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Assessment Of Health Data Transformation Capabilities Of Health Information Networks In Early Endorsers Of A Nationwide Learning Health System

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Assessment of Health Data Transformation Capabilities of Health Information Networks in Early Endorsers of a Nationwide Learning Health System

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Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Weeks, A. L., Brown, J. M., Bryant, S. P., et al. (2014). A personal health information toolkit for health intervention research. Studies in Health Technology and Informatics, 199, 35–39.

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ABSTRACT

Health research findings and health practitioner observations are key components in advancing the state of health care delivery and outcomes. Interconnected communications and computing technology can provide efficient means of gathering, analyzing and disseminating information. The Institute of Medicine introduced an early vision of a continuous health data analysis and knowledge generation system and called it a Learning Healthcare System (LHS). A learning health system that incorporates health data analysis and knowledge generation has the potential to provide many benefits to public health and individual health outcomes. The focus of this research is to use a qualitative case study approach to examine emerging learning health system capabilities of United States based or supported health data networks among four early endorsers of the learning health systems concepts in terms of system maturity, learning capability, and knowledge dissemination. Additional health data network concepts are also studied, including system use and availability, health data transformation, and sustainability.

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CHAPTER 1

INTRODUCTION

Health research findings and health practitioner observations are key components in advancing the state of health care delivery and outcomes. Health researchers perform quality research by collecting and analyzing data from study participants or existing literature to better understand health components and outcomes such as diseases, health interventions, health decisions, and consequences of health policies. Health practitioners examine patients and analyze patient information in order to understand the results of health decisions, interventions, treatments, and the health state of a population. If health practitioners had timely access to quality health research findings and health researchers had access to individual and population data, these groups could learn from one another forming a continuous loop of learning and expedite the pace of application of advancements in healthcare.

The Institute of Medicine's Roundtable on Evidence-Based Medicine coined the term "learning healthcare system" to describe an endeavor to improve "the development and application of evidence in healthcare decision making" (IOM, 2007). The goal of a learning healthcare system is to draw research closer to practice. Broad issues involved in supporting such an endeavor span technology, standards, and regulatory issues. The rate of information generation is only increasing and presents a future challenge for developing health decisions and recommendations based on the timely evidential information. Current processes in the healthcare environment may benefit from the support of dynamic discovery and dissemination of timely evidence-based recommendations.

Interconnected communications and computing technology can provide an efficient means of gathering, analyzing and disseminating information. However, the communications technology must be supported by standard data representation formats that support automated collection and transmission activities. The healthcare industry is governed by different regulations that provide a framework in which any technology and data management infrastructure must be compliant.

Service Industries use continuous data collection and analysis to constantly adjust business operations to suit present conditions and make decisions about future operations based on historical and projected data trends. Retail, manufacturing, and commercial aviation use continuous analysis of point of service information to adjust aspects of the business operation to current demand and use common industry available discoveries for continuous improvement (Friedman, & Rigby, 2013). How can the US healthcare system employ similar efforts to improve the delivery of healthcare information? Presently, the lag between transferring new research findings and discoveries to clinical practice varies considerably; for example, Friedman, Wong, & Blumenthal (2010) give a conventional wisdom estimate of 17 years for clinical knowledge to become routine practice in the United States. In healthcare, a comprehensive approach is needed in order to achieve a continuous learning system like those used by other service industries (Friedman, & Rigby, 2013). The goal is to reduce the timeframe for transitioning research to practice.

In Anderson et al's (2006) study of healthcare spending and technology use in several Organization for Economic Cooperation and Development (OECD) countries, they found that regardless of healthcare system organization, many industrialized countries are experiencing increased expense in administering healthcare nationwide. They wrote that the Centers for Medicare and Medicare Services (CMS) estimated that US healthcare spending will increase to consume up to 20% of the US Gross Domestic Product (GDP) by 2015. Anderson et al (2006) proposed health information technology adoption in the US to reduce healthcare spending and improve healthcare quality. This is a similar strategy used by other industrialized countries that are well into the process of national health information technology adoption and ahead of the United States. The United States, as other industrialized countries, is establishing a national committee to oversee the regulation and adoption of health information technology through the establishment of the Office of the National Coordinator for Health Information Technology (ONCHIT) in 2009. The groundbreaking federal legislation had also been enacted to encourage the adoption of health information technology and standards including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which contains provisions for health information privacy and standards for coding and transmission as shown in Figure 1 (Coffey et al 1997; Anderson et al, 2006). In 2009, President Barak Obama signed the American Recovery and Reinvestment Act of 2009, which included further support for the continued adoption of health information technology (Steinbrook, 2009).

Federal Laws Support Electronic Health Information:

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)
2. American Recovery and Reinvestment Act of 2009 (ARRA)

Figure 1 - Key Federal Laws Support Electronic Health Data Conversion to Digital Format

Middleton (2005) reiterated J.D. Kleinke's position, in an article appearing in the same publication, where Kleinke identifies some key issues for health IT market underperformance including a fragmented industry, slow development of HIT standards, and inequitable distribution of HIT benefits. Middleton (2005) proposed that in contrast to aggressive tactics, the government can act as a gentle "Third Hand" to encourage the adoption of standards-compliant health IT by providers and small to midsize healthcare providers through incentives for adoption and federal guidance on critical issues, such as privacy and security, and penalties for misuse. While the government can encourage adoption of health information technology, there exists other barriers to health information technology acceptance, including the cost of adoption, reduced productivity due to training, and inequitable distribution of HIT benefits to practices (Middleton, 2005; Anderson, 2006).

A learning health system that incorporates health data analysis and knowledge generation has the potential to leverage strategies used in other industry sectors to benefit public health and individual health outcomes. "Developing a nationwide cross-institutional data sharing system holds the potential for population health surveillance, quality improvement, and ultimately the formation of the digital infrastructure of a transformative, learning health system for the nation" (Bailey, et. al., 2013). A public health monitoring project conducted by Johns Hopkins and the New York City Department of Health used a retail industry strategy for analyzing point of sale data for over the counter healthcare products to infer and track potential health events (Friedman, & Rigby, 2013). Kaiser Permanente health system has demonstrated the benefits of a learning health system by using electronic health data of 1.4 million patients to identify increased health risk with the drug Vioxx, prompting the FDA to take corrective action (Friedman, Wong & Blumenthal, 2010; Grossmann, Powers & McGinnis, 2011). In the future, a nationwide learning health system could enhance infection disease tracking through the analysis of recorded patient diagnosis, individual health outcome can be aided by examining the diagnosis and treatment of similar patients, new drug treatments can be monitored for adverse reactions as documented inpatient electronic health records, and decision support rules and recommendations can be generated from analysis of treatment outcomes for large populations (Friedman, Wong, & Blumenthal, 2010).

A nationwide learning health system has the potential to extend the use of existing health information technology infrastructure and electronic health records beyond simple collection and storage. A nationwide LHS can facilitate data transformation into new insights and knowledge through analysis of large population-based datasets. The results of that analysis can benefit individuals and population through discovery, monitoring and tracking of health issues, events, disease, and outcomes. Existing health information networks, such as the Kaiser Permanente health system, provide examples of how learning from health data can provide benefits to the population. How can the existing health information networks, supported by electronic health information, incorporate learning and information transformation?

Statement of the Problem

Health data networks are capable of delivering significant functionality beyond collecting and managing health information. They are capable of aiding health-focused stakeholders in developing a better understanding of health conditions, treatments, outcomes, and other health-related activities. However, large-scale development, sharing and use of insights derived from health data are still emerging concepts. Learning health system is an emerging movement to transition health data networks from data management facilities to health decision support and investigation aids.

The focus of this research effort is to study the data transformation capabilities of early adopters of the learning health system concepts and progress toward a nationwide learning health system implementation. This research study is conducted using qualitative study methods and a survey data collection instrument to the extent of learning health system development in terms of system maturity, system use, health data transformation, and sustainability.

Sittig, et al (2005) purposed a framework for measuring progress in the development of a nationwide health information infrastructure, which included concepts of system availability, and system usage. In addition, a workshop convened by the National Science Foundation identified research questions and system requirements for a high functioning learning health system, which states that a high functioning learning health system should be economically sustainable (Friedman, et al., 2014). This effort seeks to combine these concepts in order to examine the progress of early endorsers of LHS concepts in evolving health data networks beyond collecting and storing health data in electronic form toward learning health systems that perform analysis on electronic health data in order to extract and disseminate new knowledge and/or recommendations.

Research Objectives

In an LHS, learning consists of the prioritization of data, transformation of data with input from existing evidence-based sources into new knowledge insights or recommendations, and dissemination of new knowledge beyond the originating system. This research will ascertain:

1. What progress have early LHS endorsers and their health data networks made towards achieving large-scale learning health systems?
2. What technologies, techniques, and methodologies have contributed to progress in achieving a large scale, i.e. regional, multi-regional, and/or statewide, LHS operation?
3. What challenges have presented significant barriers to progress?

Statement of Purpose

Implementation of some IT systems in health care have been unsuccessful endeavors, and resulted in the delayed or slow adoption by healthcare practices (Rastogi, Daim, & Tan, 2008). Information technology systems enable the timely inclusion of health data and information into decision making processes in order to support outcomes based on timely information and evidence. The use of information systems that gather, aggregate, and disseminate evidence-based information for timely clinician examination may not be widely or consistently used across healthcare providers. This effort strives to identify emerging trends in realizing a complex health information data and information system that may contribute to improvements in automating the process of the bringing quality evidence-based research and existing population-based findings to clinicians and eventually back to researchers. Information systems that continuously enable clinicians, researchers, and policymakers to incorporate current evidence-based information into clinical practice and policy decision making may contribute to a continuous cycle of learning from past research and outcomes in order positively affect future clinical and policy decisions.

Significance of the Study

Technology has proliferated in many areas of human life, such as manufacturing and supply chain management. Communication and network technologies have enabled the efficient movement and availability of data to improve processes involved in the construction of products and services. Efficient communication may reduce the cost of service delivery (Rastogi, Daim, & Tan, 2008; Anderson, Frogner, Johns, & Reinhardt, 2006) and enable timely access to pertinent information for decision making. Research and health practices involving the collection and examination of health information may provide insights that could improve health outcomes for future patients and lead to further advances in health research. This work seeks to further the vision of what future health information systems may contribute to continuously advance health knowledge through timely access to electronic health information and findings.

This work focuses on the system development efforts of four early endorser organizations of Learning Health System concepts and seeks to discover emerging trends in establishing LHS systems that can be applied for later endorsers. This research effort assesses early-stage progress in implementing a nationwide learning health system. The researcher uses assessment concepts described in an existing health data network assessment framework.

Assumptions

1. The interview respondents are knowledgeable about the state of the health data networks under consideration and provide truthful information in response to the interview questions and any necessary follow up inquiries.

Limitations

The limitations of this work are:

1. The selected interview candidates represent early endorsers of the learning health system concepts.
2. The candidates were not selected at random from all possible US states.
3. The study used two different modes of response collection – telephone interview and email responses to interview questions.

Terminology

Unique/Important terms used in this study are:

1. Electronic Health Record (EHR) – patient medical chart in digital form; it contains medical, diagnosis, and treatment histories.
2. Fee For Service (FFS) – Reimbursement model used in health where practitioners are paid for each service rendered
3. Learning Health System (LHS) – A large-scale sociotechnical system that incorporates interconnected and inoperable digital information systems, cultural aspects of healthcare delivery and processes for continuous knowledge generation and dissemination.

