study

This study had some limitations worth noting. A key limitation of this study is the extremely limited empirical data available on the perceptions of ISO/IEC 17025 accreditation in state public health laboratories. This resulted in the general review of the perceptions toward accreditation in the overall healthcare setting, including public health departments and hospitals, to offer context and support trends from the data (Kittle &

Liss-Levinson, 2018). Taking from the greater healthcare community in such a manner may not fully encapsulate the views coming out of the SPHL.

A second limitation is that the study did not consider the actual behavior of SPHL directors, rather, it only evaluated intention; It is possible that the participant's actual behavior may vary from their intention. Another limitation of the study is that data were only collected from laboratory directors, thereby limiting generalizability to other employees working in state public health laboratories. The cross-sectional nature of the survey left no consideration to time lag between the variables, limiting the methodology's ability to specify the direction of the association. Finally, the use of closed ended questions limited participant's ability to elaborate on their views as they relate to the constructs under study, which would have greatly enriched the data.

Recommendations

The recommendations for further research are born of the strength and limitations of the current study. The quantitative nature of this study limited investigation to a singular timeframe. It is recommended that future research apply a longitudinal study design to allow for observation of changes over time. It was previously noted that one of the goals of accreditation and quality improvement programs in general is to transition organizations to embrace a culture of quality based on standardized processes (Chapman, 2018) . Longitudinal observations could provide a greater understanding of the perceptions towards the accreditation after from longer term interactions (Beitsch et al., 2018; Ingram et al., 2018). Additionally, having the study investigating laboratories pre and post accreditation would add value to understanding the impact of ISO/IEC 17025

accreditation in the state laboratory. Even though exploratory evaluation of the differences in perception towards the accreditation between accredited and non-accredited laboratories revealed that there were significant differences between the two groups, it is recommended that the study undertake an in-depth comparison of the differences between accredited and non-accredited laboratories.

Research evaluating SPHL director's actual behavior toward the accreditation could add to the body of knowledge on ISO/IEC 17025 accreditation. This study was limited in assessing SPHL director intent, therefore, it is recommended that investigation into whether the directors actually follow through on their intent and the factors surrounding that behavior be performed. This would aid in assessing the drivers behind leadership acceptance of quality improvement programs and embedding them in the design of QI programs.

This study was limited to SPHL directors. A recommendation to support generalizability of the results would be to reproduce this study in the greater public health laboratory workforce. Using a wider sample that includes employees with different positions within the laboratory would reflect the opinions of all staff interacting with the accreditation. To gain deeper insight into SPHL director perceptions towards the accreditation, a study utilizing an alternate data collection method to a close ended questionnaire is recommended. Using methods such as live interviews may allow participants the opportunity to divulge more information than they would have with a closed ended survey.

Implications for Social Change

This study, guided by the theory of planned behavior, provides a look into SPHL directors attitudes and their intent to seek or maintain ISO/IEC 17025 accreditation. The ANOVA analysis showed that attitudes towards ISO/IEC 17025 accreditation differed based on accreditation status. Those SPHL directors from accredited and working towards accreditation laboratories had a more positive attitude towards the standard compared to those from non-accredited laboratories.

The simple linear regression analysis revealed that attitude, subjective norms and perceived behavioral controls all play a positive and significant role in intent to seek or maintain ISO/IEC 17025 accreditation. Data from the simple linear analysis revealed that independently, each variable was positively correlated with intent and therefore considerations for the three constructs should be made when implementing or evaluating accreditation programs. The multiple linear regression revealed interactive effects between the three TPB constructs and found that SN was a statistically significant predictor of SPHL directors' intent to seek or maintain ISO/IEC 17025 accreditation.

Overall, the data showed that the value of the standard was most recognized by those directors already involved in it, that accredited and working towards accreditation SPHL director networks influenced their decisions to seek or maintain the accreditation, and that most directors already perceive that they have control over decision to seek or maintain ISO/IEC 17025 accreditation.

The statistically significant findings of the study identify subjective norms as key drivers for SPHL director's intention to seek or maintain ISO/IEC 17025 accreditation. This assertion corroborates the current collaborative environment in the public health

realm that has been shown to advance other the public health initiatives across the nation. Considerations for subjective norms in implementing ISO/IEC 17025 accreditation by state public health directors may lead to a greater uptake of the program, thereby building recognized value for the program and other quality improvement initiatives, resulting in a quality driven public health laboratory system.

The results of this study can help inform the development or promotion of accreditation and quality programs within the public health laboratory to include human factors that drive intentions to implement these programs. Incorporating factors that promote intention to implement quality programs can yield a positive social change through the creation quality driven, effective programs that would ultimately improve the overall public health system.

Conclusion

State public health laboratories are critical to the safety and health of the populations they serve, where they provide crucial services, such as identifying, diagnosing, and evaluating community health hazards including prevention and control of vector borne diseases such as the West Nile virus, and food and water borne outbreaks such as salmonella infections, and environmental testing including lead poisoning (Becker & Perlman, 2011). Providing these services cannot be based on technical competencies alone. Embedding quality in every aspect of their daily operation is key to ensuring the overall quality of the services they provide and supporting their ongoing mission to improve the health of the communities they serve. Socio-behavioral theory can be used to aid in understanding attitudes towards quality programs and the drivers behind

quality improvement uptake.

Using the TPB, I evaluated the attitudes of SPHL directors towards ISO/IEC 17025 accreditation. The results of the study found that directors from accredited and working towards accreditation laboratories had a more positive attitude towards ISO/IEC 17025 accreditation than those from non-accredited laboratories. Additionally, this study showed the TPB to be an effective model for predicting intention to seek or maintain ISO/IEC 17025 accreditation with the construct of SN being a significant predictor. Addressing the SN factor may improve involvement in ISO/IEC 17025 accreditation. The TPB constructs of ATT and PBC were not significant predictors of intention, however, in addition to being part of the predictive model, both constructs were found to have a positive effect SPHL director intent and therefore they should be included in ISO/IEC 17025 accreditation development and improvement. Incorporation of the findings and recommendations of this study to ISO/IEC 17025 accreditation for state public health laboratories could lead to a greater implementation of the program. Greater implementation of the program may contribute to effective quality process improvement in state public health laboratories that benefit, support, and improve the overall public health system.

