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# THE DESIGN OF AN INSTRUMENT TO ASSESS CLINICAL LABORATORIES EFFICACY POST IMPLEMENTATION OF THE PATIENT PROTECTION AFFORDABLE CARE ACT

by

Harry McDonald Jr.

A Dissertation
Submitted to the Graduate School
and the Center for Science and Mathematics Education
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Philosophy

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ABSTRACT

THE DESIGN OF AN INSTRUMENT TO ASSESS CLINICAL LABORATORIES EFFICACY POST IMPLEMENTATION OF THE PATIENT PROTECTION AFFORDABLE CARE ACT

by Harry McDonald Jr.

May 2017

The healthcare system in the United States has undergone substantial changes in support of the Patient Protection and Affordable Care Act (PPACA). On March 23, 2010, the implementation of the new healthcare law brought universal healthcare access to all Americans, while attempting to increase quality and decrease medical costs. The new law promotes more of a quality-focused, outcome-based model rather than a pay-for-fee service model; thus, moving the paradigm from infrequent to preemptive healthcare. The PPACA postulates as the only way to achieve cost savings while increasing quality and access. Never before has there been such an extensive change to the healthcare system since the inception of the Medicare system in 1965. In 2014, approximately 49 million uninsured Americans entered the healthcare system prompting increased demands of providers in navigating the new law; therefore, encouraging institutions to adopt best practices regarding health care reform. The purpose of this study is to begin assessing those best practices in clinical laboratories, by creating an accurate instrument, based on the theory of the iron triangle of health care. William Kissick first proposed the theoretical framework in 1994, when he conceptualized that healthcare 1) as a tightly linked, self-equilibrating system of three constructs: cost, quality, and access 2) when the increase occurs in one or two of the constructs, an effect to the third construct will occur.

As a reformer to healthcare in the laboratory, the PPACA maybe a disrupter to the theory, therefore this study addresses the effects of PPACA. One-Hundredth Sixty Clinical Laboratory Improvement Amendment (CLIA) affiliated laboratory managers from 50 states provided data to validate the Clinical Laboratory Manager Inventory survey (CLMI). The data from the survey were analyzed using IBM SPSS 23 and AMOS 23 software with the statistical methodology Structural Equation Modeling *(SEM)*. The results of the study showed the CLMI explained 75% of the variance associated with PPACA effects on the laboratory, indicating that it is an accurate instrument and that PPACA acts as a disrupter to theory. This finding allows the laboratory community to have a plausible instrument to assess the impact of PPACA on subsequent research.

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# DEDICATION

First, to my lord and savior you deserve all the praise for without your will, mercy and grace none of this would be possible. To my wife, my partner, and my best friend, thank you for putting up with the long hours and picking up the slack while I wrote and completed this dissertation. To my sons, Marshawn and Collin thank you for understanding the lack of time I spent with you and for making the sacrifice so that I could achieve this professional milestone. To my mother (dad) a tried and true person, you have always had faith and instilled in me that I can do anything. Thanks for the many prayers mom (dad), and for I know without your love and support this would not be possible. To my siblings and family members' thanks for your continued support and encouragement, and setting the foundation for me, too never stop learning and always pursue my dreams. Lastly, to my ancestors, thank you for providing the shoulders for me to stand on, for without out your commitment, determination, and tenacity this moment would be difficult to envision.

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LIST OF ABBREVIATIONS

| | |
|---|---|
| *AMOS* | Analysis of Moment Structure |
| *BCPI* | Bundled Payments for Care Improvement Initiative |
| *CBO* | Congressional Budget Office |
| *CER* | Comparative Effectiveness Research |
| *CFI* | Comparative Fit Index |
| *CLIA* | Clinical Laboratory Improvement Amendment |
| *CLMI* | Clinical Laboratory Manager Inventory |
| *EHR* | Electronic Health Record |
| *GDP* | Gross Domestic Product |
| *GFI* | Goodness of Fit Index |
| *ICD* | International Code for Diseases |
| *IOM* | Institute of Medicine |
| *IRS* | Internal Revenue Services |
| *JCT* | Joint Commission on Taxation |
| *NAACLS* | National Accrediting Agency for Clinical Laboratory Sciences |
| *PPACA* | Patient Protection and Affordable Care Act |
| *RMSEA* | Root Mean Square Estimate of Approximation |
| *SEM* | Structural Equation Modeling |
| *SPSS* | Statistical Package for the Social Sciences |
| *TLI* | Tucker-Lewis Index |

# CHAPTER I - INTRODUCTION

Dr. William Kissick once said, "The forecast for the year 2000 is that we will spend between 15 and 18 percent of the gross national product on health and medical care, and I am certain, 6 percent on education" (Godfrey, 2012, p 1). The cost of healthcare in America is a contentious debate for policymakers, medical administrators, healthcare providers, and patients. Gradually, the U. S. healthcare system is becoming the defining sector of the economy. In 1960, healthcare made up roughly 5% of the gross domestic product (Bandyopadhyay et al., 2013). In 2014, health care has reached a substantial portion of the gross domestic product (GDP) at 17.5%, approximately $3.1 trillion annually (Center for Disease Control and Prevention [CDC], 2014). By 2020, expectations are that healthcare will account for 20% of the GDP with no signs of decreasing; as a consequent, new policies and reforms are necessary to decrease healthcare cost in the future (Bennett et al., 2014). Much of the U.S. public is convinced of having the greatest healthcare system in the world. As more data is gathered, this allegory slowly has begun to diminish. Although the practice of medical advances in the United States warrants recognition, these advancements have not translated into a superior healthcare system (Panning, 2014b).

Of the $3.1 trillion attributed annually to healthcare cost, approximately 19.9% ($597 billion) is spent on clinical and ancillary laboratory services (CDC, 2014). Some common causes of high health care expenditures include the fee-for-service payment system that depends on essential the quantity of healthcare and not its quality. This is because most physicians are in control of the decision-making process for healthcare purchases, thus they are not constrained in most healthcare settings by cost (Panning,

2014a). Another factor is capitation payment practices that guarantee a set amount for each patient assigned for a time period regardless of whether or not the patient seeks care. Other factors that drive U.S. healthcare costs are private healthcare insurance companies practicing medical underwriting and risk selection to better position themselves to capitalize on their return of investment (Panning, 2014b). In the absence of council and policies that mandate health care insurers' acceptance of all applicants, insurance companies pursue strategies to avoid high-risk patients. This is done by using extensive screening processes that are known to produce costly administrative fees to healthcare (Riegelman, 2011). The Institute of Medicine projects that approximately one-third of the U.S. healthcare expenditures are due to administrative costs and futile procedures (Lelflar, 2013). In addition to the increase in administrative costs, the growth in technology innovations appears to increase healthcare cost due to startup expenses that exacerbate currently strained budgets.

According to most economists, assessments of healthcare systems employ the constructs of cost, access, and quality also known as the iron triangle of health care (Carroll, 2012). In the United States, healthcare cost is approximate $9,523 per capita, more than any other industrialized country in the world (CDC, 2014). In fact, the United States spends approximately 6% more on healthcare than the second highest country with high-cost health care expenditures (CDC, 2014). With these high costs, one would expect the United States to have the best access, and best outcomes of healthcare; however, this is a false narrative (Bandyopadhyay et al., 2013). At present, the United States ranks number one in health care cost but ranks 37th of developed nations with appropriate healthcare for citizens (Truman, 2013). In terms of access, the United States is one of the

three wealthiest nations that do not ensure that all of their citizens have universal healthcare. Because of this disappointing statistic, the U.S. government has implemented changes in the health care system in the form of the PPACA (Truman, 2013).

## Statement of the Problem

The Patient Protection Affordable Care Act has a myriad of provisions that will affect health care on all levels. Among the numerous of regulations and changes is the implementation of the statute on clinical laboratories. The enactment of the statute appears to be a disrupter to the iron triangle of health care, based upon the three constructs of access, cost, and quality. Numerous clinical laboratorians and scientists, as well as the institutions that regulate them, are voicing their concerns regarding the impact of the PPACA. However assessing access, cost and quality in clinical laboratories is difficult due to the paucity of formal studies devoted to understanding their dynamics. Currently, there is not an instrument to assess the effects of the PPACA on clinical laboratories.

Hence, the purpose of this study is to design a model that accurately assesses the three constructs (access, cost, and quality) for current and future applications. Structure equation model is the statistical method used to predict a plausible model assessing the constructs' relationships between the predicted model and the observed data as a disrupter to the theory of the iron triangle. The goal of the study is to produce the most parsimonious instrument that represents the predicted structure model without sacrificing the comprehensiveness of the assessment.

## The Patient Protection Affordable Care Act

The goal of the PPACA is to increase access to health insurance for Americans while increasing quality and decreasing cost of healthcare. On March 23, 2010, Congress passed the PPACA and President Obama signed it into law (Bandyopadhyay et al., 2013). However, there was much opposition to passing this healthcare reform for fear of advocating socialized medicine, increasing cost, and partisan ideology (Lelflar, 2013). The PPACA was challenged on June 28, 2012 (*National Federation of Independent Businesses et al. v. Sibelius, Secretary of Health and Human Services et al.*, 2012*)* nonetheless it was upheld by the Supreme Court 5-4 for all provisions (Lehman, 2015).

One provision of the PPACA challenged in the courts was the mandate placed on non-exempt individuals who do not receive health insurance through an employer or government-sponsored program. These individuals must purchase insurance from a private insurer. Individuals that do not comply will be assessed a penalty collected by the Internal Revenue Service as a tax, beginning in 2014 (Internal Revenue Service [IRS], 2014). The principle of this provision is to lessen the cost of insurance premiums by employing the economy of scale as a cost-saving strategy; assuring that everyone obtains insurance in order to seek affordable healthcare. The other key provision is the expansion of Medicaid. This provision expands the scope of the program, increasing the number of individuals the states must cover. Traditionally, states covered only underprivileged adults with children. Conversely, this provision of the PPACA requires states to provide Medicaid coverage to adults with incomes up to and below the 138% of the federal poverty level (Lehman, 2015). If an adult falls into this category, the PPACA provides federal funding to offset the cost to states for subsidizing the individual. However, if a

state refuses to comply with the new coverage it may lose all federal Medicare/Medicaid funds (IRS, 2014).

The Patient Protection Affordable Care Act, also stipulates that poorer Americans and some middle-income American families, between the federal poverty line of 138% to 400%, receive subsidies to make premiums more affordable (Woodward, 2012). Since 2014, 32 states have opted into Medicaid expansion and 19 states have not for reasons of ideology, partisanship, culture, and fear that the expanded federal subsidies would overburden their state' finances in the future (Lelflar, 2013).

Other provisions include (a) prevention of insurance carriers from denying or rejecting coverage to sick individuals, (b) prevention of insurance carriers from charging unwarranted rates to seniors and the frequently ill, and (c) prevention of insurance carriers from imposing lifetime limits on benefits (Lehman, 2015). In addition, the PPACA mandates free preventive services and other anticipatory procedures making it a preemptive healthcare initiative (Lelflar, 2013).

The series of provisions brought on by the PPACA have encouraged medical institutions; to generate best operational practices that foster an atmosphere of increase access and quality, while simultaneously decreasing cost. On the contrary, the iron triangle of health care, as an assessment tool regarding healthcare systems, fosters doubt to these claims. Therefore, it is necessary to address these assertions.

The aim of this study is to develop a model based on the PPACA as a disrupter to the iron triangle and to design an instrument that will accurately assess healthcare efficacy in clinical laboratories, as it pertains to the theory post implementation of the PPACA.

## Laboratory Clinical Services

The first recorded history of clinical laboratory services was on human bodily fluids circa 300 BC, by the ancient Greek physician Hippocrates (Wolcott, Schwartz, & Goodman, 2008). In 1896, the first official clinical laboratory was opened at Johns Hopkins Hospital with the purpose of discovering diseases such as diphtheria, tuberculosis, cholera, and developing new methods to detect other maladies (Wolcott et al., 2008). The creation of these methodologies established the importance of clinical laboratory services in the 20th-century. In 1922, The American Society of Clinical Pathologists formed the first professional society supporting physicians specializing in pathology (Delwiche, 2003). In 1926, under the purview of physicians credited by the American College of Surgeons, all hospitals were required to establish clinical laboratories (Berger, 1999). Since then clinical laboratories have provided healthcare providers with objective information that assists in the prevention and diagnosis of healthcare concerns.

Currently, there are over 250,000 clinical laboratories that provide testing and services in the United States (Wolcott et al., 2008). The consolidation of these laboratories is under one statute, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 that establishes standards for record maintenance and proficiency testing for all laboratories (Berger, 1999). Clinical laboratories play a vital role in the healthcare system and perform numerous functions such as research, clinical care, and a multitude of other purposes (Wolcott et al., 2008). Furthermore, the practice of laboratory services entails a broader scope of influences beyond the activities in the laboratory. These influences include (a) consultations with providers regarding test ordering and result

interpretations (b) performance measurements for quality improvement (c) and a growing scale of direct interactions with patients and the public regarding test results (Wolcott et al, 2008). The future of the laboratory reflects the use of evidence-based medicine and clinical practice guidelines as key components of improving the continuity of care for patients. Healthcare providers, quality assurance organizations, and insurance payers are incorporating these key components as indicators to assess objectively quality, cost, and access to care for the individual patient and populations in their geographical footprint.

*Impact of the PPACA on Clinical Laboratory Services*

How will the PPACA provisions affect clinical laboratory Services? Several aspects of the laboratory are privy to implications of the PPACA. These provisions within the new law aim to promote (a) increased access to laboratory tests (b) provide a better quality of test results via an improved total testing process (c) reduce cost per laboratory test for the average citizens in the United States (Bandyopadhyay et al., 2013). The following are noteworthy effects the PPACA has in the laboratory.

*Control workflow*. In 2014, the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) estimated that the PPACA would create access for approximately 14 million nonelderly people to procure health insurance and approximately 30 million in subsequent years, bring an influx in demand for primary care (Kasoff & Buescher, 2013). Furthermore, by 2012 through 2060 the U. S. Census Bureau projects that the elderly population, age 65 and older, is expected to more than double, from 43 million to 92 million (Bennett et al., 2014). The key challenge for laboratories is the need to better define and highlight the critical role of appropriate clinical services, in

order to manage successfully the influx of newly insured individuals across its continuum of care.

*Increased Workload.* The increase in the number of individuals who now have health insurance will likely increase the workload. The availability of insurance coverage offers access to more individuals to pursue routine types of healthcare, including laboratory tests that were previously inaccessible. The workload is likely to promote the idea of new diagnostic and prognostic tools to predict better outcomes of treatment while expanding the use of genetic markers to target specific pathologies. In addition, the increased workload encourages providers to personalize medicine for chronic conditions attributed to the rise of the elder population, while improving cost and efficacy in healthcare (Bennett et al., 2014).

*Personnel.* Personnel shortages are of concern as the PPACA takes effect. As workload increases in clinical laboratories, so will the need to increase personnel to cover the growth. Nevertheless, over the last few decades, personnel numbers in the laboratory have gradually declined. This decline is due to the closure of numerous medical laboratory programs, and the retiring of senior laboratory personnel with numerous years of experience (Cearlock, 2012). To ameliorate the shortages, the profession must prepare to graduate more students from current programs, open new programs to boost numbers, and implement automation systems as a solution to accommodate the deficit. Equally, laboratories are likely to pursue other initiatives such as investing in educational opportunities (e.g. continuing education program, professional society membership, and presenting publications) to improve personnel competency (Otto, 2012). Likewise, laboratories are devoted to ensuring personnel are afforded the opportunity to earn

advanced degrees as a method of improving laboratory and provider relationship (e.g. consultation support of test results) to improve continuity of care for patients regarding the PPACA (Otto, 2012).

*Reimbursement.* Reimbursement rates for Medicare patients are of importance for laboratories. Medicare reimbursements are only at 75% of the levels they were in the 1980s for the Clinical Laboratory Fees Schedule. This is due to annually adjusting the consumer price index and the effects of sequestration cuts proposed by congress (Panning, 2014a). In addition, the elimination of the fee schedule updates for five years, and the reduction of the fee schedule has forced laboratories to develop practices that are more efficient. Consequently, since private insurance emulates Medicare practices, their reimbursements rates will be lower as well. These lower rates will require laboratories to be more efficient in seeking ways to improve quality and remove unnecessary fees from the healthcare system in order to remain viable (Futrell, 2013). There are provisions within the PPACA that encourage the reduction of spending while obtaining more value for the money spent by reducing payment for non-aligned quality target outcomes (Dowd, 2013). Value Based Purchasing Healthcare Reform focused on quality outcomes, is one initiative that has forced healthcare organizations to put emphasis on quality. The primary objective of this system is to promote safer healthcare and to eliminate unnecessary administrative and duplication costs (Futrell, 2013).

Another initiative regarding reimbursement is creating accountable care organizations that use bundled payment methods. One example is the Center for Medicare and Medicaid Services Bundled Payments for Care Improvement Initiative (BPCI) (Giles, 2011). This payment system provides a single payment for healthcare

services that patients receive across a range of care. The service is designed to incentivize caregivers to improve the quality of care through coordinated efforts across the value chain (Graham, 2015). The conceptualization of bundled payment is that one provider receives a single payment for all services provided throughout an episode of care; then this payment is divided amongst other providers based on the services rendered (Shay & Mick, 2013). All parties involved will receive a portion of the payment, therefore sharing equal responsibility for the care provided, thus improving efficiency. The intentions of bundled payments are to bridge quality gaps in care through effective collaborations and coordination of care between hospitals and providers, particularly to prevent or reduce readmissions (Shay & Mick, 2013).

