

The Intersection of Health Care Innovation and Compliance:

What Factors Influence Their Interaction

BY

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DISSERTATION

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LIST OF ABBREVIATIONS

CCO	Chief Compliance Officer
CIO	Chief Innovation Officer
CMS	Centers for Medicare & Medicaid Services
FSG	Federal Sentencing Guidelines
HCCA	Health Care Compliance Association
HIPAA	Health Insurance Portability and Accountability Act
HHS	Health and Human Services
MACRA	Medicare Access and CHIP Reauthorization Act
PPACA	Patient Protection and Affordable Care Act
OIG	Office of the Inspector General
UC CHQI	University of California Center for Health Quality Innovation

SUMMARY

To meet the demand for access, quality, safety, and population outcomes, most health care delivery systems are exploring ways to change the way they provide services. At the same time, the health care system in the United States is one of federal, state and local laws, regulations, and jurisdictions regarding the payment for, delivery of, and oversight of health care. This added complexity makes it easy for an innovative idea to step over the line from innovative to illegal, or at least ill-advised (Keckley, 2015; Goodman, 2013; Field, 2008). It is thus necessary for most, if not all, innovation projects, whether a process change, a systems change or a new technology (or new use for a technology) to undergo a review by the delivery systems' risk resources – including compliance. Unfortunately, for many, if not most, health care delivery systems, the innovation teams and the compliance teams have strained relations. Often the innovation experts view compliance departments as the place in which innovation is destroyed while compliance departments view innovators as trying to sneak past them to keep compliance from the table.

This study hopes to surface the tensions between health care innovation and compliance, which are mutually accepted but not publicly acknowledged or discussed; create a common understanding of the needs of both innovation and compliance for better health care delivery outcomes; and describe models of collaboration that lead to positive outcomes. The following five models appear to hold some of those characteristics and are discussed in more depth in the next section:

1. Learning Organizations
2. Dimensions of Conflict
3. Mental Models
4. Generative Leadership and Relationships
5. Organizational Frames

SUMMARY (continued)

These five models have commonalities in factors or characteristics, and those commonalities that have been pulled out for study. It is hoped a framework can be developed to assist the leaders of innovation and compliance to guide their respective teams toward creative and successful solutions instead of wallowing in negativity and tension.

To explore the types of perceptions and interactions between the innovation and compliance professionals in a large health care delivery system, this study employed an exploratory case study using two phases. Phase 1 consisted of semi-structured interviews with a representative sample of experts along with a review of primary source documents. Phase 2 consisted of additional one-on-one interviews with the health system subjects to discuss major themes from Phase 1.

The data were coded and the four codes that appeared in all three ways of reviewing the data are: Executive, Relationship, Strategy and TeamsGroup. The data analysis highlighted another code, in addition to the four identified above: LearningOrg Group.

Regarding *Research Question 1* (How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems, what perceptions do they have of each other, and in what ways do the interactions reflect the perceptions?), the common colloquial understanding was not supported by these research findings.

Regarding *Research Question 2* (In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance departments?), four themes were developed by studying the codes and their relationships to each other:

SUMMARY (continued)

- 1) The influence of leaders and executives: The importance of executive leadership support, role modeling of expected behaviors, and creating a culture in which both innovation and compliance were valued
- 2) The importance of innovation as an organization mission and business objective: Clear business objectives and organization mission statements set the tone for what each employee and department strive for
- 3) The need for relationship building and teamwork: The ability to form relationships and work as a team, toward that common business objective, was often cited as a reason for success
- 4) The organization operates as a learning organization: The descriptions of the organization's culture reflect the qualities of a learning organization – building shared vision, personal mastery, working with mental models, team learning, and systems thinking.

The data analysis in this study provided insight into how large health systems that have a track record of being innovative balance the boundary-breaking innovation designs and the need for compliance to federal and state laws, regulations and mandates. Specifically, the data revealed how innovation and compliance professionals might perceive each other and what factors might be the most prominent in their interactions in representative innovation-focused health care systems. The cooperation manifested in various ways, specifically in this study, as teamwork, relationships, and behaving as a learning organization.

I. BACKGROUND AND PROBLEM STATEMENT

A. Introduction

Innovation has become part of the fabric of health care in the United States and can take many forms, including new processes, new programs, or new technology. This can be seen in health care organizations as they embrace new technologies and revisit processes to ensure efficiency and effectiveness. It can be seen in the government sponsorship of innovative efforts regarding payment mechanisms, care delivery, and technology. And it can be seen in non-health care companies moving into the health care space (e.g., Amazon) seeking ways to deliver health care using their current model of success. At the same time, the health care in the United States is among the most regulated for payment mechanisms, care delivery, and technology. The United States, both federally and at the state level, has strict regulations as to how care is delivered, how organizations operate, how health information is secured, and what providers can and cannot do under their licenses (GAO, 2018; Hagland, 2016; Jain and Shrank, 2016; Kirzecky and Jones, 2013; Leventhal, 2017; Luke, 2018; Paavola, 2018; Richardson, 2013; Robinson and Smith, 2008).

At the direct care operational level, such as in hospitals or health systems, the drive to innovate and the need to ensure compliance with regulations meet head on. In its simplest context, the innovators seek to push boundaries and take risks whereas the compliance professionals seek to avoid or diminish risk to the organization by staying within rules and boundaries. These two areas – both vital for the continued health of the organization, much less the patients – often find themselves disagreeing about the balance of moving forward with risk and advancing slowly to reduce risk (Arjoon, 2006; Bloom and Chu, 2015; Kanter, 2011; Lee III, 2014).

Little study has been given to the interactions of these two disciplines. The unproven supposition is that the two engage in conflict, avoidance, and other non-productive ways of interacting, or not interacting. Yet, many health care systems have demonstrated success with

innovation and have innovation as a core value. The assumption is these systems have innovation and compliance teams that work well together and find ways to embrace change yet do so within legal and regulatory limits.

This study is designed to uncover some of the factors, or characteristics, of the interaction between successful innovation and compliance departments. It is believed by highlighting ways in which the teams interact and how management supports or encourages that interaction, other health care systems can emulate these findings and move their systems toward a future that embraces innovation and respects regulations equally.

1. Study Objectives

The health care system is under pressure from many sources to reduce costs, increase the use of technology, improve quality of care and improve patient safety. Some of that pressure comes from the federal government pushing a payment model into one more focused on population health than individual outcomes. This shift toward population health as a model for payment is fairly revolutionary in the United States, which traditionally has paid on an episodic care basis – the more care, the more revenue. The Medicare expectations for a population health approach require clinicians to approach care in the continuum from primary care through specialty care, as well as through death and dying, and to adopt best practices and evidenced-based care. As Mulvany wrote in *Healthcare Financial Management*, “physicians will need to understand the gaps in their longitudinal care management capabilities (and the up-front and ongoing costs related to filling those gaps), the potential impact on revenue from all payers, and the longitudinal cost of providing care for episodes or populations for which they will likely take risk” (Mulvany, 2016). The potential is enormous in terms of population health across the continuum. Encouraging (some

would say, requiring) health care providers and health insurance companies to take a population health view of care could, over time, radically change the health of the United States and start that slow movement from treating chronic illness after it manifests to catching it early enough to prevent bad outcomes, or even preventing it all together. This need to change one's practice and business model will likely lead to more innovative ways to approach health care throughout the system (Kirzecky and Jones, 2013; Perry and Stephenson, 2013; Eng, 2004; McPherson, et al., 2015; Cornett, 2015; Isham, et al., 2013).

To meet this demand for access, quality, safety, and population outcomes, most health care delivery systems are exploring ways to change the way they provide services. "Virtual" visits are more common and include the use of telephones and video feeds between clinician and patient. Many insurers and providers are looking to increase the use of self-care and monitoring at home to reduce costs and increase patient and family involvement in the care plan. The hospital of the future might not be a hospital at all (Cryer et al., 2012). Mercy Hospital in St. Louis, Mo., uses two-way cameras and at-home monitors so 330 employees can monitor patients from afar; Mercy calls its Virtual Care Center a "hospital without beds" (Pepitone, 2016). Virtual reality headsets are being used for everything from pain control to behavioral therapy and are being used by dentists for children undergoing procedures (Wicklund, 2016). The supercomputer IBM Watson is being inserted into health care in various ways from identifying cancer treatment recommendations for physicians to reducing the research time for new medications from years to months (Speights, 2018).

The changes cited above are all examples of innovative approaches to medical care. The innovation might be a giant, transformative leap, such as using artificial intelligence, e.g., Watson, or incremental, such as moving from telephonic visits to video visits to virtual reality visits. The possibility to reach people who have little access to specialists or even primary care providers in some rural areas, the ability to help a family go through the dying process at home where they are comfortable, the opportunity to monitor a chronic disease without making the patient physically leave his or her home or simply to make a nurse's shift less burdensome with paperwork and filled with more direct patient care are all worthy goals for a health care system seeking to ensure health care equity for a population.

At the same time, the health care system in the United States is one of federal, state, and local laws, regulations, and jurisdictions regarding the payment for, delivery of, and oversight of health care. This added complexity makes it easy for an innovative idea to step over the line from innovative to illegal, or at least ill-advised (Keckley, 2015; Goodman, 2013; Field, 2008). It is possible a change in a process or technology could lead to unintentional violations of rules regarding coding, billing, contracts, inducements, privacy rules, and hundreds of thousands of other expectations by health care organizations receiving government funding (Keckley, 2015). Innovations related to physician agreements between hospitals, other physician groups, and ancillary services could cross self-referral boundaries and other fraud-control regulations. New workflows to use advanced care practice providers to minimize physician-patient time in the clinic could cross scope of practice boundaries. It is thus necessary for most, if not all, innovation projects – whether a

process change, a systems change, or a new technology (or new use for a technology) – to undergo a review by the delivery systems’ risk resources, including compliance.

Medical center compliance offices typically have the scope of ensuring the institution meets federal, state, and local laws regarding privacy, security, fraud, waste, and abuse. The False Claims Act is legislation the federal government has been using for years against medical systems and providers for improper Medicare and Medicaid billing. The Health Insurance Portability and Accountability Act (HIPAA) is the main federal law that protects patient privacy and sets standards for medical information technology security. Other examples of regulations that can easily be violated include Stark Laws (self-referral) and medical research guidelines.

When a medical institution embraces innovation as a way to manage the payment reforms and other pressures, the result could step over the line between compliant-and noncompliant. Thus, it is critical that the compliance department be kept apprised of innovation projects and involved at some stage in the innovation process. Unfortunately, for many – if not most – health care delivery systems, the innovation teams and the compliance teams have strained relations. Often the innovation experts view compliance departments as the place in which innovation is destroyed-while compliance departments view innovators as trying to sneak past them to keep compliance from the table.

In truth, however, both are vital to the health care delivery system. Without innovation, the system cannot adjust to new demands, cannot meet ever-increasing patient and payer demands, and cannot fully explore how to reduce waste and increase quality. Without a compliance component, the system exposes itself to government scrutiny for fraud and privacy concerns, faces charges by patients for

being reckless with their personal health information, and risks having providers practice out of scope, potentially harming patients and incurring professional regulatory sanctions and/or defending against malpractice litigation.

2. Purpose of Study

Within health care delivery systems, health care innovation and health care compliance have a tense relationship. At the same time, both play a significant role in today's health care environment, as it looks for new ways to improve outcomes and reduce costs. This study hopes to surface the commonly-perceived yet unacknowledged tensions between health care innovation and compliance, create an understanding of how each perceives the other within representative large-health systems, and describe models for collaborative interaction.

The purpose of this study is to explore the relationship between compliance and innovation and increase the understanding of what factors help the two sets of professionals work toward the organization's interests. The ultimate goal would be to make visible how each "shows up" to the other and what efforts they take to meet the goals and objectives of a health care delivery system's business needs and priorities. By understanding these factors, this study can inform the field as to what may or may not work.

In this study, I will explore the perceptions health care innovation and compliance professionals have of each other as it relates to commonly understood perceptions, explore the characteristics of health care innovation and compliance professionals within large health care delivery systems and contextualize their relationship to understand better how the two do or do not interact to further the

organization's objectives, and explore the organizational factors that can contribute to a successful working relationship between the two.

B. **Background and Context**

The ultimate goal of a health care delivery system is to provide care at the right time, in the right place, and for the right cost. To be successful in today's environment, with uncertainty in payer models and increases in health care needs of the general population that are generally not covered (e.g., psychiatric care and homelessness), care delivery systems must approach care differently. To do so, the system must continually evolve its approach via new medical treatments, standards of best practices, workforce development and training, and patient preferences. In its review of the future of public health in the 21st century, the Institute of Medicine (IOM) devotes an entire chapter to the U.S. health care delivery system. In it, the IOM states:

Fundamental flaws in the systems that finance, organize, and deliver health care work to undermine the organizational structure necessary to ensure the effective translation of scientific discoveries into routine patient care, and many parts of the health care delivery system are economically vulnerable. Insurance plans and providers scramble to adapt and survive in a rapidly evolving and highly competitive market; and the variations among health insurance plans—whether public or private—in eligibility, benefits, cost sharing, plan restrictions, reimbursement policies, and other attributes create confusion, inequity, and excessive administrative burdens for both providers of care and consumers. (Institute of Medicine (US) Committee on Assuring the Health of the Public in the 21st Century, 2002).

In today's environment, it is virtually impossible for the U.S. health care system to improve health outcomes unless delivery systems embrace both innovation and compliance. Health care delivery must meet the demands of a population with higher rates of obesity, problems associated

with old age, and the incidence of diabetes at progressively younger ages. This is in addition to the potential for quickly spreading pandemics and environmental threats from climate change.

It is not just the federal or state government looking at ways to improve the overall health of the United States. Employers and payers (e.g., insurance companies) have a stake in that interest also. By raising the health of groups of people and by providing care outside of expensive hospitals, by focusing on preventing or delaying chronic conditions and by encouraging personal responsibility for one's health-related choices, and by using technology to deliver care at home and help people remain as independent as possible, overall costs should decrease (Crosson and Madvig, 2004; Hayes et al., 2016; Boling and Leff, 2014). But none of that will be possible unless the delivery systems change how and where they provide care, and that requires technological, process, and service innovation. It then follows that the innovation must meet the federal, state, and local standards of care and legal requirements that govern public and private payer models.

The convergence of technological and scientific advances, along with the demands for better population health outcomes, is changing how health care systems think about and deliver health care (Eng, 2004). For almost 20 years, the U.S. health system has been struggling to find a way to meet the goals set forth in *To Err is Human* (Kohn, et al., 1999). This landmark work thrust the quality of patient care delivery and safety to the forefront and has been used to publicly compare health care systems, hospitals, and medical groups in the quality and safety of their care (Kohn, et al., 1999). The health care system in the United States has been under cost containment pressure for years and models of health care coverage are changing, as witnessed by the Patient Protection and Affordable Care Act, signed into law in 2010 (Ginsberg, 2013; Stablie et al., 2013; Morris, 2009; Evans et al., 1991; Garber et al., 2007).

Varkey et al. (2008) cite new digital information, nanotechnology, semiconductor products, and genetic engineering as revolutions that make “old assumptions” invalid and create

“unanticipated prospects for innovation and improvement of existing processes” in health care (Varkey et al., 2008). Kirzecky and Jones describe four drivers that are disrupting “established ways of doing business” for all types of health care organizations, including delivery systems, payers, and manufacturers: 1) the explosion of medical knowledge, technologies, and information; 2) increasingly engaged and knowledgeable patients; 3) expectations for higher quality outcomes, improved safety and personalized patient benefits; and 4) demands for greater value for the money spent (Kirzecky and Jones, 2013). All these pressures mean that health care is trying to change and adjust with speed and precision.

Innovation in health care is nothing new. Every time a new monitor, drug, lab test, or surgery is created, tested, and implemented, innovation has occurred. The Veteran’s Health Administration’s Health Foundation states innovation is “the hallmark of American health care” and cites the discovery of insulin, the mapping of the human genome, antibiotic therapy, organ transplantation, and artificial joints as innovations that have moved health care forward (VHA Health Foundation, 2006). According to Herzlinger (2006), the United States government spent \$26 million on health care research and development in 2003, second only to spending on defense research and development (Herzlinger, 2006).

In the United States, health care innovation is actually written into law, with the passage in 2010 of the Patient Protection and Affordable Care Act (PPACA). Title III of the Act, harkening back to the IOM’s *To Err Is Human*, states: “Doctors, nurses and hospitals will be incentivized to improve care and reduce unnecessary errors that harm patients... a group of doctors and health care experts, not Members of Congress, will be tasked with coming up with their best ideas to improve quality and reduce costs for Medicare beneficiaries” (HHS: About the Law, 2016). The Act gives the Secretary of Health and Human Services “the authority to take steps to strengthen the Medicare program and implement reforms to improve the quality and efficiency of health care” (HHS: About

the Law, 2016). Persaud (2014) contends policies such as these, occurring in other developed nations as well, are directed toward accountability related to money spent, using best-practice and high-quality care, and redesigning and transforming health care “through learning and innovation” (Persaud, 2014). As Bloom (2011) wrote in an article about innovation and health care: “If we do what we have always done, we will get what we have always gotten – a system that is inefficient, inequitable and unaffordable. We and every country must call on its best ideas and innovations to do better” (Bloom, 2011).

Nevertheless, there is tension between innovation, which typically operates at the edges of convention, and health care compliance, which seeks stability and conformity. New or revised technology, processes, and services carry risks to the organization if they are not in line with policies, laws, and regulations. Innovation challenges the norm to keep the enterprise relevant. Compliance is geared toward moving an organization toward a standard practice and evaluating the risks associated with change so the enterprise remains in good standing with oversight bodies and other stakeholders.

Many contend the obstacles to technological innovations are numerous and include having to meet compliance or a “welter of often murky governmental regulations” (Herzlinger, 2006). Morgan Reed, executive director of ACT (the APP Association for mobile technology), was quoted in an article about health care technology and regulation as having said: “It’s not as though there are no good ideas out there, but health care is often where good ideas go to die. At least part of the reason involves regulatory barriers people face when developing apps in this space” (Raths, 2015). Reed cites HIPAA and the FDA as two “key areas” in which business leaders argue innovation is impeded. Raths references a start-up for secure messages which claims HIPAA standards forced it to hire attorneys to ensure compliance with HIPAA, something small companies and start-ups often cannot afford to do.

Others see this tension differently and would characterize the grounding factor of regulations as freedom. Fifield (2016) claims “compliance should compel you to do the impossible for your customer.” She quotes Bryan Haardt, CEO of Deciso Health, which makes a clinical decision support platform, who believes complying with regulations is “both the right thing to do” and keeps the organization accountable (Fifield, 2016).

In a blog about HIPAA and innovation, Lee III (2014) tells companies to stop saying HIPAA stifles innovation, calling it a “cop out” based on fear and not an understanding of the law. He contends embracing HIPAA would actually “grease the wheels of innovation” by making systems reliable and available, with IT staff having more time to innovate rather than fix systems issues. “By embracing the HIPAA rule and truly understanding its meaning we can stop fearing what might go wrong and, instead, start dreaming about what might go so right” (Lee III, 2014).

Even with this tension and disagreement about whether regulations and compliance stifle or spur innovation, health care delivery systems must be – and are – moving forward. Innovation is everywhere in health care, developing new models of care for chronic conditions, incorporating technologies to speed diagnoses or allow more self-care, and upending processes to create efficiencies. The Centers for Medicare and Medicaid Services supports creative payment models – and alters some rules to allow them to be tested. The question, then, is how are some health care delivery systems able to produce or adopt innovative solutions quickly and in ways that do not jeopardize the organization or create unnecessary risk to the operations? What are the factors that lead to successful innovation in some health care delivery systems that might not exist – or be surfaced – in other systems? Exploring the models of interaction or collaboration that these successful innovation systems use could help other systems adjust their thinking, adopt new ways to collaborate, or review how their system perceives innovation and compliance as a way of meeting health outcome goals and supporting business strategies.

C. **Problem Statement and Study Questions**

Innovation teams and compliance teams simultaneously push health care delivery systems to be responsive to various stakeholders – including patients, employees, and outside agencies. In the absence of optimal performance from ~~of~~ both teams, the organization could run less efficiently, be at risk of government or community scrutiny, and possibly not meet its desired business and clinical outcomes. Some health care delivery systems do not yet have a robust way to reconcile the tension between innovation's process and compliance's mandates and accountabilities. By understanding the characteristics that impact the interaction between compliance and innovation, the leaders of an innovative health care organization can create an environment that promotes flexibility yet is consistent with laws, regulations, and policies.

The research questions studied here are:

Research Question 1

How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems? What perceptions (mental models) does each have of the other? In what ways do the interactions reflect the perceptions?

Research Question 2

In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance professionals?

D. **Leadership Implications and Relevance**

Given that innovation related to health care systems, payment models, and delivery appears to be constant and necessary, it becomes important to understand how this plays out at the operational level. In large health systems that deliver care, innovators are being placed into organizations that are well-versed in caring for patients but not in the functions of innovation. In writing about the education field, Gregory (2016) contends the “human side of innovation and change is all but

ignored, and the trusting relationships in schools are a casualty of that oversight”(Gregory, 2016).

DeSouza, et. al, write that too many organizations rely on “serendipity” when it comes to the process of innovation in the context of an organization’s strengths and weaknesses, and innovation requires “organizational robustness and flexibility” (Desouza et al., 2019).

Fay et al. (2006) studied multidisciplinary teams in relationship to health care innovation. The authors discussed “out-group” team members, that is, people who are not identified with the team’s professional identity (also called social categorization): “Individuals are less likely to listen to or to accept ideas when they are presented by an out-group team member” (Fay et al., 2006). Their study found a shared vision and frequent interactions provided the “necessary integration and ‘glue.’” They suggest this factor can be offset by “the pursuit of a shared vision, high interaction frequency, trust and reflexivity.”

We believe that the shared vision and the high interaction frequency provide the necessary integration and ‘glue’. They help to overcome the negative effects of social categorization processes and to develop shared mental models. Different professional groups have different KSAs [knowledge, skills and abilities], information and networks that are associated with their different professions and organizational roles. High levels of team reflexivity and safety are needed to present the diverse and certainly sometimes hard to communicate views to the team. (Fay et al., 2006)

The role of the leader in managing these shared visions and interactions has been discussed. Gregory (2016) concluded that “leaders must create trusting relationship.” (Gregory, 2016) In a study on leadership and innovation, Jansen et al. (2009) found: “Organizational members, including middle and lower level managers, will continue ‘business as usual’ without considering improvements or refinements to existing products and services unless their leader exhibits transformational behaviors and triggers them to do so.” (Jansen, et al., 2009) According to Surie and Hazy (2006), to catalyze innovation, leaders create a system for “collections of knowledgeable individuals” to interact with “minimal friction” and optimal conditions. (Surie and Hazy, 2006) In

complex systems, such as health care delivery, Hazy and Uhl-Bien (2013) wrote that leaders perform “influence functions” in “human interactions and organizing.” (Hazy and Uhl-Bien, 2013) The role of leadership, then, appears to be critical for creating an innovative organization in which all parties can work toward a shared vision.

As for leadership’s role in compliance and ethics, the Office of the Inspector General or OIG in its discussion of the seven elements of a compliance program within the federal sentencing guidelines that dictate the program’s expected activities and structure, interprets the government rules as placing “the responsibility for controlling and preventing illegal and unethical activities squarely on the shoulders of top management” (Ferrell et al., 1998). The OIG clearly expects health care governing boards to “ensure that management consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans.” The OIG recognizes the industry is changing and is explicit in its expectations for leadership:

Compliance functions tasked with monitoring new areas of risk should take into account the increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement. New forms of reimbursement . . . lead to new incentives and compliance risks. Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. New payment models have also incentivized consolidation among health care providers and more employment and contractual relationships (e.g., between hospitals and physicians)... Emerging trends in the health care industry to increase transparency can present health care organizations with opportunities and risks. For example, the Government is collecting and publishing data on health outcomes and quality measures (e.g., Centers for Medicare & Medicaid Services (CMS) Quality Compare Measures), Medicare payment data are now publicly available (e.g., 17 See USSG § 8B2.1(b)(5). 18 See USSG § 8B2.1(c). 13 CMS physician payment data), and the Sunshine Rule¹⁹ offers public access to data on payments

from the pharmaceutical and device industries to physicians... Because so much more information is becoming public, Boards may be asked significant compliance-oriented questions by various stakeholders, including patients, employees, government officials, donors, the media, and whistleblowers (Office of the Inspector General, HHS, 2015).

At its core, this guidance points out that the health care industry is moving toward a population health model that creates incentives for caring for patients across the continuum while at the same time providing greater transparency about quality and safety. These new trends – some of which are mandated by legislation – are an attempt to solidify the patient at the center of the care. It is leadership's responsibility and accountability to ensure that happens in all areas, including innovation and compliance, and that creativity is conducted for the patient's sake. This study hopes to:

- Surface the tensions between health care innovation and compliance, which are mutually accepted but not publicly acknowledged or discussed
- Create a common understanding of the needs of both innovation and compliance for better health care delivery outcomes
- Describe models of collaboration that lead to positive outcomes

II. CONCEPTUAL AND ANALYTICAL FRAMEWORK

A. Introduction

The interactions between the innovation and compliance communities have not received a significant amount of attention in the formal literature. This could be because of the relatively newness of them as disciplines within health care. Therefore, this literature review spends some time defining and explaining health care innovation and health care compliance as they relate individually to health care delivery systems. The attempt is to explain how they function within a health care system and why they are each important to an optimally functioning health care system.

The rest of this section attempts to link various models of interaction with the interaction between innovation and compliance teams. Given the sparseness of formal studies specific to these two disciplines, a baseline can be established. Rather than testing against one particular model, the focus here is to test aspects from a few models that appear to be 1) relevant to the interactions between two potentially oppositional parties; 2) grounded in the literature related to modern organizational behavioral theories; and 3) reflect what can be gleaned from sources, both written and oral, about successful innovation and compliance interactions.

B. Literature Review

The literature review consists of two sections. In the first section, innovation and compliance are defined in terms of this paper and explored more thoroughly as to how the two intersect at a systems level and the impact each might have on the other at an operational level. Because health care compliance is a less understood and less studied concept than innovation, more attention is paid to it. For this paper, the focus is health care – specifically, health care delivery. The study will be in the context of the large health care delivery system as opposed to health plan, small provider, pharmaceutical, or consumer-focused health care innovation.

The second part of the literature review highlights five models of interaction that were reviewed for characteristics that, based on the literature review and other information, could be studied to see if they are present in the sample organizations. The five models are:

1. Learning Organizations
2. Dimensions of Conflict
3. Mental Models
4. Generative Relationships and Leadership
5. Organizational Frames

Lastly, a concept map developed based on current understanding of the problem is presented.

1. Innovation and Compliance: A Better Understanding

There are many ways to look at innovation and many ways to define innovation types and effects. A simple search in the UIC online library system for either “innovation” or “compliance” can bring up thousands of entries in hundreds of industries.

Stevenson and Kaafarani (2011) describe four levels of innovation: transformational (disruptive breakthroughs that change society), category (breakthroughs found in the application of ideas, products or services rather than creating inventions), marketplace (unique modifications for products, services and delivery methods), and operational (finding efficiencies, improving the work environment, upgrading technology to ensure the company is continually evolving) (Stevenson and Kaafarani, 2011).

Varkey et al. (2008) describe disruptive innovation as “radical, revolutionary, transformational, or nonlinear” (Varkey, et al., 2008). They describe nondisruptive innovation as “a way that allows expanded opportunities to be met, or existing problems to be solved.” They contend a nondisruptive innovation “broadens the market” by creating more uses, lowering costs, or delivering improvements. They associate nondisruptive innovation with quality improvement in that “these are typically created as an extension of current products, services, or processes” (Varkey et al., 2008).

Much of the health care innovation literature centers around new ideas that involve products, technologies, or processes that move through various stages of testing until provided to and adopted by the end user (Omachonu and Einspruch, 2010; Varkey et al., 2008; Persaud, 2014). Most of the innovation discussed in this paper would align with that – nondisruptive innovation using products, technology, or processes that benefit the end user and patient. These would fall under the Stevenson and Kaafarani (2011) rubric of category, marketplace, or operational innovation. Although transformative health care innovation is possible (e.g., new insurance products through the PPACA or a new medication such as the Hepatitis C pharmaceutical treatment), those broad, disruptive, industry-changing innovations are rare and even rarer in the delivery side of health care.

At the same time, innovation has become integral to health care delivery's economic survival and quality imperatives, federal, state, and local regulations continue to rise, restricting the use of data or setting expectations of what can and cannot be billed to Medicare or Medicaid. Health care compliance focuses on regulatory and legal requirements related to privacy (ensuring protected health information is not disclosed impermissibly), security (ensuring IT and other systems are able to resist corruption or intrusion), and-fraud, waste, and abuse (ensuring the use of government and private monies are spent in line with expected use). The Office of the Inspector General of the Department of Health and Human Services wrote in its 1998 compliance guidance for hospitals that compliance efforts are to promote prevention, detection and resolution of conduct that does not meet legal or payor requirements or the organization's own policies. (Office of the Inspector General, HHS, 1998) For this study, compliance refers to programs within health care delivery systems that are built on the seven elements of a

compliance program, assess risks associated with privacy, security, fraud, waste, and abuse, and have oversight over the internal and external operations of the enterprise.

2. Health Care Innovation and Compliance, and the Tension Between

Health care innovation is no longer a luxury for organizations with large revenues or as a pet project of someone in the organization. Innovation in health care is expected, encouraged, and intertwined with many health care organizations' cultures and visions. Indeed, it is a business imperative encoded in the Patient Protection and Affordable Care Act of 2010 with the expectation that innovation can lower costs and raise both quality and safety. The Centers for Medicare and Medicaid Services created the CMS Innovation Center to do just that through tests of models of care delivery and payment in real time with real patients (About the CMS Innovation Center, 2016).

While the government lowers reimbursements and increases demands for measuring quality and safety, health care delivery organizations continue to face myriad other pressures on their businesses. These include labor shortages, an aging population – along with a millennial population that views health care differently from other generations, and a more informed and demanding consumer. Cost containment is an overriding concern for health care delivery systems as Medicare and Medicaid seek new payment systems (Ginsburg, 2013).

All these pressures are leading health care organizations of all types and sizes to engage in innovations to create a more efficient and less costly way to use technology, improve processes, and expand services. This includes public and private ventures, examples of which are below.

Public Efforts

HHS: Invent Health Initiative: “The Invent Health initiative seeks to empower inventors both inside and outside government to create tools for better living and better clinical care. When we say inventors, we mean anyone who designs, builds, develops creative physical solutions (objects, wearables, devices) with an eye toward improving the health of themselves and others... We also believe that the U.S. Department of Health and Human Services (HHS) can provide data and resources to help spark interest in high-priority areas that would benefit from fresh perspectives”

(<http://www.hhs.gov/idealab/invent-health-initiative/>).

CMS Innovation Center: “The Innovation Center was established by section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act). Congress created the Innovation Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures ...while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program benefits” (<https://innovation.cms.gov/about/index.html>).

AHRQ’s Health Care Innovations Exchange: “The U.S. Agency for Healthcare Research and Quality (AHRQ) created the Health Care Innovations Exchange to speed the implementation of new and better ways of delivering health care. The Innovations Exchange supports the Agency's mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work with the U.S. Department of Health and Human Services (HHS) and other partners to make sure that the

evidence is understood and used. The Innovations Exchange offers busy health professionals and researchers the opportunity to share, learn about, and ultimately adopt evidence-based innovations and tools suitable for a range of health care settings and populations”

(<https://innovations.ahrq.gov/about-us>).

