

Electronic health record interoperability and quality management

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ABSTRACT

A lack of interoperability exists among health care providers' electronic health record (EHR) systems. The problem is whether quality management is related to the problem with interoperability. The purpose of the non-experimental quantitative research study was to examine the relationship between quality management and EHR interoperability in the United States. Electronic health record systems play a key role in the development of the Nationwide Health Information Network (NwHIN). If a relationship exists between ISO 9000 quality management principles and EHR interoperability, then quality management would be deemed necessary for EHR interoperability and the operation of the NwHIN. The research included a non-experimental quantitative design to determine the degree of the relationship between perceived level of EHR interoperability and quality management. Three-hundred and ninety nine health care professionals participated in the study. The participants were members of health-care related professional organizations. Analyses performed were factor analysis, correlation analysis, and multiple regression analysis. The results of the analyses determined only one factor to exist; the factor was named quality management. A correlation and simple regression were then performed between perceived interoperability level data and the quality management factor found in the analysis. A significant positive correlation existed between the perception of EHR interoperability and the quality management factor although the amount of variance is not large. Therefore, a relationship between quality management and EHR interoperability was established.

Keywords: Electronic health records, interoperability, quality management

INTRODUCTION

Interoperability is the interconnection of computer systems to exchange and use data with accuracy, efficiency, effectiveness, consistency, and security (Fetter, 2009). Lack of interoperability of healthcare information systems is a barrier to the Nationwide Health Information Network (NwHIN), the proposed infrastructure for sharing health information ("Nationwide health information network (NHIN) exchange architecture overview, draft v.0.9," 2010). While debate continues on the best infrastructure for the NwHIN, interoperability among healthcare information systems remains an important issue (Lenert, Sundwall, & Lenert, 2012)

The primary means of collecting and storing the health data that health care professionals need to share are electronic health records (EHR) systems (Blumenthal & Glaser, 2007). Basic EHR systems typically have 10 clinical functions used at a single healthcare facility, whereas comprehensive EHR systems have 24 clinical functions (Jha, DesRoches, Kralovec, & Joshi, 2010). The EHR systems collect a huge amount of data which health care professionals can use to make accurate diagnoses and care directives. Interoperable EHR systems would facilitate transfer of patient data among different healthcare facilities. The healthcare practitioners at one facility would be able to access patient data collected previously at other facilities in order to properly treat the patient.

Data quality affects the usability of data in EHR systems (Hammond, Bailey, Boucher, Spohr, & Whitaker, 2010). Minimally, data must be accurate and relevant, and the data collectors must ensure data quality (Hammond et al., 2010). Because accuracy is one of the needs for interoperability, quality management of EHR systems could be a factor impacting interoperability of healthcare data among healthcare institutions.

The problem is whether quality management relates to the challenges healthcare providers continue to face in establishing interoperable EHR systems. The purpose of the research was to examine the relationship between interoperability of EHR systems and quality management, as tested using the ISO 9000 quality management standard. If a significant relationship exists between ISO 9000 principles and EHR system interoperability, an emphasis on quality management in EHR implementation and use could lead to improved interoperability of EHR systems.

HEALTHCARE REGULATIONS AND STANDARDS

The healthcare industry functions under heavy regulation (Almgren, 2007). Governmental legislation, accreditation councils, and technology standards agencies all set regulations and standards affecting healthcare providers. An examination of major legislation and standards limited to healthcare information technology (HIT) reveals a complex regulatory environment.

Several major U.S. government legislations relate to HIT interoperability. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 mandates the use of information technology in the field of health care while also specifying security and privacy measures for health care information systems. The Health Information Technology for Economic and Clinical Health (HITECH) Act, which is part of the American Recovery and Reinvestment Act (ARRA) of 2009, charges the Office of the National Coordinator (ONC) with developing a nationwide HIT infrastructure. Both the Patient Protection and Affordable Care Act of 2010 and Health Care and Education Reconciliation Act of 2010 mandated protocols and standards for

interoperability and security in HIT for health and human service program providers at both the federal and state levels (Purcell, 2013).

Accreditation agencies influence quality standards for health care providers; these agencies include the Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations, or JCL ("About the Joint Commission," 2011), the Utilization Review Accreditation Commission, or URAC ("About URAC," 2011), and the National Committee for Quality Assurance, known as NCQA ("About NCQA," 2011). The main agencies responsible for standards pertaining to HIT include the National Institute of Standards and Technology (NIST), the Certification Commission for Health Information Technology (CCHIT), and the Healthcare Information Technology Standards Panel, or HITSP (Purcell, 2013).