Other initiatives of reimbursement are the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). The transition from ICD-9 diagnosis and procedure code sets to ICD-10 on October 1, 2014, was one of the largest changes to healthcare submission claims (Kasoff & Buescher, 2013). The ICD-10 contains codes for diseases, signs, and symptoms, abnormal findings, complaints, and external causes of injury. A successful transition for laboratories to this new system will help limit rejected claims and subsequently improve cash flow (Kasoff & Buescher, 2013).

*Comparative Effectiveness Research*. The statute emphasizes comparative effectiveness research (CER), an evidence-based approach to help healthcare professionals evaluate what tests are most appropriate for specific health conditions, subpopulations, and to evaluate treatment options (Lelflar, 2013). The inclusion of CER is important to address the problem of excessive practice variation, for the treatment of

identical conditions. These variations of treatment seem to exist due to the lack of evidence-based medicine that proclaims to produce a superior treatment over an alternative method (Agency for Healthcare Research and Quality [AHRQ], 2012). To correct the problem, CER postulates a path to publicize on a national level evidence of best-claimed practices for a particular condition. Conversely, there has been opposition from providers that all patients are different and a one-size fits all approach, is not conducive to best practice in the field of medicine (Lelflar, 2013). Nevertheless, CER is an important new initiative regarding the new statute; aimed at reducing cost and improving patient outcomes.

*Electronic Health Records (EHR).* The implementation of electronic health records is suggested as a powerful tool to prevent duplication efforts of testing when patients change healthcare or/and insurance providers (Lupino, 2015). This electronic disruptor has the potential to reduce cost and increase quality by avoiding unnecessary repeat administrative procedures and test procedures. Electronic Health Records also provide access to physicians, allowing continuity of care for patients throughout their full spectrum of treatment from one institution to another (Bandyopadhyay et al., 2013). Furthermore, institutions are investing in EHR to assist personnel with the projected increase of high throughput and complex test results.

The U.S. government has incentivized the implementation of EHR through the Informatics Incentive Program by subsidizing billions of dollars to healthcare institutions to upgrade their current systems in stage one of a two-stage process (Lupino, 2015). Conversely, fewer institutions are applying for stage two due to frustration and minimal successes for those institutions who have participated in stage one (Lupino, 2015). The

verdict is unclear as to whether EHR is improving healthcare; only the future will reveal the effects of EHR interoperability on the continuum of care as more laboratories incorporate this practice.

*The Medical Device Tax*. The medical device tax will be a huge hurdle for laboratories to overcome. On January 1, 2013, the PPACA imposed a 2.3% excise tax on the sale and import of medical devices (Kasoff & Buescher, 2013). Laboratories that purchase these devices are likely to pay the extra expenses, as suppliers, manufacturers, and distributors are likely to pass along the added expenses (Kasoff & Buescher, 2013). The U.S. government has plans to use the medical device tax as an initiative to pay startup cost for PPACA, but the laboratory community perceives the new tax as another expense that exacerbates financial pressure on an already strapped laboratory industry (Miles &Weiss, 2011). Currently, the laboratory industry along with bipartisan support in congress is fighting to ban this provision because of added economic pressure. If this tax is not repealed, the laboratory industry will likely face increased financial hurdles that could negatively affect operations.

Presently, there are several implications brought on by the PPACA that will require laboratories to become more productive and cost conscience than ever before. These changes appear to be necessary to control health care spending while producing better outcomes. However, will the PPACA be the savior to champion this control? There are laboratorians who feel that the PPACA is overwhelmed with the new changes of reimbursement cost, provisions for accessibility, and benchmarks for quality. However, it is important for laboratorians to focus on the incentives, new reimbursement models, and

prevention programs dedicated to improving the healthcare system, for the betterment of all U.S. citizens (Kasoff & Buescher, 2013).

## Purpose of the Study

The purpose of this study is to design the most theoretical, statistical instrument based on the theory of the iron triangle. This study will assess the relationships of access, cost, and quality in clinical laboratories post implementation of PPACA. The objectives of this study are to:

1. Confirm that the indicators, technology-Q, patient safety, and personnel measure the construct "Quality" as operationalized in this study.
2. Confirm that the indicators, technology-C, utilization-C, and reimbursement measure the construct "Cost" as operationalized in this study.
3. Confirm that the indicators, reform, utilization-A, and fee measure the construct "Access" together with the latent variables, Cost, and Quality as operationalized in this study.
4. Design a measurement instrument with the intent of producing a parsimonious structure without sacrificing the comprehensiveness of the assessment of PPACA on clinical laboratory services.
5. Hypothesize (a priori) that the constructs relationships in the predicted model resemble the constructs relationships in the observed data set.

## Expectations

The construct, independent variable "Cost", will be operationalized by measuring questions from the subscales of technology-C, utilization-C, and reimbursement with expectations of a decreasing relationship to the construct independent variable "Access".

The construct independent variable "Quality" will be operationalized by measuring questions from the subscales of technology-Q, patient safety, and personnel with expectations of an increasing relationship with the independent construct variable "Access". The construct independent variable "Access" will be operationalized by measuring questions from the subscales of utilization-A, reform, and fee; and from the independent construct variables of Cost and Quality. The outcomes from these relationships are expected to result in an increase in Access and Quality; while producing a decreasing relationship with Cost for patients in the healthcare value chain.

## Assumptions

Assumptions of the PPACA related to this study presume that all laboratories are affiliated with CLIA. Other assumptions are as follows:

1. Clinical laboratories adjusted their business practices regarding implementation of the PPACA.
2. The PPACA's individual mandate creates a greater demand for services. Most states are expanding their Medicaid programs, and health care exchanges are set up to help individuals purchase health insurance as a requirement of the PPACA.
3. The exemption of pre-existing conditions and subsidies for individuals and families that fall within a certain range of the federal poverty line provides an increase in laboratory services.
4. Participants with knowledge regarding quality, access, and cost in the laboratory will answer the survey honestly.

5. The survey items are sufficient indicators of the constructs post implementation of the PPACA.
6. The sample size will be sufficient to evaluate the impact of quality, cost, and access of the PPACA is having on clinical laboratory services.

## Limitations

1. The sample size is collected from selected CLIA laboratory managers from numerous states; therefore, the results may not represent other laboratory entities throughout the United States. As a result, objectification cannot be applied to every laboratory throughout the United States.
2. Some participants' responses on the survey may be biased to the effects of PPACA, depending on their ideology, partisanship, and culture.
3. The survey items focus on the three constructs (quality, access, and cost) of the iron triangle in regards to clinical laboratories efficacy post implementation of PPACA. However, there are possibly other indicators or variables available to assess efficacy in clinical laboratories.
4. Time is a limiting factor. Perhaps, if more time were available to conduct a profound number of subjects regarding the three constructs, the data from the study would be more informative and objective.

## Definitions and Terms

*Access:* Access to health care describes the relationship of availability and use of insurance for healthcare when needed.

*Bundled Payment:* The CMS Bundled Payments for Care Improvement Initiative provides a single payment for services that patients receive across a continuum of care.

*Cost:* Cost is associated with the affordability of healthcare for patients and payers at a given rate.

*Hospital laboratories:* Chief provider of laboratory services for their inpatient population as well as outpatient population receiving care from physicians who are affiliated with the hospital.

*Physician Office Laboratories:* A diagnostic laboratory in a physician's office with an abbreviated menu of tests that can be performed while the patient is in the office, so the physician can better manage the patient.

*Quality:* Quality addresses the value and benefits of the outcomes received from healthcare provided.

*10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD):* A medical classification list by the World Health Organization (WHO). It contains codes for diseases, signs, and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury (Kasoff & Buescher, 2013).

*Clinical Laboratory:* Testing services and associated practices for the assessment, diagnosis, treatment, management, or prevention of health-related conditions utilized in making patient care decisions and improving public health.

*Patient Protection and Affordable Care Act (PPACA):* Legislation, commonly referred to, as "Obamacare," enacted by the U.S. Senate and House of Representatives in 2010. This act reformed health care for all Americans (H.R. 3590).

*Reimbursement:* To make repayment for services and goods rendered to individuals for health care issues.

*Technology:* Automation of new testing methods and processes coupled with sophisticated laboratory information systems to improve efficiency.

## Hypothesis

$H_o$: There is a non-significant difference in the variables interrelationships between the predicted model and the observed model data set; therefore, this survey will serve as a plausible instrument to assess the PPACA as a disrupter to the iron triangle of health care.

$H_1$: There is a significant difference in the variables interrelationships between the predicted model and the observed model data set; therefore, this survey will not serve as a plausible instrument to assess the PPACA as a disrupter to the iron triangle of health care.

## Research Questions

1. Are the variables technology-Q, patient safety, and personnel appropriately measuring the latent variable "quality" as a disrupter to the iron triangle?
2. Are the variables technology-C, utilization-C, and reimbursement appropriately measuring the latent variable "cost" as a disrupter to the iron triangle?
3. Are the variables technology reform, utilization-A, and fee appropriately measuring the latent variable "access" as a disrupter to the iron triangle?
4. Is the goodness of fit between the predicted model and the observed data similar enough to explain the hypothesized relationships of the PPACA as a disrupter to the iron triangle?

# CHAPTER II – LITERATURE REVIEW

A comprehensive review of the literature was conducted with the impetus of determining the progression of the U.S. healthcare system and its effect on clinical laboratories. A broad review of journal articles, books, and report papers was conducted to gain insight as to the indicators used to measure healthcare cost, quality, and access in the laboratory. The following literature review provided a framework for readers to put in context the definition of cost, quality, and access as it pertains to the laboratory post the PPACA.

The literature search for background information was conducted using The University of Southern Mississippi Cook Library collections of electronic journals. Although the search was not exhaustive, it was limited by intent. PubMed, EBSCO host and Medline were used to define the database search parameters. The original phrase search was done for the phrase "iron triangle of health care for clinical laboratories", but was very limited due to the lack of studies conducted on the topic. Additionally, other search words such as access, cost, and quality were used to obtain articles that were independent studies for each of the words. Other searches using the keywords: Confirmatory factor analysis and Structural equation modeling helped to streamline articles further, in order to scale the information down to a manageable size for analysis.

## Background of the Study

The issue of healthcare insurance reform in the United States has been the subject of political debate since the early part of the 20th century. A brief history of healthcare reform is as follows:

1. During the progressive era of Theodore Roosevelt from 1901-1909, he pledged a campaign on social insurance for the sick, poor, irregular employment, and old age, because he believed that a country is incapable of being strong with a nation of sick and poor people (Palmer, 1999). Most of these initiatives took place outside the government; needless-to-say Roosevelt's conservative successors postponed the advancement of social welfare for the public for about twenty years.
2. During Franklin D. Roosevelt's tenure, from 1933-1945 healthcare insurance was considered in the Social Security Bill of 1935 and the Wagner Bill National Health Act of 1939 (Igel, 2008). However, both were failed attempts for healthcare reform due to threats of impending comprehensive social security legislation, and the resurgence of conservative partisanship against universal healthcare respectively.
3. From 1945-1953 Truman became president and health care issues finally moved to the forefront of national politics under the Fair Deal Campaign (Geselbracht, 1999). However, in 1949 strong opposition opposed the deal.
4. In 1965, President Lyndon B. Johnson created Medicare and Medicaid the first social insurance program administrated by the United States government (Palmer, 1999). Nevertheless, this program only provided health insurance coverage, for people who were 65 and older, or for individuals who met special criteria.
5. In 1972, President Nixon signed the Social Security Amendments of 1972 extending Medicare to those under 65 who were severely disabled for over

two years and introduced health care maintenance organizations (Palmer, 1999).

6. In 1985, President Regan expanded Medicare, through the Consolidated Omnibus Budget Reconciliation Act (COBRA) giving some employees the ability to continue health insurance coverage after leaving employment (Palmer, 1999).
7. George H. W. Bush repealed the Regan Medicare expansion and proposed the private insurance model and incentives to improve outcomes and reduce costs. In 1993, President Clinton proposed universal health care for all Americans through the initiative of the Health Security Act (Palmer, 1999). Due to rising opposition, the act failed to gain traction in congress and it was dismissed.
8. In 2003, President George W. Bush created the Prescription Drug Benefit for Medicare Part D, which included a prescription drug plan for the elderly and disabled Americans (Centers for Medicare & Medicaid Services [CMS], 2006). This act was the largest overhaul of Medicare in the public healthcare program's 38-year history; however, it did not become universal healthcare for all Americans.
9. After 100 years of efforts to create and pass universal health care through congress, President Obama finally, succeeded in making it possible through The Patient Protection and Affordable Care Act of 2010 (Panning, 2014b). Prior to the PPACA, the health care system was marked by fragmented healthcare delivery that resulted in poor quality patient experiences, inefficient operations, and substandard clinical outcomes (Panning, 2012).

The Patient Protection Affordable Care Act objective is to provide access to the health care system for more individuals under the age of 65, and individuals at or under the federal poverty line of 133%. Subsidies through Medicare/Medicaid will be granted to low-income individuals and children across all states to assistance with the transition into the system. Advocates for the PPACA suggest a means to improve healthcare access without increasing cost and compromising quality is to decrease inefficiencies such as; excessive administrative fees, employ the economy of scale model to reduce cost per individual, and change the delivery of healthcare from a quantity to a quality-based system. In addition, expectations of the PPACA are to realign the healthcare system to incentivize and reward preventative practices that improve the efficacy of care for American citizens.

Opponents of the PPACA postulate, the statute did nothing to improve the healthcare system. According to Carroll (2012), the new statute does conform to the theory of the iron triangle; therefore, by increasing access one will inevitably increase the cost or decrease the quality. Carroll (2012) also believes that PPACA will cost over $900 billion to fund all of its provisions. While there are suggestions of tax reliefs and spending cuts to cover these new expenses, opposition leaders are curious as to whether or not these breaks actually exist (Carroll, 2012). The ultimate question is will the PPACA, be an effective disrupter to the iron triangle? If so, as a disrupter, the biggest impacts for the laboratory will be to improve the quality of testing at an economical price, while managing the increased workload due to granting healthcare accessibility to the individualized American citizen made possible by PPACA.

## Theoretical Framework

The theoretical framework for this study is the iron triangle of health care, first proposed by William Kissick in 1994. The word iron represents the competition between the three vertices (access, cost, and quality) of the triangle (Lehman, 2015). Access to health care describes the relationship of availability of healthcare when needed. Cost is associated with the affordability of healthcare for patients and payers at a given rate. Quality addresses the value and benefits of the outcomes received from healthcare provided.

The conceptualization of the theory is that healthcare is a tightly linked, self-equilibrating system of three constructs: cost, quality, and access as seen in Figure 1.

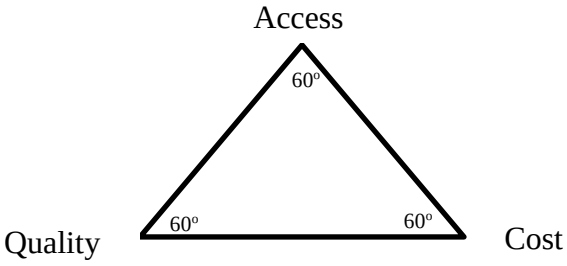


*Figure 1.* Iron Triangle of Healthcare

Illustration of the three vertices (constructs) of the iron triangle of health care based on the theory of Williams Kissick, 1994. Healthcare is measured on the three constructs access, cost, and quality, and shares equilibrium between the constructs totaling 180 degrees.

As an increase occurs in one or two of the constructs, this inevitably results in an effect on the other construct in maintaining equilibrium within the model. For example, if access is increased then cost will be increased, and or quality will be decreased to maintain the equilibrium, excluding adding other factors in the existing model (see Figure 2).

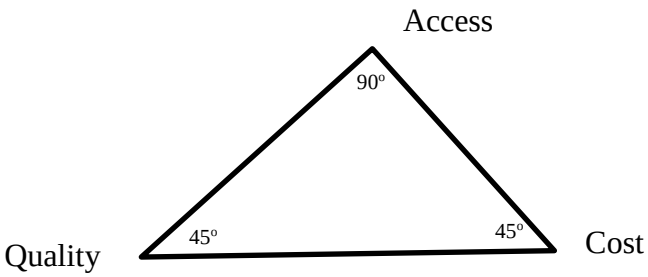


*Figure 2.* Access Increased on the Iron Triangle

Illustration of the iron triangle, as access increase to 90 degrees, one or both of the other constructs (cost and quality) must decrease to maintain 180 degrees in the triangle.

Alternatively, if the quality of care is increased then access and or cost must decrease to maintain equilibrium if no other factors are included in the model (see Figure 3).

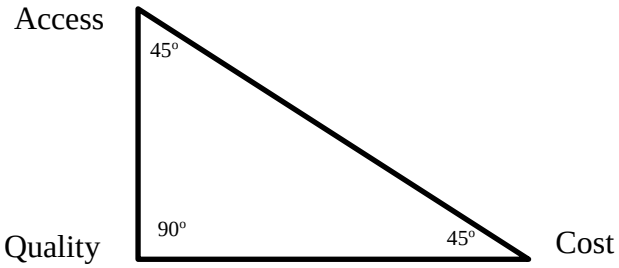


*Figure 3.* Quality Increased on the Iron Triangle

Illustration of the iron triangle, as quality increases to 90 degrees, one or both of the other constructs (access and cost) must decrease to maintain 180 degrees in the triangle.