References

Aarsand, A. K., & Sandberg, S. (2014). How to achieve harmonisation of laboratory testing -The complete picture. *Clinica Chimica Acta, 432*(Suppl. C), 8–14. https://doi.org/10.1016/j.cca.2013.12.005

Abat, C., Chaudet, H., Colson, P., Rolain, J.-M., & Raoult, D. (2015). Real-time microbiology laboratory surveillance system to detect abnormal events and emerging infections, Marseille, France. *Emerging Infectious Diseases, 21*(8), 1302–1310. https://doi.org/10.3201/eid2108.141419

Abufarsakh, B., & Okoli, C. T. C. (2021). Nursing staff attitude, subjective norms, perceived behavior control, and intention to provide tobacco treatment in a psychiatric hospital. *Journal of the American Psychiatric Nurses Association*, 10783903211045736. https://doi.org/10.1177/10783903211045737

Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes*, *50*(2), 179–211. https://doi.org/10.1016/0749-5978(91)90020-T

Ajzen, I. (2011a). The theory of planned behaviour: Reactions and reflections. *Psychology & Health*, *26*(9), 1113–1127. https://doi.org/10.1080/08870446.2011.613995

Ajzen, I. (2011b). Behavioral Interventions: Design and evaluation guided by the theory of planned behavior. In M. M. Mark, S. I. Donaldson, & B. Campbell (Eds.), *Social Psychology and Evaluation* (pp. 74–104). Guilford Press.

Albert, H., Trollip, A., Erni, D., & Kao, K. (2017). Developing a customised approach for strengthening tuberculosis laboratory quality management systems toward accreditation. *African Journal of Laboratory Medicine*, *6*(2), 1–8. https://doi.org/10.4102/ajlm.v6i2.576

Aldous, K., Das, R., Johnson, J., King, E., Nassif, J., Rhodes, B., Simmons, D., Vousden, C., & Krueger, J. (2012). *Developing biomonitoring capabilities*. Association of Public Health Laboratories.

Alers, N. (2016). Continuous quality management in the laboratory. *Medical Laboratory Observer*, *48*(8), 54. http://link.galegroup.com/apps/doc/A460373512/GRGM?sid=googlescholar

Alkhenizan, A., & Shaw, C. (2012). The attitude of health care professionals towards accreditation: A systematic review of the literature. *Journal of Family & Community Medicine*, *19*(2), 74–80. https://doi.org/10.4103/2230-8229.98281

Allen, M. (2017). *The SAGE encyclopedia of communication research methods* (Vol. 1–1–4). SAGE Publications Inc.

American Medical Association. (2016). Public health laboratories. *Journal of the American Medical Association*, *315*(16), 1796–1796. https://doi.org/10.1001/jama.2015.17083

American Public Health Association. (2013). *Supporting and sustaining the practice of quality Improvement in public health*. American Public Health Association. https://www.apha.org/policies-and-advocacy/public-health-policy-

statements/policy-database/2014/07/14/09/11/supporting-and-sustaining-the-practice-of-quality-improvement-in-public-health

Araiza-Aguilar, J. A., Rojas-Valencia, M. N., & Aguilar-Vera, R. A. (2020). Forecast generation model of municipal solid waste using multiple linear regression. *Global Journal of Environmental Science and Management*, *6*(1), 1–14.

Aschwanden, D., Strickhouser, J. E., Sesker, A. A., Lee, J. H., Luchetti, M., Terracciano, A., & Sutin, A. R. (2021). Preventive behaviors during the COVID-19 pandemic: Associations with perceived behavioral control, attitudes, and subjective norm. *Frontiers in Public Health*, *9*. https://doi.org/10.3389/fpubh.2021.662835

Association of Public Health Laboratories. (2017, February). *The role and value of public health laboratories in STD response*. https://www.aphl.org/aboutAPHL/publications/Documents/ID_2017Feb-PHL-STD-Testing-update.pdf

Association of Public Health Laboratories. (2018a, February). *A practical guide to board examination and lab leadership resources*. https://www.aphl.org/aboutAPHL/publications/Documents/work-2018Feb-Essential-Competencies-PHL-Directors.pdf

Association of Public Health Laboratories. (2018b, February). *Laboratory costs of ISO/IEC 17025 accreditation: A 2017 survey report*. https://www.aphl.org/aboutAPHL/publications/Documents/FS-2018Feb-ISO-IEC-Accreditation-Costs-Survey-Report.pdf

Association of Public Health Laboratories (APHL). (n.d.). *APHL*. APHL. Retrieved November 11, 2019, from http://www.aphl.org

Association of Public Health Laboratories (APHL). (2011). *Data summary of the 2010 core laboratory profiles survey: Snapshot of state public health laboratories*. Associate of Public Health Laboratories.

Association of Public Health Laboratories (APHL). (2019). *Best practices for submission of actionable human and animal Food testing data generated in state and local laboratories*. Association of Public Health Laboratories. https://www.aphl.org/aboutAPHL/publications/Documents/FS-Best-Practices-Food-Feed-Data-102016.pdf

Association of Public Health Laboratories, & Centers for Disease Control and Prevention. (2014). *Policy guide for public health laboratory test service sharing*. https://www.aphl.org/AboutAPHL/publications/Documents/LEI-Policy-Guide_April2014.pdf

Association of State and Territorial Health Officials. (n.d.). *A practical guide to public health laboratories for state health officials* (pp. 1–66). Association of Public Health Laboratories. https://stacks.cdc.gov/view/cdc/5568/cdc_5568_DS1.pdf

Ateş, C., Kaymaz, Ö., Kale, H. E., & Tekindal, M. A. (2019). Comparison of test statistics of nonnormal and unbalanced samples for multivariate analysis of variance in terms of type-I error rates. *Computational and Mathematical Methods in Medicine*, *2019*, 2173638. https://doi.org/10.1155/2019/2173638

Azadbakht, E. (2015). Three digital collections on the history of infectious diseases. *Journal of Electronic Resources in Medical Libraries*, *12*(3), 141–146. https://doi.org/10.1080/15424065.2015.1065670

Bangdiwala, S. I. (2018). Regression: Multiple linear. *International Journal of Injury Control and Safety Promotion*, *25*(2), 232–236. https://doi.org/10.1080/17457300.2018.1452336

Bazdaric, K., Sverko, D., Salaric, I., Martinovic, A., & Lucijanic, M. (2021). The ABC of linear regression analysis: What every author and editor should know. *European Science Editing*, *47*, e63780. https://doi.org/10.3897/ese.2021.e63780

Becker, S. J. (2017). *Position statement supporting FDA funding*. https://www.aphl.org/aboutAPHL/publications/Documents/FS-FDA-Letter-012017.pdf

Becker, S., & Perlman, E. J. (2011). An introduction to public health laboratories. In *Public Health Laboratories: Analysis, Operations and Management* (p. 14). Jones & Bartlett Publishers.

