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The Second International Conference on Health Information Technology Advancement

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# TABLE OF CONTENTS

I. Message from the Conference Co-Chairs B. Han and S. Falan ................................................................. 5

II. Message from the Transactions Editor H. Lee ..................................................................................................... 7

III. Referred Papers

A. Emerging Health Information Technology and Applications

The Role of Mobile Technology in Enhancing the Use of Personal Health Records
Mohamed Abouzahra and Joseph Tan .................................................................................................................. 9

Mobile Health Information Technology and Patient Care: Methods, Themes, and Research Gaps
Bahae Samhan, Majid Dadgar, and K. D. Joshi .................................................................................................. 18

A Balanced Perspective to Perioperative Process Management
Jim Ryan, Barbara Doster, Sandra Daily, and Carmen Lewis ............................................................................... 30

The Impact of Big Data on the Healthcare Information Systems
Kuo Lane Chen and Huei Lee .......................................................................................................................... 43

B. Health Care Communication, Literacy, and Patient Care Quality

Digital Illness Narratives: A New Form of Health Communication
Jofen Han and Jo Wiley ......................................................................................................................................... 47

Relationships, Caring, and Near Misses: Michael’s Story
Sharie Falan and Bernard Han .......................................................................................................................... 53

What is Your Informatics Skills Level? -- The Reliability of an Informatics Competency Measurement Tool
Xiaomeng Sun and Sharie Falan ......................................................................................................................... 61

C. Health Information Standardization and Interoperability

Standardization Needs for Effective Interoperability
Marilyn Skrocki .................................................................................................................................................... 76

Data Interoperability and Information Security in Healthcare
Reid Berryman, Nathan Yost, Nicholas Dunn, and Christopher Edwards ......................................................... 84

Michigan Health Information Network (MiHIN) Shared Services vs. the HIE Shared Services in Other States
Devon O’Toole, Sean O’Toole, and Logan Steely ............................................................................................... 94
D. Health Information Security and Regulation

A Threat Table Based Approach to Telemedicine Security
John C. Pendergrass, Karen Heart, C. Ranganathan, and V.N. Venkatakrishnan ............................... 104

Managing Government Regulatory Requirements for Security and Privacy Using Existing Standard Models
Gregory Schymik and Dan Shoemaker ........................................................................................................ 112

Challenges of Mobile Healthcare Application Security
Alan Rea ....................................................................................................................................................... 118

E. Healthcare Management and Administration

Analytical Methods for Planning and Scheduling Daily Work in Inpatient Care Settings:
Opportunities for Research and Practice
Laila Cure .................................................................................................................................................... 121

Predictive Modeling in Post-reform Marketplace
Wu-Chyuan Gau, Andrew France, Maria E. Moutinho, Carl D. Smith, and Morgan C. Wang .................... 131

A Study on Generic Prescription Substitution Policy as a Cost Containment Approach for Michigan’s
Medicaid System
Khandaker Nayeemul Islam ....................................................................................................................... 140

F. Health Information Technology Quality Assessment and Medical Service Delivery

Theoretical, Methodological and Practical Challenges in Designing Formative Evaluations of Personal
eHealth Tools
Michael S. Dohan and Joseph Tan ............................................................................................................. 150

The Principles of Good Health Care in the U.S. in the 2010s
Andrew Targowski .................................................................................................................................... 161

Health Information Technology in American Medicine: A Historical Perspective
Kenneth A. Fisher .......................................................................................................................................... 171

G. Health Information Technology and Medical Practice

Monitoring and Assisting Maternity-Infant Care in Rural Areas (MAMICare)
Juan C. Lavariega, Gustavo Córdova, Lorena Gómez, Alfonso Avila ...................................................... 175

An Empirical Study of Home Healthcare Robots Adoption Using the UTUAT Model
Ahmad Alaiad, Lina Zhou, and Gunes Koru .............................................................................................. 185

HDQM2: Healthcare Data Quality Maturity Model
Javier Mauricio Pinto-Valverde, Miguel Ángel Pérez-Guardado, Lorena Gomez-Martinez, Martha Corrales-
Estrada, and Juan Carlos Lavartega-Jarquin ............................................................................................. 199