For this study, Figure 4 will be of importance regarding increasing access with aspirations to increase quality while decreasing cost (Russell, 2012). If the Patient Protection and Affordable Care Act performs as predicted, then the iron triangle of health care for the laboratory will resemble that is seen Figure 4.

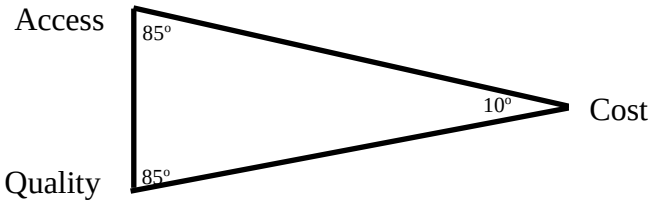


*Figure 4.* The Effect of PPACA

The Patient Protection Affordable Care Act as a disrupter to the iron triangle of health care on laboratories; the triangle presents with an increase in access and quality and a decrease in cost associated with healthcare in the laboratory.

To date, there has been limited research conducted on the conceptualization of the iron triangle regarding clinical laboratories post implementation of the PPACA's provisions. However, there are reports that focus on the three constructs (cost, access, and quality) independently of each other, providing useful information as a solid foundation for this study. The following paragraphs will discuss how the indicator variables were determined from the previous literature regarding the three constructs.

## Healthcare Access in the Laboratory

Access is concerned with providing individuals the accessibility and availability, to receive healthcare with appropriate resources in order to preserve and/or improve their health (Guillford et al., 2002). If services are available and there is adequate supply to support the service, then individuals have the opportunity to obtain healthcare. The logic seems simple; however, the term access is complex when referring to healthcare, which is viewable through different lenses. More broadly, barriers such as finance, organization structure, culture can create inequitable circumstances that influence healthcare accessibility. Therefore, for this study, access will be observed from a broader lens to gain an understanding of what it means to have healthcare access, using the Institute of Medicine Model of Access. From there, the focus will be narrowed to the category of

healthcare services within the model to clarify further the viewpoint of access to laboratory services post implementation of the PPACA.

*The Institute of Medicine (IOM) Model of Access*

The Institute of Medicine Model (IOM) of Access was developed in the 1990s, to provide specifically a structure of timely care to achieve optimal outcomes and close gaps in health care (Institute of Medicine [IOM], 1993). The conceptual framework of the IOM model is to monitor the quality of healthcare services by assessing barriers and utilization to the outcomes of care received (see Figure 5). Overcoming the barriers within the IOM model is the first step in gaining access to the system. Provisions in the PPACA like the individual mandate, open market to purchase healthcare insurance, and Medicaid expansions in states are important factors in overcoming these barriers. Use of services and mediators are the next step in the model that accounts for provider availability, procedures, and efficacy of the treatment given. Provisions within the PPACA such as new testing methodologies, education of staff, and quality versus quantity of test performance are important factors to ensure appropriate treatment. Finally, the outcome step of the IOM model of access assesses the performance of the barriers and use of services to predict the status of individual's health (outcome).

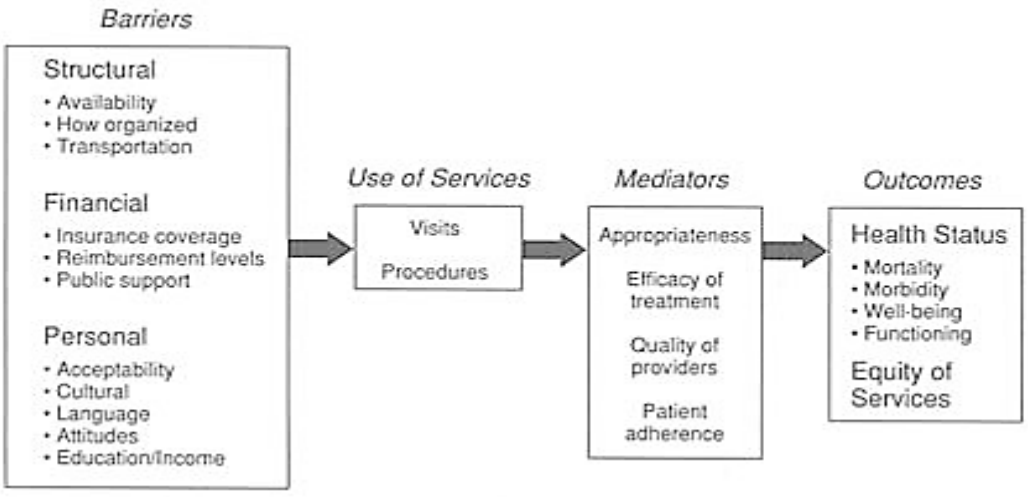


*Figure 5.* The Institute of Medicine Model of Access

The dynamics of participation in the personal healthcare system: Namely, access problems are created when barriers cause underuse of services, which in turn leads to poor outcomes. Adapted from Institute of Medicine (US) Committee on Monitoring Access to Personal Health Care Services, by M. Millman,1993; Courtesy of the National Academies Press, Washington, D.C. p. 35.

Within this model, the categories of use of healthcare services and mediators (utilization) are important indicators for assessing clinical laboratories (Karikari-Martin, 2010). One way to realize the effect of the PPACA on health services within the clinical laboratory is to develop indicators that assess the frequency of visits, and the number of laboratory tests performed over time (Millman, 1993). Identifying the correct indicators within the use of services and mediators is an important function of this study.

*Operationalization of Access in the Laboratory*

The IOM model of access was instrumental in identifying indicators to assess accurately the construct of access as it relates to healthcare in the laboratory. The indicators assembled from the model of access are reform, fee, and utilization (Otto, 2012). These indicators are posited to be the most appropriate indicators to assess access from the consensus of laboratory professionals. The operationalization of these indicators regarding access in the laboratory is as follows:

*Reform (Screening test).* Access to the laboratory for this study refers to the variables of increased screening, and diagnostic tests for patients such as Hepatitis B, Human Immunodeficiency virus, complete blood count and other tests. The number of tests performed and/or new testing platforms created provides an indication as to whether or not reform will be a valid indicator of access. In addition, screening and diagnostic tests in health plans at no or reduced cost to the consumer will result in better outcomes for the patient and provider. Furthermore, long-term costs should decrease as the severity and incidence of disease decreases. Evidence currently supports the value of a number of laboratory screening tests to accommodate the increase in the number of individuals who will have health insurance.

Direct access to laboratory testing is another important provision of reform to healthcare. It allows patients to receive test results directly from the laboratory performing the tests, without provider visitation. Direct access increases the availability and use of preventive testing, as well reduce provider cost by exempting office visits (Health and Human Services [HHS], 2014). In order to protect the public, guidelines must be inclusive regarding direct access to ensure testing is appropriate, testing is performed in certified laboratories, results are understandable, and follow-up visits are available if needed (HHS, 2014). The thought behind direct access testing is that it increases patient access, allows the patients to be more involved in their care, and it advocates that healthcare is more of a preventative type of service.

*Fee (Healthcare Cost).* The decrease in individualized healthcare cost and the reimbursement rates that influence financial capability of laboratories are the indicators for fee. The individual mandate requires all individuals to have insurance, which helps

promote the economy of scale, therefore decreasing cost per individual and increasing access for the public to obtain healthcare (IRS, 2014). The assumption is that younger healthier people will subsidize the care for the elderly and less healthy individuals (Panning, 2012). The concept is that younger people pay it forward for the older generation. As the younger generation progresses in age, subsequent generations will pay it forward to cover their health care premiums in hopes of sustaining healthcare payments infinite.

Reimbursement rates are vital to how laboratories perform after the implementation of the PPACA. Laboratories will have to increase the throughput of laboratory tests because of the expected lower reimbursement rates. Supporters of the PPACA believed that laboratories might lose money as an entity at the initiation of the change, but the system as a whole will benefit from faster, better treatment of patients as well as increased patient and physician satisfaction (Lehman, 2015). The objectives of clinical laboratories are to address fee-for-service reimbursement models and employ quality-based goals that focus on value rather than volume of comprehensive healthcare (Futrell, 2013). As a result, the reimbursement methods are projected to reduce health care cost for the individual patient and create financial stability for laboratories.

*Utilization-A (New testing).* The PPACA will place numerous demands on the laboratory in the form of an aging population, a growing prevalence of chronic diseases, and increased utilization due to expanded access to healthcare. The availability of new testing is fundamental in the laboratory community in controlling these demands. New testing techniques to screen and diagnose conditions are often available before effective innovative treatment is accessible (Bandyopadhyay et al., 2008). For the past few

decades, the clinical laboratory has been characterized by ongoing rapid and dramatic innovations coupled with remarkable growth in range and complexity of available tests and services. Advances in equipment and continued miniaturization of testing equipment are unique ways of expanding the test menu of laboratories (Bennett et al., 2013). Miniaturization of assay technology offers more high-volume testing. This type of technology is more efficient with less administrative and variable expenses to the laboratory. This new platform of testing is expected to accommodate the increased testing workload that is associated with the increase in access of the population.

## Healthcare Quality in the Laboratory

Healthcare must be safe, well-coordinated, evidence-based, responsive to patient needs, and continuously improving. The Patient Protection Affordable Care Act established the National Strategy for Quality Improvement in Health Care to guide the efforts to increase access to high quality and affordable healthcare (Agency for Healthcare Research and Quality [AHRQ] 2012). The strategy of the National Strategy for Quality is to focus on eliminating the variability of care from patient to patient, reduce the use of unnecessary care, and use data-driven decisions to improve care. The goal of the National Strategy for Quality is to ensure "that each patient receives the right care, at the right time, in the right setting every time (Shahangian & Snyder, 2009, p 420)." To achieve this quality initiative for clinical laboratories, the Institute of Medicine Model of Quality is used in this study.

### *Institute of Medicine Model of Quality*

Although America has the highest cost per capita regarding healthcare, there is evidence that suggests a disparity between standards of care and expected outcomes

(quality). At one point, the stewards of healthcare became content with its quality, until the Institute of Medicine (IOM) issued "To Err is Human: Building a Safer Health System" report in 1999, and "Crossing the Chiasm: A New Health System for the 21st Century" in 2001 (IOM, 2001). Within these reports, frequently health care either harmed or did not provide the expected benefits to patients. To address the issue of quality, the 2001 IOM report suggested filling the gaps between the standard of care and expected outcomes (IOM, 2001). The core concepts developed from the report were centered on six aims for improvement, which are "patient safety that avoids injury, effective services that provide benefit, patient-centered care designed for the individual patient, timely care, efficient care to avoid waste of resources, and equitable healthcare that does not vary from individual to individual (IOM, 2001, p 5)." It is well recognized that many medical services provided each year are unnecessary or of limited clinical value to patients. It is important for laboratorians to understand these unwarranted practices, and then use the knowledge gained to make improvements on the quality and delivery of healthcare (Futrell, 2013). The IOM model of quality was instrumental in identifying indicators to assess accurately the construct of quality as it relates to improving healthcare in the laboratory. See Figure 6 below to examine the IOM model of quality.


*Figure 6.* The Institute of Medicine on Quality, 2001

Figure portrays the dynamic role of laboratory medicine in the health care system. The premise of this diagram has is that value can be expressed in terms of achieving the six aims posed by the IOM. Adapted from 2001, P. 21 Laboratory Medicine: A National Status Report, Courtesy of the National Academics Press, Washington, D.C.

*Operationalization of Quality in the Laboratory*

According to many laboratory clinicians and providers, the quality of the laboratory is determined from the standpoint of three measurable indicators that encompass all six concepts of the quality IOM model. These measurable indicators are technology-Q, patient safety, and personnel are operationalized as follows (Otto, 2012):

*Technology-Q.* Automation addresses the need to incorporate automation instrumentation into the laboratory for performing molecular testing and other complex methodologies. The use of molecular automation testing reduces human errors and helps to avoid over test-utilization during total testing processing and interpretation of complex laboratory testing (Bennett et al., 2013). Furthermore, automation provides better

management of reflex testing and allows a seamless transmission of results that promotes better patient care. According to Joseph and Kip (2016), automation offered by molecular testing is valued to existing health data, through individualized medicine. The aim of multiplexed molecular testing is the detection of multiple causative agents or abnormalities from a single clinical specimen; therefore reducing unwarranted duplication efforts in collecting the specimen. Conversely, single-gene automation testing attempts to find the specific genetic abnormality, guiding personalized therapeutics for better-individualized care (Futrell, 2013). Balancing these divergent goals is crucial in developing an efficient laboratory diagnostic workflow. While total laboratory automation of testing processes may not be possible for all medical laboratories due to high startup cost, many have automated some portion of their operations to improve quality (Futrell, 2013). The trend for automation testing continues to grow in the laboratory as a method of improving quality across the continuum of healthcare in a variety of ways. From offering flexibility and specificity in allowing laboratories to broaden or narrow the range of assays, to the level of sophistication that can assist in the pre-analytical, analytical, and post-analytical phase of testing in the laboratory automation seems to be the future.

*Patient Safety.* Effective studies focus on patient-centered care; ensuring laboratory tests ordered by physicians are beneficial and necessary for the patient. A meta-analysis of 108 studies conducting by Cadogan, Browne, Bradley, and Cahill (2015), involving 1.6 million results of the most commonly ordered laboratory tests in medicine found that on average, 30 % of all tests are likely to be unnecessary. The implementation of PPACA encourages patient-centered quality, meaning that tests

requested by the physician are trustworthy, timely, and beneficial for the patient (efficacy). The idea for patient safety in the clinical laboratory is to ensure that the selection of "the right test, for the right patient, at the right time (Morrison, Otto & Golemboski, 2013, p 201)**".** Delivery of test results in a timely fashion with accurate interpretation and valid patient-oriented outcomes is the primary goal of patient safety.

*Personnel.* The PPACA emphasizes the need for workforce development strategies, to ensure an adequate supply of qualified professionals who are able to meet the changing demands of the healthcare system. Over the last few decades, there has been a decline in medical laboratory personnel across all ranges of educational levels (Castillo, 2000). This decline is attributed to the supply side, which is retention, retirement, and recruitment; and the demand side, which are regulatory reforms, population demographics, and advancements in medicine (Bennett et al., 2014). According to the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), in the past 15 years closure of clinical laboratory schools has reduced the number of laboratorians that are trained annually (Cearlock, 2012). Numbers show individuals graduating from laboratory programs have declined roughly 14% since 1994 to the present, and the number of laboratory training programs has decreased almost 25% (Cearlock, 2012). Program closures have been the result of a multitude of factors, including declining enrollment and cost. For many hospital-based programs, the implementation of the Medicare Prospective Payment Systems changed the hospital payment structure to a degree that medical laboratories, once a source of revenue became cost centers (Bennett et al., 2014). The transition to cost centers led to a decline in training programs, which has a profound effect on the number of clinical laboratory scientists graduating annually.

In addition, the number of experienced laboratory professionals that has reached retirement age has ignited greater concerns for the profession (Bennett et al., 2014).

To compensate for a declining workforce, the profession offers new opportunities such as; advances in laboratory information management that experienced laboratory professionals with an affinity for informatics are likely to pursue. Other efforts to address personnel issues result in many laboratories offering educational opportunities, in the form of advanced degrees to promote better physician-laboratorian relationships, and professional development opportunities such as publication of journals, and the attendance of conferences to improve competence (Passiment, 2006). In the future, the aim of the medical laboratory community is to recruit young people into the profession, retain seasoned professionals into retirement age, and engage young professionals in the workplace to enhance the profession.

## Healthcare Cost in the Laboratory

The cost of healthcare should be affordable to all individuals. Individuals must be able to manage the expenses of care and the cost of healthcare provided. While the United States has the best-trained medical personnel and the highest level of technology, the reality is that when compared to all industrialized countries, our cost is the highest and our quality and outcomes are near the lowest (Truman, 2013). Some scholars believe escalating costs are contributions of economic pressures that health care in the United States has placed upon employers' bottom line in trying to compete in the global market. The belief is that healthcare for employees significantly adds to the cost of goods and services and are disproportion with the rest of the world (Panning, 2014b).

To curb cost several options have been proposed on reimbursement methods in order to make the healthcare system less taxing on the economy. For example, Accountable Care Organizations (ACOs) link reimbursement rates to the quality of service rendered by the provider. The objective of ACOs is to ensure providers are using informed evidence-based medicine that prevents unnecessary services to the patient; thus decreasing cost but simultaneously increasing access and quality to the population. ACOs may use different payment models, such as capitation method, fee-for-service method, or the prospective method, in an effort to improve health and reduce cost (Panning, 2012).

Other models include the Patient-Centered Medical Home (PCMH) model and the Health Maintenance Organization (HMO) structure. The patient-centered medical home (PCMH) initiative is similar to ACOs in that it emphasizes the physician responsibilities across the continuum of healthcare. However, ACOs differ from PCMH by providing incentives based on the performance and the responsibility of physicians regarding coordination of care (Panning, 2012).

The Health Maintenance Organization (HMO) structure is another reimbursement method that has been around for decades. HMO differs from ACOs in that its payment method is mainly associated with capitation while the ACO uses a variety of methods such as bundled payment, the fee-for-services payment, and prospective payment coupled with incentives to oversee quality and cost of healthcare (Panning, 2012).