Beitsch, L. M., Kronstadt, J., Robin, N., & Leep, C. (2018). Has voluntary public health accreditation impacted health department perceptions and activities in quality improvement and performance management? *Journal of Public Health Management and Practice, 24*, S10. https://doi.org/10.1097/PHH.0000000000000713

Birken, S. A., Lee, S.-Y. D., & Weiner, B. J. (2012). Uncovering middle managers' role in healthcare innovation implementation. *Implementation Science, 7*(1), 28. https://doi.org/10.1186/1748-5908-7-28

Birkhead, G. S., Klompas, M., & Shah, N. R. (2015). Uses of electronic health records for public health surveillance to advance public health. *Annual Review of Public Health, 36*(1), 345–359. https://doi.org/10.1146/annurev-publhealth-031914-122747

Boulton, M. L., Beck, A. J., DeBoy, J. M., & Kim, D. H. (2013). National assessment of capacity in public health, environmental, and agricultural laboratories—United States, 2011. *MMWR. Morbidity And Mortality Weekly Report*, *62*(9), 161–164. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6209a2.htm

Braithwaite, J., Westbrook, J., Johnston, B., Clark, S., Brandon, M., Banks, M., Hughes, C., Greenfield, D., Pawsey, M., Corbett, A., Georgiou, A., Callen, J., Øvretveit, J., Pope, C., Suñol, R., Shaw, C., Debono, D., Westbrook, M., Hinchcliff, R., & Moldovan, M. (2011). Strengthening organizational performance through accreditation research-a framework for twelve interrelated studies: The ACCREDIT project study protocol. *BMC Research Notes*, *4*, 390. https://doi.org/10.1186/1756-0500-4-390

Brook, R. H. (2010). The end of the quality improvement movement: Long live improving value. *JAMA, 304*(16), 1831–1832. https://doi.org/10.1001/jama.2010.1555

Buhmann, A., & Brønn, P. S. (2018). Applying Ajzen's theory of planned behavior to predict practitioners' intentions to measure and evaluate communication outcomes. *Corporate Communications: An International Journal*, *23*(3), 377–391. https://doi.org/10.1108/CCIJ-11-2017-0107

Bulut, H. (2020). Mahalanobis distance based on minimum regularized covariance determinant estimators for high dimensional data. *Communications in Statistics - Theory and Methods*, *49*(24), 5897–5907. https://doi.org/10.1080/03610926.2020.1719420

Burgueño, R., & Medina-Casaubón, J. (2020). Sport education and sportsmanship orientations: An intervention in high school students. *International Journal of Environmental Research and Public Health*, *17*(3), 837. https://doi.org/10.3390/ijerph17030837

Canyon, D. V. (2013). Insights in public health. *Hawai'i Journal of Medicine & Public Health*, *72*(1), 27–30. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555479/

Carlton, E. L., Holsinger, J. W. J., Riddell, M., & Bush, H. (2015). Full-range public health leadership, Part 1: Quantitative analysis. *Frontiers in Public Health, 3*. https://doi.org/10.3389/fpubh.2015.00073

Carraro, P., & Plebani, M. (2007). Errors in a stat laboratory: Types and frequencies 10 years later. *Clinical Chemistry*, *53*(7), 1338-. Expanded Academic ASAP. https://doi.org/10.1373/clinchem.2007.088344

Centers for Disease Control and Prevention (CDC). (2014). *Introduction to public health laboratories|Public Health 101 Series|CDC*. https://www.cdc.gov/publichealth101/laboratories.html

Chapman, R. W. (2018). Public health accreditation impact: The performance management system. *Journal of Public Health Management and Practice*, *24*(3), S19–S21. https://doi.org/10.1097/PHH.0000000000000712

Charlton, C. L., Hull, N., Sloma, C. R., Bonifas, M., Johnson, M., Strain, A. K., Wolford, T., Staley, S., Perkins, C., Razzaque, R., Courtney, C., & Bind, E. P. (2021). How to prepare for the unexpected: A public health laboratory response. *Clinical Microbiology Reviews*, *34*(3), e00183-20. https://doi.org/10.1128/CMR.00183-20

Chen, C., Fan, Y.-W., & Farn, C.-K. (2007). Predicting electronic toll collection service adoption: An integration of the technology acceptance model and the theory of planned behavior. *Transportation Research Part C: Emerging Technologies*, *15*(5), 300–311. https://doi.org/10.1016/j.trc.2007.04.004

Chen, L.-W., Nguyen, A., Jacobson, J. J., Gupta, N., Bekmuratova, S., & Palm, D. (2015). Relationship between quality improvement implementation and accreditation seeking in local health departments. *American Journal of Public Health*, *105*(S2), S295–S302. https://doi.org/10.2105/AJPH.2014.302278

Chung, S., Park, Y. W., & Cheong, T. (2020). A mathematical programming approach for integrated multiple linear regression subset selection and validation. *Pattern Recognition*, *108*, 107565. https://doi.org/10.1016/j.patcog.2020.107565

Cohen, J. (1992). A power primer. *Psychological Bulletin*, *112*(1), 155–159. https://doi.org/10.1037/0033-2909.112.1.155

Cortez, L. (1999). The implementation of accreditation in a chemical laboratory. *Trends in Analytical Chemistry*, *18*(9–10), 638–643. https://doi.org/10.1016/S0165-9936(99)00164-8

Coughlin, S. S. (2006). Ethical issues in epidemiologic research and public health practice. *Emerging Themes in Epidemiology*, *3*(16). https://doi.org/10.1186/1742-7622-3-16

Creswell, J. W. (2014). *Research design: Qualitative, quantitative, and mixed method approaches* (Fourth). SAGE Publications Sage.

Crosby A., R., DiClemente J., R., & Salazar F., L. (2006). *Research methods in health promotion* (First). John Wiley & Sons, Inc.