IV. A List of Reviewers .................................................................................................................................. 208

V. WMU – IT Forum 2014 Call for Papers ............................................................................................... 209
Conference Co-Chairs’ Message

Bernard Han, Ph.D. and Sharie Falan, Ph.D., RN-BC, CPHIMS

It has been a turbulent ride for healthcare reform over the past three years since the health care reform bill (i.e., the Patient Protection and Affordable Care Act) was signed off on March 23, 2010. Yet, the actual progress in adopting Health Information Technology (HIT) for health care reform is still very slow. With our understanding based on many studies and reports from the health care industry, two major factors were recognized as “potential barriers” to the expedition of health care reform via meaningful use of HIT: 1) the lack of service innovations that truly match user needs and behaviors of their unique work environments; and 2) the lack of incentives that will motivate and engage health care stakeholders (e.g., service providers, practitioners, consumers, etc.) in adopting/using HIT solutions. We are also aware HIT solutions are not the panacea in solving all issues encountered by the Health Care Reform. Given this understanding, we truly believe that a dedicated Conference shall be provided a commonly-accessible forum for all health care professionals, including physicians, clinicians, HIT solution providers, scholars, and consumers to share research findings that are critical to the expedition of Health Care Reform, in particular, with a focus on service innovation and stakeholder engagement - the theme of this year’s conference.

We are very pleased that since the release of Call-for-Papers for ICHITA-2013 in October 2012, we have received more research papers than what can be accommodated for presentations in our conference. Finally, twenty-two (22) papers were accepted after a blind review process with at least two reviewers for each paper. While some papers were not accepted, we sincerely hope all authors of papers submitted to the Conference are benefitted by this process and will continue to conduct research that will produce more meaningful findings to expedite health care reform. To assist the readers of this Transactions of ICHITA, a quick summary of accepted papers with respect to their contributions and research foci is given below.

In brief, the twenty-two accepted papers can be classified into seven categories:

**Emerging Health Information Technology and Applications.** Four papers are classified in this area. Abouzahra and Tan investigate the role of mobile technology in enhancing the use of personal health records. Samhan, Dadgar, and Joshi give a very thorough research review on how mobile health information technology can be used to support patient care. Their research provides general findings toward methods, themes, and potential research topics in this area. Along the same line toward the use of emerging technologies, Ryan, Doster, Daily, and Lewis study the process management practices of balanced scorecard and dashboards to monitor and improve the perioperative process that has been aligned to overall hospital goals at strategic, tactical, and operational levels. Another paper by Lee and Chen addressed the impacts of “Big Data” applications that may be created on health information systems.

**Health Care Communication, Literacy, and Patient Care Quality.** In this category, three papers are accepted. Han and Wiley investigated on how “social media” is liked by patients to communicate about their health challenges and gain support through an online community that has become reality in the digital world. Falan and Han presented a case study that demonstrates errors may exist in the electronic health care records that subsequently cause confusion and result in near misses which may create huge “negative” impacts on the relationships between the health provider and patients. The third paper by Sun and Falan provides a solid analysis on the reliability of a nursing informatics self-assessment tool that could be effectively used by nursing students in acquiring knowledge in health informatics.

**Health Information Standardization and Interoperability.** Three papers are related to this category. Skrocki presented a research to highlight the importance of health data standardization and how it may affect health
care quality assessment, decision support, and the exchange of health information for patients served by multiple health care providers. Berryman, Yost, Dunn, and Edwards investigate the complexity and security issues related to health information systems interoperability and potential challenges in this area. Lastly, D. O’Toole, S. O’Toole, and Steely look into the implementation of Michigan Health Information Network (MiHIN) by comparing it with what have been done by other states. Their study provides a solid understanding about how these statewide networks could be connected to create a nationwide health information network.

**Health Information Security and Regulation.** Security and privacy are two critical concerns in information sharing, and it is even more true for health care information sharing than others. Three research papers have addressed issues in this area. Pendergrass, Ranganathan, Heart, and Venkatakrishnan focused the study of using a “Threat Table-Based” approach to resolving the security concerns imposed by telemedicine. Schymik and Shoemaker argue that a well-established standard approach can be easily adapted to achieve Federal Compliance to satisfy all legal and regulatory requirements for protection of patient information in health organizations. Future challenges to the use of mobile technologies and their associated application security issues are presented in Rea’s study.