All of these models are similar with slight differences in the form of payment procedures (capitation versus bundled-payments), explicit incentives offers, and the responsibility for care coordination. The aims of these models are to reduce costs, while improving quality and efficiency, through an innovative approach to delivering

comprehensive patient-centered preventive and primary care. For this study, information was combined with all three models to capture the best practices in decreasing cost while maintaining or increasing quality and access in transforming the healthcare system.

*Operationalization of Cost in the Laboratory*

The indicators selected to assess cost in the laboratory are technology-C, utilization-C and reimbursement (Otto, 2012). These variables were chosen from the perspective of laboratory managers, national reports, and the aforementioned three models (HMO, ACO, and PCMH) as the most appropriate indicators to assess cost as it pertains to the clinical laboratory.

*Technology-C (Genetic Testing).* Many new molecular diagnostic techniques and laboratory tests have been introduced through research and the pathology of diseases. Rapid advances in the areas at the molecular-level and genetic testing are dramatically changing the clinical landscape. Genetic testing is extremely efficient, using micro-samples to produce life-altering influence; therefore, it is important that these tests be subjected to appropriate regulatory compliance (Wolcott et al., 2008). These genetic tests can be used to diagnose disease and or predict maladies in the future; they are also used to pinpoint anomalies and identify genetic traits in the fetus. Currently, over 1400 diseases can be identified using genetic testing, and the genetic repository has over 7,000 orderable tests available (CDC, 2014). Genetic testing is becoming an increasingly important component of healthcare delivery and the number and availability of these new tests continue to grow. The support of information technology has revolutionized the way molecular and genetic test results are ordered and received. The American Recovery and Reinvestment Act of 2009 (ARRA) has made the interoperability of health information

systems a priority; in an effort to streamline data, reduce error, and increase workflow to encourage better outcomes for patients and providers regarding genetic testing (Bennett et al., 2014).

*Utilization-C.* Utilization is assessed by the variables aging population and test menu expansion. According to U.S. Census Bureau projections, the 65 and older age group will more than double, from 43.1 million to 92.0 million between the years of 2012-2060 (Bennett et al, 2014). This older population is projected to represent one-fifth of the U.S. population making it a priority for healthcare (Bennett et al, 2014). The demographic age shift of the population will be profound for the U.S. healthcare system as the elderly are more likely to use healthcare services at a more frequent rate than younger people are. As a result, chronic diseases will likely increase as elderly people are living longer and are more apt to exhibiting diseases that are chronic in nature.

In addition, estimates from the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) indicate that the PPACA will reduce the number of nonelderly people without health insurance coverage by 49 million, bringing a surge in the demand for primary care (Congressional Budget Office [CBO], 2013). Major changes are also anticipated in the delivery of healthcare services as the demographic shifts. The growing menu of available clinical tests will have a huge impact on providing quality and efficient services to these patients.

*Reimbursement.* Indicator variables used to assess the subcategory of reimbursement in this study are copayment and bundled payment. The majority of Medicare services provided to patients has some form of copayment that involves a percentage of the services rendered are paid for by the patient and the remaining cost paid

by the insurer. This sharing of cost reduces Medicare's overall burden of financial responsibility. In contrast to laboratory services, there is no co-payment fee, a decision that became effective in 1984 when the fee schedule was implemented (Panning, 2014a). Recently, there have been talks of considering a copayment for laboratory services. However, since laboratory tests are relatively low in price, oppositions to this idea includes that it would reduce reimbursement rates. In addition, there is concern that it would add more administrative cost to the laboratory to collect a single payment directly from patients (Panning, 2014b).

Bundled payments bring new initiatives that parallel the actions of what the PPACA is trying to do with healthcare. The bundled payment method has a triple aim: improve healthcare, improve quality and reduce cost per capita. The principal of the bundled payment is to move healthcare away from quantity services to more of a quality-based outcome model (Graham, 2015). It is believed that this principle can be achieved by aligning the services and goals of the patients, providers, and all parties involved to improve quality based on data-driven decisions. The ultimate goal of the bundled payment model is to reduce variability and cost in healthcare.

# CHAPTER III - METHOD

The project is a quantitative study that collected data from willing participants (clinical laboratories managers) throughout the United States, and then their responses analyzed using structural equation modeling (*SEM*). The collection of data consisted of using a survey to assess the constructs of access, cost, and quality of clinical laboratories post implementation of PPACA.

The target population is 250,000 CLIA Laboratory Managers throughout all 50 states. The population sample is approximately 160 hospital-based laboratories, physician-based laboratories, and reference laboratories. The sample size, the sample power, and the sample precision are based on using *SEM* to analyze data. With *SEM*, the larger the data set the more reliable the data analyses and validation of the model. According to Myers, Gamst, and Guarino (2013), a minimum of 10-20 items per indicator variable (endogenous) are needed (Chapter 16, p 878) for a *SEM* data set. For this study, nine (9) indicator variables are used, with a minimum of 15 items per indicator variable. Multiplying the nine indicators (endogenous) variables with 15 items per variable will produce a minimum of 135 participants needed for the study.

Solicitation of the participants was by e-mails to obtain permission for the study. Participants at different hospitals and clinics affiliated throughout the states were recruited via an electronic information memorandum. The memorandum described the study and its ultimate purpose. In addition, the introduction of the survey disclosed that all participants need to be 18 years or older to participate. Confirmation of individuals who were 18 years or older were verified by the participants' continuation to conduct the survey without the input of others.

The survey was sent to all clinical laboratory managers and directors via email, providing a unique survey link that tracked each participant's survey responses. Participants were able to complete a portion of the survey and return later to finish the rest at a future date. If a participant preferred a hard copy, the survey was sent to his/her preferred mailing address with an enclosed stamp envelope for convenience to return the survey. If the participant preferred the survey to be conducted by telephone, then a time was arranged at his or her convenience to conduct the survey.

Table 1 shows the relationship between research questions and survey questions regarding the constructs Access, Quality, and Cost. Survey questions 1-10 addressed the first research question concerning Access. Survey questions 11-20 addressed the second research question regarding Quality of health care since the implementation of ACA. Survey questions 21-30 addressed the third research question regarding Cost associated with changes made in the clinical laboratory to meet the challenges of PPACA.

Table 1

*Relationship Between Research Questions and Survey Questions*

| Research Questions | Survey Questions |
|---|---|
| RQ1: Are the variables technology Reform, Utilization-A, and Fee appropriately measuring the latent variable "Access" as a disrupter to the iron triangle? | 1. Your laboratory is likely to increase screening tests such as HIV, Hepatitis B, and Lipid Profiles etc.<br>2. Your laboratory is likely to incorporate direct access testing (i.e. patients are able to request test results directly from the laboratory).<br>3. Your laboratory is likely to experience an increase in first-time insurance users.<br>4. Your laboratory is likely to experience an increase in state funding due to Medicaid. |

Table 1 (continued).

| | |
|---|---|
| | 5. Your laboratory is likely to experience a decrease per individual cost for testing.<br>6. The impact of reducing reimbursement rates are not likely to affect the financial viability of your laboratory (i.e. lower rates for the clinical laboratory fee schedule, sequestration cuts, adjustments to the consumer price index etc.).<br>7. Your laboratory is likely to experience an increase in the prospective payment system (i.e. set amount per patient, regardless of the amount of care received).<br>8. Your laboratory is likely to incorporate a wide range of different laboratory tests to accommodate the projected increase in the elderly population (i.e. 65 and older)<br>9. Your laboratory is likely to experience an increase in miniaturization of assay methods to expand the test menu (i.e. lab-on-a-chip and point of care testing).<br>10. Your laboratory is likely to experience an increase in new testing platforms to improve efficiency (i.e. core lab concept). |
| RQ2: Are the variables Technology-Q, Patient Safety, and Personnel appropriately measuring the latent variable "Quality" as a disrupter to the iron triangle? | 11. Please, select three (3) neutral for this question.<br>12. Your laboratory is likely to increase automation testing to reduce over test-utilization (i.e. reduce repeat testing due to human error).<br>13. Your laboratory is likely to increase molecular and genetic testing to personalize medical care for the individual patient (i.e. individualized testing ordering based on history, algorithms and clinical information).<br>14. Automation testing is likely to promote shared information of test results in your laboratory (i.e. seamless transmission of tests results between institutions).<br>15. Your laboratory has experienced an improvement in patient outcomes (i.e. improved disease detection, prevention and or delayed onset of diseases). |

Table 1 (continued).

| | |
|---|---|
| | 16. Your laboratory has incorporated evidence-based medicine to support better patient outcomes (i.e. eliminate unnecessary testing).<br>17. Your laboratory is likely to experience an increased value-based care that focuses on test ordering that is beneficial and necessary for the patient (i.e. Evidence-based laboratory medicine; right test, for the right patient, at the right time).<br>18. Your laboratory has experienced an increase in information technology to support personnel (i.e. assist with high throughput and complex test result interpretations).<br>19. Your laboratory invests in educating personnel to improve competence (i.e. continuing education program, professional society membership and publications).<br>20. Your laboratory supports personnel earning advanced degrees to improve laboratory and provider relationship (i.e. consultation support of test results). |
| RQ3: Are the variables Technology-C, Utilization-C, and Reimbursement appropriately measuring the latent variable "Cost" as a disrupter to the iron triangle? | 21. Please, select one (1) Strongly Agree for this question.<br>22. Your laboratory is likely to maximize miniaturization of assay technology to support high volume throughput tests as a cost-effective strategy.<br>23. Electronic medical records in your laboratory are likely to decrease administrative cost (i.e. streamline data; reduce redundancy, allow seamless access to patients results in different geographical areas).<br>24. Your laboratory is likely to use or incorporate the use of bar coding technology to minimize misidentification test results.<br>25. Your laboratory is likely to implement a wide range of molecular diagnostic tests to support the increase of the elder population with insurance. (i.e. Tests that provides less expense and greater availability. |

Table 1 (continued).

| | |
|---|---|
| | 26. Your laboratory is likely to experience an increase in novel health care delivery systems to reduce costs for patients (i.e. Accountable care organization, State Innovation Models, etc.).<br>27. Your laboratory is likely to experience an increase in competitive bidding for laboratory tests (i.e. quote the best price with the best quality to gain customers).<br>28. Your laboratory is not likely to experience patient co-payment fees for laboratory tests (patient provides a co-payment to the laboratory upon visit).<br>29. Your laboratory is likely to experience an increase in the bundled payment method to reduce cost (aligning the services and goals of the patients, providers, and all parties involved to improve quality and reduce cost).<br>30. Your laboratory is likely to experience a decrease in Fee-for-service billing to curb cost. |

Note: This table explains the correlation of the research questions to the survey questions regarding the constructs of access, cost and quality operationalized in the study.

The survey was generated using the Qualtrics survey platform with the support of USM staff. The target population was 250,000 CLIA affiliated clinical laboratories throughout United States. From the targeted population, only 2,124 electronic surveys were sent out to obtain a sample. Of the 2,124 surveys sent out, only160 surveys were considered useful for the study. The goal was to obtain a diversity of laboratory managers and directors' perspectives across all geographical areas regarding the impact of PPACA. Once the survey responses were received, the first step was data screening to account for missing data to prevent systematic bias. Data screening was followed by assumptions and diagnostics of the data to correct for normality, outliers, linearity and homoscedasticity. Finally, if the data had outliers, the outliers were accounted for by using methods such as

transformation, z-scores, and truncation to correct these abnormalities. IBM SPSS 23 and IBM SPSS AMOS 23 statistical software analyzed the data, using the statistical method *SEM* with the goal of creating the most parsimonious model.

*Operationalization of the Model*

Figure 7 provides a diagram of the predicted model derived from the theory of the iron triangle on clinical laboratories.

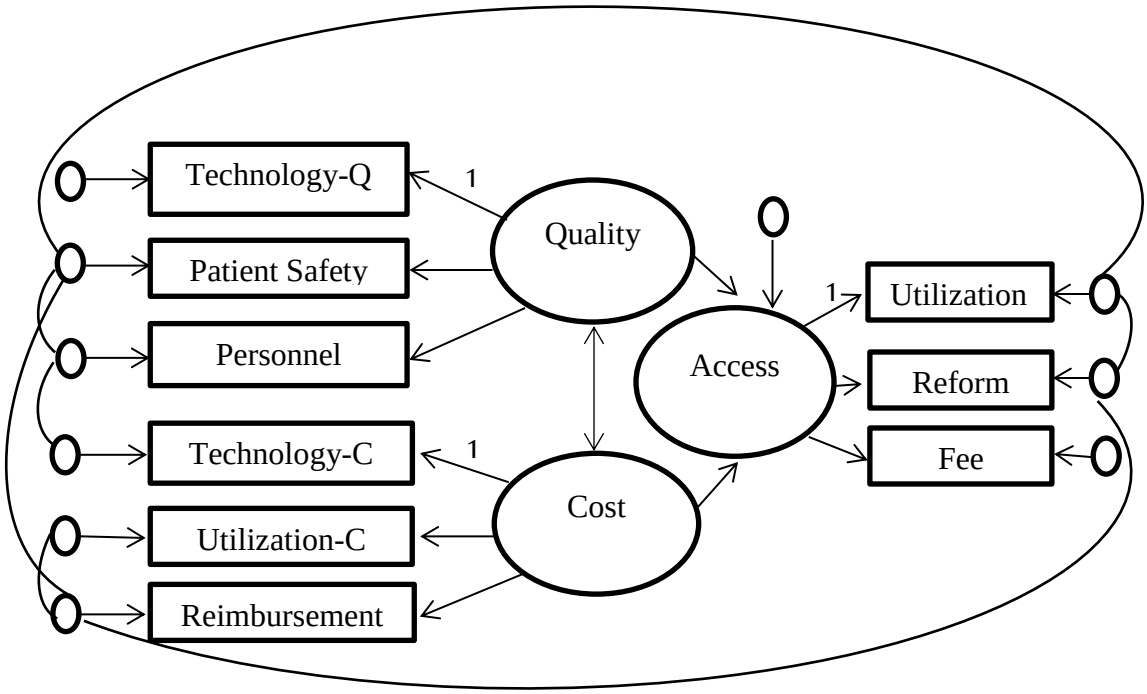


*Figure 7.* Predicted Model

The figure provides an illustration of the predicted model as a disrupter to the iron triangle of health care in the laboratory. The oval shapes represent the latent variables and the rectangle shapes represent the indicator variables in the model. The circle shapes represent the error variance in each latent and observed variable. Each latent variable is described by three indicator variables were arrows denotes these relationships.in the model. The double errors between error variances show there are shared error variances amongst the indicator variables.

The operationalization of these constructs used Likert scales to measure the constructs and assess the efficacy of clinical laboratories post implementation of the PPACA. The range of the Likert scales is as follows: using a 5-point scale (l=Strongly

agree, 2=Agree, 3=Neutral, 4=Agree, 5=Strongly disagree,) with a non-applicable option (6= Non-applicable). The constructs and operationalization of measurement for the laboratories are derived from the ideas of many laboratorians and organizations within the laboratory field. The drivers of these indicators express the concepts that are occurring now in laboratories and what is projected to happen in the near future. The ultimate goal of PPACA is to increase Access, increase Quality, and reduce Cost simultaneously for all American citizens. This achievement can be summed up as follows:

*Access.* Access describes the availability of having insurance coverage for healthcare when it is needed for the individual patient. To achieve an increase in Access, healthcare insurance must be provided to individuals with preexisting health conditions, individuals and families that fall below a certain cap of the federal poverty line are granted subsidies, and previous noninsured individuals must have access to clinical laboratory testing. For this report, the indicators of Reform, Fee, and Utilization assessed Access. The written equation of Access Operationalized: [Reform (Increase to screening tests, Increase access to diagnostic tests)] + [Fee (Decrease cost for individuals seeking healthcare, the impact of reimbursement rates from the Center for Medicare/Medicaid System on clinical laboratories financial viability)] + [Utilization (Availability of new testing to support the increase of individuals with insurance)].

*Quality.* Quality refers to both statistically measured and real treatment outcomes. It includes the understanding to develop real standards of acceptable practice that makes a difference to patients. To achieve an increase in quality the use of smart technology must improve the overall care of the patient, providers must deliver individualize health

care to the patient, and laboratories must use evidence-based medicine to benefit patients. For this report, the indicators Technology, Patient Safety, and Personnel assessed Quality. The written equation of Quality Operationalized: [Technology (Automation of Molecular Testing to avoid human errors for test interpretations and improve efficiency of testing for the individual patient)] + [Patient Safety (Effectiveness Studies, Patient-centered care that benefits the patient)] + [Personnel (Invest in human capital to improve provider-patient relationship of laboratory tests)].

*Cost.* Cost is associated with the affordability of healthcare for patients and payers at a given rate. To achieve a decrease in cost for this report, the indicators Technology, Utilization, and Reimbursement assessed Cost. The written equation of Cost Operationalized: [Technology (Genetic and predictive testing + Information technology)] + [Utilization (Aging population + Expansion of test menu)] + [Reimbursement (Co-pay + for laboratory testing, Bundled Payment)].

*Model Building*

*First Step.* The first step is model specification that involves hypothesizing the model based on being a disrupter to the theory of the iron triangle in clinical laboratories (see Figure 7). This step recognizes the relationships between the observed variables as compared to relationships of the variables within the predicted model. For this study, clinical laboratory managers and directors rated 30 items on a five (5)-point Likert scale; from strongly agree to strongly disagree regarding their beliefs and experiences of the PPACA on clinical laboratories post implementation. In addition, a Likert scale with the option (non-applicable) was offered for questions that are not relevant to the participants and was coded as missing.