Daoud, J. I. (2017). Multicollinearity and regression analysis. *Journal of Physics: Conference Series*, *949*, 012009. https://doi.org/10.1088/1742-6596/949/1/012009

Department of Health and Human Services. (2017). *RFA-FD-17-010: Maintenance and enhancement of ISO/IEC 17025 accreditation and whole genome sequencing for state food testing laboratories (U18)*. https://grants.nih.gov/grants/guide/rfa-files/rfa-fd-19-018.html

Desalegn, D. M., Abay, S., & Taye, B. (2016). The availability and functional status of focused antenatal care laboratory services at public health facilities in Addis Ababa, Ethiopia. *BMC Research Notes*, *9*(1). Expanded Academic ASAP. https://doi.org/10.1186/s13104-016-2207-z

Dowdle, W. R., Mayer, L. W., Steinberg, K. K., Ghiya, N. D., & Popovic, T. (2011). Laboratory contributions to public health. *Morbidity and Mortality Weekly Report*, *60*(4), 27–34. https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a6.htm

Downes, F. P., & Ridderhof, J. C. (2010). *The evolving public health laboratory system*. SAGE Publications Sage CA: Los Angeles, CA.

Duong, C. N., Bond, K. B., Carvalho, H., Thu, T., Bui, H., Nguyen, T., & Rush, T. (2017). Rapid ascent from zero quality to International Organization for Standardization Accreditation: A case study of Hai Duong Preventive Medicine Center in Vietnam, 2012-2013. *American Journal of Clinical Pathology*, *147*(4), 427–431. https://doi.org/10.1093/ajcp/aqx017

Ehlers, L. H., Jensen, M. B., Simonsen, K. B., Rasmussen, G. S., & Braithwaite, J. (2017). Attitudes towards accreditation among hospital employees in Denmark: A cross-sectional survey. *International Journal for Quality in Health Care*, *29*(5), 693–698. https://doi.org/10.1093/intqhc/mzx090

Ellis, L. A., Nicolaisen, A., Bie Bogh, S., Churruca, K., Braithwaite, J., & von Plessen, C. (2020). Accreditation as a management tool: A national survey of hospital managers' perceptions and use of a mandatory accreditation program in Denmark. *BMC Health Services Research*, *20*(1), 306. https://doi.org/10.1186/s12913-020-05177-7

El-Masri, M. M., Mowbray, F. I., Fox-Wasylyshyn, S. M., & Kanters, D. (2021). Multivariate outliers: A conceptual and practical overview for the nurse and

health researcher. *Canadian Journal of Nursing Research, 53*(3), 316–321. https://doi.org/10.1177/0844562120932054

Erwin, P. C., Parks, R. G., Mazzucca, S., Allen, P., Baker, E. A., Hu, H., Davis-Joyce, J., & Brownson, R. C. (2019). Evidence-based public health provided through local health departments: Importance of academic–Practice partnerships. *American Journal of Public Health*, *109*(5), 739–747. https://doi.org/10.2105/AJPH.2019.304958

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods*, *41*(4), 1149–1160. https://doi.org/10.3758/BRM.41.4.1149

Fox, M. A., & Latshaw, M. (2013). State public health laboratory biomonitoring programs: Implementation and early accomplishments. *Journal of Environmental Health*, *75*(6), 90–94.

Frankfort-Nachmias, C., & Nachmias, D. (2008). *Research methods in the social sciences* (7th ed.). Worth Publishers.

Fukukawa, K. (2002). Developing a framework for ethically questionable behavior in consumption. *Journal of Business Ethics*, *41*(1/2), 99–119. https://doi.org/10.1023/A:1021354323586

Gaines, C. G. (2015). The laboratory's role in reporting communicable diseases. *Laboratory Medicine*, *29*(7), 402–404. https://doi.org/10.1093/labmed/29.7.402

Holshue, M. L., DeBolt, C., Lindquist, S., Lofy, K. H., Wiesman, J., Bruce, H., Spitters, C., Ericson, K., Wilkerson, S., Tural, A., Diaz, G., Cohn, A., Fox, L., Patel, A.,

Gerber, S. I., Kim, L., Tong, S., Lu, X., Lindstrom, S., … Pillai, S. K. (2020). First case of 2019 novel coronavirus in the United States. *New England Journal of Medicine*, *382*(10), 929–936. https://doi.org/10.1056/NEJMoa2001191

Honsa, J. D., & McIntyre, D. A. (2003). ISO 17025: Practical benefits of implementing a quality system. *Journal of AOAC International*, *86*(5), 1038–1044.

Horney, J. A., Carbone, E. G., Lynch, M., Wang, Z. J., Jones, T., & Rose, D. A. (2017). How health department contextual factors affect public health preparedness (PHP) and perceptions of the 15 PHP capabilities. *American Journal of Public Health*, *107*(S2), S153–S160.

Hsieh, K., Kimsey, P., & Buehring, G. (2013). Using interorganizational partnerships to strengthen public health laboratory systems. *Public Health Reports*, *128*(2_suppl), 63–69. https://doi.org/10.1177/00333549131280S210

Ingram, R. C., Mays, G. P., & Kussainov, N. (2018). Changes in local public health system performance before and after attainment of national accreditation standards. *Journal of Public Health Management and Practice*, *24*(3), S25–S34. https://doi.org/10.1097/PHH.0000000000000766

Inhorn, S. L., Astles, J. R., Gradus, S., Malmberg, V., Snippes, P. M., Wilcke, B. W., & White, V. A. (2010). The state public health laboratory system. *Public Health Reports*, *125*(Suppl 2), 4–17. https://doi.org/10.1177/00333549101250S202

Inhorn, S. L., Wilcke, B. W. J., Downes, F. P. D., Adjanor, O. O. M., Cada, R. D., & Ford, J. R. B. (2006). A comprehensive laboratory services survey of state public

health laboratories. *Journal of Public Health Management*, *12*(6), 514–521. https://doi.org/10.1097/00124784-200611000-00003

Institute of Medicine. (2000). Public health systems and emerging infections: Assessing the capabilities of public and private sectors. In *Epidemiological Investigation*. National Academies Press (US). https://www.ncbi.nlm.nih.gov/books/NBK100248/