**Health Care Management and Administration.** Efficiency in health care services delivery and administration has long been recognized as one possible area for improvement. Three papers are found in this area. Cure provides an overview of how in-patient work flow scheduling can be optimized by a mathematical model. Gau, France, Moutinho, Smith, and Wang propose a predictive model to assist insurance agents in dealing with risks and uncertainties that are to be faced by all insurers in the post-reform marketplace. The third paper by Islam investigates potential cost savings through a state policy change in promoting the reimbursement for generic prescription substitution for name brand medicine.

**Health Information Technology Quality Assessment and Medical Services Delivery.** Meaningful use of HIT for health services is key to the success of health care reform. There are three papers fall into this category. Dohan and Tan present theoretical and methodological challenges in evaluating personal eHealth tools that are used for disease symptom tracking. Targowski’s paper addresses the principles of good health in the U.S. Findings show the state of health care of the Americans is in a state that is not appropriate for sustainability. Fisher’s research opens up an interesting debate on “how health care shall be covered – by either a government-centered or a patient-centered model,” in which more issues than answers are provided.

**Health Information Technology in Medical Practice.** Three real-world medical practices are investigated. Lavariega, Córdova, Gómez, and Avila reported rural maternity-infant care by using mobile devices and wireless sensors such as ECG (electrocardiogram). Alaiad, Zhou, and Koru study the key factors that influence the adoption of health care robots in a homecare facility. Finally, Pinto-Valverde, Pérez-Guardado, Gomez-Martinez, Corrales-Estrada, and Lavariega-Jarquín developed an evaluation model to measure Data Quality based on maturity and it is currently under testing in a healthcare cluster in Mexico.

Compared to the research outcomes in ICHITA-2011, there is an obvious improvement in both quality and quantity of papers reported herein. We do want to direct our thanks to all paper reviewers (see Page 208) for your tireless efforts in reviewing papers. Without your time and professional critiques, it will never be possible for us to complete this volume of intellectual discoveries to be shared by readers who will carry on the research work to benefit the health care reform.

Bernard Han & Sharié Falan
Conference Co-Chairs, ICHITA-2013
Message from the Transactions Editor

Huei Lee, Ph.D.

It is my pleasure to present the Transactions of the International Conference on Health Information Technology Advancement, which is related to the ICHTA-2013 held in the Western Michigan University, Kalamazoo, Michigan on October 17-18, 2013. Firstly, I would like to express my appreciation to Bernard Han, Program Director of the Center for HIT Advancement, and Sharie Falan, the Associate Director of the Center for HIT Advancement, for their outstanding leadership. Through their help, the editorial process became easier and smoother.

This was the second year to publish the Conference Transactions. This year, we have obtained ISSN numbers for the Transactions in both hard copy (2168-6335) and CD-ROM (2168-6343) editions. As the transactions editor, I personally believe that we cannot attract the attendance of faculty from accredited or research universities without publishing refereed publications. Attending an academic/professional conference often means a chance for tenure or tenure-track faculty to gain useful knowledge in both teaching and research. The purpose of this conference is not only to discuss the information systems of health care applications, but also to discuss academic curriculum trends and critical issues related to health care information systems. This year we received far more submissions than we had expected. This volume contains about twenty two refereed papers in seven categories, developed by more than forty authors and co-authors. These papers have been gone through a rigorous double-blind review process. The Transactions publishes hard copy, CD, and online edition. The best papers will be considered for publication in the coming issues of International Journal of Healthcare Information Systems and Informatics. Secondly, I want to thank the authors, presenters, and reviewers for their persistent hard work for these papers/reviews for the Transactions of the ICHITA-2013 conference. I know that it was a lot of hard work, but it was well worth.