Private Efforts

Forum on Healthcare Innovation: “To help push the national conversation about healthcare reform beyond its usual notion of innovation, Harvard Business School (HBS) and Harvard Medical School (HMS) have formed the Forum on Healthcare Innovation, a multifaceted effort to leverage the thought leadership and convening power of the two schools to create an interdisciplinary platform with influence greater than the sum of its parts”

(Forum on Health Care Innovation, 2016).

The Network for Excellence in Health Innovation: a nonprofit, nonpartisan health policy institute in Cambridge, Massachusetts, “dedicated to identifying innovations that improve the quality and lower the costs of health care”

(NEHI, 2016).

The Innovation Learning Network: an “organizational-based membership network made up of healthcare systems, health foundations, safety net providers, design/innovation firms, and tech companies... [with a] common goal to make healthcare better through good design” (The Innovation

Learning Network: About Us, 2016).

In his article, “The Discipline of Innovation,” Peter Drucker examines innovation from a business perspective, calling it “the means by which the entrepreneur

either creates new wealth-producing resources or endows existing resources with enhanced potential for creating wealth” (Drucker, 2013). Substitute “health” for “wealth” and the quote sums up innovation in health care fairly accurately – creating health via new resources or repurposing existing resources. Drucker further defines innovation as the “heart” of an enterprise’s activity – “the effort to create purposeful, focused change in an enterprise’s economic or social potential” (Drucker, 2013). It is here, in the creating of purposeful change in the enterprise’s potential, that a health care delivery organization strengthens its ability to serve patients with up-to-date techniques, workflows, and processes to deliver meaningful, patient-centered care.

Compliance in health care is no longer a luxury for organizations who want to stay out of the federal government’s radar. Compliance departments are expected to exist on a health system’s organizational chart. The requirement for compliance departments in organizations that receive federal monies started in the 1980s when graft and corruption were exposed in military contracts. Under the watch of the Inspector General for the Defense Department at the time, the defense industry suppliers created the Defense Industry Initiative for voluntary self-regulation, to eliminate waste and ensure appropriate pricing (Troklus and Warner, 2011). In 1986, the federal False Claims Act increased penalties, lowered evidentiary standards for liability, and eliminated barriers for whistleblowers. In addition, the Procurement Integrity Act tightened the use of proprietary data related to federal purchasing. In response, contractors created codes of conduct, established hotlines and implemented compliance programs (Levy and Bouquet, 2005).

The Inspector General for HHS has since begun a similar campaign within health care, to detect and prevent fraud and abuse and ensure the economy, efficiency,

and effectiveness of HHS programs and operations. In its guidance to health care governing boards, the OIG explains its recommended approach to health care compliance:

The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards. This responsibility includes the obligation to develop policies and procedures that provide employees guidance, the creation of incentives to promote employee compliance, the development of plans to improve or sustain compliance, the development of metrics to measure execution (particularly by management) of the program and implementation of corrective actions, and the development of reports and dashboards that help management and the Board evaluate the effectiveness of the program (Office of the Inspector General, HHS, 2015).

The OIG has been quite successful. In its 2016 Work Plan, it reported \$3 billion in recoveries for 2015 along with \$20.6 billion in saving for actions based on OIG recommendations. In addition, the OIG excluded more than 4,000 people from participating in federal health care programs, 925 criminal actions against people or entities, and 682 civil actions (Office of the Inspector General, HHS, 2015).

In 1996, The Health Insurance Portability and Accountability Act, which contains protections for a person's health information, became federal law. HIPAA has two parts: privacy and security. The privacy rule sets standards for the protection of identifiable health information by health plans, health care clearinghouses, and health care providers conducting electronic transmissions of health care information. The security rule sets standards for protecting health information that is held or transferred

electronically. It discusses the technical and nontechnical safeguards to secure health information (HIPAA for Professionals, 2016).

The outline of all compliance programs comes from chapter 8 of the Federal Sentencing Guidelines. Per Ferrell et al. (1998), the FSGs are “to self-monitor and police, aggressively work to deter unethical acts, and punish those organizational members or stakeholders who engage in unethical behavior.” (Ferrell et al., 1998) The guidelines list seven expectations of a compliance program (see Table I).

TABLE I.

THE SEVEN EXPECTATIONS OF A COMPLIANCE DEPARTMENT

Expectation	Description
Policies and Procedures	The organization shall establish standards and procedures to prevent and detect criminal conduct.
Board Oversight	The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.
Exclusions	The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct.
Training	The organization shall take reasonable steps to communicate periodically by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.
Monitoring and Auditing	The organization shall take reasonable steps to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct.
Reporting	The organization shall take reasonable steps to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.
Corrective Action	The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

Lastly, the compliance profession is increasingly seen as a discipline and a career option. The role of compliance officers within and outside of health care has grown and continues to do so. The Health Care Compliance Association for compliance professionals was established in the mid-1990s. It now offers various certifications in health care compliance including a general Certified in Healthcare Compliance recognition, as well as subspecialty certifications such as privacy, research, and ethics (Health Care Compliance Association, 2016).

Universities have begun to offer graduate certificates in health care compliance. The George Washington University describes the role of the health care corporate compliance officer as follows: “No other position can have so profound an impact on your healthcare organization's success—or failure.” It cites legislation such as the Health Insurance Portability and Accountability Act (HIPAA) and the federal Anti-Kickback and Stark Laws prohibiting self-referral and other conflicts of interest, as needing additional credentials in an “increasingly complicated field” (Graduate Certificate in Healthcare Corporate Compliance, 2016). Law schools are also promoting health care compliance. Seton Hall Law, for example, issues certificates in health care compliance as well as a master’s degree for compliance professionals (MSJ). The school also offers online programs in Pharmaceutical & Medical Device Law & Compliance, Health & Hospital Law, or Intellectual Property Law (Compliance Education for Working Professionals, 2016).

All health care delivery systems have someone designated as the compliance officers and larger systems will have an entire department of compliance professionals. At the same time, many large health care delivery systems have formalized innovation structures or procedures to encourage greater efficiency and effectiveness in the

workforce and for patient care. People within health care have differing opinions about the value of regulations when it comes to being innovative. Some see health care compliance as creating a box of regulations that everyone else must fit themselves in. Others contend that when compliance professionals emerge from “the box,” they provide value to the organization. Both disciplines, however, have their lenses on protecting and serving patients as best as they know how. It is the different focus of the lens that can create tension and disagreement on how to move forward as both an innovative and compliance organization.

Kanter refers to the “roadblock” to innovation not being human imagination and creativity but the complex system in which “most players have incentives for keeping their piece intact...” (Kanter, 2011). It is widely recognized that compliance, which in most of the literature is wrapped up in regulatory concerns, is a barrier to anything new and different (Omachonu and Einspruch, 2010; Faulkner and Kent, 2001; Herzlinger, 2006). Kanter contends health care needs to “hold innovations to an evidence standard — but without holding them hostage to resistant establishments” (Kanter, 2011). Others cite the opportunity costs because complying with regulations adds unnecessary costs to an innovation (Curtis and Schulman, 2006). Even Harvard’s Innovations in Health forum calls for “a more enlightened approach to regulation” and in its 2014 report states “unnecessary regulation intended to protect citizens... goes too far and adds cost and complexity” (Bloom and Chu, 2014).

Still others have a different perspective. Glenn Byrd, Senior Director of Specialty Care Promotional Regulatory Affairs at AstraZeneca, states: “When regulatory professionals embrace their role as an integrated team member, we are vested in the outcome’s success. It is only then that we can begin to think not just about risks, but

about opportunities and how we can achieve them. We become integrated in the strategic planning and vision of a project – and thus, become part of the solution, thinking broader, bigger, and creatively, while also navigating the risk” (Levins, 2016a,. Instead of running away from the regulatory parameters, inviting the compliance professionals to the table can encourage the innovator. Stephanie Boya, head of the EUCAN Digital Accelerator initiative at Takeda Pharmaceuticals, describes her approach: “For me, the best results come when my regulatory (compliance and legal) colleagues deeply understand what we are doing and why we are doing it. That’s why we must take them through the patient journey and explain our brand strategy...” (Levins, 2016a). Innovative regulatory professionals provide context, detailed examples and rationales behind decisions because this information can open the door for new solutions to emerge. “When regulatory professionals are fully knowledgeable about the key topics, they can effectively navigate the barriers and help formulate innovative solutions,” states Stacy Joseph-Reese, Director of Regulatory Promotional Review for Teva Pharmaceuticals (Levins, 2016b).

One federal regulation often blamed for constricting innovation – especially technical innovations such as mobile apps – is HIPAA. One section of HIPAA creates regulations related to privacy and security for protected health information. It sets national standards for electronic health care transactions, unique health identifiers, and expectations as to how electronic PHI is secured (Health Information Privacy: HIPAA for Professionals, 2016). Many innovators believe HIPAA is “inflexible” and “woefully out of date” and “doesn’t accommodate for advances in technology” (Lee, 2014).

At the same time, others view HIPAA as not an impediment but a rule-setting mechanism about the sharing of data and that it can actually spur innovation (Lee III,

2014; Raths, 2015). Ryan Panchadsaram, former Deputy Chief Technology Officer for the United States, contended in a TEDMED talk in 2013 that HIPAA “frees the data” and has led to innovations such as BlueButton, a technology that allows people to access their PHI securely online (Panchadsaram, 2014). Lee III (2014) contends blaming HIPAA for stifling innovation is a “cop out” and when properly implemented, it would “grease the wheels of innovation” by forcing the upgrading of IT systems, making them faster and more stable, and allowing the trusted sharing of data. He writes: “By embracing the HIPAA rule and truly understanding its meaning we can stop fearing what might go wrong and, instead, start dreaming about what might go so right” (Lee III, 2014). Fifield (2016) points out that “skirting a law to get your app in the App Store might seem like one badass move. But if the app in question is helping someone make health decisions, it’s not just animated GIFs on the other side of that screen.” (Fifield, 2016)

A different view of compliance is emerging—one that recognizes the “follow the rules” function but also recognizes the rules serve a purpose that not only inform the innovation process but provide a platform for spurring innovation. Many in the health care field believe compliance and regulatory professionals should be “perceived as strategic advisors providing the tools that people need to make the right decisions particularly in strong regulated, politically influenced and sensitive environments” (Levins, 2016a; Levins, 2016b; Interligi, 2010; Fifield, 2016). The easy part of being a compliance professional is saying no, but the value-added piece is partnering with other departments and functions and understanding the business, which can only help the organization become more innovative yet still protect the organization (Levins, 2016a; Lee III, 2014; Fifield, 2016; Richardson et al., 2013). Adam Richardson, an innovation

strategist, writes: “The key to spurring creativity isn’t the removal of *all* constraints. Ideally you should impose only those constraints (beyond the truly non-negotiable ones) that move you toward clarity of purpose. If a constraint enhances your understanding of the problem scope and why you’re doing what you’re doing, leave it in.” Fifield (2016) sums it up from a systems and patient point of view:

“Everyone should be served by experts who know exactly what they’re doing, regardless of the field they’re in. If someone can’t get their dialysis treatment because their broker messed up, that’s not okay. If someone’s medical history is leaked because a company thought HIPAA was too onerous, that’s not okay. We deserve more from our system.” (Fifield, 2016)

3. Models of Interaction

The tension referenced above is familiar to Scott Heisler, an innovation specialist with the Innovation Learning Network, a consortium of health care entities interested in innovation. He describes it as a dynamic in which the innovator fears the innovation will die or be killed by compliance policy and compliance fears they will be held accountable if something slips through their fingers. He sees a desired outcome of the two areas working together as: How can the innovation still be safe and not get us into trouble (S. Heisler, personal communication, Nov. 11, 2015). Mark Neu, vice president of compliance, audit and legal at Palomar Health, San Diego, describes his role as trying not to be the “skunk at the garden party” and needing to offer an alternative instead of just saying no (M. Neu, personal communication, May 5, 2016).

The question becomes, then, how do two groups of people with different foci yet the same outcome in mind (better patient care) work together in a way that is collaborative and not antagonistic. If they each have different perceptions and

expectations of the others' purpose and desired outcome, how do the two work in concert to innovate the best possible outcome for both the patient and the organization? Yet, if it is necessary for the innovation and the compliance professionals to work together to build a new service, process, or technology – and if the current relationships are fraught with tension and conflict – a model for interactions might provide a path forward for team members, leadership, and better patient care. To date, no one model has been identified as the ideal state as to how health care innovation teams and compliance departments interact or perform as teams.

Kathryn Stripling, a regulatory professional at Astra Zeneca, provides some guidance as to what could be important: “We should force ourselves to get out of our comfort zone. Informal meetings help us build relationships, eliminate misperceptions about the ‘regulatory professional’ and provide opportunities to share perspectives, discuss ideas and strategy early, and find out what’s coming. Once we have built relationships, it is more likely that business colleagues will see us as valued partners and feel more comfortable reaching out to us, and in turn, we will feel more informed and effective. Everybody wins” (Levins, 2016b).

Building those relationships might not be easy, and the characteristics needed to build those relationships might not be clear. A model of building relationships or enhancing team work between innovation and compliance could help organizational leaders and team members find the right path to more collaboration and less tension. To date, no one model has emerged in this area.

Because no model can be tested, basic research is needed to determine what factors or characteristics are contained within the relationship of innovators and compliance professionals. It is possible no current model will suffice, and, thus,

characteristics within several models that appear to fit the discussions above will be tested. This exploration, it is hoped, will either point to an established model or, at the least, provide insight to systems leaders in the types of characteristics to encourage during the innovation process and to build more collaborative teams.

The characteristics chosen will be those that align with what the literature, interviews, and experience has brought forward. Using Stripling's characterizations and the descriptions of the types of tensions described above, a few ideas that appear to be relevant are: Working in a continually evolving organization, conflict resolution, understanding others' views and scope, productive relationships in a complex systems environment, and the lenses from which the team members view the work and their part of the work. Using that, the following five models appear to hold some of those characteristics and are discussed in more depth in the next section:

1. Learning Organizations
2. Dimensions of Conflict
3. Mental Models
4. Generative Leadership and Relationships
5. Organizational Frames.

C. The Five Models

Based on the information shared in Chapters I and II, the following concepts emerged as consistent themes:

Innovation and compliance professionals have preconceived ideas about how the others act, react, and engage and/or different lenses through which they view the other.

"...unnecessary regulation intended to protect citizens... goes too far and adds cost and complexity" (Bloom and Chu, 2014).

"It's not as though there are no good ideas out there, but health care is often where good ideas go to die. At least part of the reason involves regulatory barriers..." (Raths, 2015).

“Compliance should compel you to do the impossible for your customer” (Fifield, 2016).

Innovation and compliance professionals appear to have different and perhaps oppositional ideas about organizational risk, and those differences can manifest in conflict or avoidance.

Many innovators believe HIPAA is “inflexible” and “woefully out of date” and “doesn’t accommodate for advances in technology” (Lee III, 2014).

“By embracing the HIPAA rule and truly understanding its meaning we can stop fearing what might go wrong and, instead, start dreaming about what might go so right” (Lee III, 2014).

Limited stories of success between the two appear to come out of relationships:

“For me, the best results come when my regulatory (compliance and legal) colleagues deeply understand what we are doing and why we are doing it” (Levins, 2016a).

“When regulatory professionals are fully knowledgeable about the key topics, they can effectively navigate the barriers and help formulate innovative solutions” (Levins, 2016b).

“When regulatory professionals embrace their role as an integrated team member, we... can begin to think not just about risks, but about opportunities and how we can achieve them” (Levins, 2016a).

Current organizational theories about how organizations can adapt to stay relevant focus on being adaptive and sharing knowledge:

Innovation is “the hallmark of American health care” (VHA Health Foundation, 2006).

This need to change one’s practice and business model will likely lead to more innovative ways to approach health care throughout the system (Kirzecky and Jones, 2013; Perry and Stephenson, 2013; Eng, 2004; McPherson et al., 2015; Cornett, 2015; Isham et al., 2013).

The search for relevant models focused on ones that related to these concepts. The concepts were not chosen to either prove or disprove these emerging concepts. Rather, they were chosen to provide theories that could be tested for against the data gathering and analysis.

As discussed above, it is not known which model or characteristics fit within an innovation – compliance relationship, multiple models will be reviewed as potentially valuable to develop a conceptual framework. A review of various organizational relationship models was conducted.

The criteria for the theories to be selected were created to be “neutral,” in that they were to be potentially explanatory to the emerging concepts, but varied enough that different aspects of the interactions could be studied. This avoided “group think” and researcher bias by leading the research in one direction or another as to what might be “most” explanatory.

They needed to relate to at least one of the concepts listed above.

They needed to inform the answers to the research questions. That is, they needed to focus on interactions and factors of those interactions and/or perceptions people or groups have of each other.

They needed to be well-researched via literature searches in peer-review journals.

They needed to provide a path for creating change in an organization, that is, not simply be explanatory as to the dynamics at play but provide insights into how an organization can change course, if needed.

They needed to be different from each other to avoid testing similar models, leading to biased results.

The five models discussed in this section and described in Table II (Learning Organizations; Dimensions of Conflict; Mental Models; Generative Leadership and Relationships; and Organizational Frames) have different frameworks of how multiple parties within an organization view each other, interact with each other, and create positive results for the organization. The five models below were examined based on their relevance to the concepts that emerged as themes in Chapters I and II.

These five models have commonalities in factors or characteristics, and might inform one or more of the emerging concepts listed above. However, they all approach interactions from a different lens (see Table II). It is hoped once these initial factors are tested, a framework can be

developed to assist the leaders of innovation and compliance to guide their respective teams toward creative and successful solutions, instead of wallowing in negativity and tension.

TABLE II.

THE FIVE MODEL STUDIED

Used to generate the theories and concept map to be tested with their model's main idea and the emerging concept it informs

Model	Main Ideas	Related Emerging Concept
Learning Organization (LO)	Organizations that survive focus on generative learning (creating), and adaptive learning (coping).	c, d
Dimensions of Conflict (DC)	Differences in what people believe. Can be productive, indicate the team is learning.	b, c
Mental Models (MM)	Mental models contain information people use to interact with the environment around them and allow them to describe, understand and predict that environment. Shared mental models are what team members use to describe, explain and predict the behavior of their team.	a, b
Generative Leadership & Relationships (GL)	Catalyzes innovation and creates a structure in which the team members can maintain positive and meaningful interactions in a complex environment.	c, d
Organizational Frames (OF)	Perspectives or lenses through which an employee, manager or staff interprets the activities around him or her. A way to make sense of an organization's social architecture and its consequences.	a, d
Table References		
Learning Organization (LO)	Senge (1990) Kontoghiorghes et al. (2005)	
Dimensions of Conflict (DC)	Heifetz and Linsky (2002) Rahim (2002) Song et al. (2006)	
Mental Models (MM)	Rouse et al. (1992) Mathieu et al. (2000) Jonker et al. (2010) Van den Bossche et al. (2011)	
Generative Leadership & Relationships (GL)	Surie and Hazy (2006) Lane and Maxfield (1996) Zimmerman and Hayday (2003)	
Organizational Frames (OF)	Bolman and Deal (1991)	

1. **Learning Organizations (LO)**

The concept of organizations as learning organizations has been part of the business lexicon since the 1980s and was first championed by Peter Senge via his book, “The Fifth Discipline” (Senge, 1990a; Fillion et al., 2015). Senge (1990b) believes organizations that survive are those that focus on “generative learning, which is about creating,” and “adaptive learning, which is about coping.” (Senge, 1990b) He envisions leaders as “designers, teachers, and stewards” and the employees as “continually expanding their capabilities to shape their future” (Senge, 1990b). The core capabilities for a learning organization are: building shared vision, personal mastery, working with mental models, team learning, and systems thinking (Senge, 1990a; Senge, 1992).

Kontoghiorghe et al. (2005) conducted a literature review for learning organizations and arrived at the following eight characteristics: (Kontoghiorghe, et al., 2005)

1. Open communications (Appelbaum and Reichart, 1998; Gardiner and Whiting, 1997; Phillips, 2003; Pool, 2000)
2. Risk taking (Appelbaum and Reichart, 1998; Goh, 1998; Richardson, 1995; Rowden, 2001)
3. Support and recognition for learning (Bennett and O’Brien, 1994; Griego et al., 2000; Wilkinson and Kleiner, 1993)
4. Resources to perform the job (Pedler et al., 1991)
5. Teams (Appelbaum and Goransson, 1997; Anderson, 1997; Goh, 1998; Salner, 1999; Strachan, 1996; Senge 1990a)
6. Rewards for learning (Griego et al., 2000; Lippitt, 1997; Phillips, 2003)
7. Training and learning environment (Gephart, Marsick, Van Buren, and Spiro, 1996; Goh, 1998; Robinson, Clemson, and Keating, 1997)
8. Knowledge management (Loermans, 2002; Selen, 2000)

In the literature, health care organizations and specifically hospitals have been described as learning organizations (Dias and Escoval, 2015; Ugurluoglu et al.,

2013; Persaud, 2014; deBurca, 2000; Ford and Angermeier, 2008). Dias and Escoval (2015) contend that hospitals are not just learning organizations but are learning organizations that can use such an approach to support innovation. They found a relationship between the level of the learning organization (hospitals rated basic, moderate or advanced on the learning organization index) and support for innovation. (Dias and Escoval, 2015).

Stevenson and Kaafarani (2011) describe innovation as being integral to an evolving organization, which aligns with Senge's vision of a learning organization as one that is creating. It is possible the characteristics of a learning organization would be relevant to an innovative health care delivery system. If an organization is to be both learning and innovative, the characteristics of a learning organization as outlined in Kontoghiorghes et al. (2005), could play a role in a smoother process and better working relationships.

2. Dimensions of Conflict (DC)

Conflict is part of any relationship, and within diverse organizational teams it is no different. Given the references in the environmental scan to conflict or, at a minimum, tension between health care innovators and health care compliance and regulatory professionals, it seems logical to have conflict management as part of the characteristics to be studied. According to Rahim (2002), conflict occurs when:

- A party is required to engage in an activity that is incongruent with his or her needs or interests.
- A party holds behavioral preferences, the satisfaction of which is incompatible with another person's implementation of his or her preferences.
- A party wants some mutually desirable resource that is in short supply, such that the wants of everyone may not be satisfied fully.

- A party possesses attitudes, values, skills, and goals that are salient in directing his or her behavior but are perceived to be exclusive of the attitudes, values, skills and goals held by the others.
- Two parties have partially exclusive behavioral preferences regarding their joint actions.
- Two parties are interdependent in the performance of functions or activities.

Rahim's strategies to manage such conflicts at work are:

- Minimize affective conflicts (interpersonal relationships) at various levels.
- Attain and maintain a moderate amount of substantive conflict (disagreements on task or content issues).
- Select and use appropriate conflict management strategies and behaviors.

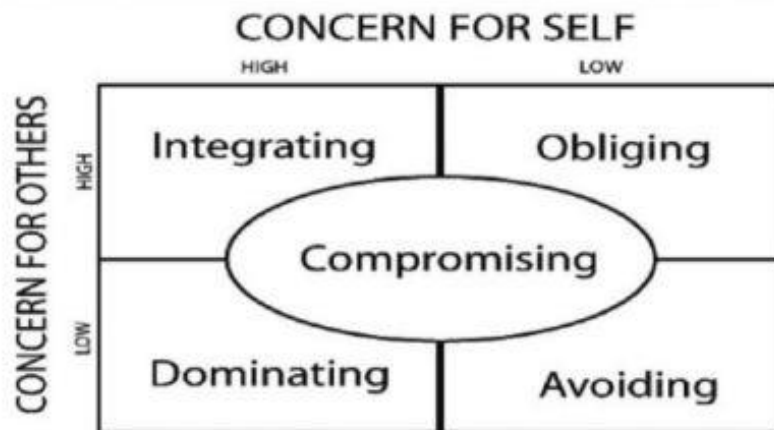
Rahim and Magner (1995) developed a model (see Figure 1) that looks at styles of handling conflict based on one's level of concern for self and concern for others: integrating, obliging, dominating, avoiding, and compromising. (Rahim and Magner, 1995) In Rahim's theory, a high concern for others along with a high concern for one's self leads to an integrating style in which both parties are equal and engaging.

In "Leadership on the Line," Heifetz and Linsky (2002) contend conflicts are, at their root, differences in what people believe and these differences "are the engine of human progress." (Heifetz and Linsky, 2002) They suggest leaders need to "constructively harness" the energy of conflict through four tactics:

1. Create a holding environment
2. Control the temperature
3. Set the pace
4. Show them the future

Senge and others have observed that visible conflicts are an indicator of a team that is continually learning and conflicts are productive in great teams (Fillion, et al., 2015). Song et al. (2006) studied conflict in terms of innovation and surmise that the different types of innovation (radical vs. incremental) and the types of tasks at early vs. late stages of innovation play a role in the type of conflict and potential for constructive vs. destructive conflict. (Song, et al., 2006) Given the tension between innovation and compliance discussed earlier, it is natural to assume discussions between those two areas include conflict in scope, process, tactics, and risk. It could be important for the team members and the leaders of those teams to find methods for positive discussion and resolution. It is those discussions and resolutions that might lead to a better and safer product, process, or technology.

FIGURE 1: Rahim's Dual Concern Model for Handling Interpersonal Conflicts (Rahim and Magner, 1995)



3. **Mental Models (MM)**

Mental models, team mental models, or shared mental models, have been studied as ways to understand a person and a team's learning behaviors, knowledge sharing, and performance (Rouse et al., 1992; Santos and Passos, 2013; Santos et al., 2015; Stout et al., 1999; Van den Bossch et al., 2011; Jonker et al., 2010; Mathieu et al., 2000).

The most common definition of mental models stresses they contain information people use to interact with the environment around them and allow them to describe, understand, and predict that environment. Shared mental models are what team members use to describe, explain, and predict the behavior of their team (Rouse et al., 1992; Mathieu et al., 2000; Jonker et al., 2010; Van den Bossche et al., 2011).

Researchers contend a team's performance is enhanced when team members "hold shared or common mental models of the tasks and team" and can predict team members' actions and needs (Mathieu et al., 2000; Jonker et al., 2010). Without "appropriate mechanisms" for creating expectations and explanations, Rouse et al. (1992) postulate team members might over communicate in what they are doing and why, or behave in ways that are counterproductive – such as not allocating resources well (Rouse et al., 1992). In reverse, they contend teams with shared mental models will:

- Be more accurate in predicting behaviors of other team members.
- Generate similar explanations for the same phenomena.
- Communicate less overtly but maintain performance.
- Be able to predict other team members' information requirements.
- Be able to sequence activities better without having discussions.

Along with Smulders (2007), Davison and Blackman (2005)-have looked at mental models in terms of innovation, particularly in terms of the knowledge generation, shared meaning, and activity. (Davison and Blackman, 2005; Smulders, 2007) Davison and Blackman's research reviews new knowledge through a lens of perceptions, and that as the new knowledge is shared, people must go through a process of reconciling it with their current knowledge to create newer knowledge. Furthermore, at the team level, this reconciliation results in creativity and innovation. If the reconciliation cannot occur, the prospect of discussions for better understanding exists simultaneously. He stresses that when managing innovation teams, creating and maintaining openness is critical and knowledge sharing and generation must be dynamic (Davison and Blackman, 2005). Although Smulders stresses product design and manufacturing in his analysis, the concepts have relevance in this context. Essentially, he argues that team members along the spectrum of the development and manufacturing process need to "engage themselves in all kinds of inter-team interactions that require specific transitional expertise in terms of understanding adequately" the mental models of the other side (Smulders, 2007).

As discussed in the background and literature review, innovators and compliance professionals have preconceived ideas about the other's point of view and how the other will behave. As Scott Heisler said, the innovator fears the innovation will die or be killed by compliance policy and compliance is scared they will be held accountable if something slips. Another person discussed that blaming HIPAA for stifling innovation is based on fear and not understanding. These mental models – that innovation professionals are out to break or change all the rules and

that compliance professionals are in the business of saying “no” – can create a wedge between these two areas. That wedge, in turn, can lead to poor, or no, relationship, or avoidance such as not inviting people to critical meetings. Such behavior, in terms of the business, leads to inefficiencies and roadblocks that prevent a new process, product, or technology from moving forward.

4. Generative Relationships and Leadership (GR)

Generative leadership has been recognized as one that supports and encourages innovation, adaptation, and performance, particularly in complex systems when the value of something cannot be seen in advance (Surie and Hazy, 2006; Lane and Maxfield, 1996; Zimmerman and Hayday, 2003). Surie and Hazy view innovation as a “social process” that develops from interactions and requires generative leadership to “catalyze”-innovation-and create a structure in which the team members can maintain positive and meaningful interactions within a complex environment. They describe an innovation team as needing “clear, stable rules and objectives” yet, in a complex system, the introduction of copious amounts of new information can overwhelm the team. They call on generative leaders to modulate the number of interactions to balance each team member’s ability to “perceive, interpret, and synthesize” knowledge but not be overloaded (Surie and Hazy, 2006)

London et al. (2012) take the generative concept to a different level, and calls teams with members who are experts in different fields regarding complex problems “generative groups.” They believe these generative groups are learning new skills and new knowledge, need the diversity of the members, and produce “innovative outcomes” (London et al., 2012). The leader’s role, then is to facilitate the process of team building so members are involved, feel empowered, and contribute to the

group. They find six elements of social cognition that group members and leaders need to develop and support:

1. Commitment
2. Interpersonal Congruence
3. Openness
4. Trust
5. Transactive memory
6. Collective Efficiency

Zimmerman and Hayday (2003) developed the generative relationship STAR model to describe and measure the generative properties of a team's relationships (see Figure 2). The length of the point of the star represents how well a team fits that description. (Zimmeran and Hayday, 2003)

S: Separateness or differences, with differences supporting generative relationships

T: Talking and listening; opportunities to challenge the status quo, sacred cows, or assumptions, as well as reflections

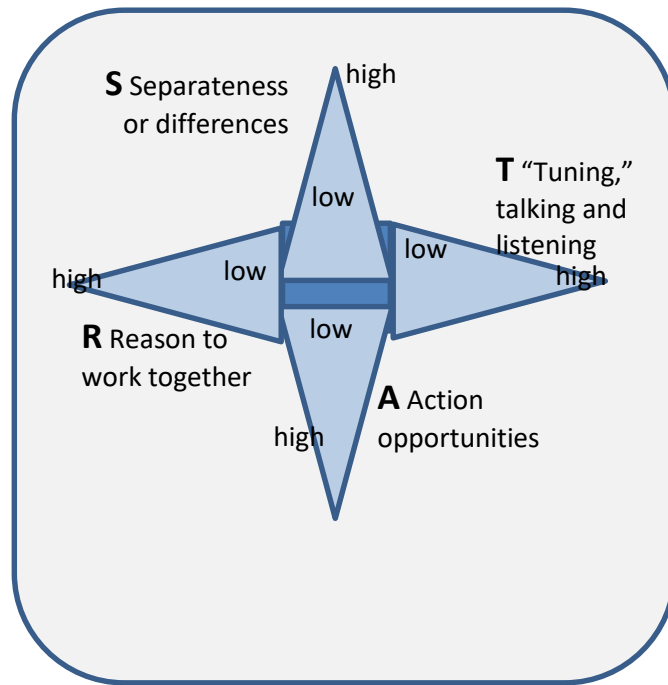
A: Action opportunities, i.e., the act of co-creating

R: Reason to work together, with a mutual benefit for all members and a reason to share

With generative relationships and leadership being held as a model that can catalyze innovation, and generative groups needing diversity, it seems likely that some characteristics of this model will contribute to the relationship between innovation and compliance. Looking at the STAR model, the need for diversity (differences), talking as well as listening, and mutual benefit seem to align positive

outcomes and could benefit teams of innovators and compliance professionals. It is possible some – or all – of these would be seen in the systems studied.