4. Standard – a defined set of guidelines that specify uniform technical specification methods or processes that have been approved by a recognized standards body or widely accepted an industry (PHDSC, 2014).
5. Health Policy – Federal or state regulatory statutes that govern the delivery of healthcare, including information technology systems
6. Technology Readiness Level (TRL) - Department of Defense technology maturity assessment model that determines the level of technology or system development as one of nine levels from basic research to mission operation.

CHAPTER 2

LITERATURE REVIEW

Learning Health System

The Institute of Medicine (IOM) put forth an early vision of a continuous health data analysis and knowledge generation system, calling it a Learning Healthcare System (LHS). Since the IOM, now named the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine, formally introduced the LHS concept, researchers, committees, and conferences have been convened to build upon this vision in order to support complexities of the healthcare systems across the nation and potentially the globe. The IOM published its definition of a learning health system for the United States as the integration "science, informatics and care culture" in an environment of on-going knowledge generation of continuous improvement in health care (Friedman, & Rigby, 2013). A broader definition of a learning health system describes an integrated health data system that enables collection, aggregation and examination of health information for research, assessment, survey, and tracking of public health more rapidly than current disparate and inoperable systems (Friedman, Wong, & Blumenthal, 2010). Grossmann, Powers, & McGinnis (2011) describe a learning health system as “a health infrastructure characterized by [the] evidence-based care that ensures proper decision making for each patient and provider, and generates scientific evidence as a natural by-product of the care process." From these definitions, a learning health system is envisioned to be a large-scale sociotechnical system that incorporates interconnected and inoperable digital information systems, cultural aspects of healthcare delivery and processes for continuous knowledge generation and dissemination. Key steps in the learning and knowledge generation process include aggregation of relevant information, analysis and insight development and dissemination to the stakeholder community as shown in Figure 2. The knowledge generation process differentiates a learning health system from a health data knowledge that only collects, manages and displays health information.

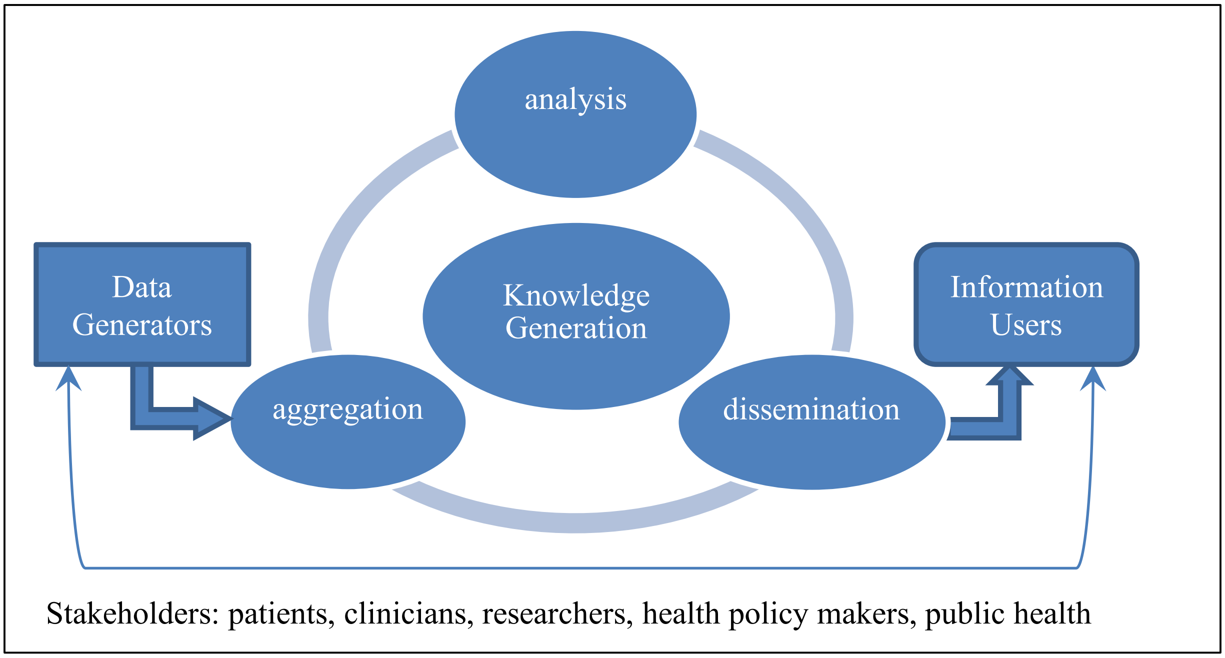


Figure 2 - Key Knowledge Generation Steps

Key steps to move toward a nationwide learning health system are well underway. A requisite step towards automating the aggregation and analysis of digital data is to get the health data in digital form. The federal government enacted the American Recovery and Reinvestment Act of 2009 that include incentives and Meaningful Use guidelines for health providers to adopt electronic health records and to incorporate the digital data EHR systems into their health practices and delivery (Carman, et. al, 2013). EHR information is a key enabler to a learning health system that provides timely information from current health information to stimulate future understanding of health outcomes and improve health decisions and delivery. (Bailey et. al., 2013).

The adoption of EHRs is not sufficient to realize the full vision of a learning health system. The system has to support multiple stakeholders including health providers, patients, advocates, policymakers, and technologists. Patient engagement entails the active partnership between health providers, patients, and their health advocates across the healthcare continuum to encourage patient involvement in their health and contribution to population health information through the collaborative development of health delivery processes, governance, and policies. The US healthcare system also includes public and private sector entities that need to jointly develop and support a resilient architecture to collect health data for research as well quality measures data of health service delivery.

A nationwide learning health system can leverage successes achieved by existing the systems that represent small-scale implementations of learning health systems or partial implementation of key system components. Large health systems, including the Department of Veteran Affairs, Kaiser Permanente, and Pennsylvania’s Geising Health System, have architectures and data repository systems that store and track electronic health records and enrollee information for millions of patients (Etheredge, 2007). Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS), funded by the Patient Centered Outcomes Research Institute (PCORI), is a research data network that engages numerous health stakeholders, including 10 health systems that have adopted IT infrastructure for clinical and research and regulatory procedures (Mandl, 2014). The architecture uses a sidecar approach that supports comparative effective research alongside existing electronic health records implementation. Shared Health Research Information Network (SHRINE) is a query based framework that enables multisite data access for sites that implement a specialized distributed computing solution, i2b2, which requires significant IT infrastructure investment (Bailey, et. al., 2013). Some private health systems and academic medical centers have implemented organization-wide learning health system accessing health data from multiple sites, including Kaiser-Permanente, Duke University, Mayo Clinic, and the Cleveland Clinic (Friedman, & Rigby, 2013). Other federally funded initiatives, such as the U.S. National Cancer Institute's Cancer Biomedical Informatics Grid (caBIG), have established extensively searchable data repositories of disease and health information using common nomenclatures (Friedman, Wong, & Blumenthal, 2010).

Numerous initiatives and implementation efforts exist that demonstrate the feasibility and potential benefits of continuous analysis of health information. However, realizing a national scale learning health system must overcome many challenges. It should address technical and social challenges among various stakeholder constituencies as summarized in Figure 3. Notable barriers include existing gaps in knowledge, data consistency issues, trust, and system scaling.

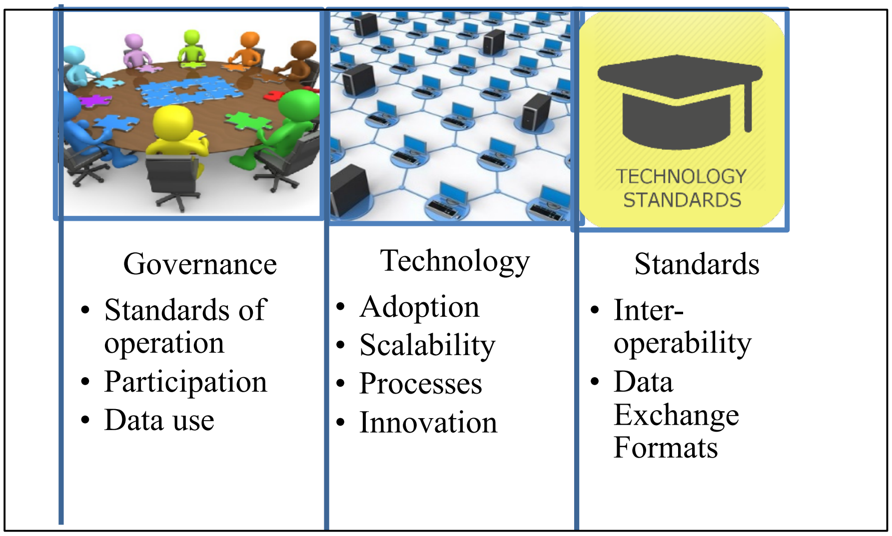


Figure 3 – Examples of Learning Health System Challenges

A system that generates new knowledge should be based on a solid foundation of existing knowledge. Gaps in the existing health knowledge base stem from multiple sources including practitioners and prevailing policies. Clinicians maintain currency with select research discoveries, possibly omitting some discoveries relevant to their work, leaving gaps in knowledge that could be used to improve their associated practice or health system (Friedman, & Rigby, 2013). Etheridge (2007) attributes some knowledge gaps to distributed policies developed by multiple agencies, including the Food and Drug Administration, National Institutes of Health (NIH), and biotechnology-based industries. While health information is available in many forms, including paper records, clinician experience, electronic health information, evidence distilled from that information may not be readily available to clinicians or insufficient for practical use (Friedman, & Rigby, 2013). The amount of information and the time needed to support a learning process and calibration is not always apparent (Fran, et. al., 2012). Proper interpretation of findings from research using different methodologies is important to learning, applying and generalizing research results, yet funding for methodological studies has lagged (Slutsky, 2007).

EHR data derived from a small number of institutions may omit geographical locations and underrepresent certain groups. Electronic representation data may encourage the aggregation of data from multiple disparate regions (Bailey et. al., 2013).

Quality of input data affects the analysis and knowledge generation results. Challenges to using data from EHR's include "differences in representation of information, variability in data capture, and governance issues" (Bailey et. al., 2013). Inadequate knowledge of treatment application and outcomes limits the amount information that can be gathered to analyze complimentary health measures such as treatment quality, cost, and potentially useful off-label application (Etheredge, 2007). Data quality varies based on the type of data collected; ubiquitous data such as demographic and vital data may be more prevalent or reliable than subjective clinician findings or decisions (Bailey et. al., 2013). Clinical trials apply an intervention or drug to a specific sample of a group that may not represent a range of people that may benefit from the treatment. The trial is applied in a controlled environment that may not align closely with real-world conditions, where patients have potentially confounding co-morbidities (Etheredge, 2007).

Stakeholder groups play a significant role in technology development. They create a demand and thus drive new development. However, stakeholders' sense of trust and risk are central to challenges in creating a system that provides societal benefits. Patients are central to healthcare and research because they bear the risks of treatment protocols. A "sense of trust" must be established to ensure that patients are not harmfully labeled or implicated based on the information that they provide (Slutsky, 2007). "Data sharing policies have been sensitive and controversial" (Etheredge, 2010). Standard definitions of measures and description patient groups based on quantitative factors require agreement by multiple groups including researchers and clinicians (Slutsky, 2007). In the past, comparative effectiveness research initiatives may have lacked overarching management (Etheredge, 2010). Initially, "NIH was ineffective in gaining voluntary compliance" for publically disseminating research findings from their public funding research until Congress enacted a mandate for public disclosure (Etheredge, 2010). Clinicians may not consistently report the same conditions for reasons including beliefs and reimbursements (Bailey et. al., 2013).