*Second Step*. The second step is Model identification, fitting a structural equation model to the data. In this step, the difference between the number of variables and the number of parameters in the model must be estimated. This estimation is achieved by generating the following parameters in the model: (a) pattern and structure coefficients of the independent and dependent variables (b) the coefficient correlation relationships between the independent variables in the model (c) and the variance of the independent variables variance must be determined (Myers, Gamst, & Guarino, 2013a,). To calculate these parameters the number of nonredundant and unknown elements must be premeditated (Bentler & Chou, 1987). According to Raykov & Marcoulides (2000), these nonredundant elements can be calculated by using the formula V (V+1)/2, where the (a) covariance or correlation matrix are counted for the dependent variables (b) and variances and coefficients for the paths of the independent variables are counted (p.757). For the unknown elements in the model (a) the variance of the latent (construct) variables (b) the variance of the unique error variances (c) pattern/structure coefficients of the latent (construct) variables (d) and the pattern/structure coefficients relating to the unique error variables (Myers et al., 2013a, pp. 850-871). With this situation, it is important to have more knowns than unknown parameters, because the unknowns are subtracted from the knowns creating a positive unique solution. This positive solution (positive degrees of freedom) creates an over-identified model, which permits the calculation of fit statistics for the evaluation of the model. Negative solutions (under identified) or even solutions (just defined) will not permit meaningful analysis to be performed; therefore, the analysis of the model cannot progress until an over-justified model is created (Bentler & Chou, 1987).

*Evaluation*. Once a structural equation model is specified and the free parameters estimated; then the fit of the proposed model to the actual data is evaluated. There are multitudes of fit indices available to evaluate the model. Traditionally, Chi-square (an absolute fit index) is used to assess the difference between the predicted and observed interrelationship in the model. Since most researchers are predicting a close fit between the predicted and observed model, the desired outcome is to have a non-significant Chi-square. Chi-square works well with relative small cases approximately 75-200; however, as cases increase so does the power of Chi-square, which is likely to produce a type II error (Myers et al., 2013a, pp. 850-871). For this reason, other fit indices categorized as absolute, relative, and parsimony are used in addition with Chi-square to assess the model.

Just as Chi-square, the root mean square error of approximation (RMSEA) is an absolute fit index. The RMSEA differs from the Chi-square in that it interprets the average residuals of the covariance/correlations matrix between the predicted and observed model (Myers et al., 2013a, pp 850-871). Therefore, it assesses the approximation of error in the sample and precision. Values equal to or less than .08 are considered acceptable values for RMSEA. Values greater than .10 are considered unacceptable values in some instances and must be followed up with theory and principle-driven decisions to accept or reject (Myers et al., 2013a, pp 850-871). In addition to the range of values for RMSEA, the 90% confidence interval is reported to present an accurate picture of the absolute fit index.

Relative fit indices are used as well in this study. Relative indices measure the observed versus the predicted fit based on an incremental continuum of the worst fit (no

relationship) to a perfect fit (statured relationship) rather than a one-time measurement as the absolute indices. The relative indices that were used in this study are the comparative fit index and the Tucker-Lewis Index. Values greater than .95 are considered acceptable as a good fit for the model regarding both relative indices. Values less than .90 are considered inadequate for the model (Myers et al., 2013a, pp 850-871).

There are numerous other fit indices available to the researcher through software packages that assist in assessing the predicted model. The use of multiple model fit indices is essential in clarifying and providing a complete picture of complex prediction models such as *SEM*. When these fit indices are used collectively, they provide the researcher with a comprehensive analysis of the model.

If the model does not have adequate fit, then the use of model re-specification and fit indices reevaluation are considered to improve the model. Depending on the theory used and researcher's end state there may be several occurrences of model re-specification. According to Joreskog (1993), only model creating would permit re-specification after the initial hypothesized model has been estimated. Once a model is re-specified, it becomes more of an exploratory procedure, such as exploratory factor analysis rather than a confirmatory procedure. In these exploratory procedures, new data must be captured to produce valid results.

## Data Analysis

IBM SPSS Statistics 23 combined with AMOS 23 was used to draw and analyze the data collected in this study. The first step is data cleaning to ensure data are accurately in SPSS. From there, data cleaning occurred to account for patterns of missing data and to account for outliers. The next step, descriptive statistics was used to tabulate

responses, calculate percentages and means, account for normality, linearity, homoscedasticity, errors, and data transformation if needed. Analysis of Moment Structure (AMOS) was used to draw the predicted model. Confirmatory factor analysis was used to assess the responses of the indicators variables in relation to the latent constructs (Quality, Cost, and Access) as described in the theory of iron triangle. Path analysis was used to assess the relationships between the predicted and observed latent variables, as well the relationships of both latent variables and their respective indicator variables in the model (Myers, Gamst, & Guarino, 2013b, pp. 974-981).

## Ethical Procedures

For this study, all participants were informed that18 years or older, is the required age needed to engage in this study. The study purpose and procedure was reviewed with each participant before consent was confirmed. Data collection consisted of a survey with semi-structured, open-ended questions. Each participant was reassured that his/her responses and name would remain confidential. It was explained to each participant that withdrawal from the study at any point in the process is an option. Prior to collecting any data, permission was obtained from the Institutional Review Board (IRB). Data were analyzed accurately to align with participants' survey responses and under no circumstance did misrepresentations occur. All data were held confidentially in a secure location and will be discarded after five years.

## Summary

Chapter III provides a description of the quantitative research design and rationale for the study's approach. Table 1 shows how the research questions related the survey questions. A detail description was given in how the construct variables were

operationalized and how the predicted model was created. Data collection procedures and data analysis were explained to together with data cleaning and data assumption techniques. Issues of trustworthiness and ethical considerations were also described in detail.

# CHAPTER IV – RESULTS

This quantitative study analyzed the impact of the PPACA on health care in the clinical laboratory. The impact of PPACA was measured on the constructs of Access, Cost, and Quality as it relates to the iron triangle of health care. Understanding the impacts of the new statute will help the laboratory community prepare and perform efficiently in the future. The purpose of this study was to analyze the impact of the PPACA on the clinical laboratory via *SEM*. Perhaps in understanding the impact of PPACA on the clinical laboratory can help (a) increase access to laboratory tests (b) provide a better quality of test results via an improved total testing process and (c) reduce the cost per laboratory test for the average citizen. This chapter summarizes the key findings obtained from the responses of 160 participants. The researcher analyzed these data using the Software from IBM SPSS 23 with the addition of AMOS 23.

## Demographics of Survey Respondents

After carefully analyzing the contact list, the following demographic data results were calculated. For this study, 2,124 surveys were emailed to eligible laboratory managers and directors. Of the 2,124 surveys emailed, 247 (12%) were returned to the researcher. Of the 247 returned, 60 (23%) were incomplete and could not be used in the study, leaving 167 possible surveys. After data cleaning, three surveys were removed due to missing data and four were removed as outliers, leaving 160 surveys available for data analysis. These completed surveys were from all 50 states, including the District of Columbia, meeting the inclusion criteria for full analysis. Of these participants, the majority represented Hospital-based laboratories, see figure 8 for a statistical breakdown of the facilities involved in providing data for this study.

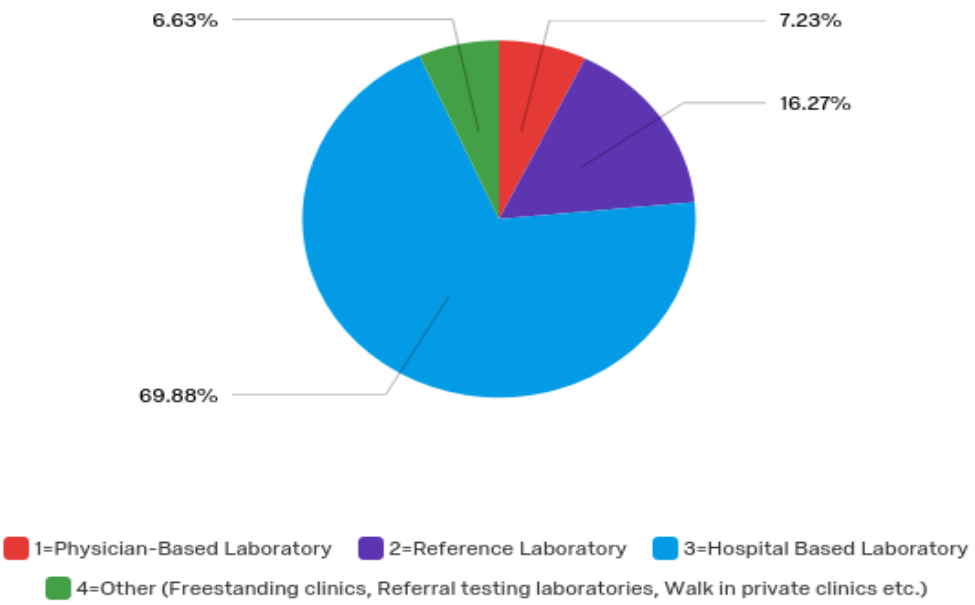


*Figure 8.* Type of Facility

In addition, the 160 completed surveys reported with the following demographic distribution seen in Table 2.

Table 2

*Demographics of Facilities and Participants*

| How would you classify your institution? | | |
|---|---|---|
| Facility Type | Percentage % | Count |
| **Public** | **70.09%** | **112** |
| Private | 23.08% | 37 |
| Unsure | 6.84% | 11 |
| **How many laboratory tests does your laboratory perform annually?** | | |
| Number of tests per year | Percentage% | Count |
| Less than 50,000 tests | 4.31% | 7 |
| 50,000 to 100,000 | 4.78% | 7 |
| 100,000 to 250,000 tests | 12.93% | 21 |
| 250,000 to 500,000 tests | 14.66% | 24 |
| **> 500, 000 tests** | **54.31%** | **87** |

Table 2 (continued).

| Number of tests per year | Percentage% | Count |
|---|---|---|
| Less than 50,000 tests | 4.31% | 7 |
| 50,000 to 100,000 tests | 4.70% | 7 |

Select years of experience as a laboratory Manager and/or Director

| Years of Experience | Percentage % | Count |
|---|---|---|
| Less than one year | 5.17% | 8 |
| One to five years | 13.79% | 22 |
| Five to ten years | 18.10% | 29 |
| **Ten to twenty years** | **37.93%** | **61** |
| > twenty years | 25.00% | 40 |

Has your state expanded Medicaid under the PPACA?

| Medicaid Expanded | Percentage % | Count |
|---|---|---|
| **Yes** | **45.61%** | **73** |
| No | 33.33% | 53 |
| An expansion is planned in my state, but not yet in place | 4.39% | 7 |
| Unsure | 16.67% | 27 |

## Reliability of Survey

Prior to conducting a full analysis of the data, it is important to access the reliability of the items on the survey that correlates with the construct variables (latent variables) and observe variables identified in the theoretical framework. There are three options regarding results obtained from reliability testing. (a) Accept the items on the survey as consistent with the variables then proceed to data analysis (b) modify the items on the survey to achieve acceptability then proceed to data analysis or (c) reject the survey because of the items listed cannot achieve reliability (Myers et al., 2013a).

According to Myers et al. (2013a), the Cronbach's alpha is traditionally the most dependable coefficient in accessing reliability amongst theory testing. Coefficient values that are .90s and above are considered excellent, high to middle values of .80s are very

good, values of low .80s are considered good, values high to the middle .70s are considered acceptable, .70s to middle .60s are considered borderline, and values of low .60s and below are considered problematic to unacceptable (p. 722).

With these numbers in mind, the first level of assessing reliability is to evaluate the construct (latent) variables Access, Quality, and Cost with the 28 items on the survey (see Table 1). The construct variables (Access, Quality, and Cost) presented with Cronbach's alpha coefficients of .656 acceptable for research, .825 good acceptable, and .712 acceptable, respectively. Although, for the construct variable Access, if Item 6 and or Item 7 were deleted from the instrument the Cronbach's alpha would increase to .676; these items were kept to provide a broader explanation of access.

The second level of accessing reliability is to evaluate the nine observed variables identified within the theoretical framework in this study. Those nine observed variables, along with the corresponding items on the survey, and Cronbach's alpha coefficients presented with the following data in Table 3.

Table 3

*Observed Variables Cronbach's Alpha*

| Observed Variable | Survey Questions | Cronbach's Alpha |
|---|---|---|
| Reform | 1-4 | .620 |
| Fee | 5-7 | .656 |
| Utilization-A | 8-10 | .682 |
| Technology-Q | 12-14 | .677 |
| Patient Safety | 15-17 | .632 |
| Personnel | 18-20 | .758 |
| Technology-C | 22-24 | .602 |
| Utilization-C | 25-27 | .659 |
| Reimbursement | 28-30 | .693 |

Although most of the observed variables Cronbach's alpha coefficient fell within the range values from high to low .60s, the researcher deemed these values acceptable to further analyze the data.

## Data Screening and Diagnosis

Laboratory managers and directors responses were evaluated with the 30-item Clinical Laboratory Managers Inventory Survey. Nine observed variables with three to four items per variable were created with the names, Reform, Fee, Utilization-A, Technology-Q, Patient Safety, Personnel, Technology-C, Utilization-C, and Reimbursement. All 30 items were scored on a 5-point summative response scale (1= strongly agree to 5= strongly disagree). Using descriptive statistics in SPSS the data were examined for missing data, skewness and kurtosis. The data presented with missing values of 2% or less, well below the tolerance limit of 5% preventing the intervention of missing value analysis; therefore, likewise deletions were used to remove cases with missing values. For univariate analysis, the data showed positive skewness for the majority of the observed variables with the exception of Reform, Patient, Utilization-C, and Reimbursement, which indicated symmetry. The data also presented with a mixture of kurtosis values (mesokurtic, leptokurtic and platykurtic) for all nine observed variables. Multivariate outliers were analyzed using Mahalanobis distance for each case regarding the nine observed variables. As a result, four cases were identified as outliers because they presented with $p < .001$ for Mahalanobis distance. These cases were removed from the dataset to prevent skewness and kurtosis of the data. The assessment of normality, homoscedasticity, and homogeneity of variance within the data displays normal distribution and equal variance across all variables. After successful screening

and performing diagnostic and assumption procedures on the data, the data are ready to proceed to data analysis.

## Data Analysis

### *Research Question Q1*

Are the variables Reform, Utilization-A, and Fee appropriately measuring the latent variable "access" as a disrupter to the iron triangle? This question is answered by the responses to the survey questions 1-10 listed in table 1. As prior of research question, 1 predicts an increase in access due to PPACA. Therefore, the responses from the participants on the survey regarding this research question should display answers that suggest choices of strongly agree to agree for the majority of the questions.

*Survey Questions 1-4.* Survey questions 1-4 regarding the observed variable Reform in Figure 9, shows high percentages for the combination of responses for strongly agree and agree. Survey question 1 presented with a value of 65%, survey question 3 with a value of 58%, and survey question 4 with a value of 44% respectively. Survey question 2, presented with different values than the expected a prior, with high a percentage for the combination response neutral and disagree at 48%. Although survey question 2 displayed different results than what was expected from the outcome, the full structural model coefficient weight for observed variable Reform presented with a value of .43 ($p < .001$). This value supports that the indicator variable Reform is measuring the latent variable access appropriately in the model.

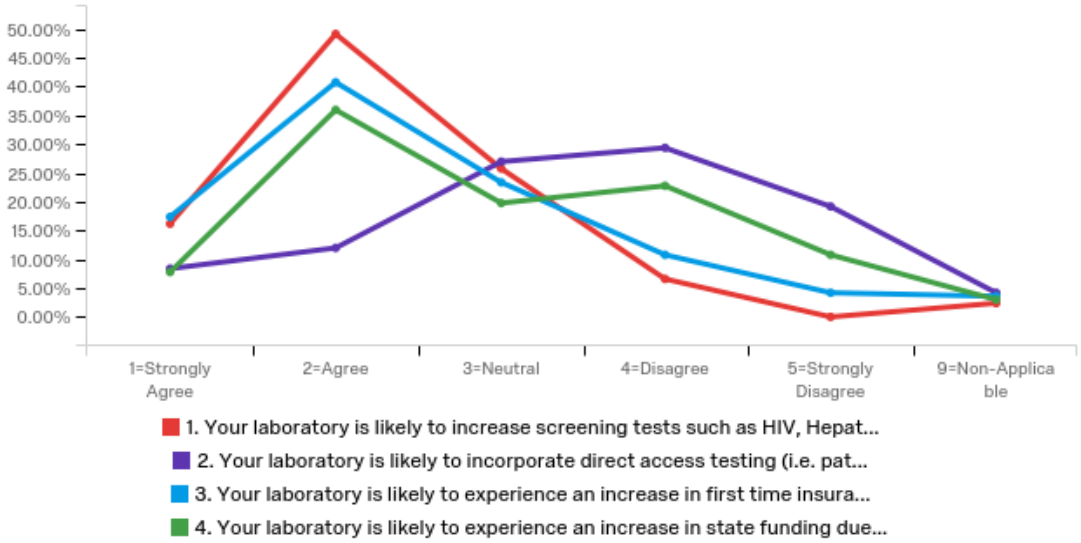


*Figure 9.* Survey Questions 1-4

Note: Illustration of the statistical breakdown in percentages by the question (1-4), regarding the 6-point Likert scale used to capture participant response.