FIGURE 2: Zimmerman and Hayday's Generative Relationship STAR Model



(Zimmerman and Hayday, 2003)

5. Organizational Frames (OF)

Organizational frames can be viewed as perspectives or lenses through which an employee, manager, or staff person interprets the activities around him or her.

Bolman and Deal (2013) see frames as a way to make sense of an organization's social architecture and its consequences. (Bolman and Deal, 2013)

In one of their early works on this topic, Bolman and Deal describe organizations as “full of ambiguity, complexity, turbulence, and confusion,” which creates the need for people to filter experiences through a lens informed by their education, their experiences, and the limits of their memory. The authors discuss four frames found in most organizations—structural, human resources, political, and symbolic—which provide a way for someone to view a situation consciously and effectively (Bolman and Deal, 1991; Bolman and Deal, 1992; Bolman and Deal, 2013). Each “frame,” or perspective, espouses a different focus or emphasis of an organization. See also Table III

- Structural Frame: Effective organizations define clear goals, differentiate people into specific roles, and use policies, rules, and chain of command
- Human Resources Frame: Organizations that meet basic human needs will work better than those that do not
- Political Frame: Organizations have continual conflict and competition for scarce resources
- Symbolic Frame: The world is chaotic; meaning and predictability are social creations; and facts are interpretive rather than objective (Bolman and Deal, 1991)

TABLE III

THE FOUR FRAMES AND THEIR RELATIONSHIP TO MANAGEMENT (Bolman and Deal (2013)

Frame	Structural	Human Resources	Political	Symbolic
Metaphor for Organization	Factory/ Machine	Family	Jungle	Carnival, temple, theater
Central Concepts	Rules, roles, goals, policies, technology, environment	Needs, skills, relationships	Power, conflict, competition, organizational politics	Culture, meaning, metaphor, ritual, ceremony, stories, heroes
Image of Leadership	Social architecture	Empowerment	Advocacy	Inspiration
Basic Leadership Challenge	Align structure to task, technology, environment	Align organization to human needs	Develop agenda and power base	Create faith, beauty, meaning

Bolman and Deal (1992) promote the use of multiple frames and “reframing” during crises or when a complex situation feels overwhelming. (Bolman and Deal, 1992) A reframing is when a leader consciously uses multiple perspectives to assess a situation. A study of school administrators showed they use at least one or two frames in “critical” situations and the most used frames are structural and human resource (Bolman and Deal, 1991). Interestingly, in a separate paper, these authors contend modern organizations suffer from a “crisis of meaning and faith” and need the spirit and imagination from the symbolic frame and team building is “at its heart a spiritual undertaking” (Bolman and Deal, 1992).

The authors call on managers and leaders to adjust their frames based on any given situation, whether it be a crisis, a decision, or a stressful period. They suggest managers need to choose a frame that fits the situation and to understand other people's perspective using "analysis, intuition, and artistry" (Bolman and Deal, 2013). It is possible the conscious selection of one or more of these frames could help innovators and compliance professionals find common ways to work together and produce results. Schneiderman (2005) studied the relatively new use of public health nurses in the child welfare system using the four frames. The study found several areas within each frame that could enhance the nurses' abilities to participate in the child welfare teams. One was the structure not being in place for referrals to use their skills appropriately, which left the nurses unable to fulfill their ~~job~~ roles. Using the human resource frame, the relationship between the nurses and social workers was strained due to ~~by~~ mistrust and lack of recognition from the-social workers (Schneiderman, 2005). This points to the possibility that by looking at an organizational area of tension, such as innovation and compliance, a review through the four frames could elucidate specific adjustments needed either organizationally or interpersonally.

6. The Common Factors

As far as application to this study and to the work and interactions of innovation teams and compliance departments, no one model has been applied or studied. Health care innovation and health care compliance are relatively new disciplines in the modern sense, and this newness creates opportunity to research without many previous studies. Given the uncertainty of whether an established model would fit the interaction or whether a new model needs development, the initial steps to be

studied in this paper, are to create a lexicon to describe what occurs when innovation teams and compliance departments work together.

Each of the models share certain characteristics or factors with at least one, often more, of the other models. As these characteristics have already been recognized as important to these tested models, they will be pulled out and studied here. These include teams, knowledge management, satisfying the needs and expectations of constituencies, ethical management or a speak up culture, and allowance for a moderate amount of substantive conflict. Each is described below and supported by the models as outlined in Table IV.

TABLE IV
FACTORS CHOSEN FOR THIS STUDY AND THE MODEL
SUPPORTING THOSE FACTORS

	LO	MM	DC	GLR	OF
Teams	X	X		X	
Knowledge Management	X		X	X	X
Needs of Constituencies		X	X		X
Ethical Management	X		X	X	X
Substantive Conflict		X	X	X	X

a. Teams

All organizational projects require teams to execute. In complex systems, such as health care systems, teams from various departments of the organization meet to share, discuss, implement, and evaluate the project at

hand. According to the literature search, teams require members who can learn from the others and support the others. The organization requires teams that can work efficiently and share the goal of completing the organizational goal.

LO: Team learning is greater than those of all its members (Fillion et al., 2015)

LO: One person cannot understand and control all the dynamic environments (Geer-Frazier, 2014)

MM: Teams must adapt quickly and predict what teammates are going to do and need. (Mathieu et al., 2000)

MM: Teams with shared mental models have a common understanding of task goals, procedures, and strategies (Santos et al., 2015)

GLR: New products, services, ideas, etc., are created by interactions and relationships of a team (Zimmerman and Hayday, 2003)

GLR: It is not just the composition of the team and interactions but-how those interactions are managed (Surie and Hazy, 2006)

b. Knowledge Management

Knowledge management is the ability for an organization and its employees to gain, use, store and share information, and to use that information to improve and sustain the organization. Knowledge that is shared across departments, systems, and other boundaries is knowledge that is useful for creating, innovating, and improving the organization.

LO: Organizations need to be good at knowledge generation, appropriation, and exploitation (Fillion et al., 2015).

LO: A learning organization is . . . skilled at creating, acquiring, and transferring knowledge, and at modifying its behavior to reflect new knowledge (Garvin, 1993).

DC: One major objective of managing conflict is to enhance organizational learning that involves knowledge acquisition, knowledge distribution, information interpretation, and organizational memorization (Rahim, 2002).

GLR: Generative group members learn new skills and knowledge (London et al., 2012).

OF: In the symbolic frame, a team develops words, phrases, and metaphors unique to its circumstances that allows team members to communicate easily with few misunderstandings (Bolman and Deal, 1992).

c. **Satisfies Needs/Expectations of Constituencies and Attains a Balance**

A well-functioning, effective team has alignment and understanding between members and functions as a team, not a group of individuals occupying the same space. This alignment, while not conflict averse, can lead to team members understand better the needs of other team members. When a team member understands another team member's goals and drivers, it becomes possible to consider those in the planning processes, avoiding divisive conflict. It stems from communication and sharing. An aligned team can spend its energy on perfecting the outcome instead of managing internal strife and misunderstandings.

DC: Multiple parties can be involved in a conflict and conflict management should lead to collective learning and organizational effectiveness (Rahim, 2002).

MM: Shared mental models foster team effectiveness because they enable members to anticipate the needs and actions of others and adapt their actions to align with colleagues (Santos et al., 2015).

MM: Under conditions in which communication is difficult (e.g., workload, time pressure, etc.) teams are not able to strategize and shared mental models allow members to predict the information and resource requirements of their teammates (Mathieu et al., 2000).

OF: The human resource frame values relationships and feelings and focuses on the interaction between individual and organizational needs (Bolman and Deal, 1992).

d. **Ethical Management (speak up/advocacy/willingness to change mind)**

Ethical management refers to the ability and acceptance of team members to engage in inquiry and advocacy and the leaders' willingness to listen and keep an open mind. Almost all the models reviewed here emphasize the importance of people being able to ask questions and share feedback, and the importance of leaders being willing to change their minds – or change direction – based on the new learnings and the feedback. It seems intuitive that a group attempting innovation but doing so in an industry that has boundaries and limitations needs to be able to explore, question, and share

freely to ensure all potential avenues are considered and the best product emerges.

LO: Leaders in learning organizations need both inquiry and advocacy skills... [T]hey need to seek to understand the other's view (Senge, 1990).

DC: A leader should be open to new information and willing to change his or her mind (Rahim, 2002).

GLR: Discursive relationships are based on permissions for the participants to talk to one another... Unless potential participants have appropriately matched permissions, the generative potential of the relationship is blocked (Lane and Maxfield, 1996).

GLR: There needs to be opportunities to challenge the status quo, sacred cows, or implicit assumptions (Zimmerman and Hayday, 2003).

OF: In the human resources frame, a leader listens well and is unusually receptive to others' input (Bolman and Deal, 1991).

e. **Moderate Amount of Substantive Conflict (content disagreements to stimulate debate and greater understanding)**

When any group of people get together, conflict seems to be inevitable. The literature research for this study agree that some conflict is necessary to stimulate creativity, but it needs to be conflict about the product or process, not about the person sitting in the next chair. And, conflict needs to be respected by management and channeled toward positive change rather than internal backbiting.

MM: Shared mental models play a role in developing intra-group conflict by stimulating constructive conflict and avoiding disruptive conflict (Santos et al., 2015).

DC: Conflict management should enhance critical and innovative thinking (Rahim, 2002).

DC: A moderate level of substantive conflict stimulates discussion and debate and helps groups attain a higher level of performance (Rahim, 2002).

DC: Without some distress, there is no incentive to change; but it is necessary to reduce a counterproductive level of tension (Heifetz and Linsky, 2002).

GLR: If all the parties are similar, they might enjoy heated debates but leave untouched or unchallenged the assumptions on which both sides of the argument are based (Zimmerman and Hayday, 2003).

OF: In the political frame, leaders see conflict as a source of energy, not a cause for alarm (Bolman and Deal, 1991).

D. Conceptual Framework

The conceptual framework for this study needs to account for the separate work streams between innovation and compliance but address the times when those streams intersect. The framework must address the five models being studied and how their roles during such the interactions. It must also look at the influence of organizational culture or accepted behaviors, as well as the purpose of the interaction, which is better quality and safe patient care.

If:

- Innovation is a risk-taking discipline focused on rapid idea generation and testing
- Compliance is a rules-based and risk-based discipline focused on following external and internal laws, regulations, and policies
- Both innovation and compliance have optimal patient care as their focus
- Each has perceptions of the other that affect behavior and relationships with each other
- Some health care delivery systems have developed innovate processes, products, or technology and thus, by inference, have developed successful collaboration with compliance departments
- Current models of organizational teamwork and interaction could inform how the innovation teams and compliance departments build a successful model of interaction

Then:

- There might be certain attributes to the innovation-compliance dynamic that yields a better, more cohesive team to support a health care delivery organization's reaction to the environment that encourages innovation efforts
- The resulting concept map has three parts:
 1. The entire set of interactions, perceptions, and outcomes (Figure 3)
 2. The organization's accepted characteristics related to teams (Figure 4)
 3. The perceptions or mental models of the team members (Figure 5)

Figure 3. The Concept Map: How interactions and behaviors affect the ability to affect the change in patient care delivery.

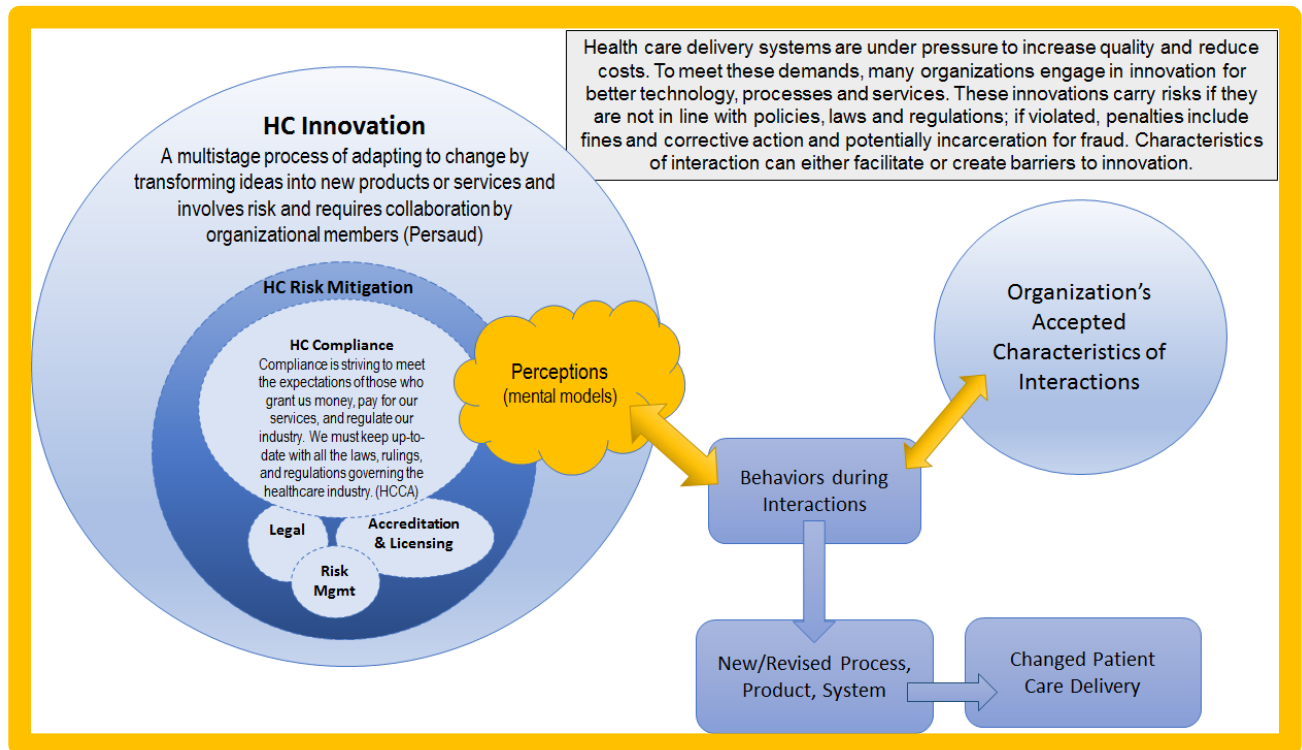


Figure 3. The Concept Map: Accepted or preferred characteristics and behaviors of teams

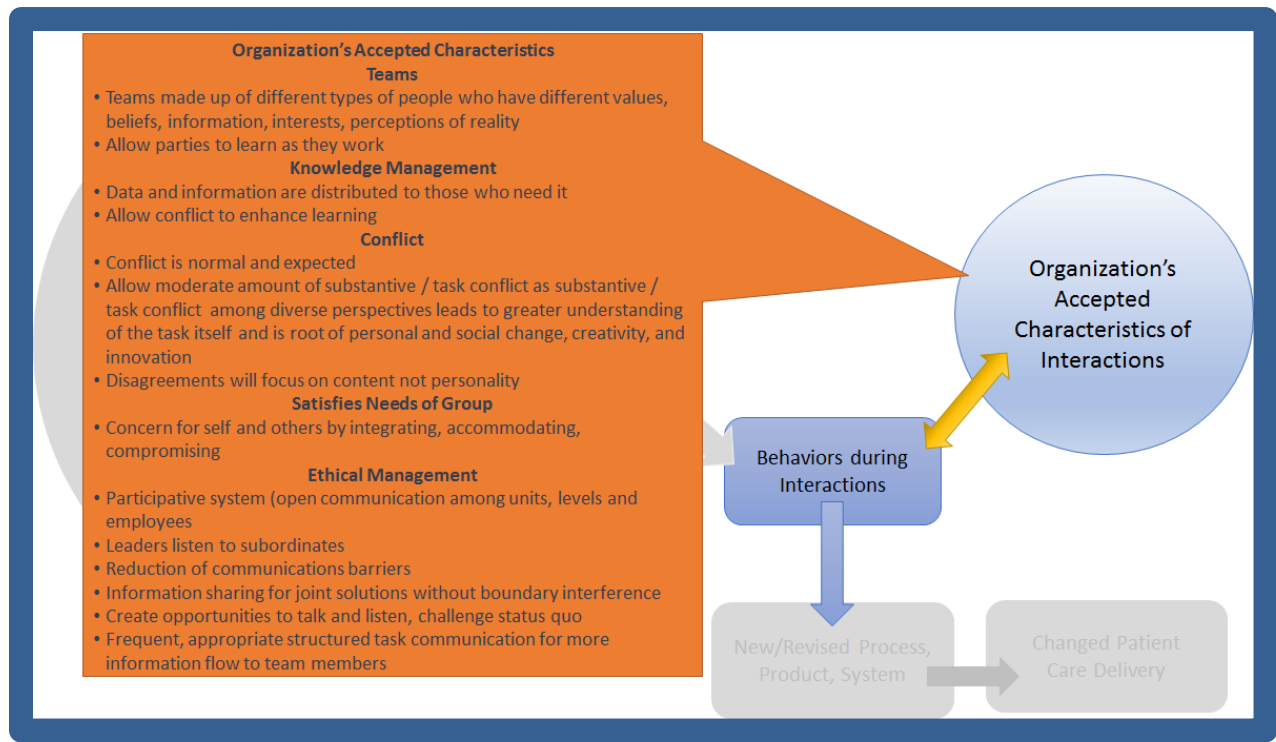
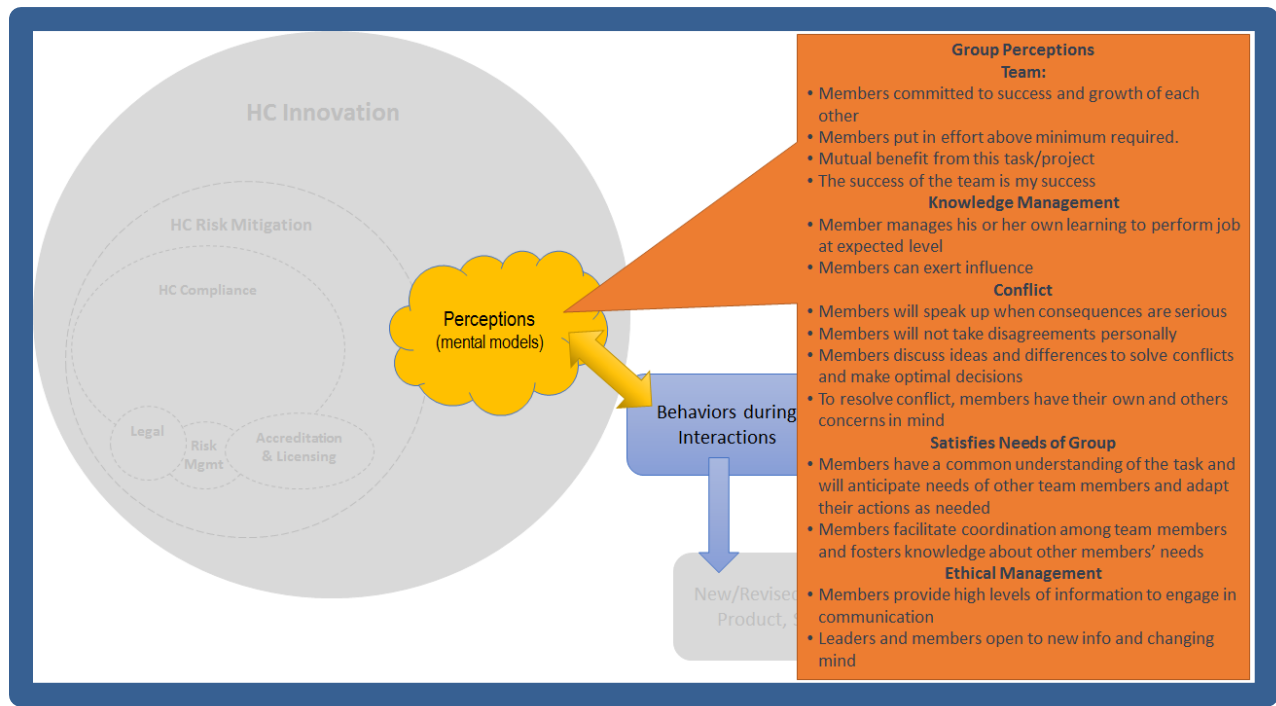


Figure 4. The Concept Map: Perceptions or mental models of other team members



III. STUDY DESIGN, DATA AND METHODS

A. Introduction

As mentioned in earlier sections, the main concept of this study – to explore the interactions of innovation and compliance professionals in-health care systems – had few previous studies to draw on for inspiration. While reviewing health systems and their innovation efforts, it became clear that each had set up its innovation efforts somewhat differently in terms of organizational structure and reporting lines. Some had operations directly under a chief innovation officer, whereas others smuggled innovation under business strategy or consulting lines. Some partnered with an outside organization to work on internal innovations. Several conducted innovation conferences and many marketed innovations that have risen from within.

Given the variety of organizational models and leadership roles, focusing on just one system might have provided a skewed perspective on a functional model of interaction. It was deemed that gathering information from several systems might have led to a pattern or set of similarities that could be extrapolated and combined into its own model or, at the very least, provide guidance to other systems on what characteristics or factors were being observed elsewhere.

B. Why a Qualitative Study

The characteristics, behaviors, and processes associated with innovation and compliance professionals interacting were more of a social phenomenon and how people do things rather than a data/numbers-driven, “how-many?” study (Miles et al., 2014; Rosaline, 2008). As Miles et al. (2014), state: those dealing with the social world, as opposed to physics, deal with “institutions, structures, practices and convention.” (Miles, et al., 2014) They described the qualitative research experience as registering processes by “making assertions and building theories to account for a real world... and to test those assertions and theories...” (Miles et al., 2014). Among what they call the “genres” of qualitative research was the following, which appeared to describe this study: “The researcher

attempts to capture data on the perceptions of local participants from the inside through a process of deep attentiveness, of empathetic understanding, and of suspending or bracketing preconceptions about the topics under discussion” (Miles et al., 2014)

Maxwell (2013) wrote the qualitative research design derives its strength from being “oriented toward the world” with an “emphasis on descriptions rather than numbers.” (Maxwell, 2013) As he described it, a qualitative researcher asks “*how* x plays a role in causing y, what the *process* was that connects x and y” (Maxwell, 2013). For this study, the second research question focused on the factors or characteristics that assist interactions between innovation and compliance professionals.

The range of qualitative methods included, among others, document review, observations, interviews, focus groups, and case studies. The one-on-one interview was considered the most common and was usually structured or semi-structured using open questions to elicit the respondents’ views (Rosaline, 2008). This study relied mostly on one-on-one interviews using a semi-structured approach with pre-defined questions, enabling the respondent to shape the discussion with his or her answers.

Another reason for utilizing qualitative research methods in this study was because the study requires flexibility in its emphasis. As Rosaline (2008) explained, qualitative research was iterative, meaning the research design, tools, and research questions might change. Thus, the “emergent hypotheses” can be tested (Rosaline, 2008). Given the newness of this topic and the assumptions by the author, it was not clear if the data would support the original theories. Maxwell describes five “intellectual goals” that qualitative studies supported. Table V aligns those intellectual goals with this study’s objectives.

C. Analytical Approach

To explore the types of perceptions and interactions between the innovation and compliance professionals in a large health care delivery system, this study employed an exploratory case study using two phases. Exploratory research can be used for a “new or relatively under-researched topic” to learn about that topic, such as the absence of adequate research. It can help “fill a gap” or provide an approach from a “different perspective to generate new and emerging insights” (Leavy, 2017). Stebbins (2011) stated regarding exploratory research: “Researchers explore when they have little or no scientific knowledge about the group, process, activity, or situation they want to examine but nevertheless have reason to believe it contains elements worth discovering.” (Stebbins, 2011) As noted in Chapter II, research on the topic of this dissertation was scarce. Maxwell (2013), who calls these types of studies “pilot” or “exploratory,” used them to test one’s ideas, ~~or~~ methods, or inductively develop grounded theory. He added that it causes the conceptual framework to change, often as a result of learnings during the study. (Maxwell, 2013)-Reiter (2017) contended exploratory research “seeks to provide new explanations that have been previously overlooked” and accomplished this through “a process of reformulating and adapting explanations, theories, and initial hypotheses inductively.” Such changes in the theories and framework presented in Chapter II are expected in this study due to the qualitative nature of the study and the newness of the topic as the subject of a researched paper.

TABLE V.

MAXWELL'S INTELLECTUAL GOALS AND HOW THIS RESEARCH STUDY
ADDRESSES THOSE GOALS

Intellectual Goal	Current Study Objectives
Understanding the meaning, for participants in the study, of the events, situations, experiences, and actions they are involved with or engage in.	<p>Research Question 1: How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems?</p> <p><i>This study seeks to understand what was occurring during interactions between innovation teams and compliance professionals as they seek to create new opportunities for their organization.</i></p>
Understanding the particular contexts within which the participants act, and the influence that this context had on their actions. Qualitative researchers typically study a relatively small number of individuals...	<p>Research Question 2: In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance professionals?</p> <p><i>This study seeks to find out what and how innovation teams and compliance professionals perceive each other health care systems that promote its innovation commitment.</i></p>
Understanding the process by which events and actions take place.	<p>Research Question 2: In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance professionals?</p> <p><i>This study seeks to understand what the organization does to ensure the interactions between innovation teams and compliance professionals are positive and move the projects forward efficiently.</i></p>
Identifying unanticipated phenomena and influences, and generating new, "grounded" theories about the latter.	<p>Research Question 1: How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems?</p> <p><i>The theories and conceptual framework of this-study are untested for this environment (innovation and compliance). It was expected and planned for unanticipated data to emerge, generating revised theories and conceptual frameworks.</i></p>
Developing causal explanations (the actual events and processes that led to a specific outcome).	<p>Research Question 2: In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance professionals?</p> <p><i>The concept map indicates a linkage between perceptions and factors and innovation outcome. The study will test the theory behind this linkage in an attempt to create a causal explanation.</i></p>

In his discussion of exploratory social science research, Reiter (2017) described exploratory research as focusing not on outcomes or results of human behavior but on the causal mechanisms that underlie and produce social mechanisms – the “why” and “how” something happened. (Reiter, 2017) All this, he states, required recognizing any explanation comes from a theory held by the investigator. According to Maxwell (2013), exploratory studies provide “an understanding of the meaning that these things, actions and events have for the people who are involved in them” and if they are not understood, the theories “will often be incomplete or mistaken.” (Maxwell, 2013)

The topic of this study, then, fits with the premises of exploratory research stated above:

- A lack of adequate research specific to this area this filling in a gap.
- 4. Little or no scientific knowledge of the groups, processes, or activities, although anecdotal and personal knowledge was available.
- 5. Focus on the causal mechanism (the factors of interaction) to explain how and why, not an outcome.
- 6. The need to perhaps reformulate and adapt theories or explanations as the data emerges.

Large health care delivery systems in the United States with an innovation focus were purposefully selected. A large system would be a system with one or more hospitals and a wide reach in the community via clinics, with thousands of staff and physicians. The systems will be “exemplars” of health care system innovation, and the path to finding exemplars was explained in detail below. As Maxwell (2013) asserted, using a comparison of successful vs. less proficient teachers, the exemplary teacher was not as likely to be defensive about discussing their teaching and might be more eager to share what they do than a teacher who might be worried about revealing inadequacies. He goes on to write that this “can be one reason... for focusing your study on successful individuals and practices...” (Maxwell, 2013).

The initial selection of systems was purposefully culled from three sources focusing on the innovation aspect, as compliance was assumed to be present in all care delivery organizations:

1. *Members of Innovation Learning Network (ILN)*: The ILN was a network of health care systems, health foundations, safety net providers, design and innovation consultants, and technology companies that meet regularly to discuss and share health care innovations and to “make healthcare better through good design.” The organization was based in Northern California, but had members from around the United States (www.iln.org).
2. *Becker’s Hospital Review* article of top Chief Innovation Officers: *Becker’s Hospital Review* contains hospital and health system business news and analysis. In July 2016, it published a list of 15 chief innovation officers at hospitals and health systems. This provides insight into the systems that would have an innovation focus and could provide information for this-study (Jayanthi and Pallardy, 2016).
3. *General research or personal knowledge of the principal investigator*: Via conferences and events hosted by, for example, the California Hospital Association and the HCCA, the author had met people at health systems involved in compliance or innovation and had personal knowledge of some systems that could be considered.

Using these sources, reviewing data regarding the system’s size and considering the ease of finding contacts, 24 systems were selected for initial review (see Appendix A). To further select systems with active and accessible innovation programs, each of the 24 was reviewed in more depth using the following criteria:

- Mentions innovation multiple times in the organization’s annual report, mission statement, or vision statement: This criterion demonstrates an institutional

commitment to innovation, as it was embedded in the core of the organization's identity.

- Has a dedicated innovation center, department, or team that was publicly facing (e.g., Web site available to external people): This criterion demonstrates the organization had an active innovation program robust enough to share with the public. That is, the organization believes the innovation program produces results the organization can be proud of and want to share. It also demonstrates a sustained innovation effort, in which the organization has enough background, history, and results to build a forward-facing e-presence.
- Conducts innovation seminars, conferences, or other public-facing events: This criterion demonstrates an involvement in the innovation community, in which the organization's innovation professionals shared ideas and content for the betterment of the entire health care community.

Eliminated from this list were systems that did not provide easy access to their innovation information online (i.e., it was not publicly available through simple searches). This was for three reasons. The first, a practical one, was that not having such information made initial background research difficult and time-consuming when other institutions were making such information easily attainable. Second, in the spirit of health care as a public service, being secretive about innovation does not enhance the population health care experience in the United States, or elsewhere. Third, it was assumed that systems with open information about their work would be more willing to participate in a research study and share details about how their organization operates and their people conduct themselves. This narrowed the selection to nine systems (see Appendix A).

Maxwell (2013) cited five goals for purposeful selection (Maxwell, 2013):

1. *Achieving representativeness:* These systems were all typical of large, complex health care delivery systems with inpatient and ambulatory services spread over a large area (some multi-state) They were stand-alone systems, and the link between them was the dedication to health care innovation while continuing operations delivering care. They each had a leadership supporting innovation efforts, they provided dedicated resources to the innovation efforts, and they participated in the health care innovation community.
2. *Achieving heterogeneity:* While these are all large U.S. health care systems with a focus on innovation, they also had differences. First, the geographic spread was across the United States. Second, they were structured differently; some had chief innovation officers, others used a business strategy executive as oversight. Some served specific populations, e.g., pediatrics, while others served populations of all types. Some had associated physician groups. Some also provided health insurance.
3. *Systems critical for testing the theories:* The study of systems embracing health care innovation necessitated studying systems with a strong presence of innovation. Studying the perceptions and interactions of health care system innovation and compliance professionals required systems that have robust innovation teams and compliance departments. The systems selected for this study included innovation in their vision or mission, have created an environment that supports innovation projects, and to meet federal regulations, and had developed a compliance program dedicated to the seven elements of a compliance program.
4. *Establish productive relationships:* Discussions with subject matter experts in preparation for the dissertation confirmed this topic was of interest to both innovation and compliance professionals. Although none of the subjects was well known to the

author, at least one was known from attending the same compliance conference.

Additionally, given the open nature of the innovation work at each of these systems, it was believed the organizational leadership might be willing to discuss their work to contribute to the field.

Both innovation and compliance professionals were interviewed. Each provided a perspective on the perceptions (research question one) and interactions (research question two) from their knowledge base. Each spoke to his or her perspective, and the perspectives of their teams, and how they saw the two interacting, as well as what kind of environment they created to encourage such interactions. Because this study was exploring the perceptions and characteristics of relationships, it was important to obtain data from both innovation and compliance experts to understand similarities and differences from each vantage point, to determine alignment – or the lack thereof.