Large-scale technology systems present challenges to developers and stakeholder groups as size and complexity increase. Technology solutions require continued investment and commitment to technological change and new discoveries. Private sector learning health systems may not scale to meet national objectives (Friedman, Wong, & Blumenthal, 2010). Technological advances may incur increased cost and exacerbate inequalities between technologically disparate entities (Crisp, 2014). A nationwide learning health system may comprise many interconnected systems and be accessed by multiple stakeholder communities. These characteristics are similar to the Ultra Large Scale (ULS) systems studied by Feiler and others (Feiler et al, 2007). An ultra large scale learning health system must contend with challenges of scale, including large numbers of component systems, many complementary and contrasting stakeholder requirements, intermittent availability of data sources and processing components, extensive communication infrastructure, and distributed management.

Based on the learning health system literature and discussions among knowledgeable researchers, practitioners, and other stakeholders attending North Carolina Healthcare Information & Communications Alliance (NCHICA) roundtable discussions on learning health systems and learning health system governance, the author proposes a high level model for a nationwide health system that incorporates policy, standards and technology components, as shown in Figure 4. The model attempts to capture the components, responsibilities, and interactions of a learning health system at a highly abstract level. Actual representation and implementation of the high-level components will be a complex and non-trivial task.

The policy component situated at top of the model represents governance and management. Governance policies apply to system stakeholders as well as standards and technologies in the system. Policies provide a general framework within which the stakeholders, standards, and technologies interact. One of the most important tasks of governance is to provide a direction for membership to access the system, general operating guidelines for membership and system activities. Governance must also incorporate prevailing regulations from applicable levels of government that may include regional, state, federal, and interstate agreements. Monitoring is necessary to ensure that stakeholders are following the rules. In addition, to general membership and management activities, policies must address consent, incentives, and conflict resolution. Participation in the learning health system must be explicitly granted since sensitive personal information may be accessed or transmitted. Stakeholders and participants in the learning health system must consent to adhere to principles, values, and operation established by governance components. Incentives encourage membership among stakeholders that can benefit from the commonly shared information, even though some stakeholders may be industry competitors. Conflict resolution measures should address non-compliant activities.

The Standards component, situated beneath the policy component, applies to technology components and receives direction from the policy component. The standards component represents a consensus that binds the systems and establishes common interfaces between systems and data exchanged between systems. Common data formats ensure that information exchanged from the data sources follow a common representation and unit designation.

Interoperability addresses issues of exchanges of data in common formats. Consistent interpretation of the information enables automated processing of data from multiple sources.

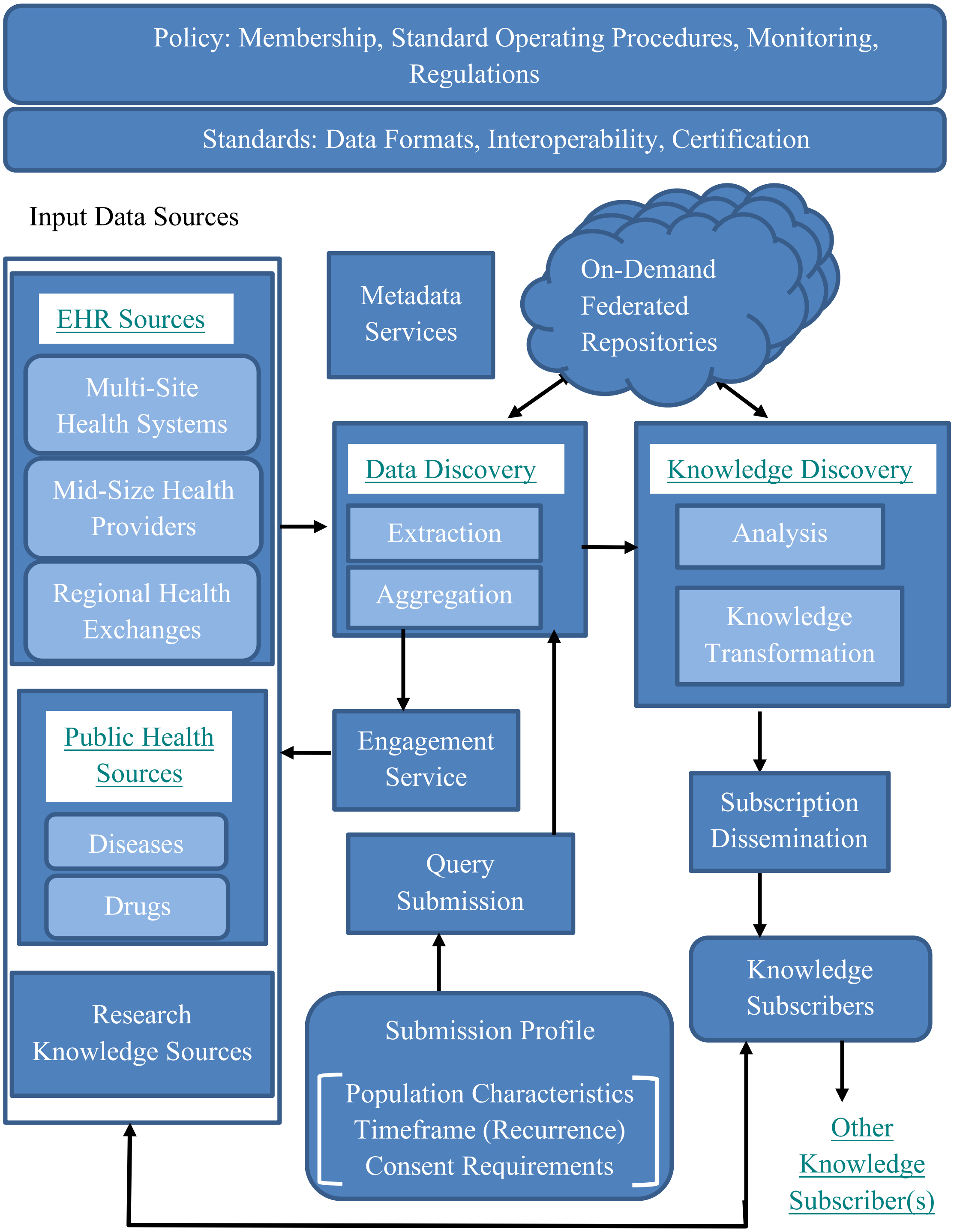


Figure 4 - Model for a Nationwide Learning Health System

Technology Maturity Assessment

Complex systems consist of module technology components interacting together to provide requisite functionality. The components may represent different technologies at different stages of technology development. Determining when a complex system exhibits necessary maturity for quality operation in its target environment is a non-trivial problem. Researchers including Sauser, Grover, and Ramirez recognize this issue when they write, "The emergence of increasingly complex systems has necessitated the development of more dynamic metrics to assess the maturity and readiness of systems and their diverse technologies" (Sauser, Gove, Ramirez-Marquez, 2010).

The early concept of technology maturity with respect to readiness and fit for execution was documented by NASA in a 1969 report (Azizian, Mazzuchi, Sarkani, Rico, 2011) and defined through the years. Technology Readiness Level (TRL) “was formally proposed in a 1989 Acta Astronautica article by Sadin, et al. and was based upon a well-known technology maturation model used by NASA at the time" (Sauser, Gove, Forbes, & Ramirez-Marquez, 2010). The original 7-level scale developed by Sadin and group was extended in 1989 to the current 9-level scale (Azizian, Mazzuchi, Sarkani, & Rico, 2011), shown in Figure 5. The levels are general enough to be applied from system development through system operation. The Technology Readiness Level (TRL), a popular metric was adopted by other government agencies, including the Department of Defense and the Department of Energy. Sauser et al (2010) report two major limitations of the TRL model: The level metric may distort the assessment of the system because it is a single level value that applies to the whole system without proving any indication of measured contributions from the system components. Moreover, TRL is unable to access the uncertainty of adding mature technology to a larger existing system. Sauser et al identify other maturity metrics that have been purposed as decision support tools, including Design Readiness Level, Manufacturing Readiness Level; Software Readiness Level; Operational Readiness Level; Human Readiness Levels; Habitation Readiness Level; Capability Readiness Levels (Sauser, Gove, Forbes, & Ramirez-Marquez, 2010).

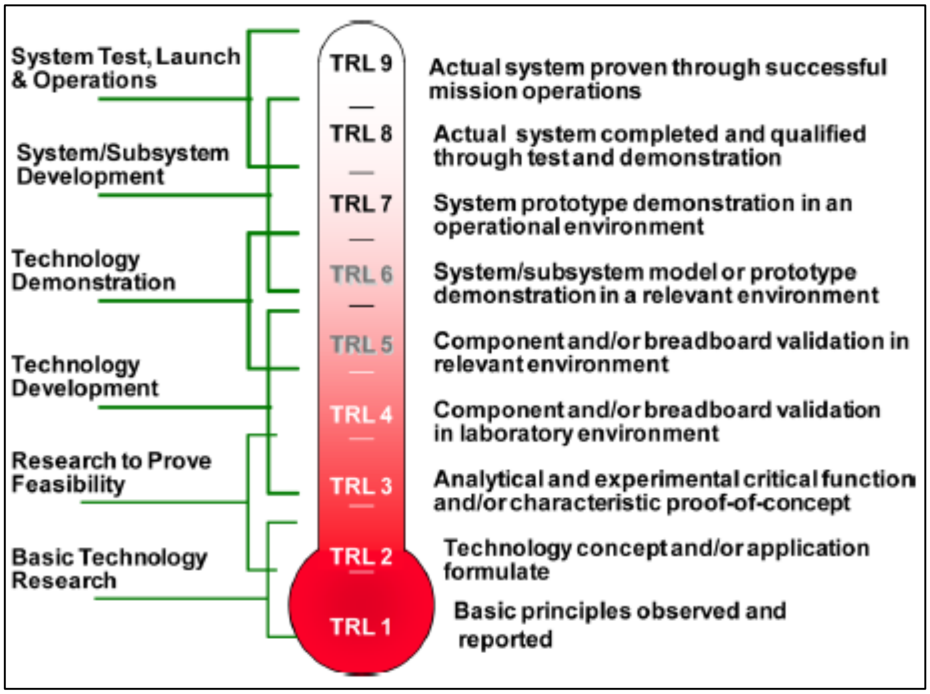


Figure 5 - Technology Readiness Levels (from Azizian, Mazzuchi, Sarkani, & Rico, 2011)

A key aspect of complex system development is integrating multiple technology subsystems in a large system. Sauser et al (2010) define integration as “the process of assembling multiple components into a successful system that meets user requirements and operates properly in its target environment”. Sauser et al purported to address one of the TRL limitations of no integration information with the Integration Readiness Levels (IRL) as an integration maturity metric for "a systematic measurement of the interfacing of compatible interactions for various technologies and the consistent comparison of the maturity between the integration points (Sauser, Gove, Forbes, & Ramirez-Marquez, 2010). The IRL is proposed as a compliment to the

TRL assessment by performing a pairwise assessment of interacting subsystems or technologies and identifying a level of integration, including basic interfacing principles, specification adherence, and practical operation. As with the TRL, the IRL is not a complete solution for systems assessment as the pairwise IRL assessment results cannot be combined into a single overall system assessment result and the IRL assessment does not take into account system development factors of research, cost, and schedule.

The ISO/IEC 9126-1 is quality model for examining state of the art systems. "ISO 9126-1 is the de facto standard for evaluating the quality of modern computer-intensive systems" (Azizian, Mazzuchi, Sarkani, Rico, 2011). It defines seven characteristics - functionality, reliability, usability, portability, maintainability, efficiency, and quality in use. Quality as defined by the American National Standards Institute, is the total features and characteristics, both functional and non-functional, of the system necessary to meet a given need (Azizian, Mazzuchi, Sarkani, Rico, 2011).