Finally, I would like to sincerely thank everyone again for their participation in the ICHITA-2013. It has been an honor and a privilege to serve as the transactions editor. Without your help and support, the Transactions would not have been possible. In addition, the committee will greatly appreciate it if you can provide them with ideas and issues so that they can improve the quality of the Transactions in the future. We wish you enjoy the conference in Western Michigan University and look forward to seeing you again in future ICHITA conferences.
Western Michigan University
Center for Health Information Technology Advancement (CHITA)

Our Vision:
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The Role of Mobile Technology in Enhancing the Use of Personal Health Records

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Abstract: Healthcare industry is essential for the wellbeing of society members, however this industry is characterized by high cost and by plagued by serious medical errors. Personal health records (PHR) can play an important role in solving healthcare problems by enhancing patients’ involvement in their treatment, and improving patient-provider communication. Despite the potential importance of PHR systems, they suffer from low adoption rate because of several factors such as digital divide and lack of training. In this paper we propose that mobile PHR systems (MPHR) can aid in overcoming barriers to adopt PHR. We present a theoretical model based on theory of planned behavior and innovation diffusion model that attempts to explain the relationship between mobile technology and MPhR. This model helps in understanding the relationship between mobile technology and PHR, and provide insight to how to overcome PHR adoption barriers.

INTRODUCTION

Healthcare is one of the fundamental and most important services in any society. The importance of healthcare stems from its direct relation to the wellness of society and the wellbeing of its members. This importance is evident in the huge budgets governments allocate for healthcare. For example, USA spent over 6 trillion dollars ($8300 per person) on healthcare in 2012.

Despite huge healthcare budgets, this industry is faced by many challenges. For example, healthcare is characterized by medical errors and lack of quality control(Piontek et al., 2010) leading to unwarranted deaths and cost increase. Another challenge is population aging which may increase the cost and the pressure on the healthcare industry to cope with the demand resulting from chronic diseases associated with the elderly. Finally, the growing use of information technology in everyday life and the demand of patients to be a part of their treatment add new challenges to the healthcare industry. To face these challenges, healthcare industry dependence on information and communication technologies increased leading to the development of decision support systems and electronic health records which improve the quality of care and aid in decreasing healthcare cost(Aron, Dutta, Janakiraman, & Pathak, 2011).

Personal health records (PHR) provide great potential in facing healthcare challenges. These systems, which provide individuals with the means to access, and control their health records in a safe and confidential environment, enable patients to participate in their own care, enhance communications between patients and providers, and improve quality of care(Archer, Fevrier-Thomas, Lokker, McKibbon, & Straus, 2011; Demiris et al., 2008). Despite PHR benefits and patients’ positive attitude towards them (Hassol et al., 2004; Ralston et al., 2007), PHR systems suffer from a low adoption rate(Archer et al., 2011). This low adoption rate is attributed to several factors such as digital divide(Roblin, Houston II, Allison, Joski, & Becker, 2009), lack of training, and the inconclusive effectiveness of PHR systems(Archer et al., 2011).

In this paper, we argue that PHR adoption can be enhanced by utilizing mobile technology to access and use PHR systems. Mobile technology is one of the most used and most popular technologies in the world with an estimated number of mobile subscription of 6.8 billion subscriptions, and 2.1 billion mobile broadband subscriptions((ITU), 2013). The introduction of smart phones and the development of high speed mobile data communication further enhanced the role of mobile technology and made it a part of individuals’ daily lives(Dery & MacCormick, 2012). In PHR context, mobile technology, especially using smart phones, provide excellent opportunity for the adoption of PHR. For example, patients are able to access their records ubiquitously. They are also able to use mobile context awareness features (e.g. mobile camera and sensors) to capture and communicate their symptoms or vital signs to
the care provider. Most importantly, the wide diffusion of mobile phones enable patients to have the skills and opportunity to use PHR systems and overcome the digital divide barrier. Finally, the use of other mobile applications, and the personalization of mobile phones create a sense of emotional attachment between users and their phones which encourages them to use their phones to access PHR systems.