D. **Data Sources, Data Collection and Management**

For this qualitative study, up to nine innovative health care systems in the United States were studied to determine the interactions between innovation and compliance professionals and what factors or characteristics were found in those systems. These characteristics can then guide other health systems to develop similar characteristics of interactions so they, too, had the potential to be innovative health care providers. As Maxwell (2013) stated, however, in qualitative studies, the research must “continually assess” how the design was working during the research and make adjustments and changes as needed. (Maxwell, 2013)

The study was conducted in two phases. Phase 1 collected baseline data to identify perceptions and models of interaction between compliance and innovation professionals via one-on-one interviews with innovation and compliance experts from the selected health systems, or people who consult with those firms about innovation or compliance. Documents from the selected health

systems that inform the study were reviewed. Phase 2 dove deeper into findings than Phase 1 with re-interviews of the health system professionals.

1. Data Sources

The data collection occurred in two phases. Phase 1 consisted of semi-structured interviews with a representative sample of experts along with review of primary source documents. The experts were either employees of large health systems with dedicated innovation centers or consulting experts. Experts from the consulting services provided intimate knowledge of the systems from a more removed lens. Phase 2 consisted of additional one-on-one interviews with the health system subjects to discuss major themes from Phase 1.

Of note, the systems were chosen at the organizational level and aligned with the research questions that were at the organizational level. However, the data were collected from individuals at those systems. The results were gathered and analyzed at an individual level to inform the questions about the factors of interaction to answer the research question. This discrepancy cannot be resolved within the scope of this study but was worth noting for either its impact on the results or for future studies.

Phase 1 involved one-on-one interviews with content-experts, or key knowledgeables, supplemented by original source documents. Interviews with consultants were conducted if they had-direct knowledge of the topic. Key knowledgeables were-people knowledgeable about a topic and who shared to provide insights into root problems, identified trends, or identified future directions (Patton, 2015). As many interviews as possible were conducted with different people. The total was limited by the willingness of subjects to participate or until the responses became homogenous enough that new information was not provided. If a new theme emerged

or the theory changed during or after the data analysis, subjects were re-contacted to discuss the new theme or to test the new theory. Those interviewed received no remuneration and were de-identified in the final product.

Documents from each system were requested but it was expected innovation and compliance documents (policies, strategic plans, meeting minutes) might be seen as proprietary, privileged, or confidential and thus could not be shared outside of the organization. Other documents more easily obtained could include widely published annual reports, blogs, or white papers.

The interview questions were written so as to uncover characteristics related to the perceptions and experiences of the innovation and compliance teams at the health care delivery systems. The structured questions will focus on eliciting responses focused on the characteristics associated with perceptions and interactions between innovation and compliance professionals to see if the characteristics align with those culled from the studied models and if they support the concept map. Within each system selected, at least one compliance and one innovation professional was contacted. Those interviewed were asked about others within their system who might have insight and be willing to be interviewed.

Subjects were contacted via an e-mail describing the study and request for interview. Follow-up telephone calls were placed to find a date and time for the interview. A consent form was provided and returned before an interview took place. A draft of interview questions is in Appendix B. The questions were designed to focus on the study's goals and framework around the characteristics of perception and interactions, but not so focused that new characteristics or themes did not emerge. The questions were inductive, in that they were based on personal experience of the

investigator, informal discussions with participants in health care innovation and compliance, and research into various models of interaction (Maxwell, 2013).

The subject was anyone in a managerial role, up to and including a system's chief innovation officer or compliance officer. The chief innovation officer role was fairly new and had responsibilities toward developing innovative products and processes, which includes developing personnel to be innovative and supporting the business units involved in innovation (DiFiore, 2014; Euchner, 2013). A talent recruiter described the role as creating a culture of innovation-in which participants are "delighted to be facilitators" and "recognize it was the ecosystem that really enables a company to scale an innovation..." (Euchner, 2013). A chief compliance officer also works at a strategic level. According to the International Association of Risk and Compliance Professionals, a chief compliance officer was the "architect and steward of enterprise compliance strategy, structure and processes" (Chief Compliance Officer, 2016). He or she oversees the compliance functions of an organization, primarily ensuring the organization and employees – including executives – comply with regulatory requirements and internal policies and procedures to prevent, detect, and mitigate noncompliance (Chief Compliance Officer, 2016; Tabuena, 2006).

It was preferred to interview at least one person in each discipline from each system. Multiple attempts were made via telephone or e-mail or, if possible, via an intermediary who knew the individual and could intercede. Data from only one source, however, was valuable to this study, as it was an attempt to provide a baseline of information on which a model might be built or tested for future work. In addition to interviews, other sources were interviewed, including consultants who worked specific to

each industry. This provided a more neutral perspective on how innovation and compliance interact at a systems level.

During each interview, the subject was asked if he or she had any documentation to share to assist in the study (see Table VI). These could include:

- Protocols and policies related to innovation processes and organizational behaviors: Some of the systems in this study had policies related to innovation processes. Other policies or codes of conduct might outline expected behaviors in team settings or how people are to relate to each other.
- Team charters: Teams sometimes used team charters to structure the work. These charters included items such as team members or departments represented, the scope of the work, how disagreements were resolved, and process flows for the project.
- Executive notes or directives: Organizational executives also could have written memos or directives that would outline work scope or behavior expectations.
- Documents in print or online, or transcripts of presentations: There was information on the innovation Web sites that indicated processes or procedures used – such as how barriers are uncovered and overcome – or how the different departments interacted during the development of the innovation.

All of the above documents, except for the last one, were available only if released by the study subjects. Each subject who provided data via interview or documents was contacted before publication to verify the interpretation and accuracy of the information being used in the dissertation either via telephone call or e-mail.

TABLE VI

POSSIBLE SOURCES OTHER THAN PERSONAL INTERVIEWS

	Policies	Codes of Conduct	Project Scope	Departments Involved	Dispute Resolution
Policies and Protocols	X	X			
Charters		X	X	X	X
Executive Memos/ Directives		X	X		X
Web sites			X	X	

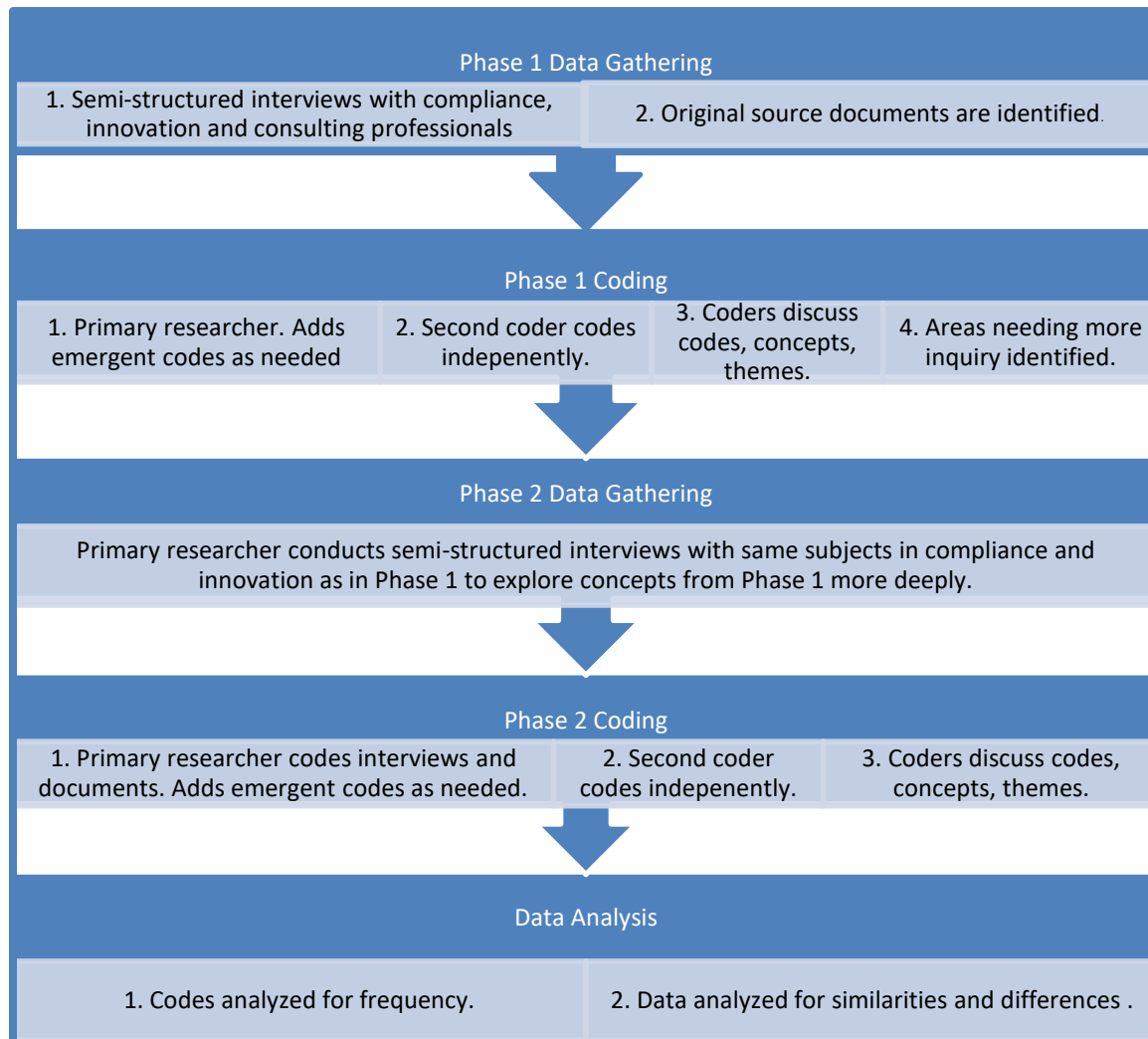
Phase 2 was used to explore more fully and in more depth the findings from Phase 1. Subjects from the first Phase were re-interviewed with a focus on specifics about what was learned about the perspectives and why certain characteristics appeared more frequently. They were asked for examples of times when they experienced the concepts being discussed either in a positive or negative way, with an exploration of what occurred and their thoughts about why it occurred. They were all asked about how the system supports or inhibits their work. See Figure 6 for the data gathering and analysis process.

2. Data Management

The interviews were scribed in a Microsoft Word document. The same interviewer – an experienced journalist – was used for each interview. This enabled the capturing of responses to questions and creating “on the fly” questions that could be appropriate, given a response to a structured question. After each conversation, the interviewer “memoed” reflections, connections to previous interviews, and themes that appeared to emerge, or added particular emphasis by the subject that might not come through in a

typed transcript (Patton, 2015; Rosaline, 2008). The interviews were in a password-protected folder on a secure drive using a computer with up-to-date malware detection. The documents included dates and mode of the interview (all were via a telephone). Consent forms were held in the same password-protected folder. The interview transcriptions and memos were uploaded into the analysis tool ATLAS.ti 8.0. Any documents were saved on the same secure drive and backed up securely. The information in the documents was-not used for any purpose other than this dissertation and will not be shared outside of the dissertation committee without permission from the subject(s). Any quoted material was credited as to the area of expertise of the person quoted (i.e., innovation professional or compliance professional).

Figure 5. Data gathering and analysis process



3. Data Analysis

The themes from the concept map and the pre-identified characteristics of perception and interaction were used to develop a codebook (see Appendix C). The initial codes stem from the theory behind the research questions – that the perceptions and interactions of innovators and compliance professionals affects the ability to be an

innovative health care system. Codes are organized by the main factors as discussed in Chapter II: teams, knowledge management, satisfying the needs and expectations of constituencies, ethical management or a speak up culture, and allowance for a moderate amount of substantive conflict. It is possible the themes or codes created before data collection will either need to be expanded, combined, or refined once the data is examined. Any new themes or codes were discussed thoroughly in Chapter IV as to why and how they have been included.

A coding protocol was created for reliability, and each interview will have a primary and secondary coder. The coding will take place separately but was monitored for consistency. ATLAS.ti 8.0 was used by both coders to ensure consistency via the coding tool.

Initial review of the interviews from each Phase will include a cross-interview analysis. This involves grouping the answers from the subjects by question for patterns, themes, or common factors (Patton, 2015). Rosaline recommends “worrying away” at the data, using an iterative process of rereading the data to continually recode and revise codes (Rosaline, 2008). Grids were used to segment the data and the subjects to see if there are any patterns based on demographic-type data. Rosaline (2008) recommends this as a way to see where exceptions might come from or to see if a particular demographic was more likely to support or negate a particular pattern. In an example, focus group responses are categorized by the codes and segmented by women, men, physician, midwives, or all respondents (Rosaline, 2008). This study will compare responses by title or expertise (i.e., CIO or CCO) as well as by female vs.-male.

4. Validity

Guided by Maxwell (2013) and Patton's (2015) concepts of validity, three validity threats were reviewed – researcher bias reactivity and construct, and two validity tests i.e., respondent validation and discrepant data or evidence (also known as negative cases). Also discussed here was external generalizability. (Maxwell, 2013; Patton, 2015)

Researcher bias: Maxwell (2013) describes research bias as the “selection of data that fit the researcher's existing theory, goals, or preconceptions.” For this study, given the author's closeness to the field and assumptions about how successful teams work, it was possible for researcher bias to enter the analysis. A second coder, along with scrutiny by the dissertation committee, will help reduce any potential bias.

Reactivity: Reactivity refers to the effect of the researcher on the setting or individuals studied. Maxwell (2013) believes reactivity was common in studies using interviews as the informant was “*always* influenced by the interviewer and the interview situation” (his emphasis). It was important to avoid leading questions or focus on responses that fit the conceptual model instead of those that offer alternative views. Transcribing both questions and answers in the semi-structured interviews will assist in reflecting on the questions and the way they are worded as a potential influencing factor. Alternative hypotheses were developed, and the data were reviewed to see if the alternative hypotheses are supported (Patton, 2015).

Construct validity: Construct validity looks at the cause-and-effect constructs in a study and requires a “clear, concise conceptual definition of the focal construct(s)” (MacKenzie, 2003). Cronbach and Meehl (1955) state: “The best construct was the one around which we can build the greatest number of inferences, in the most direct fashion.” As discussed above regarding this being an exploratory study, there was a

cause-and-effect explanation for the interactions being sought (Cronbach and Meehl, 1955; Maxwell, 2013; Reiter, 2017). According to Westin and Rosenthal (2003), “Researchers typically establish construct validity by presenting correlations between a measure of a construct and a number of other measures that should, theoretically, be associated with it (convergent validity) or vary independently of it (discriminant validity).” (Westen and Rosenthal, 2003)

Westen and Rosenthal (2003) propose construct validity had two main points: 1) construct validity was an estimate of the extent to which variance in the measure reflects variance in the underlying construct, and 2) construct validation was always theory dependent (Westen and Rosenthal, 2003). Cramines and Zeller (2011) state construct validity requires “a pattern of consistent findings involving different researchers using different theoretical structures across a number of different studies.” (Cramines and Zeller, 2011) Due to the newness of the theory in this study, construct validity might be difficult to confirm. The primary investigator through coding and using a second coder will attempt to create valid inferences from the data. The conceptual map developed at the beginning of the study also outlines specific components based on the five models to be tested against.

Respondent validation: This validity test that entailed ~~was~~ “systematically soliciting feedback about your data and conclusions from the people you are studying” (Maxwell, 2013). Maxwell states it was the most important method of ensuring responses are not misinterpreted. Those interviewed were consulted after the initial interviews should their responses generate potential misinterpretations.

Discrepant data or evidence: Patton (2015) recommends searching the exceptions to any patterns that emerge from the data (i.e., discrepant data or evidence),

as a way to “broaden understanding of the pattern, change the conceptualization of the pattern, or cast doubt on the pattern.” (Patton, 2015) Rosaline (2008) refers to this as “the analytic potential of exceptions” and an “uncomfortable gray area” that must be considered and used to refine the theory of the study. (Rosaline, 2008) Data that support the conceptual model and data that do not support the conceptual model were assessed to ensure all data are considered in the analysis.

External generalizability: Whether the research results from this study can be generalized to external health care delivery systems cannot be guaranteed. Each system had its own culture and strategies which could impact if and how teams could adopt these findings. In addition, generalizability could depend on the system’s structure, that was, having a chief innovation office and a chief compliance officer and being of similar size. It could also depend on whether the system had a formalized innovation effort or approaches innovation on an individual idea basis. However, for systems that resemble those in the study, the results here could lead to examining their teams’ perceptions and interactions and make changes that match those of these exemplar organizations.

5. Limitations

The limitations of this study include the selection of the health care systems, the response rate of the subjects, and the unknown nature of the work. First, the selected systems appear to be somewhat homogenous in their size and dedication to health care innovation within their organization. It is possible other systems have additional themes or contrary information that could be considered in the analysis. The subjects could refuse to be interviewed, and those ultimately interviewed could create a self-selection bias. Finally, the characteristics under consideration have not been tested for this

purpose and there could be characteristics that are not addressed, or characteristics are studied but not useful to the innovation work.

6. Dissertation Product and IRB Status

Once the dissertation proposal was approved by the committee, the review process began. The study was subject to the Institutional Review Board of the University of Illinois at Chicago. Included was a consent form each subject was asked to complete and sign before an interview. This consent form was based on one from the UIC Office of the Vice Chancellor of Research (and a release of documents agreement, in case the subject provides any written or softcopy material.

This dissertation had a traditional format, which included an oral defense. The final manuscript was formatted per the UIC DrPH Thesis Manual. Per UIC requirements, the manuscript was screened for appropriate citations by *iThenticate* before the defense. The dissertation committee included the required members as dictated by the UIC School of Public Health's DrPH Program.

IV. RESULTS

A. Introduction

Chapter 4 shows the study results from two sets of interviews and the primary source documents. The transcripts and primary source documents were coded by the principal investigator and a doctoral level student in public health. All the coding results were then analyzed. The analysis is discussed as they related to the research questions. A group of peer-review documents were coded in the same way and used for triangulation. The research questions are:

Research Question 1: How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems? What perceptions (mental models) does each have of the other? In what ways do the interactions reflect the perceptions?

Research Question 2: In large health care systems with dedicated innovation resources, what factors are most common in interactions between the innovation and the compliance departments?

Chapter 4 shares the analysis process and results. It is noted that the research questions are based at a systems or organizational level. The primary data, however, is gathered at the individual level. The individual data, thus, provides insight into the organizational methods and processes but does not necessarily speak for the organization. This tension remains unresolved for this study. However, given the status of the people interviewed (director level or above), who might be closer to the organization's strategic and cultural influencers, it is believed the interview data – to some degree – reflect the organization's values regarding work relationships and interactions.

The analysis results revealed a select number of codes that were used more frequently and concepts that emerged more prominently. This led to grouping the results into four themes:

- A. The Influence of Leaders and Executives
- B. Innovation as a Mission Statement and Business Objective
- C. The Need for Relationship Building and Teamwork
- D. The Organization Operates as a Learning Organization.

As discussed in Chapter III, this study was exploratory as the interactions between innovation and compliance professionals is a “new or relatively under researched topic” and there is “little or no scientific knowledge” about these interactions or the people, groups, and organizations involved (Leavy, 2017; Stebbins, 2011). The results are limited to the organizations studied. Still, insights into how the people in these “exemplar” organizations interact could provide value to other similar or disparate health care delivery systems experiencing the same environmental pressures.

B. Analysis Process

The analysis consisted of qualitative coding of interviews and documents by the primary investigator and a second coder (a PhD candidate in UCLA’s Fielding School of Public Health). The qualitative coding analysis was conducted using ATLAS.ti 8.0.

1. Phase 1

Coding occurred in several phases. Phase 1 involved the first set of interviews with six subjects as well as primary source documents. Interviews are known to be important in exploratory studies. According to Webb et al. (1981), “Exploration using interviews is more focused than exploration based on observation, primarily because the first commonly employs an interview guide, many items of which are suggested by preliminary observation and by the contents of documents written by or about those people.” (Stebbins, 2011; Webb, et al., 1981) Reviewing documents from a variety of sources outside of peer-review literature is also supported for exploratory studies (Stebbins, 2011; Webb et al., 1981).

After coding the first interviews and the primary source documents, the frequency of the codes was tallied and sorted using three ways:

- a. The frequency of the code in the interviews
- b. The frequency of the code in the documents
- c. The frequency of the code in both the interviews and documents

The results for each of the three sortings were then listed by most to least used. Phase 2 consisted of follow-up interviews with four of the subjects to delve deeper into the results of Phase 1. The data from Phase 2 was then analyzed in the same way as the Phase 1 data. After each phase, the coders reviewed the quality of the data, such as how the coding data and coding supported or did not support the research questions, and if any key findings—regardless of quantity—stood out as important or relevant. Also, after each phase, the primary investigator re-read each interview transcription without coding to assess whether the responses showed homogeneity and discord from a more holistic view of entire quotations.

Thirteen documents were coded using the same a priori and emergent codes as the interviews during Phase 1 coding. The documents were divided into two sets. One set of six documents included chapters from books and articles from peer-reviewed journals.

The other set was from seven primary source documents: Web site pages and blogs, annual reports/white papers, and a business magazine. All had some relationship with either a system in the study or were written by a subject in the study. The primary source documents were used to support and augment the data from the interviews. The documents were analyzed separately from the interviews. The results from the primary documents and the interviews were compared for similarities and differences.

The earliest document used was a peer-reviewed paper by Plsek (1999). The majority of the documents came from the mid-2010s. The peer-review documents were used for to assess the results against other researchers' findings. The complete list of documents can be found in Table I, Appendix D.

Based on characteristics in the five organization structural models and in the original concept map from Chapter III, 37 a priori codes were identified for use in the initial coding. Table II, Appendix D, lists the codes in alphabetical order, provides the associated model(s), and offers a definition used by the researcher for coding and for generating the interview guide. During the coding process, the primary investigator added seven emergent codes:

1. *Example*
2. *Executive*
3. *JustCulture*
4. *Relationship*
5. *Resistance*
6. *SystemsIssue*
7. *TeamStructure*

The two coders discussed the coding for Phase 1. They agreed that it was challenging, in some instances, to specify a particular code when two or more codes seemed conceptually linked to one or more other-codes. This appeared as bunches of codes being used in the same citation. An example would be *Teams*, *TeamStructure*, *TeamOn*, *TeamOff*. Thus, it was agreed some of the codes could be combined. After codes were combined, the tallying and sorting were rerun in the same three ways as mentioned above.

2. Phase 2

The Phase 2 interviews were conducted to obtain reflection from the subjects on the results from the first interviews and the primary source documents. The second interviews provided both confirmation of what was gleaned in the first interviews and deeper insight into some of the topics. In the initial interviews, the comments were more generalized and the volume of experiences related to the concepts was low. The topic of perception was also not explored as deeply as some of the other topics. The coding methodology remained the same for both sets of interviews and for the primary source documents.

C. Study and Participant Characteristics

1. Phase 1

Professionals from nine health systems were contacted to participate in the first round of interviews. The initial contact method included telephone and e-mail outreach. Referrals were sought using Web sites, the HCCA, or personal contacts. Some of the original contacts recommended others in their organization who they felt would provide additional information or be a better match for information related to the study's questions. All were either at the vice president or director levels. Three compliance professionals and four innovation professionals participated. One system declined to participate; one system agreed for an innovation interview but scheduling proved to be challenging; the rest were unresponsive. All the systems were recruited based on criteria that might facilitate innovation, compliance, and standardization of comparison between health systems:

- The system had more than one inpatient and outpatient site for care delivery, which in some cases crossed state lines
- The system had dedicated innovation resources

- The system had some resources dedicated to various types of patient care and process innovations – some with the commercialization of innovations (e.g., devices)
- The system, to some degree, relied on human factor design

The health systems with respondents who completed the interview process represented three regions across the United States; per the U.S. Census Bureau standards:

1. South: South Atlantic
2. West: Mountain
3. West: Pacific

Two systems provided at least one compliance and one innovation professional. One system provided only a compliance professional.

On the advice of experts in compliance and innovation, two consultants – one who focused on health care quality and innovation and one who focused on health care compliance – were also interviewed for this study. These consultants worked with one or more of the systems in the study and it was believed they could provide insight on the interactions between innovation and compliance. Table VII summarizes the systems and interviews. For more detail about the interview participants and data collection, see Tables III and IV, Appendix D.

TABLE VII

SUMMARY OF OUTREACH FOR INTERVIEWS IN PHASE 1

Category	Number
Number of Systems Contacted	9
Number of Systems Interviewed	3
Individual Interviews: Compliance	3
Individual Interviews: Innovationa	4
Number of Systems Both with Innovation and Compliance Interviewed	2
Number of Systems Compliance Only Interviewed	1
Number of Systems Innovation Only Interviewed	0
Number of Consultants Contacted	2
Number of Consultants Interviewed	2
Total Discrete Interviews ^a	8
a. One innovation interviewee did not complete the IRB consent form and was dropped from the study.	

The first set of interviews and primary source documents were counted and sorted. The first code review was a simple table listing the frequency of each code (see Table VIII). The list was ranked by the combined total of the coding for both interviews and documents. Interviews and documents were reviewed individually to understand better the alignment or differences between what the subjects were sharing and what the primary source documents supported. Table VIII displays the 15 codes with the highest combined frequency; a complete table can be found as Table V, Appendix D.

The 10 most frequent codes in combined total of both interviews and documents were: *Teamwork*, *Strategy*, *Executive*, *Success*, *Relationship*, *Data Share*, *Goal*, *Learning Organization*, *Conflict*, and *Resistance*. The top 10 for interviews only were: *Teamwork*,

Strategy, Conflict, Executive, Ethic Speaking, Success, Relationship, Communication Clarity, Resistance, Goal, and Adaptive – the last two were tied. The top 10 for documents only were: *Teamwork, Learning Organization, Systems Issue, Strategy, Data Share, Success, Relationship, Executive, Goal, and Data Use*.

The codes with nine or fewer combined frequency were: *Failure, Cycle, Effort Good, Restriction, Direction, SME Share, Ethic, EffortBad, and SMEHold*. *SMEHold* (referencing a subject matter expert would keep information from the other parties) was not used for either interviews or primary documents. *Failure* and *Ethic* would later be combined with other codes into family codes for further refinement of the analysis (see discussion regarding family codes in this section below). Excluding *SMEHold*, the interviews had zero frequency for two codes for which the primary documents had at least one use: *Funding* and *EffortBad*. Conversely, the primary documents had four codes with no uses but that had at least one use in the interviews: *PerceptionBad, PerceptionGood, Resolution Process, and Direction*. The two *Perception* codes directly relate to *research question 1*. Thus, any analysis and discussion about research questions will rely primarily – if not completely – on the interviews.

Those top 10 for Combined, Interviews, and Primary Source Documents results were then compared to ascertain which codes appear more often in all the sources or to see the sources produced different types of codes. The result showed six codes shared among all three: *Teamwork, Strategy, Executive, Success, Relationships, and Goal*, suggesting the interviews and primary source documents shared common insights and were not divergent in their thinking (Table IX).

In discussions between the primary investigator and second coder, it was agreed that the meanings of some codes were similar and it was often difficult to distinguish

which code to use. After reviewing these codes and the co-occurrence tables, the coders agreed to combine certain codes into family codes for one or both of the following reasons: 1) They appeared together for the same citation in numerous occasions (e.g., *Teamwork*, *TeamStructure*) and 2) They were a subset of another concept (e.g., *EthicSpeaking* as part of *Just Culture*). Table X shows the family codes and the individual codes that were combined to create the new code. See Table VI, Appendix D, for each code's co-occurrences table. Once the combinations were established, the table of the counts of the cited codes was rerun, with the six new grouped codes added and the individual codes within the groups removed (Table XI shows the 15 codes with the highest frequency; the full table is Table VII, Appendix D). A new "top 10" ranking for Combined, Interviews and Primary Source Documents was created (Table XII).

The list of top 10 codes found in Total, Interviews and Primary Source Documents from the original list and the subsequent list varied. After combining codes, the common codes were: *TeamsGroup*, *Learning Org Group*, *Strategy*, *Executive*, *Success*, and *Relationship*. Gone from the first analysis were *Teamwork* (replaced by *TeamsGroup*) and *Goal*. Added was *LearningOrgGroup*, which combined *Adaptive*, *Failure*, *Grow*, *Learn*, and *LearningOrg*. Thus, the four codes in common from the first analysis to the second analysis are *Executive*, *Relationship*, *Strategy*, and *Success*. *Teamwork* is subsumed under *TeamsGroup*, creating a fifth code. See Table XIII for a direct comparison of shared codes between the first and second analysis.

TABLE VIII

FREQUENCY OF EACH A PRIORI AND EMERGENT CODE

Highest to lowest according to the combined total

Code	Combined	Phase 1 Interviews	Primary Source Documents
Teamwork	117	78	39
Strategy	81	52	29
Executive	58	35	23
Success	58	33	25
Relationship	55	30	25
Data Share	51	23	28
Goal	48	27	21
Learning Organization	45	10	35
Conflict	41	38	3
Resistance	40	28	12
SystemsIssue	39	8	31
TeamStructure	39	25	14
Adaptive	34	27	7
Communication Clarity	34	30	4
Ethic Speaking	34	34	0

TABLE IX

THE 10 MOST FREQUENT CODES: TOTAL, INTERVIEWS ONLY, DOCUMENTS ONLY

The Total services as the initial ranking, and interviews and documents are listed in relationship to Total. If a code did not appear in total, it was added at the end of the table.

Code	Rank Total	Rank Interviews	Rank Primary Source Documents
Teamwork	1	1	1
Strategy	2	2	4
Executive	3	4	7
Success	3	6	6
Relationship	4	7	6
DataShare	5	—	5
Goal	6	9	8
Learning Org	7	—	2
Conflict	8	3	—
Resistance	9	8	—
SystemsIssues	—	—	3
Adaptive	—	9	—
EthicSpeaking	—	5	—
Communication Clarity	—	7	—
DataUse	—	—	9

TABLE X

CODES COMBINED INTO A GROUP AFTER THE INITIAL ANALYSIS

Conflict Group	Data Group	Just Culture Group	Learning Organization Group	Legal-Regulatory Group	Teams Group
Conflict	Data Process	Ethic Challenge	Adaptive	Law	TeamOff
Conflict Allowed	Data Share	Ethic Feedback	Failure	Regulation	TeamOn
Resistance	Data Use	Ethic Inquiry	Grow	Regulatory	TeamStructure
		Ethic Speaking	Learn		Teamwork
		JustCulture	Learning Organization		

TABLE XI

CODE FREQUENCY RESULTS AFTER CODES WERE COMBINED

In order of those with the most uses to the least when interviews and documents are combined.

Code	Combined	Phase 1 Interviews	Documents
Teams Group	183	126	57
Learning Org Group	144	88	56
Just Culture Group	112	98	14
Conflict Group	100	83	17
Data Group	95	44	51
Strategy	81	52	29
Executive	58	35	23
Success	58	33	25
Relationship	55	30	25
Goal	48	27	21
SystemsIssue	39	8	31
Legal-Regulatory Group	36	35	1
Communication Clarity	34	30	4
PerceptionBad	26	26	0
Commitment	24	17	7
Alignment	20	15	5
PerceptionGood	20	20	0
Resolution Process	18	18	0
Example	16	11	5
Funding	12	0	12
Cycle	6	3	3
EffortGood	5	4	1
Restriction	5	4	1
Direction	3	3	0
SME Share	3	2	1
EffortBad	1	0	1
SME Hold	0	0	0

TABLE XII

RANKING OF 10 MOST FREQUENT CODES AFTER COMBINING CODES: TOTAL, INTERVIEWS ONLY, DOCUMENTS ONLY

The Total serves as the initial ranking, and interviews and documents are listed in relationship to Total. If a code did not appear in Total but was ranked by interviews or documents, it was added at the end of the table.