HEALTHCARE INFORMATION TECHNOLOGY

Electronic health record interoperability impacts many related HIT (Purcell, 2013). The major HIT with which EHR systems must interact include other EHR systems, personal health record (PHR) systems, computerized physician order entry systems (CPOE), and clinical decision support systems (CDSS). Also related to EHR interoperability are regional health information organizations (RHIO) and the development of the nationwide health information network (NwHIN).

Electronic health record systems are the primary means of storing patient data (Blumenthal & Glaser, 2007). Four domains of functionality exist among EHR systems: 1) recording patients' demographic and clinical data, 2) viewing and managing results of laboratory tests and imaging data, 3) managing order entry, including electronic prescriptions, and 4) supporting clinical decisions, which includes drug interaction or contraindication warnings (DesRoches et al., 2008). The movement to incentivize the adoption of EHR in primary practice and to document meaningful use of the installed systems started in 2010 (DesRoches, Agarwal, Angst, & Fischer, 2010). The incentive program and mandates in the ARRA have accelerated the adoption of EHR in primary care, but have not necessarily ensured interoperability (Purcell, 2013).

Patients use PHR manage their own healthcare through use of information collection, sharing, exchange, and self-management (Kaelber, Jha, Johnston, Middleton, & Bates, 2008). The three models for PHR are standalone PHR, integrated PHR, and PHR portals (Detmer, Bloomrosen, Raymond, & Tang, 2008; Kaelber et al., 2008). The standalone or freestanding PHR model is a personal computer-based system in which the patient enters his or her own data manually, then can organize and store medical data. The patient also shares the data with health care providers (Detmer et al., 2008; Kaelber et al., 2008). An integrated or network Web-based PHR model allowing patients to add personal health data to their EHR, to share the data with their providers, and to control their own data while also allowing healthcare providers a number of alternatives for data entry through the capability of connecting with patient EHRs at physician offices and hospitals. A PHR portal allows patients access to their EHR with some limited capabilities for information management (Detmer et al., 2008; Kaelber et al., 2008).

Computerized physician order entry systems, which allow healthcare providers to enter all orders directly into the computer system, are dependent upon comprehensive EHR systems (Ghahramani, Lendel, Haque, & Sawruk, 2009; Harrington, Kennerly, & Johnson, 2011; Janos, 2009). Managing order entry is enabled by integration with a full CPOE system (DesRoches et

al., 2010). Members of the Institute of Medicine advocated the use of CPOE systems as a means of decreasing medical errors in healthcare institutions (Ghahramani et al., 2009).

Decision support capabilities of EHR systems are a facet of HIT facilitated by integration with a CDSS (DesRoches et al., 2008). A CDSS assists health care professionals with decisions made in the clinical setting, such as decisions regarding patient transfer to or from an intensive care unit, use of ventilation and drugs, and discharge home or to a skilled nursing facility (Hine, Farion, Michalowski, & Wilk, 2009; Weber, Courtney, & Benham-Hutchins, 2009).

Knowledge-based CDSSs are the most typical, and are comprised of a knowledge base, an inference engine, and an user interface (Stanescu & Filip, 2009). Information in the knowledge base is in the form of if-then rules (Stanescu & Filip, 2009). The inference engine contains formulas for integrating the rules from the knowledge base with the patient data (Stanescu & Filip, 2009). The user interface allows facilitates system inquiry.

Regional health information organizations are local groups composed of hospitals, insurance companies, employers, pharmacies, consumer groups, and government officials that are working together to connect the HIT systems of the separate entities (Blumenthal & Glaser, 2007). One example of a RHIO is the Massachusetts eHealth Collaborative (MAeHC), a statewide initiative that has established health information interchange throughout the state health care system (Goroll, Simon, Tripathi, Ascenzo, & Bates, 2009). The MAeHC established the ability to interchange the information through agreement on technology use, adoption barriers and facilitators, tactics for implementation, impact upon patient safety, impact on quality, and economic concerns (Goroll et al., 2009).

The ONC initially defined the NHIN (now referred to as the NwHIN) as a network of health information organizations that participate in exchanging health information with each other (Purcell, 2013). At the time, RHIOs were considered the model for developing the NwHIN (Adler-Milstein, Bates, & Jha, 2009). Under the Obama administration the ONC has shifted the strategic plan to a web-based model using direct point-to-point contact, using Google-like searches instead of RHIOs (Lenert et al., 2012). However, many in the healthcare community argue that the technology needed for the proposed web-based model is not yet feasible to implement (Lenert et al., 2012). Regardless of whether the infrastructure will be modeled on RHIOs or a web-based model, interoperability remains a necessity.