Technology system evaluation can extend beyond technical issues to consider social issues within the system's operational environment. While early assessments in health technologies tended to focus on large, expensive, machine-based technologies, the scope has gradually widened to include smaller technologies, 'softer' technologies (such as counseling), and health care needs (Bijker & Law, 1992). The Health Technology Assessment (HTA) Core Model for Diagnostic Technologies, developed by a European Working Group, provides a framework for conducting a systematic review of a target technology, exploring issues, including "information about the medical, social, economic and ethical" (EUnetHTA, 2013). The model identifies a standard vocabulary and a core set of domains, including technology use, technology characteristics, safety, accuracy, effectiveness, economic cost evaluation, ethics, organizational aspects, social aspects, and legal aspects. When evaluating a target technology, only applicable core domains are considered in the resulting evaluation report developed by a multi-disciplinary evaluation team. The HTA uses various research methods to gather information about a technology's use including but not limited to systematic literature reviews, primary research, register studies, and interviews. The HTA technology assessment delivers an extensive report which may contain more than quantitative metrics, which may limit the general applicability of the evaluation results.

Standards Development

“Early IT systems in healthcare were developed as stand-alone systems, serving a specific purpose” (Hammond, 2005). Increased computer usage in healthcare, increased volumes of data, increased errors due to duplication, and increased federal and international investment in healthcare systems by the National Library of Medicine, the National Institutes of Health and others entities led to more earnest development for technology standards (Shortliffe, 2005; Hammond, 2005). Standards enable interconnected systems to exchange information and deliver the promise of interoperable systems that can work together seamlessly. "Interoperability is a fundamental requirement for the healthcare system to derive the societal benefits promised by the adoption of electronic medical records (EMRs)" (Brailer, 2005).

Standards development in US healthcare gained momentum in the 1980s with the formation of several standards development organizations (SDO) with different focuses. "Important standards development organizations that contribute to standards used in health include the World Wide Web Consortium (W3C), Internet Engineering Task Force (IETF), the Object Management Group (OMG), and the Organization for the Advancement of Structured Information Standards (OASIS) for business standards" (Hammond, 2005). Multiple organizations are tasked with developing standards and vocabularies. Competing interests of multiple parties make standards development difficult. Confounding issues include multiple competing standards from different SDOs and other interest groups, overlapping coverage by standards, and differing development roadmap directions.

Technology standards are set of documents containing precise specifications for consistent application of a technology (Masum, Lackman, Bartleson, 2013). The standards documentation may consist of interface specifications for compatibility and/or semantic specification to establish a consistent meaning of specifications. Large-scale information systems interface specification described in standards allow modules to communication or exchange information in order to achieve the desired function. Hammond (2005) describes the general standards development process as initiated by the identification of the need for common procedures or protocols in an industry and a business case for using a standard to expand a market. An influential body of experts in the specific community is convened to develop the standard. A larger community body votes on accepting the standard. Finally, the development body presents the standard to the public for adoption and implementation. Standards are created by different means including, an ad-hoc standard developed by a complementary group, a defacto standard developed through market competition, standards mandated by government, and standards developed through a formal consensus process as used by the American National Standards Institute (ANSI), which "coordinates US voluntary standard activities" (Hammond, 2005). ANSI specifies the consensus process for adopting a standard at a national level which requires 90% of the voting body to agree on a ballot and seeks to prevent one stakeholder group from monopolizing the voting process. The ANSI consensus process also supports an accelerated consensus process for trial use standard that must be eventually converted to formal standards within two years.

There are many benefits to be gained by interoperability and standards. Masum, Lackman, and Bartleson (2013) write that standardization offers the benefits of modularization, independent component improvement and innovation, interoperability, and efficient implementation. The authors cite a German study concluding that standards enhance opportunities for trade, international competitiveness, and societal benefits. Walker et al (2005) identify interoperability benefits from standards to include a reduction in redundancy, errors, redundant communication, time handling charts, and fragmentation of health records.

Standards and interoperability may engender some resistance to change and face many barriers to acceptance and implementation from some health industry organizations. Walker et al (2005) and Brailer (2005) note a potential reduction in revenue for those who profit by health care fragmentation. Shortliffe (2005) identies cultural, business, and structural barriers to standardization. Healthcare practitioners may be reluctant to delve into unfamiliar computing technologies that induce changes in current practices and processes. Return on Investment (ROI) may not be as straightforward to calculate, thus weakening the business case for strategic investments in information technology infrastructure. The fragmented US multi-payer health care system favors local optimization resulting in poor coordination and lack of accepted standards (Shortliffe, 2005). There is no sizable funding for standards development groups as many stakeholders participate on a volunteer basis.

The International Statistical Classification of Diseases (ICD) standard is a widely recognized healthcare industry standard. The standard evolved from 1763 work by a French physician Francois Bossier de Lacroix who developed a disease classification system (Meyer, 2011). The international community, including the US, Canada, and Mexico, adopted and extended the classification system. In 1948, the World Health Organization assumed responsibility for disease reporting and continues to support the ICD standard which now includes specifications to support data analysis efforts for disease tracking. In 2008, the US Department of Health and Human Services (HHS) advised the government to mandate adoption of ICD version 10 by October 2013. ICD10 offers more specificity of disease treatment, intervention, and outcomes in order to support increased detailed disease treatment, tracking, billing, and fraud reduction. Healthcare organizations and the US government recognize the usefulness of standards. However, adoption of standards by organizations can be a major and expansive undertaking (Meyer, 2011). Walker et al (2005) argue that investments in health information exchanges and interoperability will yield as much as “$77.8 billion per year once fully implemented” to offset the cost of initial and continued investment.

Healthcare literature contains many recommendations for encouraging the standards development process to generate durable and widely accepted standards. Standards should remain vendor neutral, encourage cooperation and lower the barrier to participation (Hammond, 2005). Standards should support technology innovation through continued evolution and modular development allowing modular innovations to proceed in parallel, as opposed to single vendor-specific implementations (Hammond, 2005). Local and federal incentives and mandates are needed to increase standards and interoperability adoption (Walker et al, 2005; Coffey et al, 1997). An overall strategy for evolving standards is necessary to incorporate innovation and keep pace with industry changes and needs (Masum, Lackman, Bartleson, 2013; Coffey et al, 1997). Input from a large group of participants, including state and federal representatives, results in more durable standards that are widely accepted (Coffey et al, 1997). "We clearly need to reevaluate the balloting rules. We need to reduce the administrative overhead and shorten the balloting process while maintaining its open and balanced nature" (Hammond, 2005).

CHAPTER 3

METHODOLOGY

A qualitative research methodology is a type of scientific inquiry that focuses on the "qualities of entities, process, and meanings" (Center for Teaching, Research, and Learning, n.d.) and has objectives that include describing individual experiences and variations (Family Health International, n.d.). A goal of this research effort is to examine the progress of selected early LHS endorsers in extending their health data networks to include transformative capabilities that generate new knowledge or insights from existing health data. Organizations can employ a variety of technologies in order to create large-scale health information networks capable of storing, analyzing and disseminating health information. The researcher employed a qualitative case study approach to examine the experiences and variations in their implementation and uncover any emerging patterns that may be applied to other organizations or states towards realizing a nationwide learning health system. This method is most applicable to this research as the target systems seek to accomplish similar goals, but may use different implementation approaches. The difference in implementation approaches may present different challenges and experience varying levels of success.

The target population is early endorsers (http://www.learninghealth.org/endorsers/) of the learning health system concepts as recognized the Learning Health Community (LHC), whose vision is “to inspire a national movement to realize a national-scale (and ultimately global), person-centered, continuous and rapid learning health system” (LHC, 2015). The LHC emerged from the original learning health system activities of the Institute of Medicine in 2007 and a summit of health and health technology experts sponsored by the Kanter Foundation (Kanter Family Foundation, n.d.) as shown in Figure 6. The Learning Health Community is supported by members of the North Carolina Health Informatics and Communication Alliance and other interested state and national experts in health and health informatics. These endorsers represent organizations with a presence in one or more US states. They have signed and submitted confirmation of their endorsement of the LHS concepts. The organizations were selected in consultation with members of the NCHICA learning health system roundtable members.

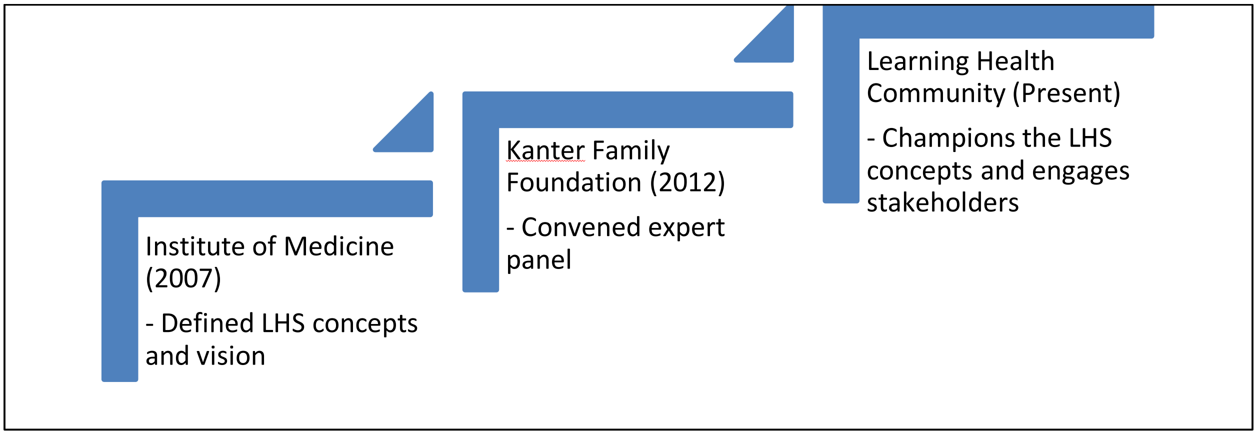


Figure 6 - Emergence of Learning Health System (LHS) and Learning Health Community

The study seeks to gather data pertaining to specific health data network concepts, including technology, system use, system availability, health data transformation, and longevity. These concepts were selected from a framework proposed in Sittig, et al (2005) and a learning health system research agenda proposed in Friedman, et al (2014). System availability is the "presence of sufficient health information network structure to 'collect, store, display and transmit patient identifiable, structure, clinical data in electronic formats' " (Sittig, et al, 2005). System use is "Hands on use of these HIT systems by patients, providers, and those involved in population health". Health data transformation is the "capability of the health information network to aggregate, analyze and disseminate information beyond the current organization, area or region." Longevity describes the funding sources and region/state/federal legislation that support the continued development and use. See Appendix A for core questions pertaining to each concept. The study format and questions structure were patterned after an existing learning health system study conducted by Morrain et. al. (2016). Figure 7 shows a summary of the combined investigation model.