Code	Rank Total	Rank Interviews	Rank Documents
Teams Group	1	1	1
LearningOrgGroup	2	3	2
Just Culture Group	3	2	—
Conflict Group	4	4	—
Data Group	5	—	3
Strategy	6	5	5
Executive	7	7	8
Success	7	9	6
Relationship	8	10	6
Goal	9	—	9
Data Group	—	6	—
Legal-Reg Group	—	8	—
SystemsIssue	—	—	4
Communication Clarity	—	10	—

TABLE XIII

ORIGINAL AND REVISED LIST OF CODES

Shows codes shared among the interviews, primary source documents before and after grouping some codes.

Original List of Shared Codes Across Total, Interviews and Primary Source Documents	Revised List of Shared Codes Using Grouped Codes Across Total, Interviews and Primary Source Documents
Executive	Executive
Goal	Learning Org Group
Relationship	Relationship
Strategy	Strategy
Success	Success
Teamwork	Teams Group

2. **Phase 2**

For Phase 2 of the study, four of the original subjects were re-interviewed to get input on their reflections based on the findings in Phase 1. Phase 2 was conducted for three reasons:

1. To provide more depth to the data and probe more deeply into the emergent concepts, using the findings from Phase 1
2. To provide more insight into the concepts that were less frequently coded
3. To request more examples of the interactions

Two compliance and two innovation subjects from health systems were contacted and agreed to an interview (see Table VIII, Appendix D, for a summary of interviews for Phases 1 and 2). The consultants were not re-interviewed in this phase to focus on those with current direct operational experience. No documents were added.

After four interviews, the homogeneity of the responses indicated that research saturation was obtained. The primary investigator paused and began the coding process.

As with the data from Phase 1, after the Phase 2 interviews were coded, they were displayed in a simple table listing the frequencies of each code. The list was ranked by the combined total of the coding for both interviews and the primary source documents. See Table XIV for the 15 codes with the highest frequency; a full table is Table IX, Appendix D).

The 10 codes with the most mentions for the total of the two sets of interviews and the primary source documents were: *TeamsGroup*, *LearningOrgGroup*, *ConflictGroup*, *JustCultureGroup*, *DataGroup*, *Strategy*, *Executive*, *Relationship*, *Success*, and *Goal*. The 10 for all interviews were: *TeamsGroup*, *LearningOrg Group*, *JustCultureGroup*, *Strategy*, *Executive*, *DataGroup*, *Reg-Legal Group*, *Relationship*, and *Communication Clarity*. As no new primary source documents are added, that Top 10 list did not change.

As in Phase 1, the codes were ranked by Combined, All Interviews, and Documents. Seven codes appear across all three: *TeamsGroup*, *LearningOrg Group*, *ConflictGroup*, *DataGroup*, *Strategy*, *Executive*, and *Relationship* (Table XV).

A table was then created to compare the codes that were found to be commonly shared within each type of analysis. The three types of analysis were based on: 1) the original list of codes (no combining of codes) with Phase 1 data; 2) the revised list of codes (in which codes were combined) with Phase 1 data; and 3) the revised list of codes including Phase 2 data. Four codes appear in all three types of analysis: *Executive*, *Relationship*, *Strategy*, and *TeamsGroup* (*Teamwork* in column 1). The codes *LearningOrgGroup* and *Success* appear in two of the three columns. *Goal*, *ConflictGroup*, and *DataGroup* appear only in one column (Table XVI).

TABLE XIV

FREQUENCIES OF CODES INCLUDING CODING FROM PHASE 2

Code	Combined	All Interviews	Primary Source Documents
TeamsGroup	231	174	57
LearningOrgGroup	212	156	56
ConflictGroup	136	119	17
JustCultureGroup	135	121	14
DataGroup	111	60	51
Strategy	110	81	29
Executive	84	61	23
Relationship	76	51	25
Success	64	39	25
Goal	54	33	21
Reg-Legal Group	54	53	1
Communication Clarity	49	45	4
SystemsIssue	43	12	31
Alignment	41	36	5
PerceptionBad	39	39	0

TABLE XV

RANKING OF MOST FREQUENTLY USED CODES INCLUDING CODING
FROM PHASE 2

Code	Rank Total	Rank All Interviews	Rank Documents
TeamsGroup	1	1	1
LearningOrgGroup	2	2	2
ConflictGroup	3	4	10
JustCultureGroup	4	3	–
DataGroup	5	7	3
Strategy	6	5	5
Executive	7	6	8
Relationship	8	9	6
Success	9	–	6
Goal	10	–	9
Reg-Legal Group	10	8	–
Communication Clarity	–	10	–
SystemsIssue	–	–	4

TABLE XVI

LISTING OF CODES SHARED IN TOP 10 RANKINGS

Original List of Shared Codes Across Total, Interviews and Documents	Revised List of Shared Codes Using Grouped Codes After 1st Interviews	Revised List of Shared Codes Using Grouped Codes After 2nd Interviews
Executive	Executive	Executive
Relationship	Relationship	Relationship
Strategy	Strategy	Strategy
Teamwork	TeamsGroup	TeamsGroup
Success	Success	ConflictGroup
Goal	Learning Org Group	DataGroup
–	–	LearningOrgGroup

3. Assessment Using Peer-Review Papers and a Book

The peer-review papers and the book were used to assess the data from the interviews and documents. The papers focused on health care innovation and a book focused on innovation and quality at a large health system in the U.S. Pacific Northwest; this set of documents will be referred to as “peer-review documents” for simplicity. Some of the documents were written by at least one of the sources in the study.

The assessment was used to determine if the primary interviews and documents were similar to what had already been published or if any novel- concepts came up. The code frequency from these papers and the book are listed in Table X, Appendix D. The top 10 codes were: *LearningOrgGroup*, *Strategy*, *TeamsGroup*, *DataGroup*, *Executive*, *Goal*, *SystemsIssues*, *Relationship*, *Success*, and *Alignment*.

These 10 peer-review codes were then ranked and compared against the rankings for the data from the interviews (both Phase 1 and Phase 2), the rank of the primary source documents, and the rank of the combined totals (Table XVII). The codes that appear in all five rankings are: *TeamsGroup*, *LearningOrgGroup*, *DataGroup*, *Strategy*, *Executive*, and *Relationship*. Table XVI was then expanded to include the results from the peer-review documents resulting in Table XVIII.

TABLE XVII

RANKINGS OF CODES COMPARED TO CODING FOR PEER REVIEW DOCUMENTS

Code	Rank Total	Rank All Interviews	Rank Documents	Peer Review
TeamsGroup	1	1	1	3
LearningOrgGroup	2	2	2	1
ConflictGroup	3	4	10	—
JustCultureGroup	4	3	—	—
DataGroup	5	7	3	4
Strategy	6	5	5	2
Executive	7	6	8	4
Relationship	8	9	6	8
Success	9	—	6	7
Goal	10	—	9	6
Reg-Legal Group	10	8	—	—
Communication Clarity	—	10	—	—
SystemsIssue	—	—	4	7

TABLE XVIII

CODES SHARED IN TOP 10 RANKINGS

Across all three ways of viewing frequencies (Phase 1, Grouped Phase 1, and Phase 1 plus Phase 2) and with a column that includes peer-review documents.

Original List of Shared Codes Across Total, Interviews and Documents	Revised List of Shared Codes Using Grouped Codes Across Totals After 1st Interviews	Revised List of Shared Codes Using Grouped Codes Across Totals After 2nd set of interviews	Revised List of Shared Codes Using Grouped Codes Across Totals including Peer Review
Executive	Executive	Executive	Executive
Relationship	Relationship	Relationship	Relationship
Strategy	Strategy	Strategy	Strategy
Teamwork	TeamsGroup	TeamsGroup	TeamsGroup
Success	Success	ConflictGroup	DataGroup
Goal	Learning Org Group	DataGroup	Learning Org Group
		Learning Org Group	

4. Codes of Perception

4.1 Findings About Perceptions

Analysis for research sub-question 1 about perceptions focused on the codes

PerceptionBad and *PerceptionGood*. These codes were created to capture those comments

or writings that directly referenced the perceptions explained more thoroughly in

Chapters I and II, based on the literature and other sources: Innovation

professionals attempt to push and break “the rules” whereas compliance

professionals always say “no” and want to keep everything within strict boundaries.

All quotes, however, were scanned for insight as to how the data supported,

explained, or was oppositional to the theories. The definitions of the codes are:

PerceptionBad: A party views another party as not helpful, a barrier, or not cooperative.

PerceptionGood: A party views another party as helpful and cooperative

All the coding occurred in interviews. Neither the primary nor peer-review documents used either code (Table XIX).

The first interviews used the codes 46 times from the original six subjects. The second interview guide had 31 uses from the four subjects in Phase 2, or about 7.5 times per subject. The code *PerceptionBad* was used 39 times and *PerceptionGood* was used 38 times. *TeamsGroup* was the highest co-occurring code for *PerceptionGood* and coded a total 73 times for both perception codes, indicating some value in working together as teams rather than in silos.

During the interviews, participants did not respond to questions about their opinions of each other. The questions about perception were asked several times but not much was revealed. Rather, the respondents discussed how and why they work together within their health care system.

PerceptionBad and *PerceptionGood* had different co-occurrent codes. The top 10 for *PerceptionBad* were: *ConflictGroup*, *TeamGroup*, *JustCultureGroup*, *Legal-RegGroup*, *PerceptionGood*, *Relationship*, *LearningOrgGroup*, *Communication Clarity*, *Alignment*, and *Restrictions*. The top 10 for *PerceptionGood* were: *TeamGroup*, *ConflictGroup*, *Relationship*, *JustCultureGroup*, *LearningOrgGroup*, *Legal-RegGroup*, *PerceptionBad*, *Alignment*, *Communication Clarity*, and *DataGroup* (see Table XI, Appendix D.)

Other than *Restrictions* (*PerceptionBad*) and *DataGroup* (*PerceptionGood*), the list was the same, albeit in different order. This points to the possibility that the different perceptions rely more on the context of the situation than on having specific

connotations. In other words, one’s negative perception can involve a lack of communication clarity or an abundance of communication clarity. Discussing the idea of perception, thus, could rely more on the quotes and their context than specific words.

TABLE XIX
FREQUENCIES OF PERCEPTION CODES FROM PHASE 1 AND PHASE 2

	PerceptionBad	PerceptionGood	Totals
Primary Source documents	0	0	0
Peer Review Documents	0	0	0
Phase 1 Interviews	26	20	46
Phase 2 Interviews	13	18	31
Totals	39	38	77

4.2 Emergence of “Notable” Codes

The four codes that appear in all three ways of reviewing the data are: *Executive*, *Relationship*, *Strategy*, and *TeamsGroup* (*Teamwork* in column 1). The codes *LearningOrgGroup* and *Success* appear in two of the three columns. *Goal*, *ConflictGroup*, and *DataGroup* appear only in one column. Those four codes, which appear in all four ways of reviewing the data, appear to have increased importance as factors in the relationship between health care innovation and compliance professionals, with the others perhaps having an important but secondary role. For future reference, the

four codes (*Executive*, *Relationship*, *Strategy*, and *TeamsGroup*) will be called “notable” codes.

The data analysis also highlighted another code, in addition to the four identified above: *LearningOrg Group*. *LearningOrgGroup* appears again and again alongside the other four notable codes in all the data sources: interviews, primary source documents, and peer-review documents. The data appear to show organizational forces play a large role in shaping the dynamic between innovation and compliance in large health care systems. The data did not support the idea that people or departments in an organization create roadblocks or barriers to the innovation process. Codes referencing subject matter experts holding back on information were rarely used. Codes that would indicate disinterest or a lack of effort on either side were also rarely used. In the code book, these would have been reflected by codes such as *SMEHold/Share* or *EffortBad/Good*. Those codes were rarely applied (see Least Frequent Codes section).

A co-occurrence table (Table XX) shows the number of times *LearningOrgGroup* was linked to one of the four notable codes. This table uses the entire data set except the peer-review documents used for comparison to findings in the literature. Looking at the totals, the most frequent code was *TeamsGroup* (n = 272) followed by *LearningOrgGroup* (n = 216), *ConflictGroup* (n = 171), *JustCultureGroup* (n = 105), *Relationship* (n = 98), *Reg-Legal Group* (n = 97), *Strategy* (n = 86), *Data Group* (n = 85), *Communication Clarity* (n = 84), *Alignment* (n = 82), and *Executive* (n = 82). Analyzing by each of the four notable codes, however, reveals *LearningOrgGroup* as the only code within the top three for the four notable codes that is not a notable code. *LearningOrgGroup* also appeared in the top 10 codes of all four analyses. It is

possible this factor is a strong influencer on the other factors without being a main driving factor. It seems necessary to include it as it keeps arising in the data. Thus, *LearningOrgGroup* will be included in the review.

TABLE XX
HIGHEST CO-OCCURRENCES WITH THE NOTABLE CODES

Notable code	Three Highest Co-Occurrences with a Notable code	No. of Co-Occurrences
Executive	LearningOrgGroup	40
	TeamsGroup	36
	ConflictGroup	26
Relationship	TeamsGroup	61
	ConflictGroup	37
	LearningOrgGroup	26
Strategy	LearningOrgGroup	78
	TeamsGroup	45
	Goal	27
TeamsGroup	ConflictGroup	87
	LearningOrgGroup	72
	Relationship	61

4.3 Least Frequent Codes

Lastly, the least frequent codes were reviewed to understand which a priori codes proved of little value to the subjects or in the documents in terms of the questions asked. After both sets of interviews and the combining into family codes, all codes had at least one frequency in the interviews. Both sets of documents had five codes with zero mentions. Table XXI shows the 10 least frequent codes for the interviews,

primary source documents, and the peer-review documents. One reason for codes appearing more in the interviews could be the interviewer via the semi-structured interview guide could prompt the subject for more thorough answers or explanations of answers; this provided additional opportunities for codes to be used. Documents are much more static and the researcher can only use what appears before him or her, creating restrictions on probing the content.

Common among the three sources were: *Direction*, *EffortBad*, *EffortGood*, *Restriction*, *SME Hold*, and *SME Share*. The definitions for these are available in Table XII, Appendix D. Similarities within the six codes are not obvious. However, the investigator reviewed all codes as the research questions were studied and themes developed via co-occurrence tables and a review of quotes was done to find any context for the codes used less frequently.

TABLE XXI

LEAST FREQUENT CODES BY INTERVIEWS, PRIMARY SOURCE DOCUMENTS, AND
PEER-REVIEW DOCUMENTS

Code	All Interviews	Code	Primary Source Documents	Code	Peer Review Documents
SME Hold	1	PerceptionBad	0	EffortBad	0
Cycle	3	PerceptionGood	0	EffortGood	0
SME Share	4	Resolution Process	0	PerceptionBad	0
Restriction	5	Direction	0	PerceptionGood	0
EffortBad	6	SME Hold	0	SME Hold	0
Direction	8	Reg-Legal Group	1	Direction	1
Funding	9	EffortGood	1	Reg-Legal Group	1
SystemsIssue	12	EffortBad	1	Resolution Process	1
EffortGood	12	Restriction	1	Restriction	1
Example	16	SME Share	1	Funding	2
				SME Share	2

D. Research Questions

1. Research Question 1

How do health care innovation teams and compliance departments currently interact with each other in health care delivery systems?

What perceptions (mental models) does each have of the other?

In what ways do the interactions reflect the perceptions?

1.1 Commonly Held Perceptions

As discussed in earlier chapters, health care innovation and compliance professionals have perceptions of each other and how each can impede the work of the other. The common colloquial understanding, as shown in the literature and environment scan, is that innovation professionals often believe compliance professionals are too quick to say “no” and impose rules and boundaries that inhibit creative solutions.

Compliance professionals, on the other hand, believe innovation puts the organization at risk and many of the solutions from innovators violate laws and regulations meant to protect the patient.

The intent of *research question 1* was to explore these perceptions directly with those who are accountable for the innovation and compliance areas within large health care systems. The first sub question was developed to explore the perceptions the innovation and compliance professionals have of each other at the health care systems represented in the sample. The second sub question was developed to explore examples of how these perceptions are realized in the workday during interactions between the two disciplines. The theory considered before the data collection based on the literature and environmental scan was that those perceptions affect behaviors that might interfere with an organization’s business outcomes.

1.2 Perceptions in the Interviews

The common colloquial understanding was not supported in this research's findings. For the health systems in the study, the perceptions were positive and the interactions productive. Subjects talked about the importance of organization imperatives creating an environment in which not "getting along" was unacceptable. As one of the consultant subjects stated: "We have found innovation leaders make the assumption that compliance is going to slow things down or somehow hijack what is happening in the innovation stage." A simple answer to the research question is: The innovation teams and compliance departments in these health systems interact in ways that move the organizational objectives forward.

During the interviews, the subjects spoke clearly and knowledgeably about the commonly held perceptions. What became apparent in the interviews was that none of the subjects – neither the innovation nor the compliance professionals – were experiencing the perceptions in their day-to-day work life, or they had found ways to address the conflicting priorities. One consultant summed up the perception as follows: "Typically either legal or compliance will say, sometimes, we can't do this because of some law, or we can't do it at the pace you want to do it because we don't have the resources to do it right." However, an innovation professional said she started out thinking the perceptions about compliance would be true but it "never materialized." One consultant shared, "People make up more myths about compliance or regulation than facts."

When participants did discuss perceptions, it appears there is some recognition that including compliance had its benefits and is not always negative. Speaking about past experiences with health care innovation teams, a consultant

stated: “Sometimes... they overlooked [compliance] and initially didn’t see the value in having them participate.” In a subsequent statement, the same consultant stated: “When compliance is included, the end product tends not only to be more successful but more efficient.”

1.3 Partners in the Enterprise

In the review of the interviews and common themes, phrases such as “being at the table,” “getting past no,” “being a partner,” and “helping the business” stood out.

An innovation professional stated compliance had never been a barrier and are included when needed: “When I have worked with them it had been positive. We just started a new ambulatory space committee, we have made a committee, one of our compliance officers is on our committee with us.”

One compliance professional stated: “If we can keep in mind that we are there to help the business, not say no, everyone is much more willing to have us at the table.” Another compliance professional talked about how innovation bringing the team together provided “a different light on things” and concluded that if innovators do not know the issues compliance had, they cannot collaborate on fixing them. Likewise, another compliance professional stated: “My approach is collaborative and I want to ensure everyone’s voice is heard... The perception had changed for those who work with us.” The subject then remembered an encounter with a physician who said he was “concerned” about coming to compliance regarding a project but afterward felt “so much better.” One compliance professional summed it up this way:

I would say, yes, we have experienced those perceptions in reality. Part of it is stemming from clear accountability and responsibility for the aspects of whatever the business transactions that are attempting

to be done. For us, it's mainly about contracting and contracts and working with... start-up companies that don't really have the concepts of compliance. Our people just want to get things done and move quickly. The Legal Department wants to make sure we have all the compliance aspects. Compliance gets into the middle of it. When people come to us, people might think we will take over in creating the contracts. . . . There had been some misinformation or people thinking, hey, compliance is going to come in and take over the operational aspects of the business transaction... [They] compliance and legal as the same thing. Working through those. Again, we are trying to assist and help. I think we do but it might not be appreciated. We've definitely run into a perception, there is conflict there.

1.4 Overcoming Perceptions

In these large innovative health systems, there seems to be a progression toward a current state in which the objective of the business overrides barriers and obstacles to partnership. Overcoming the perceptions, and possibly never having the perceptions to begin with, seemed to depend on several factors per the subjects. One of them is the idea of conflict as expected, accepted, and overcome. As one innovation professional stated: "The innovation people know how to get through [conflict]. They accept conflict. They anticipate it will happen and here's what we do...we get people together." A consultant stated almost the same idea: "[They] have to accept there is going to be some sort of blip or glitch or conflict. . . . [They] have to acknowledge that there will be conflict." One compliance professional shared a time when the innovators thought compliance and legal were holding up a project, and this created a lot of tension. The result was the creation of "templated process" to try to streamline the process and decision-making. With the chief information officer, a standard data contract was developed that addressed HIPAA and provided clear guidelines on what is and is not allowed when the organization's data is used.

Thus, the subject said, the process is “getting better” because the innovators “know their voice is heard.”

One compliance professional summed it as follows:

I’m excited about the future. I’m excited my colleagues are at the table and building the future. I just think compliance had to be optimistic and be part of the team. It doesn’t matter if it’s one of our normal operations or part of growth and innovation. It’s being flexible and responsive to your stakeholders and helping them have the best product they can.

2. Research Question 2

In large health care systems with dedicated innovation resources, what factors matter most in interactions between the innovation and the compliance departments?

Analysis for *research question 2* focused on the “notable codes” highlighted from the data. In the analysis, these codes were the most common between the data sources (interviews and primary documents). The order of the list is alphabetical and neither signifies importance nor the number of times it was coded.

- *Executive*
- *LearningOrg Group*
- *Relationship*
- *Strategy*
- *Teams Group*

These codes relate to each other in various ways. For example, *Relationship* and *Teams Group* imply the importance of working together rather than individually. *LearningOrg Group* and *Strategy* focus more on characteristics of the organization – how the organization functions and where it focuses its energy. *Executive* influences the personality of the organization as a learning organization and on its strategic imperatives. Being a learning organization implies that the organization succeeds on cooperation and sharing.

The themes below were developed by studying the five codes and their relationships to each other. The code definitions were compared for similarities and differences. Co-occurrences were reviewed visually in bar charts (see Figures 1-5, Appendix D) for recurring combinations. Finally, the codes were reviewed against the five models from which the concept map and interview questions were derived.

Ultimately, four themes were developed to capture the relationships between the codes and highlight what emerged from the conversations and readings. These themes are explored via the data to show factors that influence how the innovation and compliance departments of these health systems interact. Three themes were identified, based on the “notable” codes: *Executive*, *Relationship*, *Strategy*, and *TeamsGroup*. All the subjects spoke repeatedly about the importance of executive leadership support, role modeling of expected behaviors, and creating a culture in which both innovation and compliance were valued. Most of the health systems represented in the interviews and primary source documents cited clear business objectives and organization mission statements as setting the tone for what each employee and each department strives for. Finally, the ability to form relationships and work as a team toward that common business objective, was often cited as a reason for success.

The code *LearningOrgGroup* was used for a fourth theme. Senge’s qualities of a learning organization – building shared vision, personal mastery, working with mental models, team learning, and systems thinking – were reflected in the language of the subjects and the content of the primary source documents (Senge, 1990; Senge, 1992). The descriptions of the organization’s culture and the specific words and ideas reflect those qualities.

2.1 **Four Themes**

The themes that seem to be arising based on the analysis are:

- The influence of leaders and executives
- The importance of innovation as an organization mission and business objective
- The need for relationship building and teamwork
- The organization operates as a learning organization

2.1.1 **Theme: The Influence of Leaders and Executives**

Each subject and many of the documents discussed the importance of leadership and leaders. Most appeared to reference senior leaders (vice presidents, senior vice presidents, CEOs, etc.) in their comments about leaders. Leadership, as discussed in the interviews and the documents, sets the direction and expectations from which innovation and compliance professionals take their cues on how and when they should work and how their interactions influence the goals of the organization.

In general, all the subjects had similar views on the influence of leaders and executives in setting and communicating their expectations about supporting innovation. One compliance professional stated it was clear management had expectations the organization's departments "go over hurdles to be partners." One innovation professional discussed how valuable leadership is in changing culture and "long-held" perceptions. Another shared that getting the leaders to understand and adopt a culture of cooperation is "a big part of getting everybody else to get it" because the "engrained messages come from the top in one way or another." This was

supported by a primary source document which said: Leaders provide public and private emotional support and encouragement to those that want to try out new ideas. Another primary source document stated: Leadership must support innovation in both words and actions.

Part of that support might be related to how conflict is handled. For the subjects interviewed, none reported any negative, personalized conflict. It can arise however, as one consultant commented that the conversations can “devolve into a personality conflict, not a substantive conflict, and those things are counter-productive.” They described an atmosphere of cooperation and open dialogue. One compliance professional stated, “our conflict doesn’t quite rise to what other people feel is conflict but we are expected to work that out.” It is unclear whether this is the direct effect of the leader or if it is an intentional culture of positive or healthy conflict.

Subjects and documents also referred to leadership prioritizing innovation. One compliance professional talked about the board and management team explicitly making innovation a value of the organization, clearly raising its importance to the entire staff. Another shared that the “bigger, more resource intensive or potentially higher impact” projects have an executive sponsor. One primary source document stated that a successful innovation program “requires leadership endorsement, alignment with institutional priorities, funds and incentives, willingness to champion a project and the engagement of colleagues and peers across the system.”

One interviewee from innovation offered the following examples as to how leaders visibly show support and a willingness to engage with all levels in the organization to learn and lead:

I think of the times our front-line people see our leaders, see them engaged. The infections in the OR... The VP was in a bunny suit asking questions. [For] the staff in the OR that was very significant to them. This was a big problem the hospital was organizing. He didn't stay behind his desk. He was engaged with his problem. Those are the kinds of leaders that people want to listen to. They want to be engaged with those leaders. [The] new CEO of [another health system] goes to the cafeteria and sits down with people and had lunch with them. People love that. . . That she wanted to be embedded in the culture and the system and hear what was going on. [She] was sitting with biomedical engineers and issues they've been having. Another day a secretary on one of the floors and was telling her that she had the system's health insurance and that every month she was still paying that bill [for childbirth], and every month I think my employer doesn't care about me; they don't give me health care to cover this.

One concept comment by a compliance professional emerged referring to the need for leaders to step in and push projects through the system. This was not mentioned by the other subjects but signals that innovation influence could be concentrated among a few high-level people. The comment was about the power of the CEO and the vice presidents of certain areas – in this case, the Legal Department – being able to move projects and “work around issues” in ways their staff could not. The subject said the CEO “let us work with the chief legal officer and not just anyone in the legal department,” suggesting that the most senior leaders can introduce flexibility where others cannot. The subject continued: “The legal team at the top and given direction by the CEO will be much more creative than just approaching anyone in the legal department.” The question then becomes, *If*

senior leadership had to step in directly or be consulted directly, how does that manifest into an organizational culture that encourages and allows all levels to support innovation or take risks? Such exploration is beyond the scope of this study but worth noting for possible future studies.

2.1.2 Theme: Innovation as a Mission Statement and Business

Objective

Each compliance and innovation professional, as well as many documents, discussed the strategy of the word “innovation” or the concept of being innovative being built into the organization’s business model or, in some cases, its mission statement. Innovation is the standard way of approaching problems or reaching goals. Innovation becomes the expectation and helps describe the organization and its mission i.e., “It’s all about what we are trying to achieve as an organization.” The organization, then, becomes an innovative organization rather than an organization that uses techniques attributed to innovation i.e., “Innovation needs to be a part of the organization's core strategy not just an addition to an existing strategy.” This is an active decision on the part of ~~by~~ these organizations, as shared by one compliance professional: “[A few years ago], the board and the executive management team took a fresh look at mission, vision, values and as part of that process, innovation became a value of the organization.”

The consensus appears to be that stressing innovation as a core tenet or strategy ensures innovation as a common goal. This organizational goal seems to elevate innovation beyond a tactic to solve a problem—for example, diabetes control or operating room efficiency. Most subjects indicated that

not only is it clear that innovation is required for the organization to succeed, but also that barriers to innovation need to be thoughtfully considered, and, if possible, overcome. No one spoke about violating any code, regulation, law, or mandate to achieve this goal; rather, it was about finding alternatives i.e., “If we can keep that in mind, that we are there to help the business, not say no, everyone is much more willing to have us at the table. Interviewees spoke about the need for the two disciplines to come to a resolution when confronted with an issue or problem that creates a divide so the strategy is fulfilled. For example, “We don’t always get to consensus but resolution and agree on a process”. Disagreements or conflicts between the disciplines are often then harnessed into conversations about how to create a better product or process rather than a barrier that stalls the entire project, as in: “The objective had to get to yes. You want the organization to be successful.”

One topic that came up a few times in the documents (including peer review) was the idea of incentives or reward—in particular, a monetary incentive (e.g., a bonus). None of the interviewees mentioned having these kinds of incentives to ensure support for innovation. One primary source document stated: “Leadership must support innovation in both words and actions. Part of this process includes establishing a culture where the right incentives are in place to motivate and reward inventors and entrepreneurs within your organization. Using incentives or rewards could be a motivator for leaders, physicians and staff to work cooperatively to ensure the end product is viable.” It might be interesting to know if incentives alone can

sustain innovation at an organization, or if incentives can lead to behavior or culture change that moves an organization toward being innovative.

2.1.3 Theme: The Need for Relationship Building and Teamwork

Every subject had numerous comments that touched on the ideas of relationship building and teamwork. The idea of teamwork was less about the functioning of a team that meets every week to design a product or process and more about being included, considered, consulted, and respected. The inclusion or exclusion of people on a project team, regardless of intention, was discussed. The importance of creating a relationship was also discussed.

2.1.3.1 Compliance Inclusion/Exclusion

Team membership varies depending on the project and the organization. It was clear from the interviews that the Compliance Department is not always on an innovation team – for example, one consultant shared, “Unless the topic had naturally a large component of compliance as being essential to the innovation, the compliance people wouldn’t be on the team. One innovation professional even stated, “We don’t do a lot in the compliance space.”

Compliance professionals on the other hand talked about the benefits of them being on such teams. They stressed how they help shape the “end product” by providing input at the right time regarding compliance concerns, which would include billing standards, privacy, conflicts of interest, and other potential problems that could stall a project or cause its demise if not addressed early in the process. A sample of their comments are:

- “When compliance is included, the end product tends to be not only more successful but more efficient.”

- “In my experience compliance sits at the table from the beginning, and they decide when to bring in the substantive requirements of the regulation.”
- “I am part of the executive steering committee of the growth and innovation.”
- “I’m at the table I understand the objectives and I’m going to find a way to make it happen.”

2.1.3.2 Interdisciplinary Teams

This idea of working together can pose challenges in large systems for a variety of reasons—and all the systems represented here are large, spanning multiple geographic areas, multiple care sites, and multiple entities held together under one uniform organizational brand. The make-up of the teams was important not just by including Compliance but including people from many different disciplines. Some of the subjects and documents discussed having “diversity” within the innovation teams i.e., involving people from different departments, specialties, and backgrounds. The “diversity” appears to provide valuable input that reflects the various business needs of the organization (e.g., profitability, patient safety, or privacy) to inform the designers and innovators. As one primary source document stated, innovative companies “bring employees from different parts of their organization together to learn something new from each other” which “facilitates out-of-the-box thinking that is necessary for innovation.” Also, from a primary source document was this quote: “[O]rganizations whose staff are diverse in terms of backgrounds and ways of thinking – that bring together strongly contrasting disciplinary and professional perspectives – are more likely to be innovative.” The systems in this study were also at different levels in their team diversity journey. For example, an innovation

professional shared her organization's status: "I think we are starting to bring diverse people together. I think we are all starting to realize how hard it is to get things done when working in silos."

It is not always easy nor perfect. As one consultant stated: "Honestly, I would tell you that in almost every project, there are people who make any project about them or their power or any jeopardy of their domain." Still, even with that potential disruptor, the power of teams and collaboration remains. One primary source document made that clear from a systems-level view: "The Institute will leverage [the organization's] cross-disciplinary expertise to make tangible contributions to improving healthcare quality and value-driven outcomes for patients, providers, payers and employers." The importance of overcoming those large system challenges was clearly laid out in a primary source document:

It is important to recognize that each collaborative is different—how system-wide groups address their objectives is contingent on specialty, resources, motivation and hierarchy within the group and the individual medical centers. There is no "one size fits all." It is essential that the organizing entity recognize the organic nature of the group development, the inherent difficulties in collaborating across an expansive geography, and that collaborative members come from differing healthcare cultures. We have learned to be flexible and open to a variety of collaborative structures as the members wrestle with how to best come together across a large system.