*Survey Questions 5-7.* These questions represent the indicator variable Fee as it relates to the research question 2. Figure 10 shows that high percentages for the combination response strongly agree and agree were achieved for survey question 5 at 61%. Survey question 6 and survey question 7 showed high percentages for the combination response disagree and strongly disagree at 65% and at 57% respectively. The results from these survey questions are consistent with the predicted outcome. In addition, the full structural model coefficient for Fee presented with a significant value of -.16 ($p$ = .031). This value is indicative in that the observed variable Fee is measuring the latent variable access appropriately. The coefficient value also provides evidence that the construct variable Cost is decreased per individual as it relates to Access.

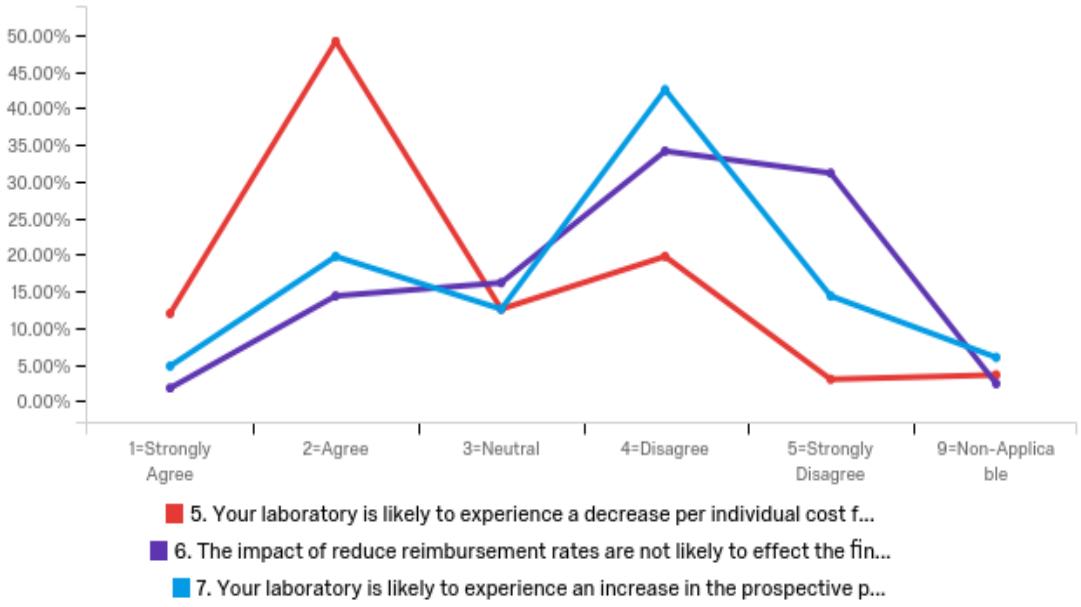


*Figure 10.* Survey Questions 5-7

Note: Illustration of the statistical breakdown in percentages by question (5-7), regarding the 5-point Likert scale used to capture participant response

*Survey Questions 8-10.* These questions address the observed variable Utilization-A as it relates to research question 1. The outcome of these survey questions is expected to produce high percentages for the combined choice strongly agree and agree. Figure 11 displays the percentage of survey questions 8-10 at 51%, 47%, and 69% respectively, illustrating that the survey questions achieved the expected outcome. In addition to percentage outcome of the questions, the full structural model coefficient weight for the observed variable utilization A presented with a significant value of .57 ($p < .001$). This value is an indication that the observed variable Utilization A is measuring the latent variable Access appropriately, as predicted by the model.

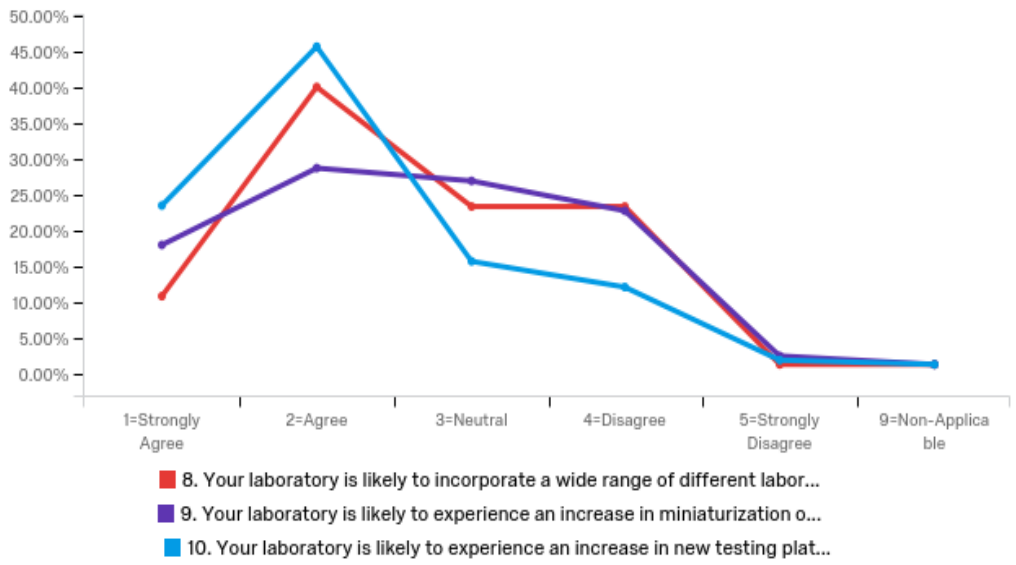


*Figure 11.* Survey Questions 8-10

Note: Illustration of the statistical breakdown in percentages by the question (8-10), regarding the 5-point Likert scale used to capture participants' responses.

*Research Question Q2:*

Are the variables Technology-Q, Patient Safety, and Personnel appropriately measuring the latent variable "quality" as a disrupter to the iron triangle? Survey questions 12-20 as seen in Table 1 are used to assess research question 2. Results from these questions are expected to indicate an increase in quality as it relates to an increase in access regarding the iron triangle of health care in the laboratory. Therefore, the majority of the responses to these questions should reflect answers that correspond with strongly agree to agree.

*Survey Questions 12-14.* These questions regarding the indicator variable technology Q in Figure 12 displays high percentages for the combination response strongly agree and agree. Survey question 12 presents with a value of 78%, survey question 13 with a value of 76%, and survey question 14 with a value of 72%;

respectively. The full structural model coefficient for Technology Q presented with a significant value of .64 ($p < .001$). This value is indicative the indicator variable Technology Q measuring the latent variable quality appropriately.

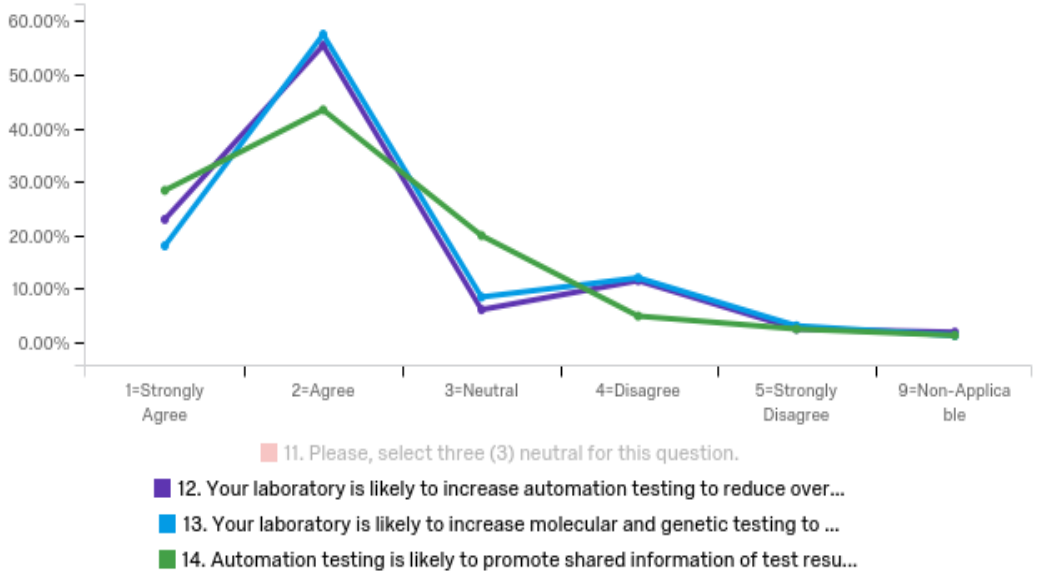


*Figure 12.* Survey Questions 12-14

Note: Illustration of the statistical breakdown in percentages by the question (12-14), regarding the 5-point Likert scale used to capture participant response.

*Survey Questions 15-17.* These questions address the responses for the indicator variable Patient Safety, as it relates to research question 2. Strongly agree and agree are the expected responses from these questions. In Figure 13 the data displays high percentages for combined choices agree and neutrality for question 15 at 74%, slightly different from the expected responses for this question. Question 16 and question 17 presented with a high percentage of the combined choices of strongly agree and agree at 72% and 77% respectively. The full structural model coefficient for Patient Safety presented with a value of .82 ($p < .001$). This value indicates the substantial strength of

survey questions 15-17for the observed variable patient safety, and that the observed value (patient safety) is measuring quality appropriately.

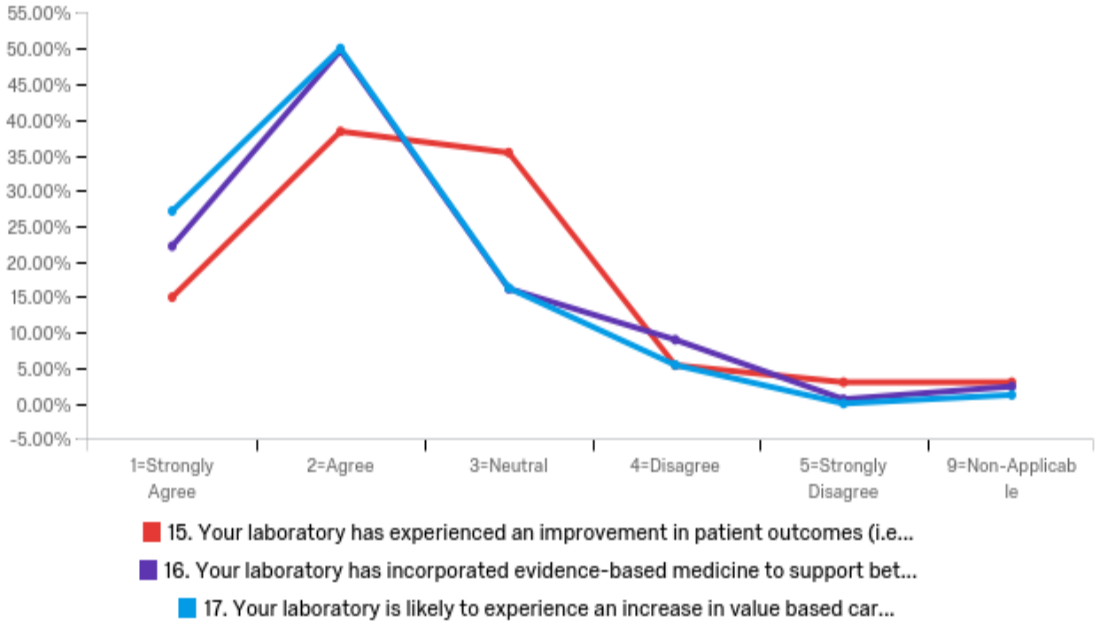


*Figure 13.* Survey Questions 15-17

Note: Illustration of the statistical breakdown in percentages by the question (15-17), using a 6-point Likert scale to capture participant responses.

*Survey Questions 18-20.* These questions address the responses for the indicator variable Personnel as they relate to research question 2. Strongly agree and agree combined choice from the instrument is posited to receive high percentages for survey questions 18-20. Figure 14 displays the results of these questions, with response percentages of 61%, 80%, and 70% respectively. In addition, the full structural model coefficient weight for personnel presented with a value of .66 ($p < .001$). This value indicates the substantial strength of questions 18-20 as good indicators for the observed variable Personnel, and that the observed variable (Personnel) is measuring the latent variable Quality appropriately.

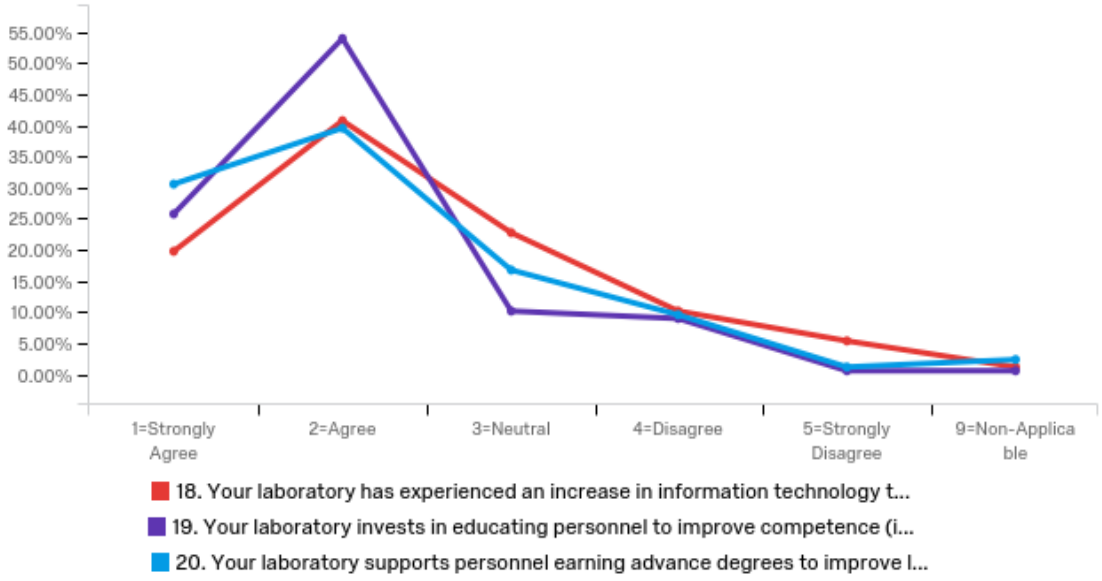


*Figure 14.* Survey Questions 18-20

Note: Illustration of the statistical breakdown in percentages by the question (18-20), using a 6-point Likert scale to capture participant responses.

*Research Question Q3:*

Are the variables technology-C, utilization-C, and reimbursement appropriately measuring the latent variable "cost" as a disrupter to the iron triangle? Questions 22-30 on the instrument are used to address research question 3. The responses of questions 22-30 are expected to have a high combined percentage of choices strongly agree and agree. The overall analysis of the data is expected to produce results that decrease the latent variable cost as it pertains to the effects of PPACA.

*Survey Questions 22-24.* These questions on the survey address the observed variable Technology-C as it pertains to the latent variable cost. The Outcome of the responses for these questions is expected to have high percentages for the combined choices of strongly agree and agree. As seen in Figure 15, these results hold true to expected outcome as questions 22-24 present with the following percentages of 59%,

58%, and 80% respectively. The full structural model also supports the predicted outcome, with a coefficient weight for Technology C presenting with a value of .34 ($p <$ .001). This value indicates the modest strength of questions 22-24for the observed value technology C; therefore holding true that Technology C measures the latent variable Cost appropriately.

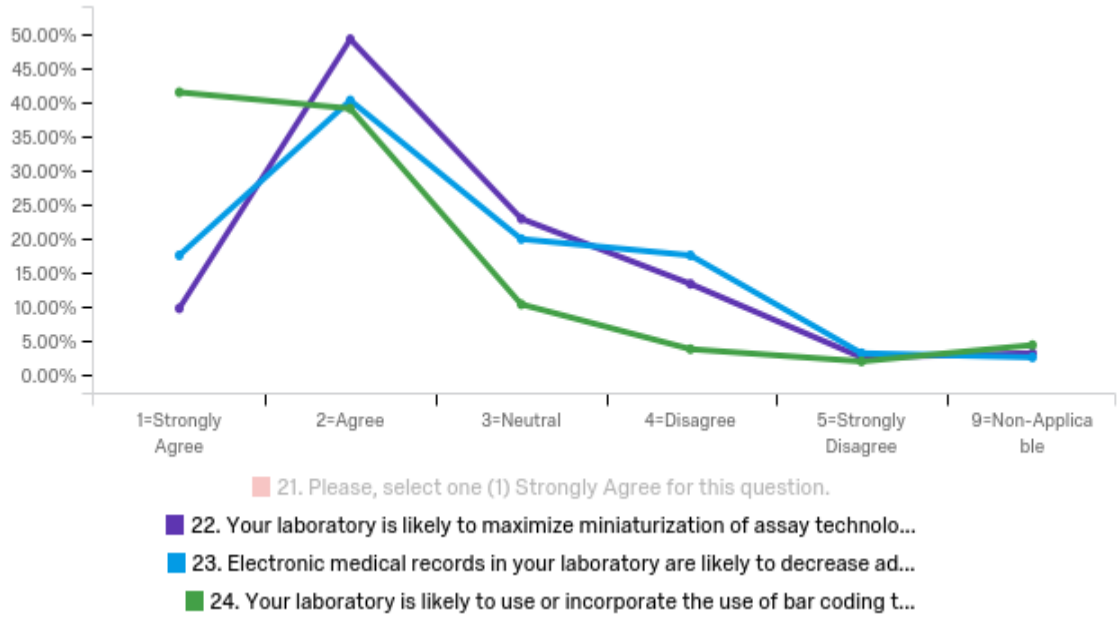


*Figure 15.* Survey Questions 22-24

Note Illustration of the statistical breakdown in percentages by the question (22-24), using a 6-point Likert scale to capture participant responses.