QUALITY MANAGEMENT ISSUES IN HIT

One quality management concern in HIT is the quality of the data itself. The definition of data quality is the completeness, accuracy, and comparability of data (Chan, Fowles, & Weiner, 2010). Chan defines data completeness as the level of missing data for a particular data item. Data accuracy is the extent to which captured data reflect the underlying medical situation; for example, a medication list would need to have all medications and the related dosages to be accurate. Data comparability is a similarity in the data quality as well as the availability of specific data items to use in a measure across different entities, such as different health care plans (Chan et al., 2010).

Inherent in concerns about HIT are the issues of data security and privacy, a main focus of HIPPA and ARRA. Patients express unease regarding security and privacy of HIT as researchers continue to solve related problems. Health data control and access are key concerns pertaining to PHR privacy and security (Kaelber et al., 2008; Tejero & Torre, 2012).

Several quality management standards and techniques were reviewed in the research study: the Baldrige National Quality Program, TQM, six sigma, and ISO 9000/9001 (Purcell, 2013). Professionals in many different industries use these quality management standards and techniques. The ISO 9000 standard was selected as the universal quality management standard for the study based on its similarity to the Joint Commission's principles respecting core performance measurement activities. The ISO 9000 principles of leadership, customer focus, involvement of people, and mutually beneficial supplier relationships relate to the Joint Commission's first three principles, which emphasize the importance of stakeholder interests and the need for strong healthcare leadership. The process and systems approaches, continual quality management, and factual decision making standards from ISO 9000 have an emphasis similar to the fourth through eighth Joint Commission principles (Purcell, 2013). The ISO 9000 quality management standard is essentially a process approach to quality management. The relationship ISO 9000 has with the Joint Commission's principles indicate that the standard could be considered an operationalized implementation of the principles.

RESEARCH METHODOLOGY

The problem is whether the quality management relates to the reasons that health care providers are struggling with the problem of interoperability in the full implementation of their EHR systems. The ISO 9000 quality management standard was used as the basis for a survey of healthcare professionals to determine whether a significant relation existed between the ISO 9000 quality management standard and EHR interoperability. If interoperability relates to some or all of the eight principles in the ISO 9000 quality management standard, ensuring use of the principles could result in better interoperability and higher EHR adoption rates; not adopting the principles could mean continued poor interoperability and low EHR adoption rates (Purcell, 2013).

A nonexperimental quantitative design was adopted for the research. The research involved ascertaining whether perceived EHR interoperability and ISO quality management principles covary (Purcell, 2013). A survey instrument was developed containing groups of four questions for each of the eight quality management principles in the ISO 9000 standard. Each group of questions had a related null hypothesis and alternative hypothesis. The research questions and hypotheses addressed were as follows:

- Q1.** To what extent, if any, does customer focus relate to perceived electronic health record interoperability?
- H1₀.** Customer focus is not significantly correlated to perceived electronic health record interoperability.
- H1_A.** Customer focus is significantly correlated to perceived electronic health record interoperability in hospitals.
- Q2.** To what extent, if any, does leadership relate to perceived electronic health record interoperability?
- H2₀.** Leadership is not significantly correlated to perceived electronic health record interoperability.
- H2_A.** Leadership is significantly correlated to perceived electronic health record interoperability.
- Q3.** To what extent, if any, does involvement of people relate to perceived electronic health record interoperability?

- H3₀**. Involvement of people is not significantly correlated to perceived electronic health record interoperability.
- H3_A**. Involvement of people is significantly correlated to perceived electronic health record interoperability.
- Q4**. To what extent, if any, does a process approach relate to perceived electronic health record interoperability?
- H4₀**. A process approach is not significantly correlated to perceived electronic health record interoperability.
- H4_A**. A process approach is significantly correlated to perceived electronic health record interoperability.
- Q5**. To what extent, if any, does a systems approach to management relate to perceived electronic health record interoperability?
- H5₀**. A systems approach to management is not significantly correlated to perceived electronic health record interoperability.
- H5_A**. A systems approach to management is significantly correlated to perceived electronic health record interoperability.
- Q6**. To what extent, if any, does continual improvement relate to perceived electronic health record interoperability?
- H6₀**. Continual improvement is not significantly correlated to perceived electronic health record interoperability.
- H6_A**. Continual improvement is significantly correlated to perceived electronic health record interoperability.
- Q7**. To what extent, if any, does a factual approach to decision making relate to perceived electronic health record interoperability?
- H7₀**. A factual approach to decision making is not significantly correlated to perceived electronic health record interoperability.
- H7_A**. A factual approach to decision making is significantly correlated to perceived electronic health record interoperability.
- Q8**. To what extent, if any, do mutually beneficial relationships relate to perceived electronic health record interoperability?
- H8₀**. Mutually beneficial relationships are not significantly correlated to perceived electronic health record interoperability.
- H8_A**. Mutually beneficial relationships are significantly correlated to perceived electronic health record interoperability (Purcell, 2013).