2.1.3.3 Building Relationships

To a person—the subjects agreed—the key to creating these productive teams, the key to moving on from perceptions to reality, and the key to meeting the business objectives was by forming relationships. Each subject discussed

how creating relationships with the other disciplines helped move the innovation concept or design—or simply created the opportunity to say, “we ran it by Compliance.” The impetus for creating relationships is multi-layered and falls back to other themes discussed earlier: executive influence on an innovative culture, clear business objectives, and a widely shared mission.

The earlier discussion in the theme “The Influence of Leaders and Executives,” included statements from subjects about “how valuable leadership is in changing culture” and getting the leaders to understand and adopt a culture of cooperation is “a big part of getting everybody else to get it.” That leadership-driven culture can have an important influence for creating an innovative organization. As one compliance professional stated: “Make everybody feel they have a say. This is the goal and it had to be a very vocally supported goal by the very senior people in the organization.” One of the primary source documents reviewed the aspects of a “culture of innovation.” The purpose of the article was to assess how a team ~~it~~ promotes innovation. In the document’s discussion about relationships, it cited a study that found: “A differentiating factor of highly innovative firms was their ability to create a sense of community in the workplace with a family feeling, a sense of trust and caring... less innovative units functioned more like traditional bureaucracies.” In that same primary source document on relationships it shared another organization’s philosophy:

What’s equally tough, of course, is getting talented people to work effectively with one another. That takes trust and respect, which we as managers can’t mandate; they must be earned over time. What we can do is create an environment that nurtures trusting and respectful relationships and

unleashes everyone's creativity. If we get that right, the result is a vibrant community where talented people are loyal to one another and their collective work, everyone feels that they are part of something extraordinary....

One building block most subjects in this study found useful was personal, one-on-one interaction. Subjects talked about “hallway conversations,” “personal requests,” and “having connections.” One compliance professional said: “I’m a one-on-one person. I try to energize people and get them excited about what we do.” Subjects also mentioned trying to learn more about what the objective is, and what the other person is looking for. One innovation professional discussed being “very open to asking people what they want rather than jamming [something] down their throat.” Another said to “always ask a lot of questions” and “try to understand where they are coming from.” In the end, though, one compliance professional summed it up as: “Relationships.... when it gets down to it, it is about the mission and what we want to get done.” The organization’s core strategy, thus, is the reason for building that connection and meaningful relationship.

2.1.4 Theme: The Organization Operates as a Learning

Organization

Earlier in this paper, a learning organization was defined as: Organizations that survive focus on generative learning (creating), and adaptive learning (coping). None of the subjects definitively said, “yes, we are a learning organization.” Rather, they all talked about attributes of their organization, which align with those of a learning organization. When discussing health

care organizations as learning organizations, one consultant stated he finds best to engage in “generative learning, the creating, looking for something new” and further stated they “have to” to be successful.

Several of the primary source documents also talked about needing to become a learning organization to succeed at innovation. Words and phrases that indicate this include:

- *Culture of continuous improvement*
- *Process improvements*
- *Take more risks*
- *What are the systems solutions?*
- *Ask a lot of questions*
- *Benefit from learning*
- *Looking for something new*
- *Organizational ‘permission’ to try, fail, learn from failure*
- *Celebrate learning even if ideas are not successful*
- *Adapt to new evidence*
- *Take risk and experience failure*
- *When information is widely gathered, easily accessible, rapidly transmitted, and honestly communicated*

Ultimately, four subthemes emerged and are explored below:

Continuous Improvement, Shared Learnings, Allowed to Try, and Knowledge Management.

2.1.4.1 Continuous Improvement

One compliance professional stated simply: [Y]ou just can’t stay the same and survive,” referencing the challenging business environment of health care. This person described her organization as one with “culture of continuous improvement” and always engaging in “process improvements” as a response to that environment. At this organization, improvement boards are used in departments and “tracked up” to leadership and, some “have

enough legs to grow to innovation.” And, per the compliance professional, “Your daily work is to say do you have any suggestions about how to make this better.”

One organization’s primary source document described its “improvement methodology” as purposefully taking “reusable components” to create the “next care-model design better” and then repeating the process in “a continued drive for the creating of enhanced value.”

At each step, participants seek to use (and, equally important, refine for future reuse) features, techniques, or components of previously successful care models. This approach allows each effort to both benefit from and systematically add to Geisinger’s overall “innovation architecture”—creating reusable components and parts (whether human processes, software, technology, or analytics) that make the next care-model design better, faster, or cheaper. This approach parallels the evolutionary rapid development process from software engineering wherein innovations failing to deliver results are dropped and those meeting or exceeding expectations are advanced. This process is then repeated in a continued drive for the creation of enhanced value.

Another organization wrote about the adaptive nature of transformational innovation and how new ideas are “tied to the past” and making “incremental improvements” on current situation.

Transformational, not new, innovation is not about instilling a new change or launching a new project within an organization. It’s the result of synthesizing something new—an idea, project, or initiative—into something

transformational, thought-provoking, or potentially problem-solving. New ideas are often tied to the past. They might make incremental improvements on what is already in place. Truly innovative ideas turn a problem on its head and reveal a solution that was impossible to see before i.e., a solution with measurable and attainable results.

The innovation professionals did not discuss the ideas around continuous learning as much as the compliance professionals or consultants. One talked about innovation being “only as effective as the ability to maintain it once in place” while “at the same time finding a way to improve those standards as you work.” That, however, is more about the innovation framework and philosophy than continuous learning. The genesis of this is unclear from the data.

2.1.4.2 Shared Learnings (Internally and Externally)

Part of the incremental change referenced above appears to be the building on what had come before, or what had been done elsewhere within or outside of the organization. One primary source document, for example, discussed partnering with other hospitals, health systems, and insurers as well as business and communities in its quest for new learnings and ideas to adapt or adopt. An organization’s document stated: “At each step, participants seek to use (and, equally important, refine for future reuse) features, techniques, or components of previously successful care models.” Another shared how the organization’s senior management team “team brings in innovation experts from retail, travel, and other industries that are further up the learning curve in certain areas (e.g., consumer and digital) than healthcare is.”

As for internal sharing, a primary source document described how one innovation center found providers and leaders from across its system were interested in meeting with colleagues involved in innovation efforts to “share and compare various quality improvement efforts within their specialty areas and to learn from each other.” A compliance professional mentioned that senior leaders meet every morning to “share learnings.”

2.1.4.3 Allowed to Try

Being able to try – and being able to fail – is a key part of learning organization behavior. This idea – sometimes called being able to take risks or learning from failure – provides a level of assurance to those involved with innovation efforts that can yield a less than positive outcome without necessarily hurting their career. As one compliance professional said: “They are not all going to be home runs.” One documented reported: “Innovators must understand that success, learning, and insight usually come after “failing” many times.” Another stated: “The willingness to both take risk and experience failure (and the tremendous insights failure may provide) is crucial to fostering innovation.”

This idea of being allowed to engage in risk-taking as suggested earlier in the dissertation, seems antithetical to the role of a compliance department. For these organizations, however, the strategy of innovation is clear, and the compliance professionals are tasked with recognizing, escalating, and managing that risk. As one subject said, “We know innovation is a priority but at the same time, what is the organizational risk threshold?”

Also, “We want to be sure if the decision-makers want to accept that risk, they are making the informed decision.”

The innovation professionals understood the importance of trying, learning, failing, and repeating. “The whole issue of failing. We talk about it. We talk about success,” one subject said. The message from the executives is important here, too. In reference to the style in some other health care organizations, one innovation professional talked about how when something bad happens, people ask “whose fault it is, who can we fire” and that high level leaders who want to blame a person or people, compared to the organization in the study, in which the executives ask how it happened and “What are the systems solutions?” One primary source document shared its belief that “Equally important are committed professional staff with an entrepreneurial bent and experience, along with the organizational “permission” to try, fail, learn from failure, and ultimately succeed.” Even so, the norm had not completely changed, as one innovation professional said, “[I’m] not sure it’s a learning organization issue versus an issue of personalities... Some people just move on, whereas some personalities basically say that’s it, you failed we aren’t trying again. [It] hadn’t happened to me but... maybe the personalities around me are willing to try and be a learning organization.”

One innovation professional referenced the idea of “resilience engineering,” which tries to move past waiting for failure by anticipating how processes can be built with the risks – and risk adjustments – in mind. The

other subjects did not discuss “failure” in this way, but rather as a process or technology not working at some point as planned.

2.1.4.4 Knowledge Management

One component of a learning organization is knowledge management.

Knowledge management was defined earlier as the ability for an organization and its employees to gain, use, store, and share information, and to use that information to improve and sustain the organization. In healthcare, much of that knowledge is in the form of data—from electronic medical records, claims, and billing. One document stated: “We create better conditions for innovation when information, both from within and outside the organization or system, is widely gathered, easily accessible, rapidly transmitted, and honestly communicated.” That ideal is not always the reality as expressed by many of the subjects.

One challenge expressed by both innovation and compliance professionals is the access to the data. It appears the need to protect data and data systems is paramount. This can be driven by people acting proprietarily. One compliance professional said, “We have pots of data that people believe are their data and it’s a challenge.” The multiple programs and IT systems most large health care systems use do not help. An innovation professional shared it is “hard to piece all the data together to paint a picture. System access and getting to where the data lives is a huge.” One consultant suggested the innovation teams need to “sit with data owners” to “talk about the goal, what kind of information they need.”

As health care organizations, the subjects recognized the importance of patient privacy and adherence to privacy laws including HIPAA. One compliance professional talked about “making sure” partners in innovation have the “appropriate protections” of your data. This was stated in the context of both internal innovators and when working with outside organizations who might not have worked with protected health information before and do not have a “track record.” He cautioned against getting “hung up” on the privacy elements if it is a priority for the organization. The answer comes back to expectations: “...here’s how you need to store the data, here’s the type of people you can and can’t have attending the meetings.”

E. Summary

Data for this study were collected from two sets of interviews with people and from primary source documents at a variety of large health systems in the United States. Peer-review documents were used to assess the study data. Analyses of the data brought four codes to the surface: *Executive*, *Relationship*, *Strategy*, and *TeamsGroup*. A fifth code, *LearningOrgGroup*, was added due to the frequency with which it appeared alongside the other four codes.

The commonly held perceptions about innovation and compliance were understood by the subjects. The perceptions were not actualized in daily practice, however. Four themes about the factors of interactions between innovation and compliance were discussed:

1. The influence of leaders and executives
2. The importance of innovation as an organization mission and business objective
3. The need for relationship building and teamwork
4. The organization operates as a learning organization

V. DISCUSSION

A. Introduction

The data analysis in this study provides insight into how large health systems that have a track record of being innovative balance the boundary-breaking innovation designs and the need for compliance to federal and state laws, regulations, and mandates. Specifically, the data reveals how innovation and compliance professionals might perceive each other and what factors might be the most prominent during their interactions for representative innovation-focused health care systems. Interviews were conducted with health system professionals and consultants and documents from the health systems were reviewed in health systems found to prioritize innovation. The dual imperatives in health care to be both innovative and compliant could appear to be contradictory, or at least oppositional. The health systems and health systems' executives in this study have found ways for innovation and compliance professionals to work in concert, supporting both business objectives. Those business objectives, formed by an organization's mission and strategies, appear to be the catalyst for cooperation.

The cooperation manifests in various ways, specifically in this study, as teamwork, relationships, and behaving as a learning organization. This discussion will focus on a few aspects of what the data for this study reveals. Firstly, the issue of the commonly held beliefs about the tension between innovators and compliance professionals is reviewed as it pertains to the professionals interviewed in this study. Secondly, the influence of the business imperatives in health care – both in general and for those studied here—is explored. The study results are discussed in relation to the five models reviewed in Chapter II. Finally, the implications for leadership in health care are discussed and the original concept map is adjusted to reflect the findings in this study.

B. Perception Is Not Reality

Research Question 1 explored the perceptions among innovation and compliance professionals about the other. A commonly held belief is that innovation had little respect for boundaries or limitations while compliance had little patience for pushing boundaries or ignoring limitations. The conversations with the subjects in this study showed that belief was not an active factor in their daily work. In fact, the idea of perception was explored in the interviews but the subjects cited few, if any, examples in which the perceptions created barriers. Most of the examples were about people having concerns before approaching the other side and then finding those concerns were not realized. One compliance professional, for example, talked about a physician who had trepidations about approaching the Compliance Department fearing his ideas would be dismissed as not feasible; he came away from the encounter with a revised paradigm about how helpful the Compliance personnel could be.

In the second set of interviews, comments regarding perception from the Phase 1 interviews were shared, whether confirmatory or dispelling. Most of the subjects stated they see similar issues of perception, or lack thereof, in their own system. It did establish that the original findings were indeed valid, and that there exists a homogeny of responses.

It appears in these health systems that the subjects can move past the perceptions. One factor in this is the emphasis by the organization and the executive leadership on innovation as a strategy. This public and laser-like focus, in effect, forces the staff to prioritize the organization's objectives and work together. The challenge comes in the day-to-day work, in balancing time and resources, and in taking the time to have the conversations necessary to move an innovation project forward. For organizations experiencing negative conflict and barriers between innovation and compliance, they might consider how innovation is perceived as a corporate imperative and how executives display their expectations to staff.

Innovation can fall victim to the same challenges all health care organizations face. The data pointed to one area in particular which could threaten the collaboration between innovation and compliance: resources and funding. In its self-evaluation, the UC Center for Health Quality and Innovation noted that key barriers include, among others, variation in alignment of clinical priorities, lack of resources, need for early integration with existing health system initiatives, and need for engagement with multiple stakeholders (UCLA Health, 2016). As one innovation professional interviewee stated: Because teams are smaller one person's opinion can really damage... Sometimes when resources are too thin, that's when projects fall off the deck. It's not retaliation, [it] just died by default because there are so many priorities. In an online blog from Intermountain Healthcare about transforming healthcare, the writer stated, "Organizations need to ensure that dedicated time and resources are spent addressing the challenging process of developing ideas into actual practice" (Hamilton, 2017). During a discussion about being "at the table" and having credibility, a compliance professional posited that credibility reflects the maturity of the department, which, in essence, is a function of what the compliance department looks like and how it is resourced.

C. Leadership, Business Imperatives and Missions

This study found that innovation as a mandate and as expressed by the executive-in-charge was critical to ensuring departments as disparate in function as innovation and compliance find common ground and function synergistically. In his book about the Virginia Mason Health System's "transformation" with Lean and innovation, Plsek (2013) found successful organizations have "big, hairy, audacious goals" driving unimaginable levels of performance and that "linking innovation targets to strategic priorities and being able to articulate a clear, multifaceted case of need, further signals the importance of the call for innovation" (Plsek, 2013). He further states: "Leaders signal that innovation is highly desirable by setting aspirational goals in specific areas, and challenging others to find ways to realize the vision" (Plsek, 2013). In a review of two different health systems

and their implementation of innovation programs, two of McCutcheon's key findings involved leaders, leadership, and leading in health care:

Innovation is fundamental to an organization's commitment to leadership in healthcare. Quality and value, integrated with transformation programs, start at the highest level (McCutcheon, 2016).

One reason such strong, visible, and committed leadership exists is because "If one tries to move an organization away from its usual and customary way of operating, strong forces pull the organization back to the status quo ante... The status quo is a strong 'attractor'" (Samet & Smith, 2016). Thus, the leader of an innovative organization needs to, as Plesk (2013) defines it, "influence others to change" via "goal-setting, communications, appeal to intrinsic motivation, insight, analytical and facilitative skills, the ability to work well with others, and so on."

1. Business Imperative

Health care delivery, payment, and operations are undergoing a transformation that one could say has not been seen since the Social Security Amendments that created Medicare in 1965. Mergers between insurers, hospitals, and even insurers merging with retail establishments (e.g., CVS and Aetna) create new opportunities but also threaten traditional processes and systems. The "great disrupter," Amazon, keeps putting its toe into various health care ventures as the world waits to see which ones are successful. The back and forth of whether the Affordable Care Act will survive the Republican control of the federal government makes setting rates and predicting budgets more of a guessing game than any business would like. On the other hand, the proposals for a single-payer system would upend the current structure completely.

The answer from health care deliverers and payers had been to turn to innovation to drive down costs, increase patient satisfaction, and be nimbler in a volatile economy.

Some health systems use innovation to create spin-offs or joint ventures. Others use innovation to increase a tele-presence and deliver more care telephonically, reducing patient wait times and increasing access. Some use innovation to develop better processes, eliminate waste, or increase safety. It is neither practical nor feasible for any part of an organization to create barriers to these business imperatives.

2. Leadership and Missions

For the organizations in this study, innovation had clearly become a business strategy and for some, it had been embedded in the mission statement. The mission statement is driven by the board of directors, which indicates the people at the very top of the organization believe innovation is imperative. In its self-evaluation, the UC CHQI stated: “[L]eadership commitment and endorsement are important to foster and monitor progress of initiatives during their growth Phase” (UCLA Health, 2016). In a review of Geisinger Health’s experience with innovation, Paulus et al. (2008) partly credited the organization’s founding mission to “make it the best” as a reason the healthy system “had repeatedly taken risks to produce innovative care and payment models.” (Paulus, et al., 2008) This becomes reflected in this study by what one compliance professional said: “Look... we have the same mission... just involve [innovators] in the process.” Another compliance professional at a different organization stated: “I have never seen a group of employees that are more committed to the mission. It’s not always about the dollar [but] a commitment to improve care, decrease costs...” That positive attitude and ability to perform is, in this study, somewhat associated with the organization’s leaders and leadership, and the express intent as stated in the mission, vision, or other organizational statements.

It could be that leadership skills, in addition to robust innovation or compliance teams, are what push an organization into being an “exemplar” organization regarding innovation. As shared in Chapter IV, one compliance professional said the senior management team had a talk every day about what did or did not go well the previous day and next steps. Those types of multidisciplinary conversations start at the top and get role modeled down. If it doesn’t roll down, it’s going to be hard to be successful because that is what sets the tone.

One organization had workshops where the people who were structurally leading the innovation work were attuned with compliance and created a space where that conversation could take place. For others, some of that is just being embedded in a continual emphasis on annual compliance trainings and specialized trainings. At some point, with the right mix of training and leadership role modeling, it could become part of the culture.

D. The Five Models

The theory on which the study was developed stemmed from five models:

1. Learning Organization
2. Mental Models
3. Dimensions of Conflict
4. Generative Leadership/Relationships
5. Organizational Frames.

From these models, five areas of commonality were found: teams, knowledge management, needs of constituencies, ethical management, and substantive conflict. These areas were then used to create the semi-structured interview questions.

Generative Leadership/Relationships appears in several ways, particularly in the importance of executive leadership and relationship-building. *Learning Organization* was one of the five codes that

rose to the top in terms of frequency and was developed into its own theme. *Mental Models* corresponds directly with the question of perception. *Organizational Frames*—a way to make sense of an organization’s social architecture and its consequences—can be seen in how the organization responds to mission statements and strategies to ensure those are met through one’s work.

1. The Type and Role of Conflict

Of the five models, *Dimensions of Conflict* was the least discussed. Conflict codes were merged into one family code and had a fairly high frequency. However, the negative types of conflict—being positional, creating barriers, and refusing to participate—were not visible in these exemplar organizations. Dimensions of Conflict in the organizations studied seem to lean on the side of conflict that is approached as a way to induce discussion rather than set up barriers. A question in the interviews asked if there were any process, model or policy the organization followed for dealing with conflict. Nobody said we have this model or that model of dealing with conflict. Thus, there might be various ways of moving toward that healthy conflict without being codified.

There were several references to “healthy” conflict—conflict that comes from different perspectives or viewpoints but that feeds creativity as a path to resolution. MedStar refers to it as “constructive controversy” in one of its online blogs about innovation; constructive controversy is defined as “where group members discuss their opposing views openly for mutual benefit” and contend this promotes risk-taking behavior that encourages innovation and allows for recovery from mistakes (Culture of Innovation, 2018). One innovation professional declared, “Personally I think conflict is healthy.”

This was interesting because based on the literature review, the expectation was to find more references about negative conflict than positive conflict. Given the perceptions in the disciplines about each other – perceptions that are oppositional – the researcher

expected to find more reflection on negative interactions related to conflict and disagreements.

There might be something at play here that is more than simply acting with respect while having a differing opinion. The literature, and some of those interviewed, see conflict as an innovation tool for generating new ideas. Song et al. (2006) wrote that the view of conflict as negative – “a nuisance to be rid of” – to be simplistic and non-contextual. (Song, et al., 2006) As far back as 1998, Dyer and ~~&~~ Song (1998) wrote how “companies today are reconsidering a historically negative view of conflict and sanctioning conflict to invigorate, change, and gain a competitive advantage in innovation.” (Dyer and Song, 1998) In their study about the relationship between innovation strategy (new product and market development) and task conflict (as non-personal disagreements over work goals, objectives, and methods), the results suggested that conflict management is a controllable factor and proactive tool and, thus, “managers may need to promote a planned *sanctioning* of certain types of conflict and of certain conflict handling mechanisms to promote positive outcomes for cross-functional relationships” (Dyer and Song, 1998). A later study by Song, Dyer, and Thieme (2006) looked at the relationships among five behavioral conflict-handling strategies, destructive and constructive conflict, and innovation performance (integrating, accommodating, compromising, forcing, and avoiding). They found “a strong positive association between constructive conflict and innovation performance and a strong negative association between destructive conflict and innovation performance” (Song et al., 2006). Eichbaum (2018) writes that in health professions, “conflict is often considered disruptive, inefficient, unprofessional, and a potential source of error that can impact patient safety” and thus, health professionals “tend to avoid conflict or resolve it quickly.” He asks: “Does conflict have a constructive role in the health professions, or should health professionals try

to avoid it?” (Eichbaum, 2018). He found three approaches to resolve this: 1) make interpersonal risk-taking safe, 2) view conflict as a source of learning and innovation, and 3) democratize hierarchies of power.

A comment earlier in the dissertation continues to resonate in this discussion. In defense of HIPPA not being an innovation killer-but rather, a stimulus for innovation—by making systems reliable and available, with IT staff having more time to innovate rather than fix systems issues—Lee III (2014) states: “By embracing the HIPAA rule and truly understanding its meaning we can stop fearing what might go wrong and, instead, start dreaming about what might go so right.” The move to positive (or constructive) conflict and creating expectations and processes about positive conflict might move an organization along the innovation highway. In the book *Positive Conflict*, Checketts (2007) sees this as “fusion” – bringing together diverse elements to form a new whole that is distinct and somehow more useful or interesting. (Checketts, 2007) He writes:

There is no greater human triumph than when a group of people cease their contentions and decide that some purpose deserves the commitment of all. Then comes the pulling together. Teamwork is strength in numbers, creativity through diversity, hard work and some fun. (Checketts, 2007)

TABLE XXII

THE FIVE MODELS FROM CHAPTER II, THEIR MAIN IDEA, AND THEIR ASSOCIATION WITH THE RESULTS AND ANALYSIS

Model	Main Ideas	Results & Analysis
Learning Organization (LO)	Organizations that survive focus on generative learning (creating) and adaptive learning (coping).	Relates to themes: The influence of leaders and executives; the organization operates as a learning organization
Dimensions of Conflict (DC)	Differences in what people believe. Can be productive; indicate the team is learning.	Relates to the themes: The need for relationship building and teamwork; the influence of leaders and executives
Mental Models (MM)	Mental models contain information people use to interact with the environment around them and allow them to describe, understand, and predict that environment. Shared mental models are what team members use to describe, explain, and predict the behavior of their team.	Relates to theme: The need for relationship building and teamwork
Generative Leadership & Relationships (GL)	Catalyzes innovation and creates a structure in which the team members can maintain positive and meaningful interactions in a complex environment.	Relates to the themes: The importance of innovation as an organization mission and business objective; the need for relationship building and teamwork; the organization operates as a learning organization
Organizational Frames (OF)	Perspectives or lenses through which an employee, manager, or staff interprets the activities around him or her. A way to make sense of an organization's social architecture and its consequences.	Relates to the theme: The influence of leaders and executives

2. Relationships

Relationships were part of every subject's conversation. Reaching out, having conversations in a more casual setting rather than in meetings, trying to understand the other person's perspectives and goals, and discussing how they fit in with the organization's strategy – all helped these organizations move into a more cooperative state. It was the interpersonal dynamic that made the work easier and less fraught with tension. Finding more goals in common than differences can create a greater bond among the team members of a project. Neither are innovation professionals interested in violating privacy rules nor are compliance professionals interested in keeping the organization from developing creative solutions.

In his book on Virginia Mason, Plsek (2013) states: "Innovative ideas are rarely the product of a lone genius. Even when they might appear to be, delving further into the story nearly always reveals that the idea was formed over time and through multiple interactions with others that fueled the process." In their review of Geisinger's innovation efforts, Paulus, Davis, and Steel (2008) suggest "Cross-stakeholder collaboration [including external stakeholders in this review] should be not only allowed but encouraged, to drive idealized care." (Paulus, et al., 2008) Each organization in the study talked about the need for and essence of teams. None believed innovation could be done in a silo, and all knew that cross-team cooperation was organizationally desired and critical for success.

The challenge arises during the day-to-day work, in balancing time and resources, and when taking the time to have the conversations necessary to move an innovation project forward. Innovation can fall victim to the same challenges all health care organizations face—including competing priorities, resources, and lack of teamwork—and thus, can fail to come to fruition. Samet and Smith (2016) call this the "tyranny of the daily" in which people easily

get caught up in the urgent, but not necessarily important, daily activities of work and lose focus on the bigger picture. (Samet and Smith, 2016)

E. Revised Concept Map

The original concept map from Chapter 2 was revised (see Figure 7) to reflect the findings from the analysis. The revised map relies more on people than departments, given the interweaving of the concepts studied.

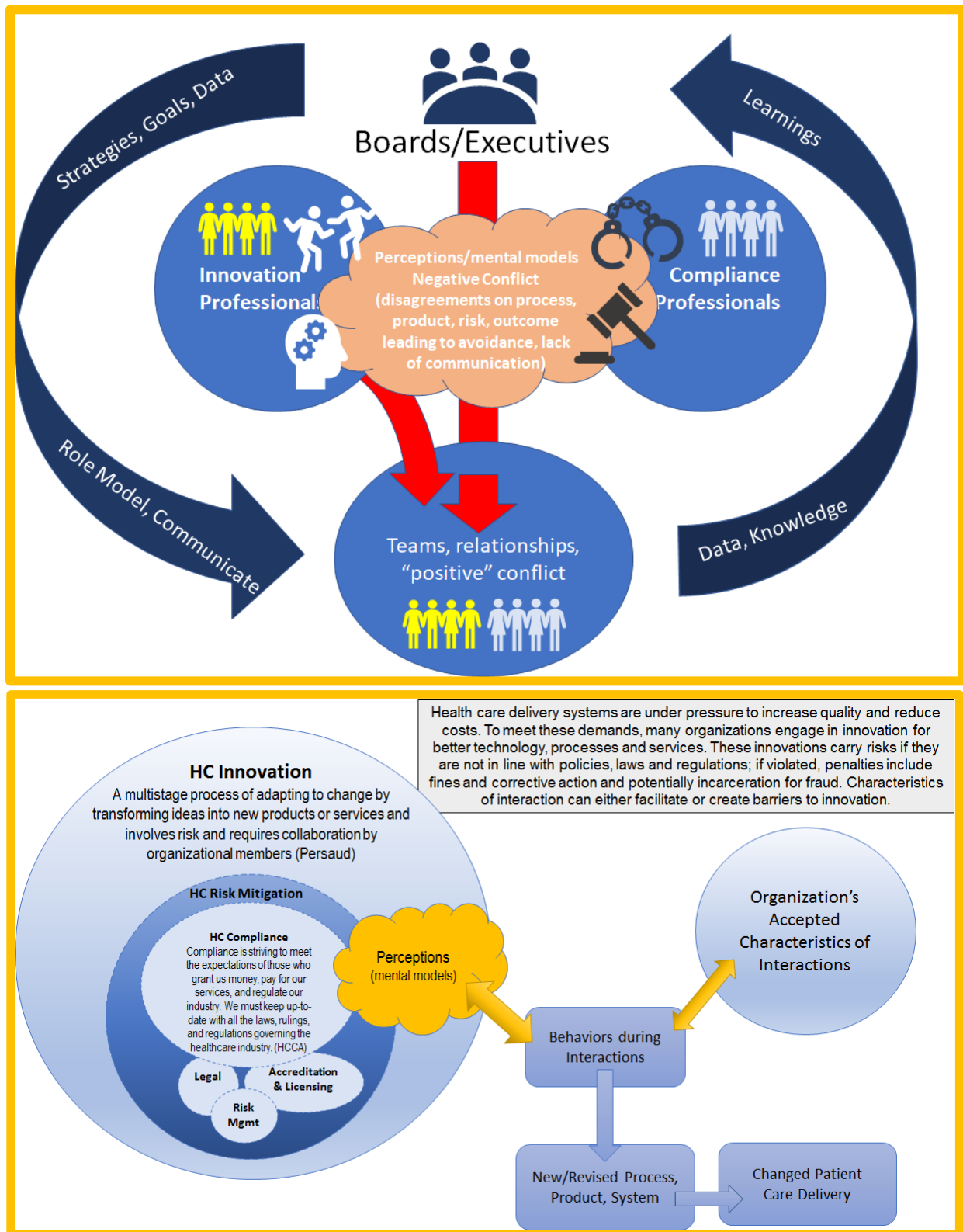
For example, in the context of conflict, relationships and positive conflict might be aligned—the stronger the relationships and the greater the trust, the fewer the positional challenges and the better the outcomes. So, it could be finding such-relationships and finding a way within organizations to create those relationships will, by default, create a path to having a more positive conflict relationship rather than a positional one. And the relationships might develop as mental models or evolved perceptions. All of this, as founded by our study occurs through the influence of the leadership.

Organizational leadership (the board and executives) is now called out specifically as having roles in setting the strategy, pushing the staff through the perceptions, addressing conflict, and receiving the learnings from their teams. They, along with the innovation and compliance professionals, play a role in setting and resetting perceptions. The innovation and compliance professionals participate in that reprocessing of perceptions to reach a place where they have developed supportive relationships and teams. In the earlier model, the perceptions were isolated within the various departments, separate from the broader organization's influence.

In the earlier model, the flow ended with a changed patient care delivery experience. While that goal remains relevant, the revised model reflects the learning aspect of the organization, in which the strategies, goals, and data are processed into new data and learnings that, in turn, influence executives to update strategies and goals.

The updated concept map is, thus, less linear. It shows more of the iterative nature of how organizations process information, learning from past programs and efforts to create, one hopes, stronger, better systems and programs.

Figure 6. The original concept map (top) was revised (bottom) to reflect the analysis and results from the study data



F. Limitations

1. Sources

This study had several limitations. Firstly, the sample size was small. The interviews represented only three health care delivery systems and two consulting firms. The primary source documents were from five health systems. Secondly, the study criteria were confined to health systems that had an active presence in health care innovation, thus the data are from “exemplars” of health innovation. These “exemplars” are models to which other health systems would aspire. The implication, thus, is these “exemplars” have reached a level of interoperability that allows for success. Lastly, little research has been conducted on this specific topic. The models used and factors studied were culled from a finite set of sources.