*Survey Questions 25-27.* These questions are used to address the observed variable Utilization-C as it pertains to the latent variable cost. Expected outcome of the responses for these questions is to have high percentages for the combined choices of strongly agree and agree. As seen in Figure 16, these results hold true to expected outcome as questions 25-27 present with the following percentages 58%, 57%, and 50 % respectively. The full structural model coefficient for Utilization C presented with a value of .48 ($p <$ .001). This value indicates the modest strength of questions 25-27for the

observed value Utilization C. The results of these questions are indicative that Utilization C is measuring the latent variable Cost appropriately.

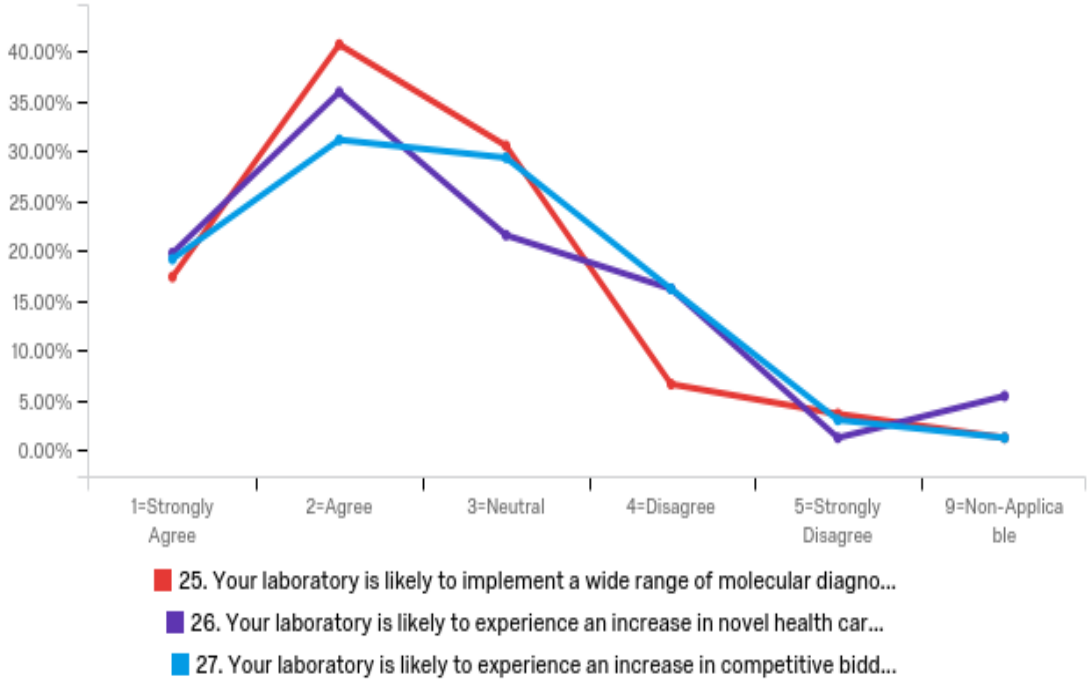


*Figure 16.* Survey Questions 25-27

Note: Illustration of the statistical breakdown in percentages by the question (25-27), using a 6-point Likert scale to capture participant responses.

*Survey Questions 28-30.* These questions address the observed variable Reimbursement as it refers to the latent variable cost. Expected outcome of the survey questions is to have high percentages for the combined choices of strongly agree and agree. As seen in Figure 17, these results hold true to expected outcome as questions 28-30 present with the following percentages 53%, 72%, and 79 % respectively. The full structural model coefficient for Reimbursement presented with a value of .32 ($p < .001$). This value indicates a modest strength of questions 28-30 measuring the observed variable Reimbursement. The results of these questions indicate that the indicator variable Reimbursement is measuring the latent variable Cost appropriately.

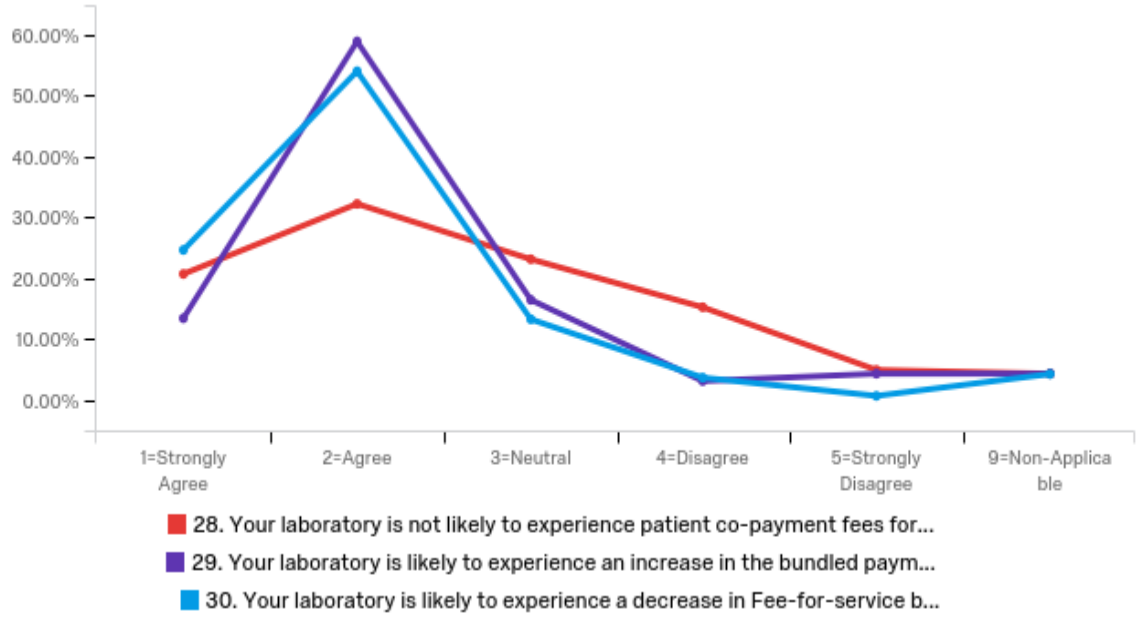


*Figure 17.* Survey Questions 28-30

Note: Illustration of the statistical breakdown in percentages by the question (28-30), using a 6-point Likert scale to capture participant responses.

*Research Question Q4:*

Is the goodness of fit between the predicted model and the observed data similar enough to explain the hypothesized relationships of the PPACA as a disrupter to the iron triangle? After carefully analyzing the data using structural equation modeling in SPSS and SPSS AMOS 23, the data analysis should support coefficients that indicate goodness of fit measures for Chi-square, GFI, TLI, CFI and RMSEA that are acceptable to begin full structure analysis. Prior to conducting the measurement model, the error variances within the model are correlated in accordance with theory and real-world practicality (see Figure 18).

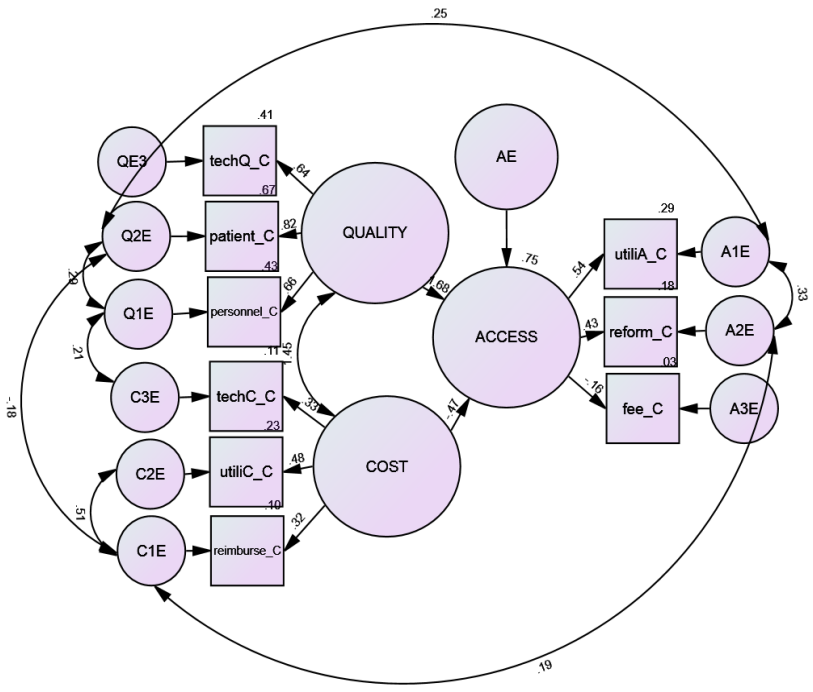


*Figure 18.* Measurement Model with Correlated Error Variances

The theoretical justification for the correlation of the error variances are as follows:

1. The correlation of the error variance A1E (Utilization) with error variance Q2E (patient safety) makes theoretical sense. This makes sense because the utilization of diverse testing platforms, the use of new methodologies and diverse testing is likely to improve patient safety as the new provisions suggest; by means of improving disease detection, eliminate unnecessary testing and ensuring evidence-based medicine.
2. The correlation of the error variance A1E (Utilization) with error variance A2E (Reform) makes theoretical sense. This makes sense because the implications of the reform laws within the PPAC is likely to improve the utilization of smart technology, the utilization of new testing methodologies,

and the utilization of evidence medicine based medicine on managing the influx of new patients within the healthcare system.

3. The correlation of error variance C1E (Reimbursement) with error variance C2E (utilization) is theory applicable. This is practical in the sense that increasing utilization of novel healthcare delivery systems to reduce costs in accordance with PPACA is likely to encourage laboratories to decrease the practice of other legacy delivery systems (i.e. fee for services).
4. The correlation of error variance C3E (technology) with error variance Q1E (personnel) is justifiable. This is practical in the sense that laboratory personnel receiving higher education are likely to provide better consultation support to the physician regarding complex test interpretations.
5. The correlation of error variance Q1E (personnel) with error variance Q2E (patient safety) makes theoretical sense. This is practical in the sense that laboratory personnel will use information technology to support high throughput testing while maintaining high quality due to the provisions in the PPACA.
6. Correlating error variance C1E (reimbursement) with error variance Q2E (patient safety) is practical to theory. The reimbursement methods associated with the PPACA indirectly affects the type of service provided to improve patient outcomes. The new initiatives within the PPACA encourage the use of bundled payment services, where primary care providers share ideas to provide each patient the absolute best care available, without overcharging for the service provided.

7. Correlating the error variance A2E (reform) with error variance C1E (reimbursement) theoretically, make sense. Provisions within PPACA promote bundled reimbursement methods, where coordinated efforts for healthcare services are provided throughout the full spectrum of care. The payment for the services is then divided amongst providers; therefore all parties involved (patient, provider, and insurer) are aligning healthcare outcomes with quality benchmarks.

The data from the measurement model displayed a chi-square of 33.5 (17) $p$ = .001. The GFI had a value of .958. The RMSEA presented with a value of .078 with a 90% CI [.037 to .117]. The TLI presented a value of .929 and the CFI presented with value of .966. See Table 4 for a full display of the goodness of fit model indices.

Table 4

*Measurement Model Fit Indices*

| Fit Index | Value | Score | Fit |
|---|---|---|---|
| Chi-square | 33.5/(df=17) | 1.97 | Good Fit |
| GFI | .958 | NA | Acceptable |
| CFI | .966 | NA | Good Fit |
| TLI | .929 | NA | Good Fit |
| RMSEA | .078 CI 90%(.037 to .117) | NA | Good Fit |

Note: The abbreviation NA = Non-Applicable meaning the fit index does not have a score that corresponds to the category. The abbreviation df= degrees of freedom within the model. The abbreviation CI= Coefficient interval.

The correlation of latent variables range from .703 to .784, this is indication that the measured variables are good indicators of their respective factors. This also suggests that the latent variable correlations did not exceed .80 indicating that collinearity is not an issue.

In addition, the correlated error terms displayed significant correlations weights ranging from -.181 to 1.454.provding veracity that these correlations are meaningful in justifying the theory. See table 5 for all correlated error terms and correlations weights.

Table 5

*Correlations of Error Variances*

| Factors and Error Variances | | | Correlation Value | *p* value |
|---|---|---|---|---|
| QUALITY | <--> | COST | 1.454 | <.001 |
| C1E | <--> | C2E | .513 | <.001 |
| Q1E | <--> | C3E | .207 | .012 |
| Q1E | <--> | Q2E | .293 | .049 |
| Q2E | <--> | C1E | -.181 | .017 |
| A1E | <--> | A2E | .328 | .116 |
| Q2E | <--> | A1E | .253 | .008 |
| C1E | <--> | A2E | .190 | .005 |

These fit indices and correlated error variances demonstrated a good fit for the measurement model; therefore, the predicted model can be further evaluated as a full structural model.

*Full Structural Model Analysis*

The full structural analysis presented with a chi-square value of 33.5 (17) $p$ = .010. The GFI, CFI, and TLI were 958, .966, and .929, respectively. The RMSEA presented with a value of .078 with a 90%CI (.037 to .117). These fit indices are equivalent to the fit statistics seen in the measurement model. Based on these indices, the model indicates a good fit to the data. In addition, the coefficient estimates, unstandardized and standardized regression weights were obtained from the analysis. These *Beta* coefficients ranged from -.16 to 1.70 indicating respectable indicators of their respective latent factors. See Table 6 for a complete detail of the fit indices and *Beta* coefficients of the full structural model.

Table 6

*Full Model Fit Indices*

| Fit Index | Value | Score | Fit |
|---|---|---|---|
| Chi-square | 33.5/(df=17) | 1.97 | Good Fit |
| GFI | .958 | NA | Acceptable |
| CFI | .966 | NA | Good Fit |
| TLI | .929 | NA | Good Fit |
| RMSEA | .078 (CI 90% .037-.117) | NA | Good Fit |

Standardize Regression Weights

| Construct and Indicator | Beta Value | *p* Value |
|---|---|---|
| ACCESS ← COST | -.469 | .121 |
| ACCESS ← QUALITY | 1.681 | <.001 |
| Personnel ← QUALITY | .658 | <.001 |
| Patient Safety ← QUALITY | .818 | <.001 |
| Technology-Q ← QUALITY | .641 | <.001 |
| Utilization-A ← ACCESS | .536 | <.001 |
| Reform ← ACCESS | .427 | <.001 |
| Fee ← ACCESS | -.159 | .031 |
| Reimbursement ← COST | .320 | <.001 |
| Utilization-C ← COST | .477 | <.001 |
| Technology-C ← COST | .335 | <.001 |

## Summary

Chapter IV presents the findings of PPACA on clinical laboratories as it relates to the theory of the iron triangle. The findings present as follows (a) the observed variables, technology-Q, patient safety, and personnel appropriately measured the latent variable quality as a disrupter to the iron triangle. (b) The observed variables technology-C, utilization-C, and reimbursement appropriately measuring the latent variable "cost" as a disrupter to the iron triangle. (c) The observed variables technology reform, utilization-A, and fee appropriately measured the latent variable "access" as a disrupter to the iron triangle. (d) Confirm that the indicators, reform, utilization-A, and fee measured the construct "Access" together with the latent variables, Cost, and Quality as

operationalized in this study. (e) Confirmed that the goodness of fit between the predicted model and the observed data similar enough to explain the hypothesized relationships of the PPACA as a disrupter to the iron triangle.

# CHAPTER V – DISCUSSION

This is the first quantitative study devoted to developing a comprehensive survey to evaluate the effects of PPACA on clinical laboratories. The study collected data from 160 CLIA certified hospital-laboratories, physician-based laboratories, and reference laboratories throughout all 50 states. The design of the survey used the theory of the iron triangle to assess the relationships of Access, Cost, and Quality. The results of the study will potentially help laboratory managers assess the implications of PPACA on laboratories today, and provide the laboratory community with a plausible instrument to assess the influence of PPACA for subsequent research in the future.

The structural model shown schematically in Figure 18 assessed the direct and indirect effects of nine observed variables and three latent variables on PPACA as a disrupter to the theory of the iron triangle in laboratories. The model consisted of the following three structural equations: The first predicted equation is that cost in relation to access would decrease due to the implementation of PPACA on clinical laboratories. Secondly, the predicted equation is that quality in correlation to access would increase as to the effects of PPACA. Thirdly, it is predicted that cost and quality would directly increase access to laboratory healthcare because of PPACA. In addition, it was hypothesized that the exogenous variables Cost and Quality would be positively correlated.

Each of the latent variables was measured with three indicator variables as illustrated in the measurement model in Figure 18. The indicators of Access were measured by the new statutes in the PPACA: Increase testing (Utilization A), mandatory enrollment for all citizens (Reform), and the amount of cost per individual (Fee). The

indicators of Quality were assessed by patient outcome: Patient outcome based on employees competency (Personnel), use of electronic information to improve care (Technology), and use of evidence-based medicine to benefit patient (patient safety). Advances in new technology and payment methods assessed the indicators of cost: The use of molecular testing to provide better throughput, better flexibility and less expense (Utilization C), Prevention of human errors (Technology C), and the incorporation of novel repayment methods (reimbursement).