Despite the potential importance of PHR and the successful use of mobile technology in different personal and professional contexts such as social networking and mobile commerce, the possible role of mobile technology in enhancing PHR adoption has seldom been studied before. Such a study would have important theoretical and practical implications. Theoretically, this study will help in understanding the relationship between mobile technology constructs and PHR adoption. Practically, it will enable PHR developers and providers to appreciate the role of mobile technology in PHR diffusion and hence, incorporate mobile technology factors in PHR system design and implementations. In this research paper, we attempt to answer two main questions: (1) Can mobile technology enhance the adoption of PHR? And (2) What factors, if any, contribute to the adoption of mobile PHR systems (MPHR)?

To answer these questions, we develop a theoretical model based on the theory of planned behavior and innovation diffusion theory that attempts to explain the relationship between mobile technology and MPHR adoption. The rest of the paper is organized as follows: we start by providing a theoretical background on the theory of planned behavior and innovation diffusion model, then we present our theoretical model and hypotheses. Finally we conclude our paper with a discussion of the implication of the model and its limitations.

THEORETICAL BACKGROUND

The theory of planned behavior (TPB) extends the theory of reasoned action (TRA) in broadening the limited explanation of TRA on willful behavior, that is, behavior that is under incomplete volitional control (I. Ajzen, 1985; Fishbein & Ajzen, 1975). TPB has been used to explain a wide range of behavior and has received strong empirical support in explaining these behaviors (Sheppard, Hartwick, & Warshaw, 1988).

In TPB, intention to perform a behavior represents the central factor in explaining behavior. Intention is a behavioral disposition formed by an individual and translated into a behavior in the right time and under the right circumstances (Icek Ajzen, 2005). Intention was found to correlate with performing a behavior with an average correlation of .53 (Sheppard et al., 1988) with stronger correlation when the behavior is completely under the individual control because, in this case, it is enough to have an intention to perform the behavior (I Ajzen, 1991). Intention is predicted by attitude towards a behavior, subjective norms, and perceived behavior control (I. Ajzen, 1985).

Attitude towards a behavior represents the personal motivational incentives towards a behavior, and is associated with an individual’s beliefs about the behavior. If individuals associate a behavior with high value, then they are more likely to have the intention to perform this behavior.

Subjective norms refer to the social pressure towards performing a behavior (Icek Ajzen, 2005). This pressure may come from significant others, where the importance of people depends on the context of the behavior, and how the behavior is seen as important (I Ajzen, 1991). For example, in a personal context, friends and family may represent the important people, while in a work environment, colleagues and managers may be considered the significant others. Subjective norms may also include how the behavior is represented in the media and the attractiveness of this behavior.

Attitudes and subjective norms are important in predicting behavior. However, TPB adds perceived behavior control (PBC) as another factor to predict intention and behavior. PBC represents the non-motivational factors in predicting behavior (I Ajzen, 1991). PBC is associated with the perception of an individual of how easy or difficult it is to perform a behavior (I Ajzen, 1991). Originally, PBC was considered in single dimension related to how individuals perceive their own ability to perform a behavior (I. Ajzen, 1988) and was considered equivalent to self-efficacy. However, it has been argued that PBC has two dimensions that reflect both perceived internal capability to perform a behavior and external factors (e.g. opportunity and information) that facilitate performing the behavior. These dimensions are: (1) Self-efficacy and (2) Controllability (I. Ajzen, 2002; Pavlou & Fygenson, 2006).
Self-efficacy is defined as the individual’s perceived capabilities to perform a behavior (A. Bandura, 1997). Self-efficacy represents internal perceived behavior control and it has found to play an important role in predicting behavior (Sheppard et al., 1988). However, individuals’ capability to perform a behavior does not depend only on their confidence in themselves, but also on external factors such as adequate resources and opportunities to perform the behavior (e.g. skills and education). These factors are grouped under the controllability dimension of PBC which is defined as the perceived availability of resources and opportunities to perform a behavior (I. Ajzen, 2002).

Innovation diffusion theory is a sociology based theory that has been used to study the adoption of innovations in different domains (Tornatzky & Klein, 1982). In the IS field, the innovation diffusion theory has been used to examine the adoption of new information systems (Moore & Benbasat, 1991). According to this theory, the adoption of innovation is determined by: (1) The relative advantage of this innovation which is the benefits it provides over existing predecessors (2) Compatibility which refers to the consistency of the innovation with the users’ prior values, beliefs, and past experiences. (3) Visibility: the degree by which the outcome of innovation use is visible to others. (4) Complexity: the perceived difficulty of using the innovation. And (5) Trialability: The ability of the users to try the innovation before adoption (Rogers, 2010).