2. Researcher Bias and Response Bias

The primary researcher works directly in the compliance discipline. She currently works for a large health system which, like the ones-in this study, has dedicated significant resources toward health care innovation. In her role in compliance at a medical center, the primary researcher had experienced situations similar to those described throughout the study. During the analysis, responses were reviewed for homogeneity and disagreement, and discussed as needed. Responses from other subjects were woven into the interviews to test meanings and interpretations. The second coder had no researcher bias about these topics, and the second set of codes closely matched the primary researcher’s coding, indicating the bias was limited.

Not all contacted systems-provided a source for interviews. This limited the available pool of systems represented. To compensate, the researcher used equal numbers of innovation and compliance personnel, as well as two consultants—one specializing in innovation and one in compliance.

3. External Validity

As stated above, the health systems in this study are “exemplars” in terms of health care innovation. At the same time, the manifestation of that focus on innovation differed in structure, resources, and personnel. They all conducted innovation work to improve patient care but at least one also used it to develop outside ventures.

4. Construct Validity

As noted in Chapter III, construct validity is a consideration as a threat because the constructs were not valid, per se.

G. Leadership Implications

Before the research for this study was conducted, potential leadership implications of the study were shared. Prior to data analysis, conflict was believed to be a significant factor affecting the relationship between innovation and compliance professionals. It was theorized that because of conflict, leaders would have to insert their influence to resolve conflicting views.

The analysis of the data did suggest the importance of leaders inserting their influence. However, rather than doing so to resolve conflict between innovation and compliance professionals, the influence provided a platform for developing relationships and functioning in teams. The study found in these systems that with a leader setting and communicating expectations about innovation, the innovation and compliance professionals found ways to be partners. More than one subject mentioned a leader’s importance in changing long-held perceptions and adopting a culture of cooperation.

Focusing on innovation as a priority was another research outcome. All the health systems in this study either had innovation explicitly stated in their mission statements or as a clear business strategy. Innovation appeared to be elevated as a way of doing business. Given that, the two disciplines seemed to approach discussions and projects as part of doing the organization’s business

and reaching those common goals. The leader in this study showed up more as a coach or a mentor rather than as a disciplinarian or referee.

The sites had some commonalities that might function as “best practices” for others to consider:

- A dedicated innovation function and team: All of the sites had a team of people who supported and moved forward innovation designs and implementation. Some had fairly large centers with different teams. Others had smaller groups that were part of other departments. The key might be dedicated resources and funding.
- A dedication to the concepts of a learning organization. Being a learning organization encompasses a lot of attributes. One area in particular was consistent – allowing for people to try and fail, learn from the failure, and then try a new or revised approach. This “learning from failure” attitude was mentioned by all the sites and in many of the documents. Both the innovation and the compliance professionals embraced it and the leaders supported it.
- Listen to the front-line employees: As one innovation professional said, “you won’t be able to sustain an improvement or a change if the staff don’t like it.” Several ways of reaching front-line staff were cited by subjects. In one case, a vice president observed a surgery to understand better how infections can occur in an operating room. One CEO ate lunch in the cafeteria and listened to employees share their health care experiences. Integrating human design methods—as at least one site has done—requires visiting the department, observing how the work is accomplished, and speaking with the staff about their challenges.

H. Future Research

Future research could focus on a variety of areas. One concept that might be interesting to explore is focusing on the health care organization leaders and promoters of the collaboration efforts and how they influence the relationships within the organization – particularly, for areas as oppositional on the surface as innovation and compliance. Another possibility is exploring the learning organization aspects of innovation and compliance more deeply – particularly, as it relates to creating opportunities for perceptions to be managed, relationships to be built, and compliant innovation to occur. Another focus could be to conduct a case study on a health care organization struggling with innovation and conduct an action research project to find and move past the pain points. The subjects often talked about Legal Departments when discussing Compliance. Legal Departments have a different mandate than Compliance, but most people are not going to see the subtle differences. Perhaps that dynamic of Compliance as a barrier needs to be viewed with a lens toward the Legal Department. It could be barriers from Legal get combined with Compliance, and it might be worth studying how to avoid perceiving both areas as barriers. Finally, the “reverse” of this study could shed additional light on the innovation-compliance dynamic. That is, perhaps looking at organizations that are not “exemplars” but that struggle and answer the same research questions from that perspective.

I. Conclusion

Health care innovation and compliance professionals are not as far apart as the myth might portray. With the right leadership and strategies, those two areas, along with other areas in the organization, can focus on the strategy, not the personalities. An organization that also encourages relationship building, sharing knowledge freely, and healthy conflict creates a platform for identifying creative solutions for the multi-pronged challenges that exist in health care today.

APPENDICES

APPENDIX A: HEALTH SYSTEMS RESEARCHED FOR THIS STUDY

TABLE XXIII, APPENDIX A

ORIGINAL LIST OF POTENTIAL HEALTH SYSTEMS

Source¹	Organization	Notes re: Innovation Work	Possible Contacts	ILN Members
BHR	Geisinger Health System (Pa.)	innovation is everywhere in their system	Gregory J. Moore, MD, PhD, Chief Emerging Technology and Informatics Officer	
BHR	University Hospitals (Cleveland).	Executive Office of Innovation, University Hospitals Institute for Health Care Quality & Innovation http://www.uhhospitals.org/about/university-hospitals-institute-for-health-care-quality-and-innovation	Marco Costa, MD, PhD, Vice President and Chief Innovation Officer	
BHR	UPMC (Pittsburgh).	http://enterprises.upmc.com/about-us/	Rasu Shrestha, MD, Chief Innovation Officer	
BHR	Brigham and Women's Hospital (Boston)	http://www.disruptingmedicine.org/	Lesley Solomon Executive Director Brigham's Innovation Hub and director of strategy and innovation	
BHR	NewYorkPresbyterian Hospital	IT focused	Peter Fleischut, MD, Associate Chief Innovation Officer	
BHR	Southern Illinois Healthcare (Carbondale)	IT focused	Jerry Mourey, Vice President, Chief Innovation Officer	
BHR	University of Pennsylvania (Philadelphia)		Roy Rosin, Chief Innovation Officer,	
BHR	Children's Hospital of Orange (Calif.)	Sharon Disney Lund Medical Intelligence Innovations Institute (MI3) and a new collaboration called The Innovation Institute.	Anthony Chang, MD, Chief Intelligence and Innovation Officer	

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BHR	Boston Children's Hospital	http://www.childrenshospital.org/research-and-innovation/innovation	John Brownstein, PhD, Chief Innovation Officer,	C. E. Small, MBA Senior Director of Innovation
BHR	Henry Ford Health System (Detroit)	https://www.henryford.com/body_open.cfm?id=60086	Mark Coticchia, Vice President and Chief Innovation officer,	
BHR	MedStar Health (Columbia, Md)	http://mi2.medstarhealth.org/#q={ MedStar Institute for Innovation: human factors, data science, influence, emerging technologies, simulation	Mark Smith, MD, Chief Innovation Officer	
GR	Intermountain Healthcare (Utah)	https://intermountainhealthcare.org/about/transforming-healthcare/innovation/	Jared W. Henricksen, MD Medical Director	
GR	Children's Hospital Los Angeles (CHLA)	The Center for Innovation at Children's Hospital Los Angeles http://www.chla.org/center-innovation	Jessica Rousset	
GR	Mayo Clinic	Center for Innovation http://centerforinnovation.mayo.edu/		
GR	Dana-Farber Cancer Institute	http://www.dana-farber.org/Research/Technology-Transfer/About-Us.aspx focused on technology transfer. Belfer Office for Dana-Farber Innovations	Gary M. Sclar, JD Vice President, Dana-Farber Innovations	
GR	USC Health Center	Center for Health Systems Innovation (CHSI) https://chsi.usc.edu/ vision to create a learning health system started 2015	Dr. Carol Peden	
ILN	Carolinas HealthCare System	Health care's most wired winner 2016. Dickson Advanced Analytics innovation tools. Innovation Engine http://www.carolinashealthcare.org/edison-nation-medical	Carol Lovin, EVP, Chief Strategy Officer,	W. Edward Dunlow, Director, PI

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TABLE XXIII, APPENDIX A				
ILN	U.S. Department of Veterans Affairs, VA Center for Innovation	http://www.innovation.va.gov/ identifies, tests, and evaluates new approaches to efficiently and effectively meet the current and future needs of Veterans through innovations rooted in data, design-thinking, and agile development. Competitions, human-centered design, innovators network internally, fellowships	Patrick Littlefield, Director	A. Schleuning, Deputy Director
ILN	UC Center for Health Quality and Innovation	http://health.universityofcalifornia.edu/innovation-center/ started in 2010; had annual Colloquium Convenes experts to identify best practices and innovations that contribute to patient-centered coordinated care consistent with the Triple Aim.	Karyn DiGiorgio	
ILN	Adventist Health	Adventist Health Corporate Innovations Council 2011 provides seed money no separate web site or page	JoAline Olson, chief human resources and innovation officer,	J. May, CIO St. Helena Hospital, J. Waters, Innovation Resident, J. Gilbert, Transdisciplinary Consortium for Innovation Leadership

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TABLE XXIII, APPENDIX A				
ILN	Centura Health	In order to truly unlock the power of our health care system, our experts continuously collaborate on best practices and innovative ways to care for our communities.	Pam Nicholson, SVP, Strategy	K. Overbey, Asst VP Health Systems Excellence K. Vuturo, VP, Planning & Strategy; J. Dauer, SVP, Chief Strategy Officer, J. Elkus, Director of Innovation & Design,
ILN	Cincinnati Childrens Hospital Medical Center	https://www.cincinnatichildrens.org/service/j/anderson-center The Anderson Center Learning Networks Core helps to build and support sustainable collaborative networks that measurably improve health outcomes. Pediatrics considers Learning Networks the best way to achieve population outcomes at scale.		J. Dauer, Sr Vice President, Chief Strategy Officer Strategy & Growth, . U. Kotagal, MBBS, MSc Senior VP, Quality, Safety
ILN	City of Hope		Debra Fields , Executive Vice President and Chief Transformation Officer, dfields@coh.org	S. Johnson Chief Nursing Officer

¹ BHR = Becker's Hospital Review; GR = General Research; ILN = Innovation Learning Network

TABLE XXIV, APPENDIX A

TABLE XXIV, APPENDIX A

HEALTH CARE SYSTEMS IDENTIFIED FOR INCLUSION IN THE STUDY

System Name & Location (State)	Source ¹	Innovation Information
Boston Children's Hospital, Massachusetts	Becker's	<p>Our mission is to ensure that life-changing innovations know no boundaries and reach those who matter most: our children. We empower clinicians, researchers and entrepreneurs to transform pediatric health care—within our walls and throughout the world—turning groundbreaking visions into reality. Collaboration—an open community of innovation that welcomes partners from all communities regardless of geography or industry—is central to our mission.</p> <p>Hosts annual Global Pediatric Innovation Summit + Awards</p>
Carolinas HealthCare System, North Carolina	ILN	<p>Collaboration with Edison National Medical.</p> <p>Every idea submitted for consideration will be screened for meeting three principles: Improving patient care; Improving and streamlining processes that lead to lower costs; Fostering innovations that can demonstrate a return-on-investment for all stakeholders</p>
Children's Hospital of Orange, California	Becker's	<p>The Sharon Disney Lund Medical Intelligence and Innovation Institute (MI3) : MI3 aims to foster robust developments in artificial intelligence methodologies, as well as innovative advances in emerging areas such as genomic medicine, regenerative medicine, robotics, nanotechnology and medical applications/devices. MI3 is dedicated to empowering data intelligence and medical innovation at CHOC, and driving innovation leadership in the international pediatrics community.</p> <p>Holds monthly innovation meetings open to the public.</p>

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Geisinger Health System, Pennsylvania	Becker's	<p>Center for Emerging Technologies & Informatics: Disruptive Technology & Gadgets; Human Interface Technology in Healthcare; Novel Data Streams & Big Data Analytics; and Special Projects</p> <p>Geisinger Center for Healthcare Systems Reengineering: Human Factors Engineering Laboratory; Modeling/Simulation & Operations Research Laboratory; Partnerships; Inquiry and Discovery; Learning; and Education</p> <p>Center for Clinical Innovation: Disruptive Innovations & Population Health Technologies; Learning Healthcare System Technologies; and Patient and Family Engagement:</p>
Henry Ford Health System, Michigan	Becker's	The mission of Henry Ford Innovations is to engineer the future of healthcare. Our core programs include the Henry Ford Innovation Institute, technology management, corporate innovation, and international programs.
Intermountain Healthcare, Utah	personal	Intermountain Healthcare is uniquely positioned in the nation to provide technological advancements and innovative solutions that help meet the demand for high quality care at a sustainable cost. We have a long history of excellence in health technology and development, and this is an exciting time for Intermountain as we continue to build on our legacy in clinical information systems to find solutions that help patients and those who provide their care.
MedStar Health, Maryland	Becker's	<p>The MedStar Institute for Innovation is about creating a vibrant innovation ecosystem at MedStar to transform care and advance health. We develop and deploy deep technical capabilities – human factors, data science, influence, emerging technologies, and simulation – to enable new models of care delivery and operations. We serve as a portal for new ideas and better practices inside and outside healthcare. We catalyze innovation energy by inspiring and equipping associates to unlock their potential to create and improve.</p> <p>Hosts annual forum: Innovations in... Thinking Differently</p>
University of California System, California	ILN	The center is designed to promote, support and nurture innovations at UC medical center campuses and hospitals to improve quality, access and value in the delivery of health care. The center's goal is to support innovations at the UC health campuses that can transform the way the health needs of Californians are addressed and advance the health of California and beyond.
U.S. Department of Veteran's Affairs, Washington, D.C.	ILN	<p>The VA Center for Innovation identifies, tests, and evaluates new approaches to efficiently and effectively meet the current and future needs of Veterans through innovations rooted in data, design-thinking, and agile development.</p> <p>Data should drive decisions. User needs should drive development of products, services, programs... everything. We must test small, fail small, and scale big</p>

¹ BHR = Becker's Hospital Review; GR = General Research; ILN = Innovation Learning Network

APPENDIX B

APPENDIX B: INTERVIEW GUIDES

PHASE 1 INTERVIEW GUIDE

Questions	Response
<p>Hello. My name is Nancy Hays and I am researching a dissertation regarding health care innovation and compliance. Specifically, I am looking at the interactions between these two groups of people to understand more about how they can work successfully to meet the organization's goals. I am curious about the perceptions of each other and what characteristics or factors can be seen in their relationships.</p> <p>As I explained in my earlier contacts, I am looking specifically at large health systems that have an established innovation program. I am seeking to speak with both the chief innovation officer, or designee, and chief compliance officer, or designee, at each system.</p> <p>This dissertation is to fulfill the requirements of my doctorate in public health through the University of Illinois at Chicago.</p> <p>Thank you for taking time to speak with me.</p> <p>First, I want to ensure I collect the proper attribution for you and your title at [ORGANIZATION].</p> <p>First, could you give me a general description of the innovation process at [ORGANIZATION]</p>	
TEAMS	
<p>I have six factors I'd like to explore with you. The first is the idea of teams and how teams' function. I define a team as a group of individuals representing innovation and compliance and who are tasked with designing, evaluating or approving an innovative service, process or technology.</p> <p>How would you describe the diversity of your innovation project teams?</p> <p>What types of people are on team? Titles? Interests, departments?</p> <p>Are you familiar with the terms a "learning team/organization" or "adaptive team"? [EXPLAIN IF NOT] How would you characterize your innovation project teams using these terms?</p> <p>Are the members clear on the goals and strategy of the project?</p> <p>How have you as the executive spent time on goals and strategies? How are the executives of your organization aligned in this strategy?</p> <p>What are your thoughts about whether all the members of the team are committed to the success of the project?</p> <p>Are all the team members convinced the others have the best interests of the organization and project in mind? What evidence do you have to support this?</p>	<hr/> <hr/> <hr/> <hr/>

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KNOWLEDGE MANAGEMENT

The next factor I'd like to explore is knowledge management. I define this as the attainment, use, storage and sharing of information across the organization to benefit the organization.

First, how easy and clear are the processes to collect and retrieve data for innovation projects?

How do team members share data?

Are the team members actively seeking data to support or clarify decisions? How are the data shared? Is this expectation codified in the team charter?

Does their "ownership" of data ever get in the way of moving forward with the innovation?

Many departments have their own way of speaking, using lingo or jargon. How do the teams clarify jargon and reach a common understanding of the language?

CONFLICT

The next factor is conflict. I define conflict as disagreements between team members and organizational departments, which can be interpersonal or related to the process, goal or expected outcome of the team.

How does your organization view the role of conflict. Conflict and creativity?

Do you believe there can be "healthy" conflict? If so, how do you encourage it? If not, how do you manage conflict in a team?

Are conflict resolution processes well defined in policy, charters or by directive?

SATISFIES THE NEEDS OF THE GROUP

Only two factors left. The next is whether the team members work to "satisfies needs of the group." I define this as "the team members function for the team instead of individual interests." This requires communication and understanding, which I want to explore with you.

How are organizational goals around innovation communicated broadly and specifically for an innovation team and its project?

When teams are working on an innovation project, what expectations does leadership have of their work processes – that is, how independent are they or do they rely on executive direction heavily?

How aligned are individual and department goals at [ORGANIZATION]? Do team members share their individual and department goals with each other?

Do you think each team member believes he or she plays a purpose on innovation projects and are valued for their contributions?

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ETHICAL MANAGEMENT

The last factor is ethical management. I define this as how the organization permits and encourages management and staff to speak up, ask questions, advocate, listen to feedback and adjust based on that feedback without retribution. Some refer to this as a speak up culture or just culture.

What does your organization believe about speaking up freely? How does the organization encourage this, or not? If encouraged, how is this communicated broadly and to the innovation teams?

What evidence do you have that leaders accept the feedback and adjust their thinking or goals?

Is there any specific training for the staff to learn how to speak up and advocate?

How open do you believe the dialogues are in the innovation meetings?

Do you see team members using advocacy and inquiry actively? Is it codified in team charters?

Which projects can you recall that benefited from someone speaking up or advocating to change direction or consider an important point?

DOCUMENT REQUEST

Thank you for exploring these factors with me.

Based on our conversation, I'd like to know if there are any documents I could review as part of this dissertation. This might include team charters, executive memos regarding any of these concepts, meeting minutes, policies or procedures. Having even some of these documents will help me validate my findings and make them more useful to our community. Are there any you can share with me confidentially for this dissertation?

CONCLUSION

Once again, thank you for your openness and for helping me create a framework I hope others can follow to invigorate health care innovation and compliance collaboration.

If you think of anything else to add to our conversation, please contact me by telephone at 310-995-4297 (personal cell) or nhays3@uic.edu (university e-mail account).

APPENDIX B

Phase 2 Interview Guide

QUESTION

RESPONSE

Hello. Thank you for agreeing to talk with me again. As a reminder, I am researching a dissertation regarding health care innovation and compliance. Specifically, I am looking at the interactions between these two groups to understand more about how they can work successfully to meet the organization's goals. I am curious about the perceptions of each other and what characteristics or factors can be seen in their relationships.

Based on the first round of questions, I am conducting focused interviews on the major findings as they relate to my research questions.

This interview will probe the perceptions about innovation and compliance, and it will probe the following factors and their impact on successful innovation and compliance partnerships.

Executive Leadership

Teams and Teamwork

Learning Organization Concepts

Just Culture

Relationships

First, I want to ensure your title had not changed since last we talked. Also, I want to confirm the original consent document is still valid for this conversation.

Perceptions

My first research question looks at the perceptions innovation and compliance professionals have of each other. What I learned is those interviewed related the perceptions of innovation pushing the limits and compliance being a barrier or slowing down the process. And, it appears based on the collaboration at each site, the perceptions were no longer valid, or at the least were diminished, for their organization.

I'm curious about your reaction to that finding. Can you tell me about a time when you had negative perceptions about [the other discipline]? How did that affect your ability to complete projects?

Can you describe a time when the perceptions started changing? Was there a particular project, or a directive from leadership? What do you consider top two or three factors that influenced changing those perceptions?

What do you say to colleagues in your discipline who complain about [the other discipline] and how difficult they are to work with?

APPENDIX B

Executive Support

My initial research suggests Executive Leadership is critical in making all this work possible. I define executive leadership as the board of directors and members of the “C-Suite.” The executive influence is defined as providing a strategy that focuses on innovation; creating a culture of innovation; and resourcing the work.

In your organization, what actions did the executive leadership take to ensure innovation was a priority and needed to be supported by all other areas? How did they create a strategy, create a culture, resource the effort?

How did your leadership set and convey expectations to you about working with [the other discipline]? Was there a particular event or project you can cite that illustrates this?

Can you name one or two actions by senior leaders that helped create a culture of innovation, that is, that helped innovation and compliance move past perceptions into cooperation?

Teamwork

Teams, teamwork and relationships seem to be intertwined. I’ll pursue questions about relationships in a bit. First, I’m seeing two aspects of teams in my work: 1), keeping the organization’s goals in mind over individual or departmental needs; and 2) diversity in subject matter expertise.

What role does your executive leadership team play in getting teams to function in terms of keeping organizational goals top of mind? Can you cite an instance in which a team you worked on was at risk of not being able to move forward because of disagreements between innovation and compliance? What role, if any, did senior leaders or organizational goals play in getting the project back on track?

What does it look like when Compliance is excluded and needs to be at the table? (example?)

An article in *Health Affairs* noted that diverse stakeholder participation should be not only allowed but encouraged to drive idealized care. Tell me how your organization manifests that ideal. Was there a project when compliance should have been included and was not? What were the results of that project?

Relationships

Solid teamwork requires solid relationships, or at least mutual respect.

Tell me more about how you moved toward a relationship with people about whom you held negative perceptions? What tactics worked best? Formalized meetings? Lunch? Coffee?

Tell me about the project or the instance in which those relationships developed more strongly?

APPENDIX B

Just Culture

Almost all the organizations studied talked about being on a “just culture” or “speak up” journey. This includes people feeling comfortable in voicing opinions and ideas, and in management responding without retaliation and taking comments seriously.

Given that, how does a just culture manifest itself in terms of how innovation and compliance work together? What creates an environment in which innovation can push boundaries and compliance can share risks without holding back or feeling like an impediment or barrier?

I'd like to hear about a project in which one of you was hesitant to speak up and what happened with the project. I'd also like to hear about a project in which one of you did speak up and what happened.

Learning Organization Concepts

Learning organizations take what works – and what does not work as well – and learn from both to create a better process, product, or experience – continually evolving to be better.

On a larger scale, what evidence do you have that you function in a learning organization?

What factors influence being a learning organization? And how had that created an environment in which compliance and innovation can partner?

Can you tell me about an innovation project that had experienced failure because of a compliance issue and how that was resolved?

CONCLUSION

Once again, thank you for your openness and for helping me create a framework I hope others can follow to invigorate health care innovation and compliance collaboration.

I will send you a version of this at a later date to ensure I have captured your responses accurately. If you think of anything add, please contact me by at 310-995-4297 or nhays3@uic.edu (university e-mail account).

APPENDIX C: TABLE XXV: ORIGINAL CODING TABLE

Factor	Characteristics to Explore	Sample Code
Team The team is a group of individuals representing innovation and compliance and who are tasked with designing, evaluating or approving an innovative service, process or technology.	Diversity of innovation project teams: Specialization	TeamOn TeamOff
	Learning Team	Learn
	Adaptive Team	Adaptive Grow Cycle Failure
	Common understanding of goals, strategy	Goal Strategy Direction Alignment
	Members believe others are committed to success: Statements on the understanding of the team members perceptions of the other (innovation and compliance)	Success Commitment PerceptionGood PerceptionBad
	Each believes the success of team is also their success: Statements on the understanding of the team members perceptions of the other (innovation and compliance)	Success
Knowledge management The attainment, use, storage and sharing of information across the organization to benefit the organization.	Members believe others put in effort above minimum: Statements on the understanding of the team members perceptions of the other (innovation and compliance)	EffortGood EffortBad
	Data are available: Processes to collect and retrieve data are easy and clear	DataProcess
	Data are encouraged to be shared: Teams are expected to share data between departments	DataShare
	Seeks and shares data: Teams seek data during decision making processes	DataUse
	Shares subject matter expert knowledge: Team members freely and consistently share information	SMEShare SMEHold
	Speaks “common” language: Jargon is reduced for common understanding of information	CommClarity

TABLE XXV, APPENDIX C

<p>Conflict</p> <p>Disagreements between team members and organizational departments, which can be interpersonal or related to the process, goal or expected outcome of the team.</p>	View of conflict within working teams by management: The organization understands the role of conflict, that it will occur and that it generates creativity	Conflict
	“Healthy” conflict is valued: Healthy vs unhealthy conflict is understood, and healthy conflict encouraged as part of the creative process	Conflict
	The look of manifestations of conflict between innovators and compliance professionals: Conflict resolution processes are defined and used	Conflict
	Conflict allowed in meetings: Conflict is allowed and not avoided during meetings	ConflictAllow
	Conflict benefits the team and product: Conflict encouraged as part of the creative process	Conflict
<p>Satisfies needs of group</p> <p>This relates to team members functioning for the team instead of individual interests and requires communication and understanding.</p>	Expectations that team members function for the greater good of the team as opposed to individual actors:	Team
	Encourages direct interaction between team members: Teams are expected to work together through the processes and not rely on executive direction	Team
	Team members are aware of other members’ roles and imperatives: Team members share department missions and goals	Team
	Team members adapt to the needs of the team: Team members view individual and department goals through the lens of organizational and project goals	Team
	Team members value the other team members: Each team member plays a purpose in the project and is valued for contributions.	Team
<p>Ethical management</p> <p>How the organization permits and encourages management and staff to speak up, ask questions, listen to feedback and adjust based on that feedback without retribution.</p>	The organization had a “speak up” culture.	Ethic
	The organization encourages inquiry of peers and leaders and the challenging of assumptions:	Ethic
	The organization’s leaders are willing to change course based on team feedback.	Ethic
	Staff are trained on inquiry and advocacy	Ethic
	Processes are built around feedback and change based on the feedback.	Ethic

APPENDIX D: ADDITIONAL FIGURES, TABLES AND CHARTS FOR CHAPTER IV**TABLE XXVI, APPENDIX D**

Documents coded in Phase 1, separated as journals/books and “other,” including Web sites and annual reports.

Title/Publisher	Publication Type	Author/System	Year	Subject
Journal Articles and Books				
<i>Accelerating Health Care Transformation with Lean and Innovation</i> (excerpts)	Book	Paul Plsek	2014	Focuses on the use of Lean in a Pacific Northwest Hospital system. Had sections related to Executive code, Teamwork code and Communications code (Plsek, 2013)
Business Model Disruption: Innovation as a Catalyst/ <i>Frontiers of Health Service Mgmt</i>	Journal	Anthony Aramda, Aaron Martin	2016	Innovation as practiced at various health care systems (Armada, 2016)
Continuous Innovation in Health Care: Implications of The Geisinger Experience / <i>Health Affairs</i>	Peer Review Journal	Ronald Paulus, et al./ Geisinger	2008	Geisinger Health System’s innovation strategy for care model redesign in an integrated system (Paulus et al., 2008)
Innovation and Transformation that Drive Value/ <i>Frontiers of Health Service Mgmt</i>	Journal	Stephanie S. McCutcheon	2016	A review of the key initiatives that have driven the evolution and performance results of system innovation programs at MedStar Health and OSF HealthCare (McCutcheon, 2016)
Innovation in Pediatric Cardiac Intensive Care: An Exponential Convergence Toward Transformation of Care/ <i>World Journal for Pediatric and Congenital Heart Surgery</i>	Peer Reviewed Journal	Kevin Maher, Anthony Change (CHOC)	2015	Addresses the issue of innovation in pediatric medicine with relevance to cardiac intensive care (Maher and Chang, 2015)
Innovative Thinking for the Improvement of Medical Systems, <i>Ann Int Med</i>	Peer Review Journal	Paul Plsek	1999	Uses a case example to show that groups of health care professionals can produce useful and innovative ideas (Plsek, 1999)

APPENDIX D

TABLE XXVI, APPENDIX D

Documents coded in Phase 1, separated as journals/books and “other,” including Web sites and annual reports.

Websites, Annual Reports/Whitepapers, Magazine Articles (for Primary Source Data Analysis)

Elements of Culture of Innovation/Website	Medstar Institute for Innovation (Web page)	Adapted from Paul Plsek	Captured 2017	Identifies seven “elements of culture” an innovative health care organization must demonstrate (Culture of Innovation, 2018)
Eureka Index: Most Innovative Companies: Henry Ford Health/ <i>Crain’s Detroit Business</i>	Magazine	Leslie Green	2016	Focuses on innovations that move to market. Discusses communication briefly Identifies seven “elements of culture” an innovative health care organization must demonstrate (Green, 2016)
Geisinger Annual Report 2013: Transforming Healthcare Through Innovation	Annual Report	n/a	2013	Focuses on innovation and innovations at Geisinger (Geisinger, 2013)
Report: UC Center for Health Quality and Innovation: CHQI Impact and Evaluation 2010-2016	White Paper/ Report	UC Center for Health Quality and Innovation	2016	Quantifies and shares impact of programs and projects from 2011 to 2015 from the UC Center for Health Quality and Innovation (CHQI). (DiGiorgio et al., 2017)
Transforming Healthcare: Four Things Every Innovation Program Needs to Succeed	Website Blog	George Hamilton	2017	Discusses four concepts used by Intermountain Healthcare to explore, test, and even commercialize ideas for improving care: Dedication, Culture, Quality, Funding (Hamilton, 2017)
Transforming Healthcare: Giving Meaning to Innovation	Website Blog	George Hamilton	2016	Employees from Intermountain Innovations discuss their work (Hamilton, 2016)
Transforming Healthcare: How to Be Innovative, Tips for Companies and Individuals	Website Blog	George Hamilton	2017	Discusses how organizations can encourage their workforce to rethink how things are currently being done and to challenge the status quo (Hamilton, 2017)

APPENDIX D

TABLE XXVII, APPENDIX D

THE CODES, THE RELATED MODEL(S) AND DEFINITION

Code	Models	Definition
Adaptive	Learning Organization	Able to change to suite a situation
Alignment	Mental Model Generative Leadership	Two or more parties work from the same expectations and toward the same goal in similar ways
Commitment	Mental Models Organizational Frames	Agrees to a standard, goal or strategy
Communication Clarity	Learning Organization Organizational Frame	Leadership and managers convey expectations clearly
Conflict	Dimensions of Conflict	Parties do not agree or get along
Conflict allowed	Dimensions of Conflict Generative Leadership/Relationship	Conflict is encouraged if healthy conflict.
Cycle	Learning Organization	Refers to the cycle of a project
Data Process	Learning Organization	The way data are gathered and reported on
Data Share	Learning Organization Generative Leadership/Relationship	Departments within an organization and their willingness to share department-specific data
Data Use	Learning Organization	How data are used in relation to the business objective
EffortBad	Mental Models	The effort of a person or department is perceived as not helpful or adequate
EffortGood	Mental Models	The effort of a person or department is perceived as helpful or adequate
Ethic	Organizational Frame	How an organization's culture is reflected in its people and its work
Ethic Challenge	Learning Organization Generative	Someone is confronted with a situation that requires a moral judgment
Ethic Feedback	Learning Organization Generative Leadership/Relationship	Someone provides or wants to provide information to another person without retaliation
Ethic Inquiry	Learning Organization Generative Leadership/Relationship	Someone asks or wants to ask about a project or initiative without retaliation
Ethic Speaking	Learning Organization Generative Leadership/Relationship	Employees are able to state their truth without retaliation
Example	–	Examples of any of the codes

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TABLE XXVII, APPENDIX D

THE CODES, THE RELATED MODEL(S)
AND DEFINITION

Executive	Organizational Frame Generative Leadership/Relationship	Includes leadership/C-suite influence, support for compliance/innovation, or encouraging the interaction between compliance, innovation and other disciplines.
Failure	Learning Organization	Not meeting personal or business expectations
Goal	Learning Organization	Purposeful metric as a subset of a strategy
Grow	Learning Organization Organizational Frame	Able to take situations and become a better employee by learning from them
JustCulture	Learning Organization Generative Leadership/Relationship Organizational Frame	Involves a patient safety aspect and includes speaking up about concerns and leadership responses
Law	Organizational Frame	The legal aspect of a decision
Learn	Learning Organization	Ability to take situations and adapt learnings to other situations
Learning Organization	Learning Organization	The organization accepts and makes changes based on experience
PerceptionBad	Mental Models	A party views another party as not helpful, a barrier, not cooperative
PerceptionGood	Mental Model	A party views another party as helpful, cooperative
Regulation	Organizational Frame	A ruling by a government agency that impacts a project
Regulatory	Organizational Frame	The regulation aspect of a decision
Relationship	Generative Leadership/Relationship	Parties that were estranged or not engaging meet and form a bond or agreements
Resistance	Mental Models Dimensions of Conflict	More passive than confrontational conflict and not interactive; avoidance, pushback.
Resolution Process	Dimensions of Conflict Generative Leadership	How conflict is resolved
SME Hold	Conflict Generative Leadership/Relationship	Subject matter experts not sharing information
SME Share	Conflict Generative Leadership/Relationship	Subject matter experts sharing information

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TABLE XXVII, APPENDIX D

THE CODES, THE RELATED
MODEL(S) AND DEFINITION

Strategy	Organizational Frame	An organization's overarching plan over more than one year
Success	Learning Organization Organizational Frame	A goal is met
SystemsIssue	Organizational Frame	Part of Just Culture and of an environment that produces positive interactions.
TeamOff	Mental Model Generative Leadership/Relationship	Who is not on a team (i.e., excluded)
TeamOn	Mental Model Generative Leadership/Relationship	Who is on a team
TeamStructure	Organizational Frame	How the team is formed and how it reports
Teamwork	Mental Model Generative	People gather and perform to meet an organizational goal

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TABLE XXVIII, APPENDIX D

SUMMARY GRID OF PHASE 1 INTERVIEW PARTICIPANTS

	1:1 Interview Participants			
	A	E	F	G
	South: South Atlantic	West: Mountain	West: Pacific	[consultants]
Interview Compliance	C1	C2	C3	CN1, CN2
Interview Innovation ¹	I1, I2, I3a	0	I4	
Doc: Website	Yes	Yes	No	No
Doc: Annual Report	Yes	Yes	Yes	No
Doc: Internal	No	No	No	No

¹ One innovation interviewee did not complete the IRB consent form and was dropped from the study.