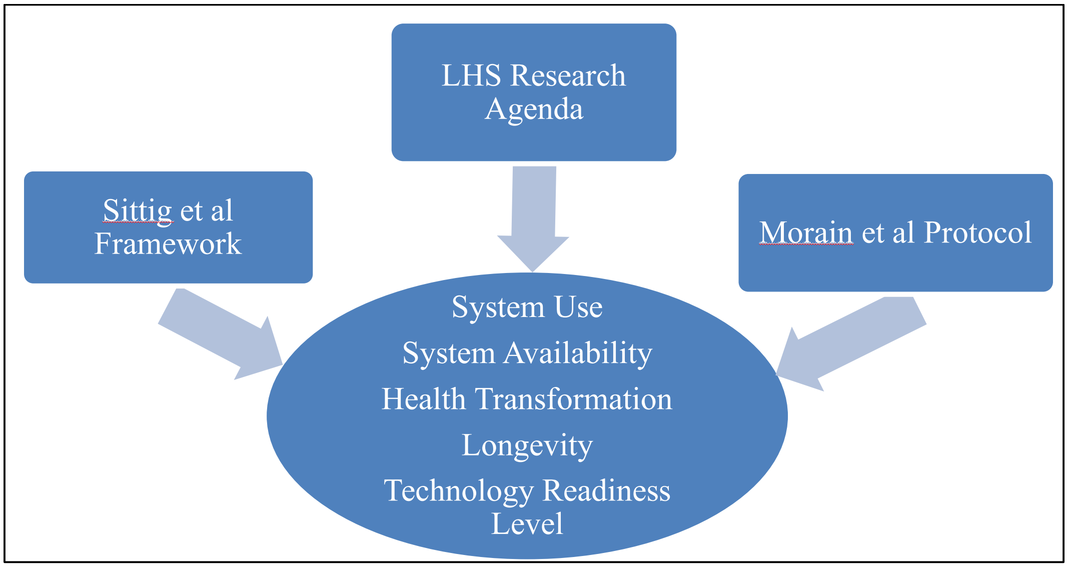
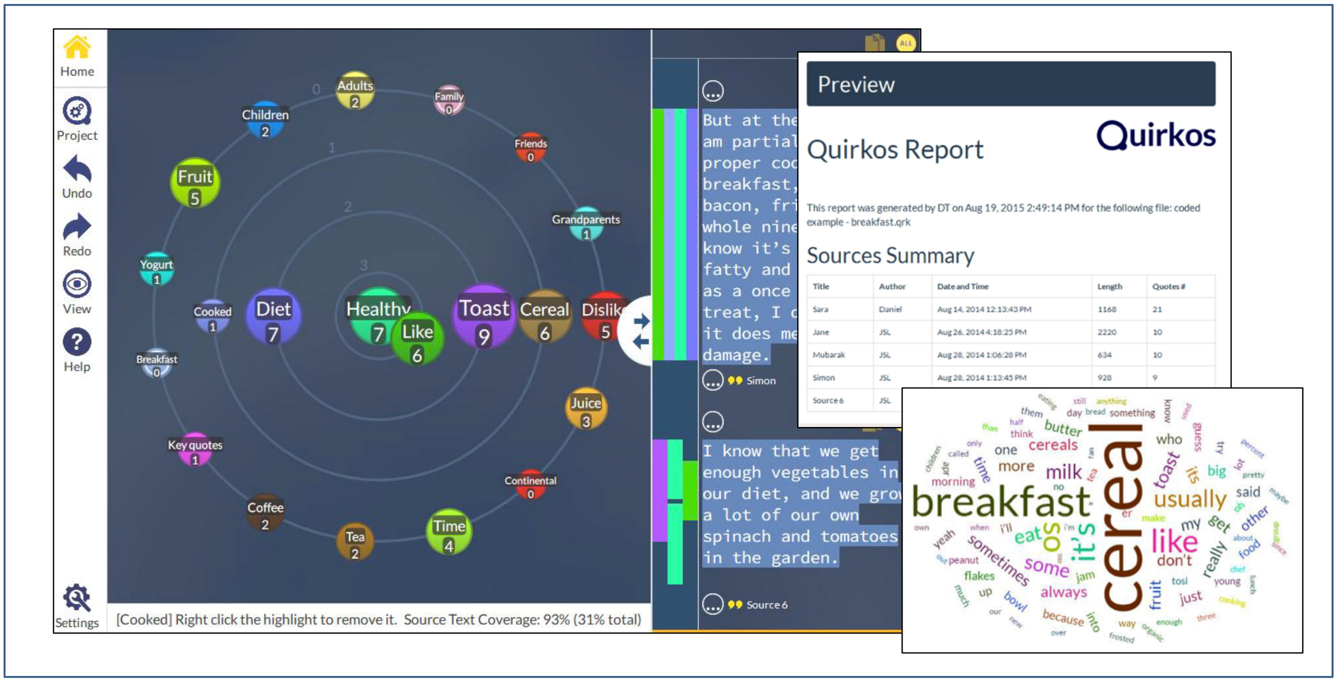


Figure 7 - Combined Investigation Model

The researcher invited practitioners from learning health system organizations to participate in the research study using electronic mailings, which included a participant invitation describing the aims of the research study, an informed consent form detailing the study procedures and the participant's rights, and the interview protocol containing the interview questions. The researcher offered the participants a choice to either provide responses to interview questions via directed email to the researcher or participate in a recorded telephone interview. The researcher also reserved the option of follow-up mailings or interviews, if necessary to clarify information. During data collection and subsequent analysis of study data, participants were identified using a designated identifier. The researcher reported findings in an aggregated and non-identifiable manner.

Respondent information was initially categorized using the core concepts discussed above. Additional categories that emerged during the examination of respondent information were also captured. The categorized information was examined for similarity and difference as well as emerging patterns. The research reserved the option to employ qualitative data analysis software in order to facilitate organization and tracking of information. The researcher made efforts to limit technology related bias in relying on software for categorizing information as discussed by Jones (2007). The findings are reported by general progress of the health data network according to the selected concepts, the maturity of the health data transformation capabilities, similarities and differences in development challenges, and emerging successful implementation patterns or strategies.

The researcher used Quirkos (Quirkos, 2017), which is a licensed commercial qualitative data analysis software package. The software features include text data import facilities, dataset management, theme/topic (referred to as Quirks) creation and management, color coding passages, author attribution of themes and text selection, search capabilities, and data visualization and reporting. Figure 8 shows the Quirkos main input screen and examples of basic information reports generated from imported qualitative data. The software can be licensed for various organization structures, including educational institutions and students. The student software licensing includes a reduced price license fee and permanent license key for the current full-featured software version release with no further recurring costs. As discussed above, the researcher reduced software or automation bias by not using any automated theme or topic detection mechanisms. The researcher used qualitative data analysis software for tasks including managing the transcribed interview text, highlighting relevant passages according to research identified themes, and data visualization and reporting.



[Cooked] Right click the highlight to remove it. Source Text Coverage: 93% (31% total)

But at the
am partial
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it does me
damage.

Simon

I know that we get
enough vegetables in
our diet, and we grow
a lot of our own
spinach and tomatoes
in the garden.

Source 6

Quirkos Report

This report was generated by DT on Aug 19, 2015 2:49:14 PM for the following file: coded example - breakfast.qrk

Sources Summary

Title	Author	Date and Time	Length	Quotes #
Sara	Daniel	Aug 14, 2014 12:13:43 PM	1168	21
Jane	JSL	Aug 26, 2014 4:18:25 PM	2220	10
Mubarak	JSL	Aug 28, 2014 1:06:28 PM	634	10
Simon	JSL	Aug 28, 2014 1:13:45 PM	928	9
Source 6	JSL			

Figure 8 - Qurikos Qualitative Data Analysis Software Main Screen and Reports

The qualitative research method uses a different validation method than validation in quantitative studies. Quantitative studies rely on statistical methods to detect mathematically significant changes in research variables. Qualitative analysis validation relies on methods including examination, discussion, and consensus on alignment with or deviation from existing subject area literature and/or activities (Creswell & Creswell, 2018). A consensus in qualitative studies may be gained through a review of the same set of data documents and discussion among multiple researchers. The researchers reach an agreement on the final set of thematic concepts. Qualitative findings can be validated through review of study findings by study participants, peer reviewers, and/or independent auditors that review findings for accuracy and pose questions to clarify aspects of the research.

Research Procedure

The researcher conducted this research study in the following phases: study approval, participant invitation, data gathering, data analysis, and data reporting. Since this study effort included human subjects, the research study required review and approval by the university's Institutional Review Board (IRB) to ensure proper protection of human subjects. IRB performed an expedited review of this research study because the study did not collect personally identifiable information and the adverse risk to the study participants was minimal. The researcher sought to reduce the risks to the participants through identifying them by an identification number during data collection and reporting the results in aggregated form without attributing statements to specific participants. The Ph.D. program at Indiana State University (ISU) is a consortium program whose coursework is shared among five universities. In accordance with the program structure, the ISU IRB reviewed the research study application, documentation and granted study approval. East Carolina University (ECU), the researcher's home-school, accepted the decision of ISU IRB.

IRB approval was required before any study participants were engaged and invited participate in this research study. The researcher selected study participants from the LHS community as recommended by the learning health community membership and review of Learning Health System journal published authors. Selected participants were working specifically with LHS implementation. The researcher invited members of the LHS community to participate in this research study by sending email notices to each perspective participant. The email invitation included brief invitation text describing the study and IRB approved documents, including a full description of the research study and participant’s rights, a consent document, and the research interview protocol. The researcher invited twenty-six LHS practitioners to participate in the study. Four LHS practitioners agreed to participate in this study by returning an affirmative reply along with a signed consent document. Two participants from the same organization agreed to participate in this study.

The researcher offered participants two options of participating in this research study – email or personal interview. Each participation option used the same interview protocol document. For participants that chose the email option, the participants self-administered the interview protocol and provided text responses to the interview protocol questions. For participants that chose the personal interview, the researcher conducted the interviews via a telephone call. The researcher recorded each interview for later audio playback and verbatim transcription into a text document.

The researcher performed data aggregation and analysis using the Quikos qualitative data analysis software (QDAS), as described above. The researcher imported text-based interview protocol documents containing each participants’ responses. Initially, the researcher selected themes based on progress measures and the combined investigation model concepts. New concepts were created for text excerpts that addressed issues beyond the pre-determined themes. The researcher examined each response document as it appeared in the QDAS application. The researcher examined each section of text, containing one or more sentences, and used the QDAS color coding scheme to associate each text section to a specific theme. Some text sections were associated with more than one theme. The thematic findings included the process measure concepts and the investigation model concepts. Emerging concepts were derived from topics discussed beyond the set of pre-determined themes.

The researcher reported data in aggregated form. The researcher reported progress measure findings based on each distinct system. Investigation model concept findings were reported based on summarized information from the survey responses. The researcher included discussion quotes as support for the findings, but without attribution to specific study participants.

CHAPTER 4

FINDINGS

The presented research study findings were distilled from semi-structured interviews and emailed survey responses. Data collection was conducted between September 2017 and December 2017 with four study participants. Two study participants represented the same organization, so the four study participants represented three distinct systems. Three participants chose a telephone interview and one respondent submitted responses to study questions through email. The organizations, representing LHS endorser organizations in three US states, were located in the northeast, southeast, and southwest regions of the United States, see Figure 9. The researcher found that respondents participating in telephone personal interviews provided responses to the study questions, as well as discussed related topics beyond the structure set of questions topics. The additional information was helpful in identifying emerging themes and recommendations for further consideration and study.