DATA COLLECTION

The survey based on characteristic outcomes of each of the eight ISO 9000 quality management principles was administered to members of several professional associations of healthcare practitioners: the American Medical Informatics Association (AMIA), the Pennsylvania State Nurses Association (PSNA), and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). The criterion variable was the perceived level of interoperability of EHR systems, which was a nominal variable measured on a Likert-type scale. The predictor variables, the eight ISO 9000 principles, were ordinal variables; four questions were asked for each and the questions were measured on a Likert-type scale. Validity and reliability of the survey instrument were established through use of an expert committee to study

the survey instrument, a pilot test of the survey instrument, and use of a representative sample size of the population based upon a power analysis. The number of responses was sufficient to provide a power level of .80 and a confidence level of 0.05 (Purcell, 2013).

Data collection occurred in Spring and Summer 2012. Statistical analyses performed on the data were descriptive statistics, exploratory factor analysis, and correlation analysis. Missing items were not included through the use of the delete listwise option in SPSS (Purcell, 2013).

ANALYSIS

Analysis of demographic characteristics indicate that just over half of the respondents (54.8%) worked with EHR for at least 10 years, and 80 respondents (23.7%) worked with EHR for over 15 years. The largest professional group represented were nurses, who accounting for 167 (64%) of the responses. Nearly all of the respondents were college graduates, with a total of 337 (99.5%) responses. The largest percentage of respondents, 228 (67.3%) of all respondents, had finished graduate school; 87 (25.7%) of the respondents had a baccalaureate degree, and 22 (6.5%) of the respondents had completed a 2-year college degree. Community hospital respondents accounted for 127 (37.5%) responses and respondents from teaching and research hospitals accounted for 100 (29.5%) responses (Purcell, 2013).

An exploratory factor analysis of the 32 quality-management-related questions was conducted to determine whether the eight groups of questions on the survey represented distinct, conceptually relevant, and intact dimensions of the overall construct. The Kaiser-Meyer-Okin results of .935 ($p < .001$) indicated that the sample was adequate to allow the correlation matrix to be analyzed. Eight of the questions (one question from each group) had results reversed before analysis because the questions were asked in a negative fashion as a check on the test (Purcell, 2013).

The exploratory factor analysis results included six components with eigenvalues greater than 1. However, the six components only accounted for 58.22% of the variance. Based on the analysis of the data, most of the variable loading occurred on Component 1, with two variables loading on either Component 1 or Component 2, and one variable each loading occurring on Components 3 and 4. An abbreviated version of the component matrix demonstrates the factor loading, as indicated in Table 1. The table shows factor loadings of .467 and above. The cutoff point of .467 was used instead of .5 to allow all the variables to be loaded into the factor (Purcell, 2013).

The exploratory factor analysis did not yield eight unique factors. However, significant factor loading occurred on the first factor found, indicating the existence of one significant factor, which will be identified as the quality management factor. Testing using Cronbach's alpha of resulted in a .944 level of internal consistency, indicating that the single quality management factor could be further tested. To perform further analysis, an analysis of the mean of the variables was performed to generate a value for the quality management factor. The Pearson product-moment correlation between the quality management factor and perceived level of interoperability yielded $r(292) = .301, p < .000$, indicating a small but significant positive relationship between the two variables. A simple regression analysis was then performed indicating the quality management factor significantly correlated with interoperability. However, the amount of variance in the outcome variable explained by the predictor was not large (0.091) meaning that quality management is not the only factor that correlates with interoperability.

RECOMMENDATION

Lack of interoperability impedes the level of health information sharing necessary for the NwHIN. Knowing factors related to interoperability of EHR systems could lead to an improvement in the overall level of interoperability among HIT systems. The research indicates that quality management is significantly correlated with interoperability (Purcell, 2013).

The major recommendation of the research is careful attention to quality management in EHR implementation and operation. Implementation issues can be significant due to the rapid adoption of EHR systems in recent years. The main reason for the increase in adoption rates since 2011 is the Medicare and Medicaid EHR Incentive Programs.