TABLE XXIX, APPENDIX D

PHASE 2 INTERVIEWS BY TYPE AND LOCATION

	1:1 Interview Participants, Phase 2			
	A	E	F	G
	South: South Atlantic	West: Mountain	West: Pacific	[consultants]
Interview Compliance	n/a	C2	C3	n/a
Interview Innovation	I2	0	I4	n/a

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TABLE XXX, APPENDIX D

FREQUENCY OF EACH A PRIORI AND EMERGENT CODE, HIGHEST TO LOWEST
PER THE COMBINED TOTAL

Code	Combined	Phase 1 Interviews	Primary Source Documents
Teamwork	117	78	39
Strategy	81	52	29
Executive	58	35	23
Success	58	33	25
Relationship	55	30	25
Data Share	51	23	28
Goal	48	27	21
Learning Organization	45	10	35
Conflict	41	38	3
Resistance	40	28	12
SystemsIssue	39	8	31
TeamStructure	39	25	14
Adaptive	34	27	7
Communication Clarity	34	30	4
Ethic Speaking	34	34	0
Learn	29	25	4
JustCulture	28	24	4
Grow	27	20	7
PerceptionBad	26	26	0
Commitment	24	17	7
Data Use	24	8	16
Alignment	20	15	5
Data Process	20	13	7
Ethic Inquiry	20	12	8
PerceptionGood	20	20	0
Conflict allowed	19	17	2
Resolution Process	18	18	0
Ethic Challenge	17	15	2
TeamOn	17	14	3
Example	16	11	5
Regulatory	16	15	1
Funding	12	0	12
Ethic Feedback	11	11	0
Law	10	10	0
Regulation	10	10	0
TeamOff	10	9	1
Failure	9	6	3
Cycle	6	3	3
EffortGood	5	4	1
Restriction	5	4	1
Direction	3	3	0
SME Share	3	2	1
Ethic	2	2	0
EffortBad	1	0	1
SME Hold	0	0	0

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TABLE XXXI, APPENDIX D

CO-OCCURRENCE TABLES FOR THE CODES COMBINED INTO FAMILY CODES

CONFLICT GROUP	Conflict	Conflict Allowed	Resistance
Conflict	–	11	1
Conflict Allowed	11	–	–
Resistance	15	4	–

DATA GROUP	Data Process	Data Share	Data Use
Data Process	–	10	8
Data Share	10	–	12
Data Use	8	12	–

JUST CULTURE GROUP	Ethic Challenge	Ethic Feedback	Ethic Inquiry	Ethic Speaking	JustCulture
Ethic Challenge	–	0	4	12	8
Ethic Feedback	0	–	1	7	2
Ethic Inquiry	4	1	–	5	5
Ethic Speaking	12	7	5	–	16
JustCulture	8	2	5	16	–

LEARNING ORGANIZATION	Adaptive	Failure	Grow	Learn	Learning Organization
Adaptive	–	1	17	22	14
Failure	1	–	0	1	1
Grow	17	0	–	20	8
Learn	22	1	20	–	7
Learning Organization	14	1	8	7	–

LEGAL-REGULATORY GROUP	Law	Regulation	Regulatory
Law	–	0	4
Regulation	0	–	5
Regulatory	4	5	–

TEAMS GROUP	TeamOff	TeamOn	TeamStructure	Teamwork
TeamOff	–	0	2	3
TeamOn	0	–	10	9
TeamStructure	2	10	–	23
Teamwork	3	9	23	–

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TABLE XXXII, APPENDIX D

CODE FREQUENCY RESULTS AFTER CODES WERE COMBINED. In order of those with the most uses to the least when interviews and documents are combined.

Code	Combined	Phase 1 Interviews	Documents
Teams Group	183	126	57
Learning Org Group	144	88	56
Just Culture Group	112	98	14
Conflict Group	100	83	17
Data Group	95	44	51
Strategy	81	52	29
Executive	58	35	23
Success	58	33	25
Relationship	55	30	25
Goal	48	27	21
SystemsIssue	39	8	31
Legal-Regulatory Group	36	35	1
Communication Clarity	34	30	4
PerceptionBad	26	26	0
Commitment	24	17	7
Alignment	20	15	5
PerceptionGood	20	20	0
Resolution Process	18	18	0
Example	16	11	5
Funding	12	0	12
Cycle	6	3	3
EffortGood	5	4	1
Restriction	5	4	1
Direction	3	3	0
SME Share	3	2	1

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TABLE XXXIII, APPENDIX D

INTERVIEW SUMMARY GRID WITH PHASE 2 ADDED

Interview Type	Phase 1	Phase 2
Number of Systems Contacted	9	3
Number of Systems Interviewed	3	3
Individual Interviews: Compliance	3	2
Individual Interviews: Innovationa	4	2
Number of Systems Both with Innovation and Compliance Interviewed	2	1
Number of Systems Compliance Only Interviewed	1	1
Number of Systems Innovation Only Interviewed	0	1
Number of Consultants Contacted	2	0
Number of Consultants Interviewed	2	0
Total Discrete Interviewsa	8	4

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TABLE XXXIV, APPENDIX D

FREQUENCIES OF CODES INCLUDING CODING FROM PHASE 2 INTERVIEWS

Code	Combined	All Interviews	Primary Source Documents
TeamsGroup	231	174	57
LearningOrgGroup	212	156	56
ConflictGroup	136	119	17
JustCultureGroup	135	121	14
DataGroup	111	60	51
Strategy	110	81	29
Executive	84	61	23
Relationship	76	51	25
Success	64	39	25
Goal	54	33	21
Reg-Legal Group	54	53	1
Communication Clarity	49	45	4
SystemsIssue	43	12	31
Alignment	41	36	5
PerceptionBad	39	39	0
PerceptionGood	38	38	0
Commitment	36	29	7
Resolution Process	28	28	0
Example	21	16	5
Funding	21	9	12
EffortGood	13	12	1
Direction	8	8	0
EffortBad	7	6	1
Cycle	6	3	3
Restriction	6	5	1
SME Share	5	4	1
SME Hold	1	1	0

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TABLE XXXV, APPENDIX D

CODE FREQUENCY FOR PEER REVIEW DOCUMENTS

Codes	Frequency
Learning Org Group	55
Strategy	37
TeamsGroup	34
Data Group	29
Executive	29
Goal	15
SystemsIssue	13
Relationship	12
Success	12
Alignment	11
JustCultureGroup	9
Conflict Group	8
Commitment	7
Adaptive	5
Communication Clarity	4
Cycle	3
Example	3
Funding	2
SME Share	2
Reg–LegalGroup	1
Direction	1
Resolution Process	1
Restriction	1
EffortBad	0
EffortGood	0
PerceptionBad	0
PerceptionGood	0
SME Hold	0

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TABLE XXXVI, APPENDIX D

CO-OCCURRENCES FOR CODES PERCEPTIONBAD AND PERCEPTIONGOOD

	PerceptionBad		PerceptionGood
ConflictGroup	40	TeamGroup	40
TeamGroup	33	ConflictGroup	29
JustCultureGroup	16	Relationship	19
Legal-RegGroup	16	JustCultureGroup	17
PerceptionGood	14	LearningOrgGroup	17
Relationship	14	Legal-RegGroup	17
LearningOrgGroup	11	PerceptionBad	14
Communication Clarity	9	Alignment	10
Alignment	5	Communication Clarity	10
Restriction	4	DataGroup	9
Success	4	Success	8
Commitment	3	Strategy	7
DataGroup	3	EffortGood	6
EffortBad	3	Example	4
Resolution Process	3	Goal	4
Strategy	3	Resolution Process	4
Example	2	Commitment	2
Executive	2	Direction	2
Goal	2	EffortBad	2
EffortGood	1	Executive	2
Funding	1	SME Share	2
SystemsIssue	1	SystemsIssue	2
Cycle	0	Funding	1
Direction	0	SME Hold	1
PerceptionBad	0	Cycle	0
SME Hold	0	PerceptionGood	0
SME Share	0	Restriction	0

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TABLE XXXVII, APPENDIX D

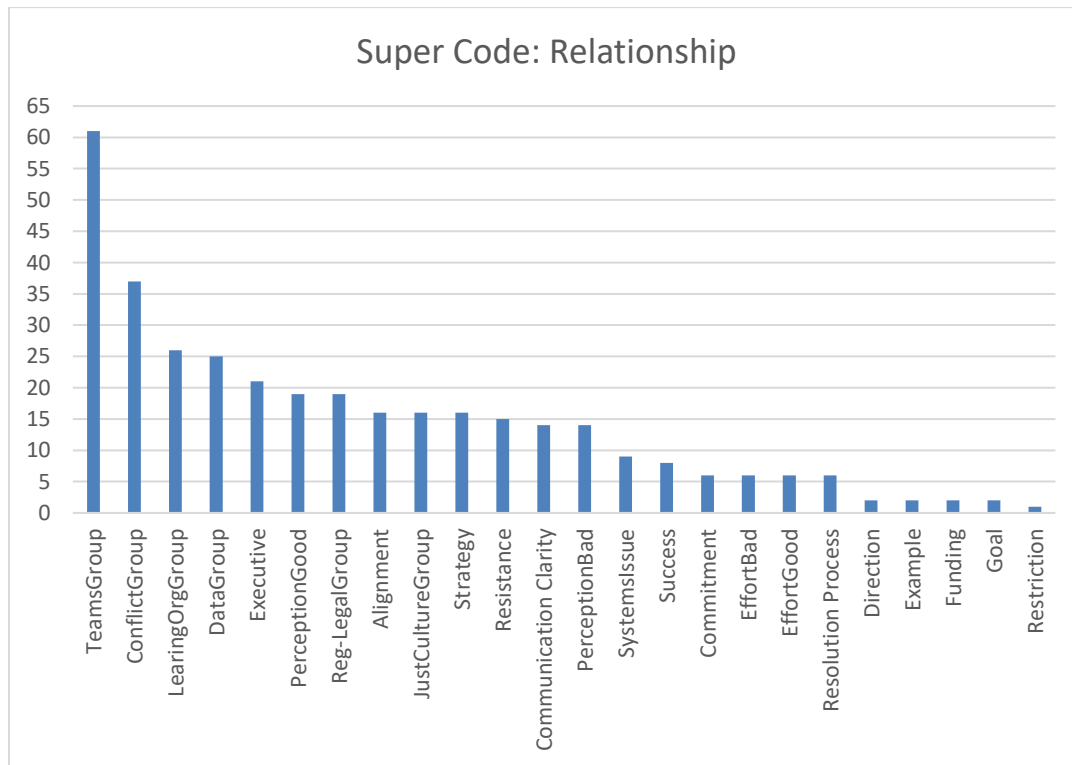
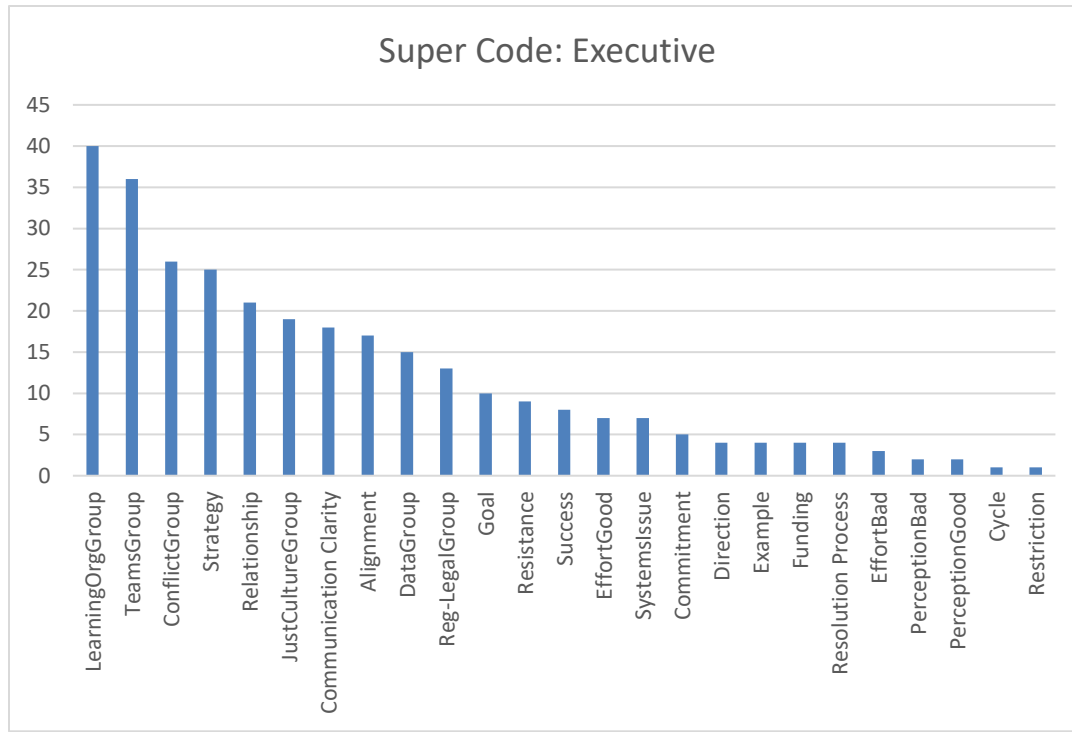
LEAST FREQUENCY USED CODES WITH MODEL AND DEFINITION

Code	Models	Definition
Direction	Generative Leadership	Suggestions or orders from senior leaders on how to proceed
EffortBad	Mental Models	The effort of a person or department is perceived as not helpful or adequate
EffortGood	Mental Models	The effort of a person or department is perceived as helpful or adequate
	Conflict	
Restriction	Mental Models	Limits on what is allowed
	Conflict	
SME Hold	Generative Leadership	Subject matter expert not sharing information
	Conflict	
SME Share	Generative Leadership	Subject matter expert sharing information

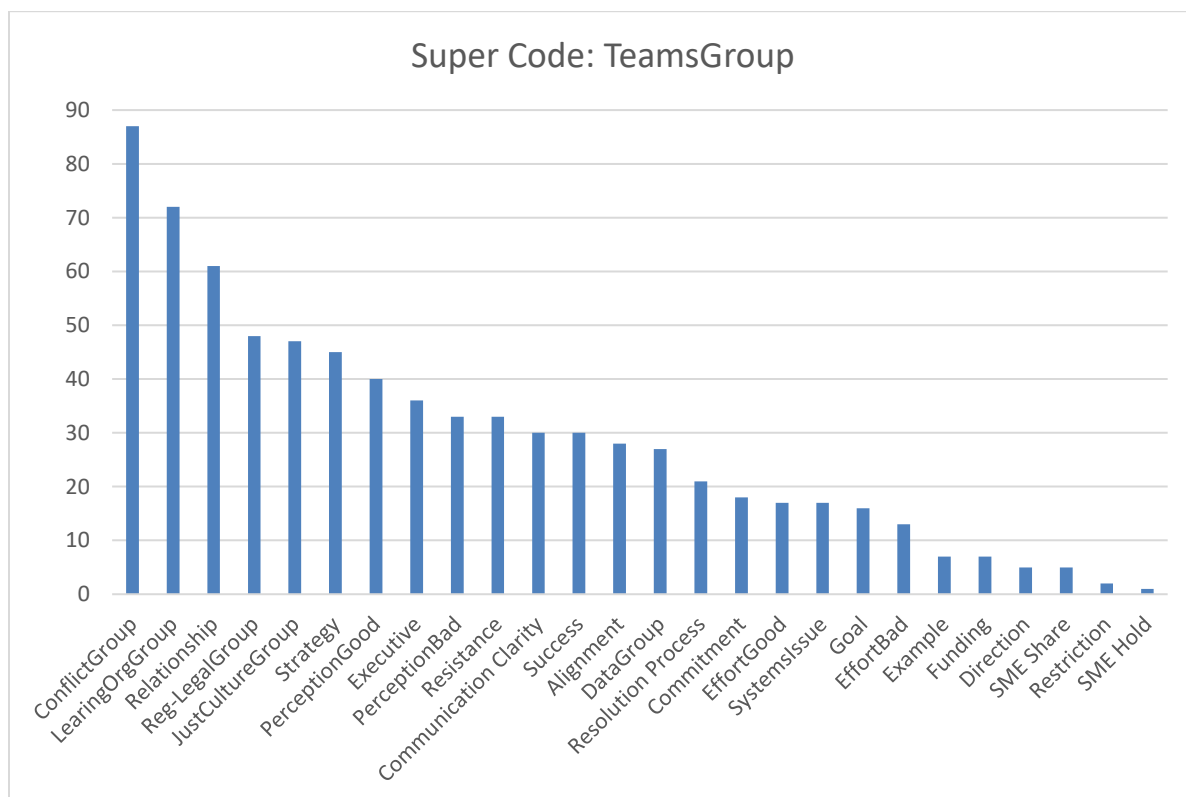
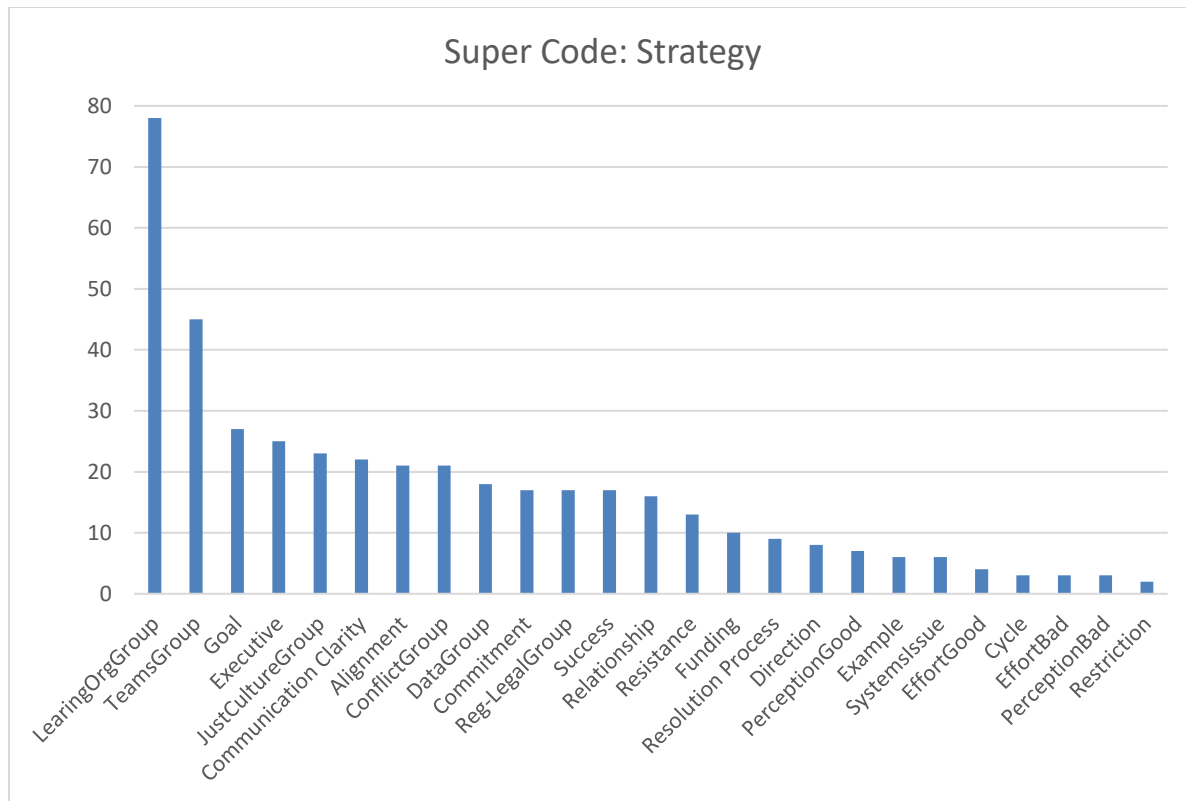
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FIGURES 8-12, APPENDIX D

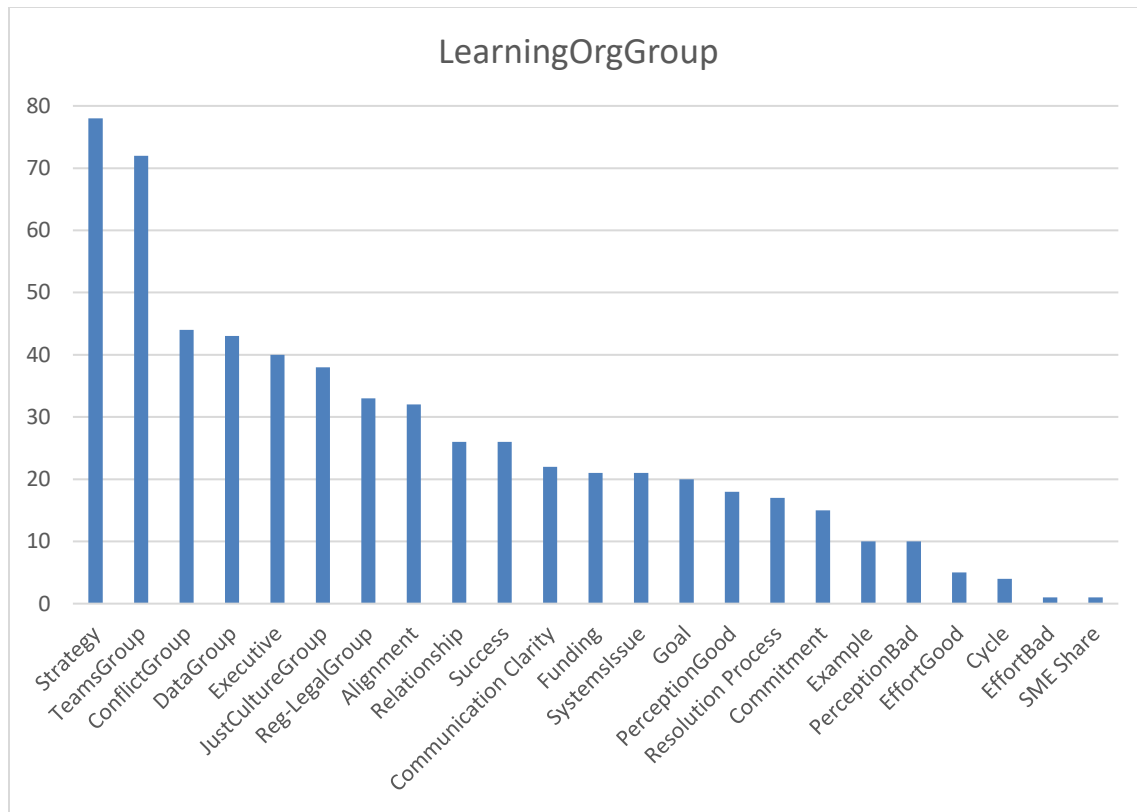
CHARTS SHOWING FREQUENCIES OF CO-OCCURRENCES FOR NOTABLE CODES



APPENDIX D



APPENDIX D



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(pp. 197-214). Human Systems Dynamics Institute Press, 2003.

VITA

NAME: Nancy K. Hays

EDUCATION

Bachelor of Arts, English Literature, Northwestern University, Evanston, Illinois, 1986

Master of Public Health, UCLA Fielding School of Public Health, Los Angeles, California, 1999

Doctor of Public Health, The University of Illinois at Chicago, School of Public Health, Chicago, Illinois, 2019

TEACHING EXPERIENCE

Department of Health Care Administration, California State University, Long Beach; HCA 422: Global Health Systems (upper classman elective), HCA 428: Population Health for Management (required class for major), Fall 2015 – present

WORK EXPERIENCE

Kaiser Permanente South Bay Medical Center

Medical Center Compliance & Privacy Officer Dec 2011–current

Served as Compliance Manager from December 2011 to July 2013. Promoted to Medical Center Compliance & Privacy Officer as of August 2013. Support all compliance-related activities across the medical center, in particular privacy and security; and fraud, waste and abuse. South Bay service area includes a 231-bed acute-care hospital with 11 medical offices buildings from Long Beach to Torrance, Calif., about 3,000 employees and 500 physicians, and almost 200,000 KP members.

Kaiser Permanente South Bay Medical Center

Practice Leader Consultant May 2010 – Dec 2011

Reported to hospital chief executive officer, responsible for implementing hospital-based initiatives including Readmissions/PE – STAR (Safe Transitions Avoiding Readmissions); Patient Classification Specialists; Hospital Throughput, Collaborating for Outcomes (The Advisory Board Model); Primary Stroke Center Certification. Attended “Wave V” Improvement Advisor Series (Green Belt) in 2011.

Kaiser Foundation Health Plan/Hospitals (Kaiser Permanente)

Office of the President

Executive Manager Dec 2006 – May 2010

Ran Office of the President (KP regional president for Southern California) overseeing high-level initiatives and projects. Led the Performance Management Department, which tracked strategic initiatives via scorecards and other tools. Managed regional Flu Oversight Group for 2009 H1N1 Flu (Swine Flu). Worked with multiple parties to enhance services to members with autism and their families based on internal review and findings from the Department of Managed Health Care.

VITA

Kaiser Foundation Health Plan/Hospitals (Kaiser Permanente)

Executive Offices

Project Manager II Sep 2004 – Dec 2006

Supported chief operating officer on operations for health plan / hospitals and conducted special projects. Designed new structure for regional and medical center operations and leadership, including changing from seven services areas to 12 medical centers, the addition of two senior vice presidents of operations, and changing medical center leaders.

Southern California Permanente Medical Group (Kaiser Permanente)

Consulting & Implementation/Practice Enhancement for Physicians

Project Manager II Jan 2002 – Sep 2004

Used a four-step, PDSA-type process-improvement technique known as Practice Enhancement for Physicians with small groups of physicians.

Cedars-Sinai Medical Network Services

Manager, Administrative Services Jul 1999 – Jan 2002

Reported to the chief executive officer of a physician group affiliated with Cedars-Sinai Medical Center. Worked as project manager to develop and maintain physician network for a management services organization that oversees two physician organizations.

Laurel Health System

National Rural Health Association, Administrator Fellowship Jun 1998 – Sep 1998

One of 12 students chosen to be a Rural Administrator Fellow through a Kellogg Foundation grant. Worked for the chief executive officer and president of Laurel Health System, a nonprofit, community-based system serving the rural population of Tioga County, Pa. System consisted of acute care; long-term care; primary care; home health care; and various community services for children, youth and seniors.

Miramar Communications

Managing Editor, *TeamRehab Report* Nov 1995 – Aug 1997

TeamRehab Report, monthly nonpaid trade magazine, serves professionals in the long-term physical rehabilitation field. Led a team that won two Maggie awards from the Western Publishing Association

Jems Communications (Mosby Inc.)

Senior Editor, *Journal of Emergency Medical Services* Feb 1992–Jul 1995

Project Coordinator, Emergency Care Information Center Jul 1995–Sep 1995

JEMS was a monthly magazine serving the EMS community. The Emergency Care Information Center was the consulting arm of Jems Communications.

VITA

Gemological Institute of America

Assistant Editor, *Gems & Gemology* May 1987 – Jan 1992

Managing Editor, *In Focus* May 1988 – Jan 1992

Graduate School Employment

Student Research Associate

William Cunningham, MD, MPH, Assistant Professor Oct 1998 -Aug 1999

Student Research Associate

UCLA Center for Health Policy Research Apr 1998–Jun 1998

Event Medical Services

Emergency Medical Technician Jan 1992–Dec 1997

AWARDS

Ruth F. Richards Outstanding Student Award, UCLA Department of Health Services, 1999

Top student, Health Care Systems Organization and Financing, UCLA Department of Health Services, 1997

Best group presentation, Health Care Systems Organization and Financing, UCLA Department of Health Services, 1997

Maggie Award (Western Publishing Trade Association), Best Medical/Dental Trade Magazine, *TeamRehab Report* (October 1997 issue), 1998

Maggie Award (Western Publishing Trade Association), Best Editorial, 1997

Photograph ("Unstoppable"), *TeamRehab Report* (October 1996 issue), 1997

"Jewels of the Edwardians" (*Gems & Gemology*), First Place/Best Article Award, 1993

PUBLICATIONS AND PAPERS

Levan, R, Brown, ER., Hays, N. Wyn R. (1999) Disparity in job-based health coverage places California's Latinos at risk of being uninsured. *Center for Health Policy Research Policy Brief*, April 1999.

Hays, N. (1997) The young ones: early intervention is growing. *TeamRehab Report*, June: 21-22, 24, 1997

Hays, N. (1997) Women, age and disabilities. *TeamRehab Report*, May: 33-34, 36, 1997.

Misiorowski, EB., Hays, NK (1993) Jewels of the Edwardians. *Gems & Gemology*, 29:3, 152-171, 1993.

VITA

MEMBERSHIPS

Board Member, Long Beach Day Nursery, Long Beach, 2016–present

Member, Health Care Compliance Association, 2011- present

Volunteer, Long Beach Unified School District, Buffum Total Learning Center, 2012

Board Member, UCLA Health Services Alumni Association, 2004–2007

Associate, UCLA Prehospital Care Research Forum, 1999–present

Iota Chapter, Delta Omega, 1999

Northwestern Alumni Admission Council, Los Angeles Chapter, 2002–2013