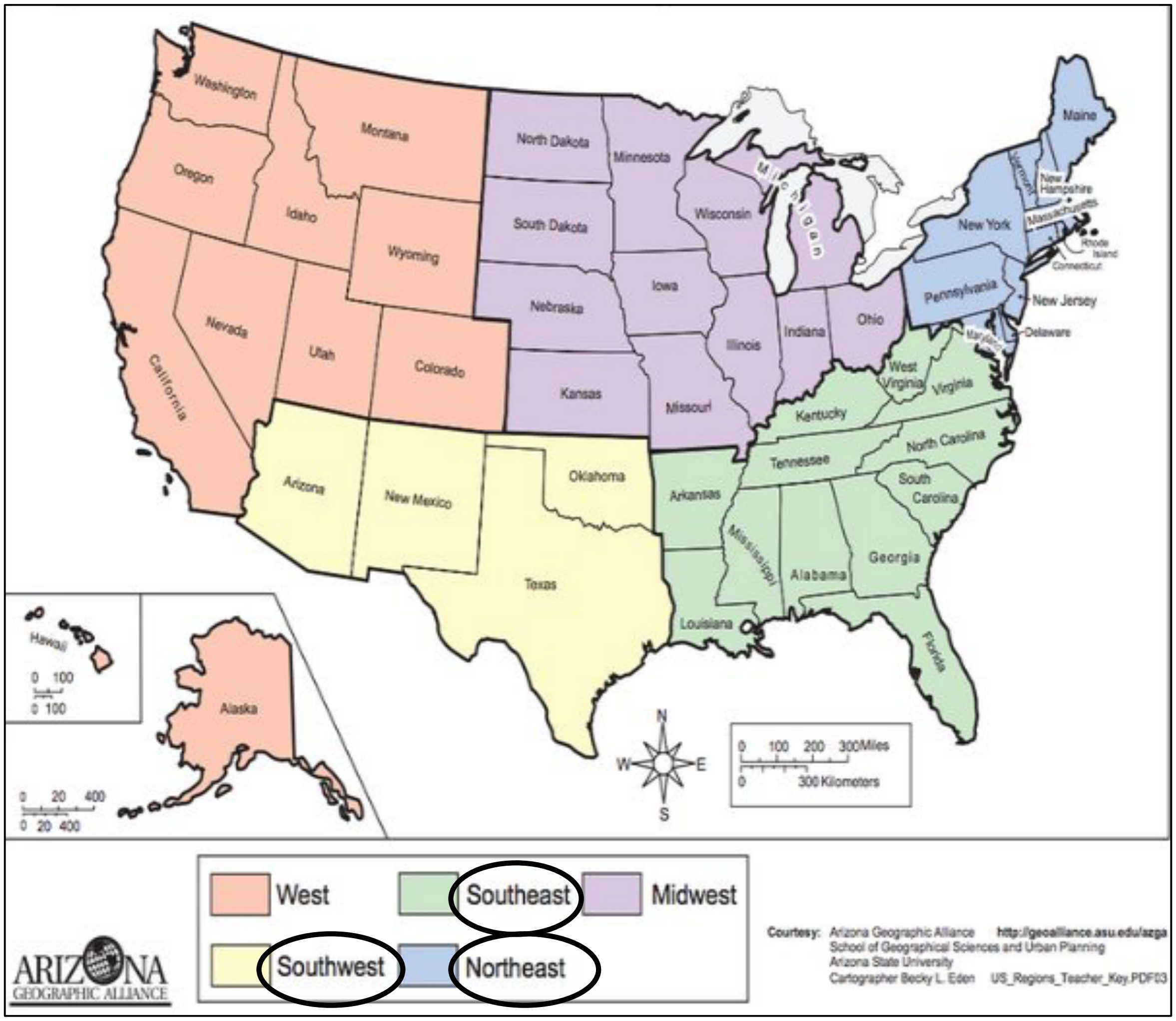

Figure 9 - US Regions Represented by Study Participant Organizations (http://geoalliance.asu.edu/sites/default/files/maps/US_Regions_Teacher_Key.pdf)

Participant Organizations and Systems

The study participants represented organizations described as educational, research, and singular disease-focused registry organizations. The organizations plan to achieve the full learning health system (LHS) vision and goals through forming strategic partnerships. The partnering organizations agreed to provide complementary LHS capabilities including data analysis, data sharing of different population records and information, and networking infrastructure and support. Some of the organizations have specific LHS inspired goals. One participant expressed the organization’s goal as “We aim to build a learning health system where patients, providers, and researchers partner to co-produce optimal health and high-value care”. Another organization’s goal includes developing metrics to measure “improvement in health outcomes for the county [where the organization is located]”.

The study participants had job functions that involved supporting the implementation of the LHS vision as well as overseeing the technical implementation. Their job titles included the designation of director or chief. One participant’s job title specifically included the phrase “learning health system”. Including the phrase “learning health system” in a director level job titles indicates that organizations recognize learning health system development as a strategic business goal and a part of an organization’s culture.

Summary of Progress Measures to LHS operation

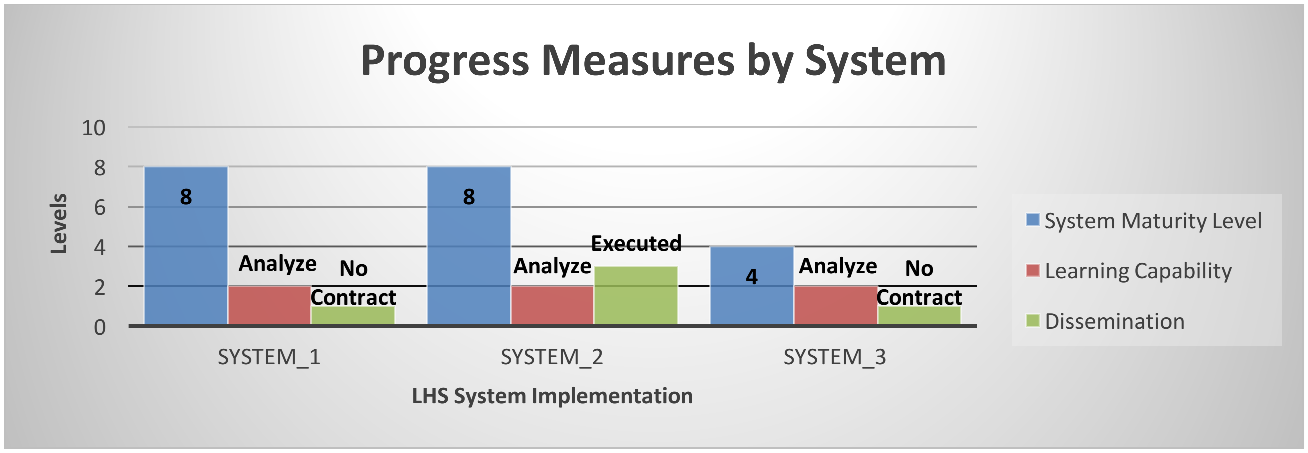

Figure 10 - Progress Measures

Figure 10 shows a summary of the proposed progress measures toward learning health system operation. Two organizations assessed their systems’ maturity levels as at most Technology Readiness Level (TRL) level 8. The health data networks and support services have been tested and the systems are operational. One system is still emerging and not yet operational. The organization plans to begin system operation in Fall 2017. For this system, use cases and designs of major system components have been completed and testing plans are in place. This system has not reached the base TRL level 5 operation yet. All of the systems provide some level of data analysis either resident at the main site or through their organization partners. However, much of the analysis was restricted to operational matters. The systems had not reached the stage of data transformation or learning capability for knowledge generation pertaining to health outcomes. All of the systems were developing plans and processes to support learning and knowledge generation. Two of the systems had not attempted to transfer information to external organizations. One organization was developing plans for external information dissemination. At least one system was regularly transferring information to other organizations, including internal partners and externally organizations. The data transmission process is performed using ad-hoc processes. Aggregate findings and discussion of each measure are presented below.

Systems Maturity

The four respondents described three systems that are striving to achieve learning health system capabilities. Two systems are operational but have not reached full production as full learning health system capable systems. One system is in technology development, TRL level 4, and has limited operational capabilities; this organization has partnerships with other organizations with operational systems focused on health information exchange. The participant described their learning health system's technology development as "we have a number of use cases, but have not been piloted". The participant described the system as "somewhere between level 4 and 5." The system did not meet this research study's target minimum system maturity level of TRL level 5 for technology demonstration. The operational systems completed technology demonstration, TRL level 5 – 6, activities including piloting programs to demonstrate learning health system capabilities. For one system, the pilot program focused on examining operating metrics to reduce patient waiting times for health services. Another pilot program focused on demonstrating a data core capability "to aggregate data for the purposes of doing analytics, visualization, and distribution of data."

The operational systems have completed some system and subsystem development activities, as required for TRL levels 6 -7. One participant stated that they have completed some technology demonstrations, but have not completed demonstrations of all planned learning health system capabilities. The participant added that "The technology is well ahead of our ability to understand and use and develop learning health systems." For the system that has only reached TRL level 5, there are plans in place for conducting integration and prototype demonstrations, but the implementation of capabilities has not been completed.

None of the systems represented in this study had reached full production learning health system operation, TRL level 8 – 9. One participant said that their system had fully functioning dashboards with live patient data. The study respondents did not believe or directly state that their current systems met all of the goals of a learning health system. This is consistent with Friedman, Rubin, & Sullivan (2017) who state that "fully functioning LHS infrastructures … do not yet exist… but pieces of LHS infrastructure that provide specific services … are emerging."

Data Transformation and Learning

The participants' systems use on-site or depend on their partners' systems to aggregate electronic health information. The systems use data warehouse technology to store electronic health information. They also provide features to query the data repository and segment data into data pools or data marts for a specific project or research use. At least one organization has developed a web-based application for data identification and extraction. While one organization developed a custom data aggregation service, the participant recognizes the need to transition to a more national or widely used platform for interoperability purposes. At least one organization is incorporating health and socio-economic information from public sources, such as the health information exchange; they endeavor to incorporate public transportation and the housing information into their data aggregation process. At least one organization uses a data request system, developed by IBM that helps identify data relevant to specific data requests and extract data in a specified format. One organization has developed an online system to facilitate request submission and “then expedite their requests to be filled by the data owners, partners, and clinics.”

Data analysis is a key activity in data transformation and learning. One organization relies on its partners’ on-site data analysts’ knowledge and understanding of the resident data repositories’ structure to extract relevant data.

None of the systems represented in this study have achieved a fully automated data transformation process. Some organizations depend on manual or person-driven processes. The organizations have developed governance systems or use institutional review boards that establish the bounds of data collection and analysis activities. One participant says in reference to data requests, “Of course they go through an IRB process”.

Prioritization of data requests sometimes depends on the organizational and business concerns. One participant says that at this time, data requests “facilitate operations” are prioritized so that the staff can start “seeing patients on time”.

Data Exchange and Dissemination

The participants' systems are capable of or plan to receive information from and/or transmit information to external sources. The organizations depend on outside sources for research and population-focused health data. One participant indicated that clinicians that focus on patient care are more focused on internal information from internal electronic health records; while researchers who are interested in studying cohorts are interested in data from both internal and external sources. For organizations that partner with health information exchanges, they may have access to data from other health information exchanges. At least one organization had not tried to exchange data externally, but there are plans and approvals in place.

Data exchange for this group of participants' systems is ad-hoc and rudimentary and not very routine or automated. One participant said that the "level of success in terms of how easily or quickly they can get access to that data varies quite a bit from organization to organization." Data exchange may require prior knowledge of data available in partners' systems or submission of a data request. On-site data analysts that are familiar with the data repository design and contents extract data from their repositories and transfer the data to the requestor according to established agreements between the partnering organizations. Some organizations use commercial vendor electronic health records to facilitate interoperability among their partner sites; however, exchanging data with external organization using different electronic health information products still presents challenges. One participant's system was able to deliver patient information to an outside organization using the same commercial vendor software with favorable results; the participant attributed the successful transmission to using the same commercial product. Even for organizations using the same commercial product, organizations participating in data exchange many still need prior knowledge of the location of a patient's data to facilitate data transmission. At least one participant indicated that there are concerns with exchanging personally identifiable information with external sources due to "dangers with cybersecurity issues".