International Organization for Standardization. (n.d.-a). *Certification*. International Organization for Standardization. Retrieved April 3, 2018, from https://www.iso.org/certification.html

International Organization for Standardization. (n.d.-b). *How we develop standards*. Developing Standards. Retrieved May 2, 2018, from https://www.iso.org/developing-standards.html

International Organization for Standardization. (2014, February 22). *Conformity assessment bodies – accreditation*. https://www.iso.org/sites/cascoregulators/documents/Annex%203%20-%20Conformity%20assessment%20techniques%20-%20Accreditation.pdf

International Organization for Standardization. (2016). *ISO in Brief*. https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/isoinbrief_2015.pdf

International Organization for Standardization. (2017). *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*. International Organization for Standardization. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf

ISO. (n.d.-a). *ISO - ISO/IEC 17025—Testing and calibration laboratories*. ISO. Retrieved March 25, 2021, from https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

ISO. (n.d.-b). *ISO/IEC 17025:2005*. ISO. Retrieved March 12, 2021, from https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/03/98/39883.html

ISO. (2017). *ISO/IEC 17025—General requirements for the competence of testing and calibration laboratories [Brochure]*. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf

ISO. (2019). *ISO in Brief [Brochure]*. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100007.pdf

ISO's Committee on Conformity Assessment. (2014). *ISO CASCO - Using conformity assessment tools in regulation*. https://www.iso.org/sites/cascoregulators/01_3_conformity-assessment-bodies.html

Jadhav, E. D., Holsinger, J. W., Anderson, B. W., & Homant, N. (2017). Leadership for public health 3.0: A preliminary assessment of competencies for local health department leaders. *Frontiers in Public Health, 5*. https://doi.org/10.3389/fpubh.2017.00272

Jang, M.-A., Yoon, Y. A., Song, J., Kim, J.-H., Min, W.-K., Lee, J. S., Lee, Y.-W., & Lee, Y. K. (2017). Effect of accreditation on accuracy of diagnostic tests in

medical laboratories. *Annals of Laboratory Medicine*, *37*(3), 213–222. https://doi.org/10.3343/alm.2017.37.3.213

Jones, D. S., Dicker, R. C., Fontaine, R. E., Boore, A. L., Omolo, J. O., Ashgar, R. J., & Baggett, H. C. (2017). Building global epidemiology and response capacity with field epidemiology training programs. *Emerging Infectious Diseases*, *23*, S158–S165. https://doi.org/10.3201/eid2313.170509

Kaml, C., Weiss, C. C., Dezendorf, P., Ishida, M., Rice, D. H., Klein, R., & Salfinger, Y. (2014). Developing a competency framework for U.S. state food and feed testing laboratory personnel. *Journal of AOAC International*, *97*(3), 768–772. https://doi.org/10.5740/jaoacint.13-400

Karthiyayini, N., & Rajendran, C. (2017). Critical factors and performance indicators: Accreditation of testing- and calibration-laboratories. *Benchmarking: An International Journal*, *24*(7), 1814–1833. https://doi.org/10.1108/BIJ-04-2016-0058

Khushubu, K., & Yadav, S. (2018). *Linear regression analysis study*. https://www.j-pcs.org/article.asp?issn=2395-5414;year=2018;volume=4;issue=1;spage=33;epage=36;aulast=Kumari

Kim, H.-Y. (2018). Statistical notes for clinical researchers: Simple linear regression 1 – basic concepts. *Restorative Dentistry & Endodontics*, *43*(2), e21. https://doi.org/10.5395/rde.2018.43.e21

Kim, H.-Y. (2019). Statistical notes for clinical researchers: Simple linear regression 3 – residual analysis. *Restorative Dentistry & Endodontics, 44*(1), e11. https://doi.org/10.5395/rde.2019.44.e11

Kitchen, S., Olson, J. D., & Preston, F. E. (Eds.). (2013). *Quality in laboratory hemostasis and thrombosis* (2nd ed). Wiley-Blackwell.

Kittle, A., & Liss-Levinson, R. (2018). State health agencies' perceptions of the benefits of accreditation. *Journal of Public Health Management and Practice, 24*(3), S98–S101. https://doi.org/10.1097/PHH.0000000000000719

Lakshmi, S., & Mohideen, M. A. (2013). Issues in reliability and validity of research. *International Journal of Management Research and Reviews; Meerut, 3*(4), 2752–2758. http://search.proquest.com/docview/1415612380/abstract/89848638A9914661PQ/1

Long-mira, E., Washetine, K., & Hofman, P. (2016). Sense and nonsense in the process of accreditation of a pathology laboratory. *Virchows Archiv; Heidelberg*, *468*(1), 43–49.

McLaughlin, H. P., Hiatt, B. C., Russell, D., Carlson, C. M., Jacobs, J. R., Perez-Osorio, A. C., Holshue, M. L., Choi, S. W., & Gautom, R. K. (2021). COVID-19 response efforts of Washington State public health laboratory: Lessons learned. *American Journal of Public Health*, *111*(5), 867–875. http://dx.doi.org/10.2105/AJPH.2021.306212)

McLees, A. W., Nawaz, S., Thomas, C., & Young, A. (2015). Defining and assessing quality improvement outcomes: A framework for public health. *American Journal of Public Health*, *105*(Suppl 2), S167–S173. https://doi.org/10.2105/AJPH.2014.302533

Mertler, C. A. (2018). *Introduction to educational research*. SAGE Publications. https://books.google.com/books?id=64ZADwAAQBAJ

Millar, R., & Shevlin, M. (2003). Predicting career information-seeking behavior of school pupils using the theory of planned behavior. *Journal of Vocational Behavior*, *62*(1), 26–42. https://doi.org/10.1016/S0001-8791(02)00045-3

Murphy, G. D. (2009). Improving the quality of manually acquired data: Applying the theory of planned behaviour to data quality. *Reliability Engineering & System Safety*, *94*(12), 1881–1886. https://doi.org/10.1016/j.ress.2009.05.008

Murthy, B. P., Molinari, N.-A. T., LeBlanc, T. T., Vagi, S. J., & Avchen, R. N. (2017). Progress in public health emergency preparedness—United States, 2001–2016. *American Journal of Public Health, 107,* S180–S185. https://doi.org/10.2105/AJPH.2017.304038