A two-step structural equation modeling strategy was used to assess the predicted model. The first step used the measurement model (confirmatory factor analysis) to assess how well the indicator variables measured the latent variables in the model. As well, the measurement model provides convergent confirmation and discriminant validity of latent variables in the model. The measurement model used five criteria to assess the model fit. The chi-square test, which was statistically significant, $\chi^2$ (24, $N$ = 160) 113.40, $p$ < .001indicating that the model failed to fit the data. However, chi-square is affected by strong correlations of the factors, which are presented in the model. Equally, if the alternate option was used to capture the chi-square, (dividing the chi-square by the degrees of freedom 113.4/24 = 4.7; an acceptable fit is considered between 2 and 5) then it is suggested as an acceptable fit (Marsh & Hocevar, 1985). For this study, the alternate option was used to adjust for strong correlations regarding the chi-square. The goodness of fit index (GFI), the comparative fit index (CFI) and Tucker-Lewis index (TLI) were .864, .818 and .742 respectively for the measurement model, indicating adequate to poor fit. The root mean square error of approximation (RMSEA) was .153 with a 90% confidence interval of .125 to .182. The RMSEA with a value greater than .10 is

considered borderline acceptable; however, the RMSEA is possibly inflated due to sample size less than 200 (Paxton, Hipp, & Marquart-Pyatt, 2011). All coefficients within the model achieved statistical significance ($p < .05$) as well as real world significance (values >.30). Lastly, the correlations between the latent variables presented with values ranging from .70 to .78, indicating substantial discriminant validity amongst the latent variables. No modifications were made to improve the measurement model because of *a prior* theory justification and suitable coefficient weights for the model.

The next step was conducting the full structural analysis of the predicted model. All indicator variables, latent variables along with the correlation of the indicator variable error variances are presented in Figure18. The overall results of the full structural model presented with an excellent fit. Using the alternate method suggested by Marsh and Hocevar (1985) the $\chi^2$ (17, $N$ =160) =33.5, $p$ = .010 resulted with a value of 1.97 (33.5/17 = 1.97). The GFI, CFI, and TLI values were .958, .966, and .942 respectively. The RMESA was .078 with a 90% CI (.037 to. 117). Overall, the model explained 75% of the variance of Access regarding healthcare in the laboratory; indicating the model was an excellent fit to the predicted data regarding PPACA on clinical laboratories. Mostly, Access was driven by the direct influence of Quality, with an increasing relationship as predicted by PPACA. Cost did not show a significant effect on Access; however, it did show a decreasing relationship to Access as predicted by PPACA.

## Interpretation of Data

After analyzing the data, it is apparent that clinical laboratories have adjusted their business practices regarding the implementation of the PPACA. Data suggest that the PPACA (a) increased access to laboratory tests (b) provided a better quality of test

results via an improved total testing process and (c) reduced the cost per laboratory test for the average citizen in the United States. However, this data cannot be generalized to every laboratory in the United States because not all laboratories fall under the decree of CLIA.

The data in questions 1-30 in correlations with the research questions 1-3in Table 1, along with the Figures 9-17, demonstrates that the observed data confirms the accuracy of the hypothesized data. With the majority of the results showing a combination response of strong agree and agree questions 1-30. In addition, the nine observed variables that measured the three latent variables (access, cost and quality) provided coefficient regression weights ranging from -.16 (modest indication) to .82 (substantial indication) with significant $p<.05$ values that the survey items are sufficient indicators of the constructs variables post implementation of the PPACA.

Furthermore, the relationship between the construct variables Quality and Access provided substantial coefficient weights indicating an increasing relationship as predicted by the model. Although Cost did not provide a significant coefficient value, it did show a decreasing relationship between the construct variable Access as predicted. Data also show that 45.6% of the states in the U.S (as seen in Table 2) have expanded their Medicaid Programs to help individuals purchase health insurance; with an additional 4.4% of non-committed states have future plans to expand their Medicaid programs to support PPACA.

The total outcome of the study confirms that the *Ho* is true: There is no significant difference in the variables interrelationships between the predicted model and the observed model data set; therefore, this survey will serve as a plausible instrument to

assess the PPACA. In addition, the series of provisions brought on by the Patient Protection Affordable Care Act have encouraged clinical laboratories; to generate best operational practices that foster an atmosphere of increase access and quality, while simultaneously decreasing cost. Therefore, the PPACA acts as a disrupter to the iron triangle of health care in the clinical laboratory.

## Recommendation for Future Research

Additional research should be conducted to fully explore the recommendations listed below. Addressing these recommendations will allow this instrument to be a stronger assessment tool to evaluate the effects of PPACA on the laboratory in the future. Perhaps this tool can help laboratory managers and directors strategically use different ways and means to create better patient outcomes.

1. Although the fit indices, coefficient regression weights, and total variance showed an excellent fit for the full structural model, the measurement model fit indices were adequate to poor. This fact raised an interesting question that requires an investigation: What does it mean to have a full structural model that fits well and accounts for a large amount of variance, but have an adequate to poor measurement model? Perhaps this is attributed to the number of subjects used in the model. According to Raykov and Marcoulides (2006), the fit indices for *SEM* models are more favorable to larger data sets greater than 200 particular for the fit index RMSEA. In this study, the data set consisted of 160 participants; the small data set may have created significant fit indices for the measurement model, when possibly none exists. However, for the full structure model, the error variances were correlated with one

another, in accordance with the theory of the iron triangle of health care in the laboratory, and real-world practicality. Therefore, the fit indices and regression weight coefficients improved significantly for the full structural model to present with an excellent fit. Alternatively, perhaps this is due to the theory of the iron triangle, where the relationships of the three constructs are tightly interlinked. As a result, the correlations coefficient weights of each construct would create substantial weights in the model, thus producing poor fit indices when none exists (Kenny, 2003).

2. The reliability scores (Cronbach's Alpha) of the items on the Clinical Laboratory Manager Inventory survey were borderline adequate, indicating the consistency of the same responses for the items amongst participants was marginal. This finding possibly concluded that the items of the survey may have been too vague and requires more detail information to improve the consistency of the answers. Perhaps an item correlated with a construct should be moved to another construct, or deleted from the inventory. Likewise, it may indicate that the data set of 160 participants was not large enough to build a consistent amount of responses for each item on the survey.
3. Recommend this study use the mixed method approach. This method allows the researcher to gather an in-depth feel for each item on the survey. It also gives the researcher the opportunity to employ the senses of listening and seeing subjective responses first hand, therefore enabling the researcher to analyze the data from multiple perspectives.

APPENDIX A – Clinical Laboratory Managers Inventory

CLINICAL LABORATORY MANAGERS INVENTORY

CONDUCTED BY:

Harry McDonald Jr,
Center for Science Education,
University of Southern Mississippi

**YOUR RESPONSES TO THIS SURVEY ARE CONFIDENTIAL**

Individual participants will not be identified by name in any analyses or reports. Responses will be aggregated and reported as summary statistics only.

FOR QUESTIONS PERTAINING TO THIS SURVEY, CONTACT: HARRY MCDONALD JR, PRIMARY INVESTIGATOR, (xxx) xxx-xxxx or x.xxxxxxxxx@usm.edu

PLEASE RETURN THE SURVEY AT YOUR EARLIEST CONVENIENCE.

**YOUR ASSISTANCE IS VERY MUCH APPRECIATED.**

PPACA
Welcome to the Patient Protection Affordable Care Act Survey regarding clinical laboratories!

Use the scale below to determine the one phrase that best represents your laboratory response post implementation of the Patient Protection and Affordable Care Act. Using the following scale, please indicate whether you agree or disagree with the following statements:

Please answer, the questions as they relate **Reform to Access** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 1. Your laboratory is likely to increase screening tests such as HIV, Hepatitis B, Lipid Profiles etc. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 2. Your laboratory is likely to incorporate direct access testing (i.e. patients are able to request test results directly from the laboratory). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 3. Your laboratory is likely to experience an increase in first-time insurance users. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 4. Your laboratory is likely to experience an increase in state funding due to Medicaid expansion. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Fee to Access** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 5. Your laboratory is likely to experience a decrease per individual cost for testing. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 6. The impact of reduced reimbursement rates is not likely to affect the financial viability of your laboratory (i.e. lower rates for the clinical laboratory fee schedule, sequestration cuts, adjustments to the consumer price index etc.). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 7. Your laboratory is likely to experience an increase in the prospective payment system (i.e. set amount per patient, regardless of the amount of care received). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Utilization to Access** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 8. Your laboratory is likely to incorporate a wide range of different laboratory tests to accommodate the projected increase in the elderly population (i.e. 65 and older). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 9. Your laboratory is likely to experience an increase in miniaturization of assay methods to expand the test menu (i.e. lab-on-a-chip and point of care testing). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 10. Your laboratory is likely to experience an increase in new testing platforms to improve efficiency (i.e. core lab concept). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Technology to Quality** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 11. Please select three (3) neutral for this question. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 12. Your laboratory is likely to increase automation testing to reduce over test-utilization (i.e. reduce repeat testing due to human error). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 13. Your laboratory is likely to increase molecular and genetic testing to personalize medical care for the individual patient (i.e. individualized testing ordering based on history, algorithms and clinical information). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 14. Automation testing is likely to promote shared information of test results in your laboratory (i.e. seamless transmission of tests results between institutions). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Patient Safety to Quality** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 15. Your laboratory has experienced an improvement in patient outcomes (i.e. improved disease detection, prevention and or delayed onset of diseases). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 16. Your laboratory has incorporated evidence-based medicine to support better patient outcomes (i.e. eliminate unnecessary testing). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 17. Your laboratory is likely to experience an increase in value-based care that focuses on test ordering that is beneficial and necessary for the patient (i.e. Evidence-based laboratory medicine; right test, for the right patient, at the right time). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Personnel to Quality** post implementation of the Patient Protection Affordable Care Act.

| | **1= Strongly Agree** | **2=Agree** | **3= Neutral** | **4= Disagree** | **5= Strongly Disagree** | **9=NA** |
|---|---|---|---|---|---|---|
| 18. Your laboratory has experienced an increase in information technology to support personnel (i.e. assist with high throughput and complex test result interpretations). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 19. Your laboratory invests in educating personnel to improve competence (i.e. continuing education program, professional society membership and publications). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 20. Your laboratory supports personnel earning advanced degrees to improve laboratory and provider relationship (i.e. consultation support of test results). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Technology to Cost** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 21. Please, select one (1) Strongly Agree for this question. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 22. Your laboratory is likely to maximize miniaturization of assay technology to support high volume throughput tests as a cost-effective strategy. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 23. Electronic medical records in your laboratory are likely to decrease administrative cost (i.e. streamline data; reduce redundancy, allow seamless access to patients results in different geographical areas). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 24. Your laboratory is likely to use or incorporate the use of bar coding technology to minimize misidentification test results. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Utilization to Cost** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 25. Your laboratory is likely to implement a wide range of molecular diagnostic tests to support the increase of the elder population with insurance. (i.e. Tests that provides less expense and greater availability) | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 26. Your laboratory is likely to experience an increase in novel health care delivery systems to reduce costs for patients (i.e. Accountable care organization, State Innovation Models, etc.). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 27. Your laboratory is likely to experience an increase in competitive bidding for laboratory tests (i.e. quote the best price with the best quality to gain customers). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

Please answer, the questions as they relate **Reimbursement to Cost** post implementation of the Patient Protection Affordable Care Act.

| | 1= Strongly Agree | 2=Agree | 3= Neutral | 4= Disagree | 5= Strongly Disagree | 9=NA |
|---|---|---|---|---|---|---|
| 28. Your laboratory is not likely to experience patient co-payment fees for laboratory tests (patient provides a co-payment to the laboratory upon visit). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 29. Your laboratory is likely to experience an increase in the bundled payment method to reduce cost (aligning the services and goals of the patients, providers, and all parties involved to improve quality and reduce cost). | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |
| 30. Your laboratory is likely to experience a decrease in Fee-for-Service billing to curb cost. | ❍ | ❍ | ❍ | ❍ | ❍ | ❍ |

DEMOGRAPHICS

Please provide the following demographic information regarding you and your institution by selecting one answer per question or filling in the blank space provided.

1 Select your facility type:

- ❍ 1=Physician-Based Laboratory
- ❍ 2=Reference Laboratory
- ❍ 3=Hospital Based Laboratory
- ❍ 4=Other (Freestanding clinics, Referral testing laboratories, Walk in private clinics etc.)

2 How would you classify your institution?

- ❍ 1=Public
- ❍ 2=Private
- ❍ 3=Unsure

3 How many laboratory tests does your laboratory perform annually?

- 1=Less than 50,000 tests
- 2=50,000 to 100,000 tests
- 3=100,000 to 250,000 tests
- 4=250,000 to 500,000 tests
- 5= > 500, 000 tests

4 How long have you worked for this facility?

- 1=Less than one year
- 2=One to five years
- 3=Five to ten years
- 4=Ten to twenty years
- 5= > twenty years

5 Select years of experience as a laboratory Manager and/or Director:

- 1=Less than one year
- 2=One to five years
- 3=Five to ten years
- 4=Ten to twenty years
- 5= > twenty years

6 Please select your age range.

- 18-29 Years old
- 30-40 Years old
- 41-50 Years old
- >50 Years old

7 What is your certification affiliation? Please select all that apply.

- 1=ASCP
- 2=NCA
- 3=AMT
- 4=Other
- 5=None

8 Has your state expanded Medicaid under the PPACA?

- ❍ 1=Yes
- ❍ 2=No
- ❍ 3=An expansion is planned in my state, but not yet in place
- ❍ 4=Unsure

9 Provide the name of your state in the space below

_____

APPENDIX B – Information Letter

Harry McDonald Jr.
Ph.D. Candidate, Science-Medical Laboratory Science
University of Southern Mississippi

Dear Mr. or Mrs.:

I am Harry McDonald, a Clinical Laboratory Officer in the United States Army. I have 17 years of medical laboratory science experience and have worked as the director and chief in numerous positions within the laboratory, and therefore, have firsthand knowledge of federal laws that influence clinical laboratory capabilities. I am conducting a study to design an instrument that will assess post implementation effects of the Patient Protection Affordable Care Act (PPACA) on clinical laboratories. The purpose of this study is to design the most theoretical, accurate instrument based on the theory of the iron triangle in order to assess the relationships of access, cost, and quality. The results of this study will help laboratory managers assess the implications of PPACA on laboratories today, and provide the laboratory community with a plausible instrument to assess the influence of PPACA for subsequent research in the future.

Your name was purposefully selected from the list of the Clinical Laboratory Improvement Amendments Program. I would sincerely appreciate your help by completing the enclosed or attached questionnaire. The survey is anonymous and I will use pseudonyms to prevent disclosure of your information. I am interested in your honest opinion and your invaluable input to this study. If you prefer not to answer a question, please leave it blank.

The survey should take approximately 15 minutes to complete. Participation can be in the form of an electronic survey, hardcopy, or telephonically depending on your preference. If you prefer the electronic survey, it will be sent to your e-mail address and can be conducted on any computer at your convenience. If you prefer a hardcopy, the survey will be sent to your preferred mailing address with an enclosed stamp envelope for your convenience to return the survey. If you prefer the survey be conducted telephonically, then a time can be arranged at your convenience. I would appreciate you returning the completed survey to me no later than January 15, 2017.

Participation is voluntary and that refusal to participate will not result in any consequences. All participants have a right to confidentiality and can withdraw from the study at any time without any consequences. No names will be recorded and all data will be made anonymous by the researcher. Participants must be ages 18 or older and affiliated with the Clinical Laboratory Improvement Amendments Program to fill out this survey. If you have pertinent questions about the research and research subjects' rights, I can be reached at the following: Ph. # xxx-xxx-xxxx, email: x.xxxxxxxx@edu.usm.

Thank you in advance for your cooperation with this important endeavor. Your answers will make significant contributions to our understanding of the contemporary and future issues that involves all of us regarding post implementation of PPACA on clinical laboratories. If you would like a summary of my findings, please send your request in an e-mail, and I will forward the findings to you when the study has been completed.
Sincerely,

Harry McDonald Jr, M.S. MLS (ASCP) SSB
Ph.D. Candidate

# APPENDIX C – IRB Approval Letter

THE UNIVERSITY OF
SOUTHERN MISSISSIPPI.

**INSTITUTIONAL REVIEW BOARD**
118 College Drive #5147 | Hattiesburg, MS 39406-0001
Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

**NOTICE OF COMMITTEE ACTION**

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
  Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16092903
PROJECT TITLE: The Design of an Instrument to Assess Clinical Laboratories Efficacy Post Implementation of the Patient Protection Affordable Care Act
PROJECT TYPE: New Project
RESEARCHER(S): Harry McDonald, Jr.
COLLEGE/DIVISION: College of Science and Technology
DEPARTMENT: Center for Science and Mathematics Education (MLS)
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Exempt Review Approval
PERIOD OF APPROVAL: 10/19/2016 to 10/18/2017
**Lawrence A. Hosman, Ph.D.**
**Institutional Review Board**

# APPENDIX D – Permission Letter for Figures 5 & 6

*The National Academies of*
SCIENCES · ENGINEERING · MEDICINE

**National Academies Press**
**Rights & Permissions**

February 20, 2017 **Reference #: 02201701**

Harry McDonald Jr.
University of Southern Mississippi
118 College Drive
Hattiesburg, MS 39406

Dear Mr. McDonald:

You have requested permission to adapt reproduce the following material copyrighted by the National Academy of Sciences in your PhD dissertation:

***Figure 2-1, Access to Health Care in America, 1993***
***Excerpts, Pages 5 and 6, Crossing the Quality Chasm: A New Health System for the 21st Century, 2001***

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