Systems Technologies

The organizations' learning health systems were implemented as distributed data communication networks, where network infrastructure and services are distributed and shared among more than one organization. One participant characterized their organization's learning health system as an integration of "data feed forward systems, patient-centered clinical decision support dashboards, meaningful reports available to patients and providers, patient and provider networks, and multi-stakeholder learning collaboratives." Another participant described the organization's LHS system as "integrating research networks" and "services for certain populations". While one of the systems in this research study was not operational, the organization did have partnerships with other organizations that had operational health network systems.

Table 1 – Summary of Technology Trends in LHS Implementations

LHS Technology Trends	
Electronic Health Records 1) Commercial: Epic, Athena Health, Cerner 2) Mature, Certified, Not Interoperable	Data Analysis 3) Machine Learning Algorithms 4) Structured and Non-structured Analysis 5) Data Analysts
Data Management 6) Large Capacity: Data Warehouse, Cloud Based 7) Query Based 8) Web-Based Services	Integrated Platforms I. I2b2: Informatics for Integrating Biology & the Bedside II. Broad Application III. Facilitate Interoperability
Service Oriented Architectures 9) Systems without borders 10) Partnerships and Strategic Alliances	Security

The systems employ or have plans to employ various components and technologies to achieve learning health system capabilities. Table 1 shows a summary of technologies used in the LHS implementations. The major technical components include data warehouses and supporting data management features, high capacity storage systems, electronic health records applications, and data representation and presentation technologies. Some organizations implemented their systems as tradition service platforms. In addition, one organization's system supports or plans to support various application programmer interfaces (APIs) to allow partners to develop customized service implementations. Some custom algorithms are planned to trigger input of data directly into electronic health records. Electronic health records from commercial vendors including Epic, Cerner, Meditech, Athena Health, and others. Data warehouse and management includes SQL based databases, I2B2 data management and software platform (Murphy, 2010), JSON (n.d.) data stores, and Cerner Electronic Data Warehouse (EDW). Data representation technologies include JavaScript Object Notation (JSON), Fast Health Information

Resources (FHIR) standard framework representation (HL7, 2017), and other custom representations. High capacity data storage technologies, includes cloud-based storage, which can be on-site and/or remote solutions. One organization's system that is integrating existing health data networks and services to achieve LHS goals has also employed Mirth messaging technologies to achieve interoperability among systems.

Challenges

The study organizations are transitioning existing health data systems to LHS systems or implementing new LHS systems. The study participants identified both technical and environmental challenges in developing LHS systems as listed in Table 2. The organizations encountered technical challenges in areas including, patient identification, data representation, data quality, and data exchange. The organizations experienced challenges in healthcare and research environment challenges in terms of processes, legal permissions and trust, and service reimbursement.

Table 2 - Summary of LHS Challenges

Technical Challenges	Environment Challenges
Patient Identification	Processes
Data Representation	Legal Permission
Data Quality	Trust
Data Exchange	Service Reimbursement

Identifying patients in different systems is a critical issue as it can affect the ability to merge electronic health data together into a comprehensive characterization of a patient's health history. It may also result in the misidentification of a patient if the identifying information, such as name, is different in more than one care provider's system. One participant said, "Unfortunately, we do not have a universal identifier number. We are stuck with trying to identify individuals in multiple systems." Another participant said that with the absence of uniform patient identification, it is "hard to then create adequate identifications and linkages across these [health data] systems."

Data representation standards are still not uniformly used among independent organizations and even within collaboration organizations. Some controlled vocabularies, terminologies, or coding systems have multiple codes that represent the same clinical concept. In addition to controlled vocabularies, organizations may adopt local vocabulary variants that can result in loss of information during integration and mapping activities. A participant shared that some data standards "don't necessarily mirror the complexity that clinicians or researchers may want from the data."

Data transport standards describing the process for moving data across organizational boundaries are not universally implemented and used among organizations. Health data exchanges address some issues of sharing health data; however, the information may not address the data needs of some clinicians and researchers.

Data quality varies from system to system and the manner of data collection may not be captured along with the data originating from an external source. A participant said that "not understanding where it [data] was collected and how it was collected can also affect how you analyze it and interpret it.” Another participant indicated that “data quality is not well documented in different systems.”

Organizations experience process and technical challenges when they submit or respond to data requests. The organizations may use different processes for servicing data requests and allowing access to data. For one participant, “to find where data are for a cohort of patients or a single patient is hard because these [data] are not necessarily easily available.” The participant added that “You have to talk to somebody in another organization and try to understand what their data systems are and also understand what is the process to get access to that data.”

Organizations must also handle issues with legal permissions. It is costly to engage legal representation during some data request activities. Failure to engage legal representation can inhibit data access and limit data availability. Public trust is an issue. One participant stated that there is “concern about the use of the data … in terms of what analysis will be conducted and what that analysis would reveal. And there is uncertainty and risks to that.”

Healthcare is a complex and regulated environment. The regulations and governance affect learning health system development and operation. The current fee for service (FFS) healthcare environment does not necessarily support all of the aims of value-based healthcare. The fee for service environment is focused primarily on direct reimbursement for services rendered. However, the structure of reimbursement information as claims data may not capture the rich data required for clinicians and researchers, and other stakeholders who are focusing on value-based care. One participant noted that the “distinction between a clinical record and claims record is really challenging and in many cases that level of detail is in an area of note or unstructured data.” Clinicians and researchers need to resort to different methods, such as text-based analysis or machine learning, to extract and analyze the unstructured information. Data analysis and learning is a multistep process that may involve multiple partner organization with differing operational, business, and staffing capabilities and needs. When more than one organization participates in the data aggregation, analysis, and sharing process, there are challenges in determining the reimbursement funds are allocated among the organizations participating the data transformation activities. Healthcare regulations and legislation are changing to support value-based care activities by exploring alternative payment models.

The combined investigation model includes operational concepts for assessing health data networks and learning health system capabilities. Table 3 shows a summary of finding for the models operational concepts: system usage and availability, learning capability, and sustainability. The detailed findings for those concepts are discussed below.

Table 3 - Summary of Findings for Combined Investigation Model Operational Concepts

Concept	Findings
System Usage and Availability	1. Organizations advertise system availability through web services including websites and data dashboards with de-identified data 2. The systems are used mostly by clinicians and researchers 3. Public access to EHR data through patient portals is low.
Sustainability	1. Learning health system efforts are funded on a per project basis through a mixture of federal, local, private foundation, and individual sources. 2. There is no comprehensive strategy for funding learning health system efforts. 3. Legislative support varies by location, support is focused on broad health care issues that include learning health system development.
Learning Capability	4. The systems were able to perform basic analysis (operations and staffing). 5. The analysis processes were ad-hoc. 6. None of the system reached the capability of generating health insights from the data.

System Availability

The study participants advertised their systems and data available via web-based services to internal and potential external users. One system uses an online web presence to advertise available information pertaining to their targeted health conditions. Another organization is piloting dashboards to display information among multiple care programs. At least one organization's system is not yet operational; however, the organization depends on its partners' systems to determine how to advertise the system's data availability. This system advertises data availability mainly to clinicians engaging patients and in some cases researchers directly affiliated with the organization or its partners. None of the systems advertise the availability of features and data, even in de-identified and/or summarized forms, to external non-healthcare affiliated stakeholders. Some participants cited security, privacy, and legal concerns of exporting information outside of their systems.

System Usage

Clinicians and researchers make the most use of the systems in this study. The systems are available to other internal stakeholders that have access to increasing amounts of electronic data as EHR and health-related data in electronic form becomes more pervasive. One participant described the system usage thusly "As far as usage is concerned, I think it is used at the point of care for the routine business and then each organization depending on their capability, resources and expertise available uses that data for quality improvement and population health." The number of clinicians and researchers using the participant's system numbered in the hundreds.

One participant estimated the usage of the system information to be approaching one thousand users during the course of a recent pilot project.

The number of people accessing electronic health records is orders of magnitude less than the number of electronic health records available. One participant shared that “The adoption of electronic health records is fairly high in our region as it has been growing nationally.” One participant’s systems managed tens of millions of electronic health records and approaching one hundred million records. Another participant estimated the disease registry managed electronic information for approximately 30,000 people. Another participant indicated that most of the health record information among the partner systems was in electronic form, but some of the specialty clinics in the area were still using paper records. While electronic health records are widely adopted, the adoption has not been completed in some areas. The electronic health information is managed by traditional healthcare organizations, as well as health-related organizations, such as specific disease registries. Fracco et al (2017) performed a meta-analysis of patient portal adoption rates and reported that the adoption rate by the public was 25%, which is lower than the 53% adoption rate in random controlled trials. The number of people accessing available electronic health information is substantially low.

Funding Sources

The systems represented in this study are supported by a mixture of funding sources, including federal programs, state initiatives, disease-focused and private foundations, and commercial technology organizations, such as IBM, Apple, Google, and others. One participant stated that there is a lack of a cohesive funding strategy "to produce a true learning health system." The participant added that the funding streams are narrowly focused on project-specific efforts. A disease-focused foundation and a private foundation supported the development of the disease registry system. Some systems were supported by grants from federal funding agencies. Some funds come from educational institutions funding. One organization's system development was supported by state-mandated taxpayer funds. Funding also comes from "donations from families interested in specific conditions or disorders."

Legislative Support

Support for learning health system development from federal, state, and other lawmakers and enacted laws vary by location. One participant recognized that "our state senator has been the major champion of these health care initiatives" that include learning health systems. Many organizations depend on legislation from government agencies, including the Center for Medicare and Medicaid Services and the Medicaid office that support value-based care. One participant said that "We are working closely with the Medicaid office to figure out what are the avenues where a learning health system can help improve the program, providing better services and improving outcomes for the beneficiaries of Medicaid and at the same time managing costs of the program." The participant acknowledges support from the city through taxpayer funds for building use cases, value propositions, and being able to think about reimbursement from a different perspective." One participant did not identify any type of legislative support.

Participants who chose the interview option spoke about topics beyond the interview questions. Additional topics emerging from the interview discussion included learning health system evolution in scope and definition, and recommendations for the learning health system community activity. Table 4 shows a summary of the findings for the emerging learning health system concepts.

Table 4 - Summary of Findings for Emerging Learning Health System Themes

Theme	Findings
Learning Health Systems Evolution	1. LHS vision is expanding to encompass data sources beyond electronic health record data and including mobile platform sources. 2. LHS can be a source of health and organizational best practices. 3. LHS practitioners are using innovative decision support technologies and learning algorithms to their fullest capabilities. 4. The complete vision of a learning health system is still unclear to some LHS practitioners.
Recommendations to Learning Health Community	1. The LHS community needs to lead broader discussions on the effects of community scope, metrics, embracing new value-based legislative efforts, sustainability, and collaboration. 2. The LHS community needs to discuss methods to represent socio-economic data in an electronic form suitable for automated analysis.

Learning Health System Evolution

The concept of a learning health system has evolved to encompass learning from various data sources that influence or effect. Leading learning health system researchers Friedman, Rubin, & Sullivan (2017) acknowledge that the “h” in learning health system is interpreted by some as “health care”, focusing on health care delivery, while others interpret health as promoting public and population health. Expanding the concept of health has implications for practitioners trying to embrace the learning health system vision. Learning health system practitioners are contemplating this expanded definition and scope and what it means to achieve a functioning learning health system. A participant is “recognizing the fact that a lot of factors including the environment in which you live and the difference between inner city and rural and urban have an influence on the health of individuals." But just more data is not enough. This participant believes that learning health systems focus also "depends on when that data becomes available, the quality of the data and the trustworthiness of the data and whether it answers the question you have or not." A participant states that LHS requires understanding the importance of data beyond just clinical data. This participant also believes that learning health systems should also endeavor to spread best practices among participating organizations and support the aims of both clinicians, researchers, and other stakeholders.