National Association of County and City Health Officials. (2005). *Operational definition of a functional local health department*. National Association of County and City Health Officials. https://www.naccho.org/uploads/downloadable-resources/OperationalDefinitionBrochure-2.pdf

Ned-Sykes, R., Johnson, C., Ridderhof, J. C., Perlman, E., Pollock, A., DeBoy, J. M., Control, C. for D., & Prevention (CDC). (2015). Competency guidelines for

public health laboratory professionals: CDC and the Association of Public Health Laboratories. *Morbidity and Mortality Weekly Report (MMWR), 64*(Suppl 1), 1–81. https://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm

Ned-Sykes, R. M., Pentella, M., Kurimski, L., Zanto, S., Matt Charles, E., Bean, C., Gibson, D., Breckenridge, K., Su, B., & Ridderhof, J. (2021). Regional consortia: A framework for public health laboratory collaboration and service sharing. *Public Health Reports*, 00333549211002774. https://doi.org/10.1177/00333549211002774

Newman, I., Hitchcock, J. H., & Newman, D. (2015). The use of research syntheses and nomological networks to develop HRD theory. *Advances in Developing Human Resources*, *17*(1), 117–134. https://doi.org/10.1177/1523422314559810

Nii-Trebi, N. I. (2017). Emerging and Neglected Infectious Diseases: Insights, Advances, and Challenges. *BioMed Research International*. https://doi.org/10.1155/2017/5245021

Nsubuga, P., White, M. E., Thacker, S. B., Anderson, M. A., Blount, S. B., Broome, C. V., Chiller, T. M., Espitia, V., Imtiaz, R., Sosin, D., Stroup, D. F., Tauxe, R. V., Vijayaraghavan, M., & Trostle, M. (2006). Public health surveillance: A tool for targeting and monitoring interventions. In D. T. Jamison, J. G. Breman, A. R. Measham, G. Alleyne, M. Claeson, D. B. Evans, P. Jha, A. Mills, & P. Musgrove (Eds.), *Disease Control Priorities in Developing Countries* (2nd ed.). World Bank. http://www.ncbi.nlm.nih.gov/books/NBK11770/

Office of the Federal Register, National Archives and Records Administration (2011). 42 CFR 493.1445—Standard; Laboratory director responsibilities, 493 C.F.R § 1445. https://www.govinfo.gov/app/details/CFR-2011-title42-vol5/CFR-2011-title42-vol5-sec493-1445

Okezue, M. A., Adeyeye, M. C., Byrn, S. J., Abiola, V. O., & Clase, K. L. (2020). Impact of ISO/IEC 17025 laboratory accreditation in sub-Saharan Africa: A case study. *BMC Health Services Research, 20*(1), 1065. https://doi.org/10.1186/s12913-020-05934-8

Olsen, A. A., McLaughlin, J. E., & Harpe, S. E. (2020). Using multiple linear regression in pharmacy education scholarship. *Currents in Pharmacy Teaching and Learning*, *12*(10), 1258–1268. https://doi.org/10.1016/j.cptl.2020.05.017

Olsen, S. J., MacKinon, L. C., Bean, N. H., & Slutsker, L. (2000). Surveillance for foodborne disease outbreaks—United States, 1993-1997. *MMWR CDC Surveill Summ*, *49*(1), 1–62. https://www.cdc.gov/MMWR/PREVIEW/mmwrhtml/ss4901a1.htm

Park, Y. S., Konge, L., & Artino, A. R. J. (2020). The positivism paradigm of research. *Academic Medicine, 95*(5), 690–694. https://doi.org/10.1097/ACM.0000000000003093

Peter, T. F., Rotz, P. D., Blair, D. H., Khine, A.-A., Freeman, R. R., & Murtagh, M. M. (2010). Impact of laboratory accreditation on patient care and the health system. *American Journal of Clinical Pathology*, *134*(4), 550–555. https://doi.org/10.1309/AJCPH1SKQ1HNWGHF

Petrusevska, A., Dimitrievska, V., Zisovska, E., & Spasovski, M. (2016). Standpoint of medical staff about accreditation in a preaccreditation period in hospitals in Republic of Macedonia. *International Journal of Sciences: Basic and Applied Research (IJSBAR), 26*(2), 242–251. http://gssrr.org/index.php?journal=JournalOfBasicAndApplied&page=article&op=view&path%5B%5D=5525&path%5B%5D=2828

Plebani, M., Sciacovelli, L., Aita, A., Padoan, A., & Chiozza, M. L. (2014). Quality indicators to detect pre-analytical errors in laboratory testing. *Clinica Chimica Acta*, *432*, 44–48. https://doi.org/10.1016/j.cca.2013.07.033

Poland, G. A., & Jacobson, R. M. (2012). The re-emergence of measles in developed countries: Time to develop the next-generation measles vaccines? *Vaccine, 30*(2), 103–104. https://doi.org/10.1016/j.vaccine.2011.11.085

Pomey, M.-P., Lemieux-Charles, L., Champagne, F., Angus, D., Shabah, A., & Contandriopoulos, A.-P. (2010). Does accreditation stimulate change? A study of the impact of the accreditation process on Canadian healthcare organizations. *Implementation Science : IS*, *5*, 31. https://doi.org/10.1186/1748-5908-5-31

Quality Improvement in Public Health: It Works! [Brochure]. (n.d.). Retrieved March 22, 2021, from https://www.apha.org/~/media/files/pdf/factsheets/qi_in_ph_it_works.ashx

Randolph, R., Salfinger, Y., Thiex, N., Shea, S., & Larson, K. (2019). Strengthening data defensibility in government human and animal food testing laboratories through accreditation: Lessons learned from the FDA accreditation support program.