The Medicare and Medicaid EHR Incentive Programs mandated implementation of EHR systems and meaningful use of those systems by 2015. To qualify for full incentive, healthcare practitioners needed to adopt EHR systems by 2012. In 2015, the incentive portion of the mandate would end for EHR implementation. If meaningful use of the systems was not started by 2015, Medicare and Medicaid payments to the healthcare provider would be reduced, starting with a 1% reduction the first year and incrementing up to 5% ("Introduction to Medicaid EHR incentive programs for eligible professionals," 2014; "Introduction to Medicare EHR incentive program for eligible professionals," 2014).

While the mandate supports a worthy ideal, implementation of EHR systems could have been rushed with attention to quality sacrificed for speed of implementation to reap the highest incentive payments. A rushed implementation could ultimately result in a poor EHR system. Poorly designed, implemented, or applied systems were cited as increasing patient safety risks and possibly degrading the quality of health care (*Health IT and Patient Safety: Building Safer Systems for Better Care*, 2012). Quality of EHR systems is therefore an on-going concern in spite of exiting mandates.

FURTHER RESEARCH

A few areas of related research became evident during the study. One area of research is focused on establishing standard data quality measures such as granularity, timeliness, and comparability (Chan et al., 2010). Implementation of standard data quality measures and establishment of benchmarks for the measures would influence quality management. The examination of organizational culture could expose another factor correlated with interoperability. Several researchers indicated a relationship between organizational culture and quality management (Belohlav, 2010; Naor, 2008; Stock, 2010; Zu, 2008). A study of organizational cultures in healthcare organizations with high levels of quality could provide a model for a culture of quality healthcare management. Changes in workflow patterns was cited by many researchers and mentioned as a reason for abandonment of active use of EHR (Purcell, 2013; Wiedemann, 2012). Workflow patterns could therefore influence interoperability. Healthcare professionals also argue that the proliferation of proprietary systems have a major impact on interoperability problems (Mandl, 2012). Proprietary systems typically exchange data only with similar systems, rendering interoperability with systems from other manufacturers impractical or impossible.

CONCLUSION

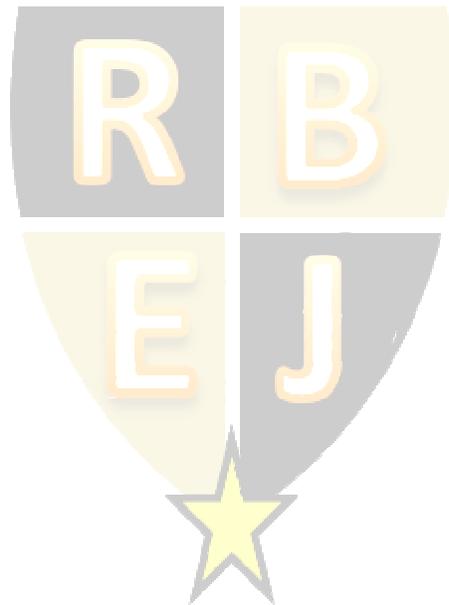
The research indicates that quality management is correlated with interoperability of EHR systems. The current lack of interoperability could be mitigated to a degree by adherence to quality management in the implementation and operation of EHR systems. Unfortunately, the research indicated that other factors also influenced interoperability, so improvement of quality management is not the sole response. Other possible factors which could correlate with EHR interoperability are data quality measures, organizational culture, workflow patterns, and proprietary systems.

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Component Matrix: Six Factors

	Component					
	1	2	3	4	5	6
Customer Focus 1	.530					
Leadership 1	.639					
Involvement of People 1	.483	.490				
Process Approach 1	.616					
Systems Approach 1	.532	.504				
Continual Improvement 1	.580					
Factual Approach 1	.547				.497	
Mutual Beneficial Relationship 1	.718					
Customer Focus 2	.711					
Leadership 2	.661					
Involvement of People 2	.199			.603		
Process Approach 2	.621					
Systems Approach 2	.600					
Continual Improvement 2	.684					
Factual Approach 2	.607					
Mutual Beneficial Relationship 2	.664					
Customer Focus 3	.702					
Leadership 3	.520					
Involvement of People 3	.590					
Process Approach 3	.609					
Systems Approach 3	.636					
Continual Improvement 3	.518					
Factual Approach 3	.677					
Mutual Beneficial Relationship 3	.619					
Customer Focus 4	.353		.501			
Leadership 4	.688					
Involvement of People 4	.467					
Process Approach 4	.690					
Systems Approach 4	.746					
Continual Improvement 4	.691					
Factual Approach 4	.688					
Mutual Beneficial Relationship 4	.700					

(Purcell, 2013) Purcell, B.

Table 1