Learning health systems may need to consider a set of technologies as implementation options. One participant believes that there are standards mature enough to describe the movement of various types of data necessary for a learning health system implementation. Learning health systems contain clinical decision support (CDS) algorithms, yet practitioners are still searching for the motivation to use them to their fullest capabilities. A participant says that "we are seeing a transition to mobile health … a learning health system has really got to learn how to accommodate that transition from a physical facility that delivers healthcare to a system without walls, without boundaries." The evolving LHS focus may also encompass other large scale health data and analysis efforts, such as the National Institutes of Health's All of Us program, formally Precision Medicine Initiative (National Institutes of Health, 2017). While the high level learning health system concept is still evolving, one participant feels that practitioners should determine what knowledge can be extracted from available data and shared in the community. One participant, even as a practitioner, feels that "we are still in the dark ages as to what a true learning health system is going to be."

Recommendations to the Learning Health Systems Community

Participants in this study were interested in broader discussion or activities in learning health system community pertaining to community scope, metrics, embracing new value-based legislative efforts, sustainability, and collaboration. Practitioners are interested in community discussions in developing definitive definitions of learning health systems that address the interests of different stakeholders, including funding organizations and business that support learning health system development. One participant proposed that learning health system organizations publish a set of performance statistics that would help organizations compare and optimize learning health system for improvement. The community must consider relevant socio-economic data that affect health and determine how to represent that data for analysis. A participant was interested in how other organizations were handling new value-based health legislation, such as the Medicare and CHIP Reauthorization Act of 2015 (MACRA) and alternative payment models. The community should further explore value-based care as a means of sustaining learning health development and innovation; effective use of data “to save cost and improve outcomes actually results in the revenue stream for maintaining an infrastructure like this [learning health system].” One participant felt that health care initiatives and changes to encourage a healthier population may reduce the overall healthcare patient population and may increase competition among organizations, yet the community should still explore models of collaboration that support broad data sharing among organizations. A participant proposed “really getting some work to look at the whole picture. And this looks at everything from artificial intelligence, machine learning, data visualization, moving data, single languages, single models…. All those sorts of things in such a way that helps us understand the global community, not even just the US, but globally what’s happening.”

Discussion of Research Questions

Research Question 1: What progress have early LHS endorsers and their health data networks made towards achieving large-scale learning health systems?

Progress toward a nationwide Learning Health System is measured by examining the progress of LHS implementation in three US states, representing the Northwest, Southeast, and the Southwest US regions. The progress measures are system maturity, learning capability, and knowledge dissemination. The Department of Defense's Technology Readiness Level model is used to assess system maturity. Learning capability is determined by three discreet categories - aggregate, analyze, and knowledge generation. Knowledge dissemination is determined by three discrete categories – "no contract", planned, executed.

The systems examined in this study show that progress is being made toward a nationwide learning health system, but a nationwide implementation has not been achieved. Two of the three systems achieved an operation maturity level, above TRL 5. All of the systems achieved a minimum degree of data analysis, but lacked the capability to generate health-related insights or address research related inquiries. All of the systems achieved internal data exchange. One system was able to achieve data exchange with external organizations; this system was able to transmit information to a health data network in the Western region of the US. This means that data is capable of being exchanged among LHS systems covering four out of five US regions. Existing dissemination processes are ad-hoc and include manual components. This study did not examine systems located in the Midwest. However, the extent of data coverage represented here shows that nationwide exchange of data among LHS installations is achievable. LHS organizations need to do more in achieving a nationwide LHS system.

Research Question 2: What technologies, techniques, and methodologies have contributed to progress in achieving a large scale, i.e. regional, multi-regional, and/or statewide, LHS operation?

Organizations are implementing LHS systems in distributed manners and combining multiple technologies to achieve the LHS vision. LHS implementations include electronic health record applications, data management and storage components, data analysis, security components. Service oriented architectures or platforms are used manage the technology components. Commercial EHR applications include Epic, Athena Health, and Cerner; these applications are mature and certified to adhere to necessary health mandates. There are interoperability issues in exchanging data between the applications. Data management implementation must handle large volumes of health data. Data management solutions include query based database applications, web services, and cloud based storage. One organization used Informatics for Integrating Biology & the Bedside (I2B2) platform which is an integrated application that manages multiple components and service application. LHS system are being implemented as distributed systems whose components are implemented and shared by partnering organizations. Practitioners in this study have suggested that the community identify reference set of technologies suitable for LHS operation.

Research Question 3: What challenges have presented significant barriers to progress?

LHS practitioners are implementing large-scale distributed health data and learning systems that operate across physical and system management domains. Practitioners are encountering socio-technical system issues that include challenges with people, processes, and technologies. Critical issues include patient identification, data management, legal and reimbursement issues. US healthcare does not have a nationwide patient identification system so identifying patients across different health provider systems is hindering the construction an individual's complete health history. Health data systems depend heavily on the health data collected by providers; however, there are challenges with consistent data representation, data quality, and interoperable data exchange. Practitioners experience challenges with gaining legal permission to personal information; the cost of legal consultation and representation can be cost prohibitive to research and learning. LHS systems aid in decision making and identifying effective health solutions; however, LHS activities, such as knowledge generation, are not viewed as part of health care delivery and may not be directly reimbursed. Also, learning health system activities may be spread over multiple organizations. There are challenges in receiving reimbursement for these value-added activities. New value-based legislations, which support alternative payment models, may help to address this issue. Practitioners need more guidance in applying alternative payment models and value-based legislation to learning health system development.

Validation

The researcher used Quikos qualitative analysis software as discussed in the methodology section above. The researcher used the preliminary Quikos reports to list and track the number and purpose of each created theme and identify repeatedly appearing keywords in coded text excerpts. The keywords were generated in a word cloud report. The size of the word in the word cloud is directly proportional to the number of times that the keyword is mentioned in the set of coded document excerpts. The researcher only used the Quikos reports as guidance. The researcher did not use any automated theme generation features. To reduce software bias, the research relied on complete sentences or sections of text that address a specific theme or concept. The additional text provided context beyond just recognition of keywords. The researcher manually determined and created all themes. The research adjusted themes to ensure a particular view was shared by two or more study participants. The researcher conducted at least three rounds of theme examination and adjustment to arrive at the final set of thematic findings.

To check the appropriateness of the final set of thematic concepts and findings, the researcher compared the concepts to themes discussed in published literature pertaining to learning health systems, system maturity, and health data network development. The themes and findings presented were consistent with topics discussed in the relevant literature as presented in the literature review section and references. Bailey et. al. (2013) and Etheridge (2007) discuss issues of data quality in electronic health records, including differences in treatment attribution to controlled vocabulary concepts. Feiler et. al (2007) discuss challenges in ultra large scale system including distributed management of multi component systems. Walker et. al. (2005), Brailer (2005), and Shortliffe (2005) discuss issues and challenges in interoperability and standards development, including ease of data transfer, delayed standards adoption, and competition among stakeholders. Leading LHS researchers, Friedman, Rubin, & Sullivan (2017) and Anderson (2017), acknowledge that the learning health system concept continues to evolve and LHS implementations demonstrate component level progress. Yet, LHS implementations have not reached the vision of operational learning health systems that generate knowledge on a routine basis.

CHAPTER 5

SUMMARY AND CONCLUSIONS

The concept of a learning health system continues to evolve from its initial conception by the IOM that focused on electronic health records and analytics. Friedman, Rubin, & Sullivan (2017) provide the following characterization of a learning health system, “LHS as a socio-technical system with the primary goal of significantly and safely improving health while reducing costs and other harms … a cyber social system composed of people and technology”. In addition to the definition, they identify five characteristics of fully functioning learning health system: (1) it includes health characteristics of a “very large” number of people, (2) best practice knowledge distilled from data support the aims of multiple stakeholder groups, (3) “learning and improvement are routine and continuous processes”, (4) infrastructure supports continuous learning, and (5) continuous learning is ingrained in the organizational culture. In light of this evolved learning health system characterization, researchers in the LHS community conclude that while advances have been made toward the development of a nationwide learning health system, there is still much work to be done in order to reach a fully functional status of a learning health system by individual organizations and collectively in connecting and routinely exchanging information among the various installations.

The research study examined technologies operational and measurement concepts for three existing learning health system implementations. Operational concepts included system availability, data transformation, and sustainability. Progress measure included system maturity, learning capability and dissemination activities. The learning health system implementations examined in this study had varying level of capabilities necessary to be a learning health system. The systems maturity ranged from technology design phase to technology prototyping and demonstration. This set of learning health system implementations have not reached the level of fully functioning learning health system. Examination of the systems reveals that development of components of a learning health system is well underway and experiencing some success. In addition, the number of organizations embracing the learning health system is growing, resulting in more organization collaborating to further the learning health system cause. Challenges in reaching a nationwide learning health systems capabilities include data standards and representation, interoperability and broad data exchange, development of effective learning strategies and dissemination, and developing use cases and partnerships to encourage funding for continued development and innovation.

Future Research Opportunities

The Learning Health Systems concepts continue to emerge in the health research area. The learning health community has developed an LHS Vision 2024, which details components development targets in realizing an operational learning health system by 2024 (Anderson, 2017). An expanded and more comprehensive study based on the frameworks mentioned and developed in this effort could explore continued advances toward large-scale operational learning health system implementations.

Computing across borders presents a unique challenge in assessing the maturity of a system. Defining the bounds of a system and its operation is challenging. Organizations with partnership agreements may or may use all of the components of each others systems. The maturity of each system component may not give complete insight into the maturity of the whole system. Legal issues may affect the manner of sharing between organizations in different jurisdictional borders. With sociotechnical systems that include people, technology, and processes, a complete assessment of a system needs to include assessment of the processes supporting the technology, for example, a sociotechnical assessment model developed by Sittig, & Singh, H. (2010). Future studies in assessing maturity in learning health system implementations may use sociotechnical assessment models that examine technical and social aspects of system operation, combining qualitative and quantitative assessment measures.

Other countries are embracing the learning health systems concepts. Researchers representing the European Commission have published information about the TRANSFoRM system (Delaney, et. al., 2015). The United Kingdom's Farr Institute of Health Informatics Research (http://www.farrinstitute.org) is conducting research efforts in health analytics. While the US has a distributed healthcare system, some countries have a single national health care system. A future multinational research opportunity could explore learning health systems development and challenges among countries with differing health care system models.

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APPENDIX A: CORE INTEVIEW QUESTIONS

System Availability: Presence of sufficient health information network structure to "collect, store, display and transmit patient identifiable, structure, clinical data in electronic formats" (Sittig, et al, 2005).

Question SA1: Describe typical schedule when the system is operational?

Question SA2: During operational periods, how do you advertise the systems availability?

System Use: "Hands on use of these HIT systems by patients, providers, and those involved in population health" (Sittig, et al, 2005).

Question SU1: What is the percentage of patients in your area/state/region that have their health data in electronic form?

Question SU2: To what extend do clinicians access electronic health information in your health data network?

Question SU3: To what extend do clinician request access to health information from health data networks outside of your region or state?

Question SU4: What challenges has your state experienced in exchanging health information with other states?