Public Health Reports, *134*(2_suppl), 29S-36S. https://doi.org/10.1177/0033354919867723

Ratseou, E., & Ramphal, R. (2014). The impact of laboratory quality assurance standards on laboratory operational performance. *African Journal of Hospitality, Tourism and Leisure*, *3*(2), 1–13. https://uir.unisa.ac.za/bitstream/handle/10500/20657/The%20impact%20of%20laboratory%20quality%20assurance%20standards%20on.pdf?sequence=1

Ridderhof, J. C., & Wilcke, B. W. (2013). Public health laboratory systems: At the crossroads. *Public Health Reports*, *128*(2_suppl), 1–6. https://doi.org/10.1177/00333549131280S201

Riley, W. J., Lownik, E. M., Scutchfield, F. D., Mays, G. P., Corso, L. C., & Beitsch, L. M. (2012). Public health department accreditation. *American Journal of Preventive Medicine*, *42*(3), 263–271. https://doi.org/10.1016/j.amepre.2011.10.021

Riley, W., W Moran, J., Corso, L., Beitsch, L., Bialek, R., & Cofsky, A. (2010). *Defining Quality Improvement in Public Health* (Vol. 16). https://doi.org/10.1097/PHH.0b013e3181bedb49

Rimer, B., & Glanz, K. (2005). *Theory at a Glance: A Guide For Health Promotion Practice* [Guide]. U.S Department of Health and Human Services, National Institutes of Health. https://cancercontrol.cancer.gov/sites/default/files/2020-06/theory.pdf

Ross, P. T., & Bibler Zaidi, N. L. (2019). Limited by our limitations. *Perspectives on Medical Education*, *8*(4), 261–264. https://doi.org/10.1007/s40037-019-00530-x

Ryan, E. T. (2013). Eyes on the prize: Lessons from the cholera wars for modern scientists, physicians, and public health officials. *The American Journal of Tropical Medicine and Hygiene*, *89*(4), 610–614. https://doi.org/10.4269/ajtmh.13-0173

Sadikoglu, E., & Temur, T. (2012). The relationship between ISO 17025 quality management system accreditation and laboratory performance. In *Quality Management and Practices*. INTECH Open Access Publisher. https://cdn.intechopen.com/pdfs-wm/36162.pdf

Salfinger, M. (2016). A state public health laboratory director's experiences implementing efficiencies. *Clinical Leadership & Management Review*, *30*(1), 17. https://eds.p.ebscohost.com/eds/pdfviewer/pdfviewer?vid=1&sid=2d9053f8-4a76-4632-904a-7481c6f84f2b%40redis

Selya, A. S., Rose, J. S., Dierker, L. C., Hedeker, D., & Mermelstein, R. J. (2012). A practical guide to calculating Cohen's f2, a measure of local effect size, from PROC MIXED. *Frontiers in Psychology*, *3*. https://doi.org/10.3389/fpsyg.2012.00111

Setia, M. S. (2016). Methodology series module 3: Cross-sectional studies. *Indian Journal of Dermatology, 61*(3), 261–264. https://doi.org/10.4103/0019-5154.182410

Shim, S., Eastlick, M. A., Lotz, S. L., & Warrington, P. (2001). An online prepurchase intentions model: The role of intention to search: Best overall paper award—the sixth triennial AMS/ACRA retailing conference, 2000☆11☆ decision made by a panel of journal of retailing editorial board members. *Journal of Retailing*, *77*(3), 397–416. https://doi.org/10.1016/S0022-4359(01)00051-3

Siani, A. (2019). Measles outbreaks in Italy: A paradigm of the re-emergence of vaccine-preventable diseases in developed countries. *Preventive Medicine*, *121*, 99–104. https://doi.org/10.1016/j.ypmed.2019.02.011

Smith, K., Lamb, K. N., & Henson, R. K. (2020). Making meaning out of MANOVA: The need for multivariate post hoc testing in gifted education research. *Gifted Child Quarterly*, *64*(1), 41–55. https://doi.org/10.1177/0016986219890352

Smith, P. F., Hadler, J. L. M., Stanbury, M. M., Rolfs, R. T. M., Hopkins, R. S. M., & Group, the C. S. S. (2013). "Blueprint Version 2.0": Updating public health surveillance for the 21st century. *Journal of Public Health Management*, *19*(3), 231–239. https://doi.org/10.1097/PHH.0b013e318262906e

St. George, K., Ned-Sykes, R., Salerno, R., & Pentella, M. A. (2019). Advancing the public health laboratory system through partnerships. *Public Health Reports*, *134*(2_suppl), 3S-5S. https://doi.org/10.1177/0033354919882704

Stephan, U., Patterson, M., Kelly, C., & Mair, J. (2016). Organizations driving positive social change: A review and integrative framework of change processess. *Journal of Management*, *42*(5), 1250–1281. https://doi.org/10.1177/0149206316633268

Su, B., & Vagnone, P. S. (2013). State public health laboratory system quality improvement activities. *Public Health Reports*, *128*(Suppl 2), 34–39. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3730003/

Syazali, M., Putra, F. G., Rinaldi, A., Utami, L. F., Umam, W., Rofiqul, & Jermsittiparsert, K. (2019). Partial correlation analysis using multiple linear regression: Impact on business environment of digital marketing interest in the era of industrial revolution 4.0. *Management Science Letters*, 1875–1886. https://doi.org/10.5267/j.msl.2019.6.005

Tavakol, M., & Dennick, R. (2011). Making sense of Cronbach's alpha. *International Journal of Medical Education*, *2*, 53–55. https://doi.org/10.5116/ijme.4dfb.8dfd

Tavakol, M., & Sandars, J. (2014). Quantitative and qualitative methods in medical education research: AMEE Guide No 90: Part I. *Medical Teacher*, *36*(9), 746–756. https://doi.org/10.3109/0142159X.2014.915298

Thompson, C. G., Kim, R. S., Aloe, A. M., & Becker, B. J. (2017). Extracting the variance inflation factor and other multicollinearity diagnostics from typical regression results. *Basic and Applied Social Psychology*, *39*(2), 81–90. https://doi.org/10.1080/01973533.2016.1277529

Tognotti, E. (2013). Lessons from the history of quarantine, from plague to Influenza A. *Emerging Infectious Diseases*, *19*. https://doi.org/10.3201/eid1902.120312

Toney, D., Pentella, M., Blank, E., & Becker, S. (2021). Creating a blueprint for the future: Lessons learned from public health laboratories in the COVID-19

Response. *Journal of Public Health Management and Practice*, *27*(1), S101–S105. https://doi.org/10.1097/PHH.0000000000001285

Umble, K., Steffen, D., Porter, J., Miller, D., Hummer-McLaughlin, K., Lowman, A., & Zelt, S. (2005). The National Public Health Leadership Institute: Evaluation of a team-based approach to developing collaborative public health leaders. *American Journal of Public Health*, *95*(4), 641–644. https://doi.org/10.2105/AJPH.2004.047993

United Nations Industrial Development Organization. (2009). *Complying with ISO 17025*. https://www.unido.org/sites/default/files/2010-08/Complying_with_ISO_17025_A_practical_guidebook_0.pdf

U.S. Department of Health and Human Services Health Resources and Services Administration. (2011, April). *Quality Improvement*. https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf

Vatcheva, K. P., Lee, M., McCormick, J. B., & Rahbar, M. H. (2016). Multicollinearity in regression analyses conducted in epidemiologic studies. *Epidemiology (Sunnyvale, Calif.)*, *6*(2), 227. https://doi.org/10.4172/2161-1165.1000227

Verstraete, A., Boeckel, E. van, Thys, M., & Engelen, F. (1998). Attitude of laboratory personnel towards accreditation. *International Journal of Health Care Quality Assurance*, *11*(1), 27–30. https://doi.org/10.1108/09526869810199629

Wilson, I., Smye, M., & Wallace, I. J. C. (2016). Meta-audit of laboratory ISO accreditation inspections: Measuring the old emperor's clothes. *MicrobiologyOpen*, *5*(1), 95–105. https://doi.org/10.1002/mbo3.314

Witt-Kushner, J., Astles, R. J., Ridderhof, J. C., Martin, R. A., Wilcke, J. B., Downes, F. P., Inhorn, S. L., Kelley, P. H., Kimsey, P. B., Mills, D. E., Salfinger, M., Shult, P. A., Verma, M. P., Becker, S. J., & Drabkowski, D. J. (2002). Core functions and capabilities of state public health laboratories. *Morbidity and Mortality Weekly Report*, *51*, 1–8. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm

World Health Organization. (2011). *Laboratory Quality Management System*. WHO Lyon Office - International Health Regulations Coordination.

Yun, H., Park, S., Kim, D., Jung, E., & Yoon, M. (2020). The influence of academic level and course delivery mode on the use of motivational regulation strategies and learning engagement. *Australasian Journal of Educational Technology*, *36*(3), 89–103. https://doi.org/10.14742/ajet.5879

Zohrabi, M. (2013). Mixed method research: Instruments, validity, reliability and reporting findings. *Theory and Practice in Language Studies; London*, *3*(2), 254–262. http://search.proquest.com/docview/1330861295/abstract/8E1B58B7E19147A4PQ/1

Zuur, A. F., & Ieno, E. N. (2016). A protocol for conducting and presenting results of regression-type analyses. *Methods in Ecology and Evolution*, *7*(6), 636–645. https://doi.org/10.1111/2041-210X.12577

Appendix A: Survey Questionnaire

Demographic Data:

Gender: Female___ Male____

Age:

30-40
41-50
51-60
61+

Education:

Bachelors
Masters
Doctoral

Years in position:

<5
5-10
11-20
>20

ISO/IEC 17025 accreditation status:

Accredited
Not accredited
Working towards accreditation

Please indicate your experience on each statement, using the following scales:
1, strongly disagree; 2, disagree; 3, somewhat disagree; 4, neither agree nor disagree; 5, somewhat agree; 6, agree; 7, strongly agree.

Attitude towards ISO/IEC 17025 accreditation (ATT)

ATT1 Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is smart

1 2 3 4 5 6 7

ATT2 Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is valuable

1 2 3 4 5 6 7

ATT3 Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency has many benefits

1 2 3 4 5 6 7

ATT4 Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is interesting

1 2 3 4 5 6 7

ATT5 Seeking or maintaining ISO/IEC 17025 accreditation related to technical competency is a good thing to do

1 2 3 4 5 6 7

Subjective norms toward ISO/IEC 17025 accreditation (SN)

SN1 Most people who are important to me in my line of work think that I should seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

SN2 Most people like me in my line of work have sought or are maintaining ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

SN3 Most people who influence my decisions in my line of work think I should seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

SN4 People whose opinion I value in my line of work would prefer that I seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

SN5 Most people who are important to me in my line of work want me to be seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

Perceived behavioral control toward ISO/IEC 17025 accreditation(PBC)

PBC1 Whether I seek or maintain ISO/IEC 17025 accreditation related to technical competency completely up to me.
1 2 3 4 5 6 7

PBC2 I am confident that if I want to I can seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

PBC3 I have the skills to seek or maintain ISO/IEC 17025 accreditation related to technical competency. 1 2 3 4 5 6 7

PBC4 I generally have management support to seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

PBC5 I have the resources and time to seek or maintain ISO/IEC 17025 accreditation related to technical competency.
1 2 3 4 5 6 7

Intention to seek or maintain ISO/IEC 17025 accreditation (IN)

IN1 I am willing to seek or maintain ISO/IEC 17025 accreditation related to technical competency
1 2 3 4 5 6 7

IN2 I plan to seek or maintain ISO/IEC 17025 accreditation related to technical competency

1 2 3 4 5 6 7

IN3 I will make an effort to seek or maintain ISO/IEC 17025 accreditation related to technical competency
1 2 3 4 5 6 7

Appendix B: Core Competency Areas for Leadership Professionals in SPHLs

1. Quality management system
2. Ethics
3. Management and leadership
4. Communication
5. Security
6. Emergency management and response
7. Workforce training
8. General laboratory practice
9. Safety
10. Surveillance
11. Informatics
12. Microbiology
13. Chemistry
14. Bioinformatics
15. Other testing areas and research (APHL, 2018a

Appendix C: Permission to Use Survey Instrument

Buhmann, Alexander <alexander.buhmann@bi.no>

Tue 4/27/2021 3:20 AM

To: Christine Kilonzo

Hi Christine, I am very happy for you to use the instrument. Just cite the original work and, in your own work, be transparent in describing potential changes to the measures.

I wish you all the best for your work! Best wishes, Alex

Dr. Alexander Buhmann
Associate Professor
Director, Nordic Alliance for Communication & Management
BI Norwegian Business School
Mobile: +47 464 101 82
Book a consultation

Social Media: Google Scholar – Twitter – Linkedin – Facebook

Recent publications:

Managing algorithmic accountability. Balancing reputational concerns, engagement strategies and the potential of rational discourse, *2020, Journal of Business Ethics.*

Muzzling social media: The adverse effects of moderating stakeholder conversations online, 2021, *Technology in Society.*

Envisioning PR research without taking organizations as collective actors for granted, 2021, *Public Relations Inquiry.*