In this research we mainly use the theory of planned behavior to explain the relation between mobile communications and MPHR. However, we adopt the notion of relative advantage and compatibility from the innovation diffusion theory to explain specifically how attitude towards using MPHR is affected by the idiosyncrasies of mobile technology.

THEORETICAL MODEL

Figure 1 shows the theoretical model we use in this study

![Theoretical Model Diagram]

**Figure 1: Theoretical Model**

**Intention to Use MPHR**

According to TPB, intention to perform a behavior predicts the actual behavior. This proposal is supported by empirical results that found an average correlation of 0.53 between intention and behavior (Sheeran, 2002). Moreover, Icek Ajzen (2005) argued that intention is expected to have stronger correlation with the behavior than
other predictors. In the context of information systems, intention has been found to predict information systems adoption (Taylor & Todd, 1995).

**Subjective Norm**

In the context of this research, subjective norm is divided into two components: (1) How the providers or physicians perceive the importance of using MPHR and how they communicate the importance of using MPHR to users. And (2) How the important others surrounding the user of MPHR such as family and friends perceive the behavior of using MPHR and the level of support and encouragement they provide to users of MPHR. Healthcare literature demonstrated the importance of patient-physician relationship as well as the role of family support and encouragement in patient’ compliance with treatment plans (Cameron, 1996; Griffith, 1990; Waggoner, Jackson, & Kern, 1981). Furthermore, in a 2005 survey on the use of PHR, 21% of PHR users attributed their use to physician’s advice (Holland, 2006). Therefore, we propose that subjective norm has a significant effect on the adoption of MPHR.

*H1: Subjective norms are positively related with the intention to use MPHR*

**Attitude towards MPHR**

Attitude towards behavior represent the motivational factor of performing the behavior, and they refer to the value an individual associates with performing a behavior (I. Ajzen, 1991). In the context of MPHR, Attitude reflects the value users associate with using MPHR. We propose that attitude towards MPHR determines the intention to adopt MPHR, hence:

*H2: Attitude towards MPHR is positively related with the intention to use MPHR.*

**Perceived Behavior Control (PBC)**

In the context of users’ participation and contribution to OSN, PBC is the perception of how easy or difficult it is to participate in OSN. Following (Pavlou & Fygenson, 2006), We propose that PBC has two components: (1) Controllability, and (2) Self-efficacy.

**Controllability**

We define controllability in this study as the perceived availability of opportunities and resources to use MPHR (I. Ajzen, 2002). In MPHR context, users may need to access their health records, or communicate with their health providers in cases of emergency. In order to do so, they need to have the necessary skills and opportunities such as accessibility to mobile communications.

**MPHR Self-efficacy**

Self-efficacy is the individual’s perceived capability of using mobile technology. Self-efficacy represents a major factor in most technology adoption models such as TAM (Moon & Kim, 2001), and TPB (I. Ajzen, 1991). In the context of mobile technology, self-efficacy has been found to affect mobile Internet acceptance (Chong, Zhang, Lai, & Nie, 2012), in the adoption of mobile commerce (Islam, Khan, Ramayah, & Hossain, 2011) and mobile payment.

We expect mobile self-efficacy to positively affect the use of MPHR because, as we mentioned earlier, using MPHR requires users to utilize mobile technology features to facilitate their use of MPHR, and hence how they perceive their capability of using these features encourages them to exert more effort and overcome usage obstacles (Albert Bandura & Schunk, 1981).

Based on the above discussion we propose:

*H3: Perceived behavior control has a positive relationship with the intention to use MPHR*
Relative Advantage

The relative advantage of MPHR reflects the benefits of MPHR over traditional health information systems such as paper based personal health records.

Research identified several advantages that influence MPHR adoption. Enhanced communications between users and healthcare providers is a key benefit of MPHR. MPHR enable patients to communicate their medical condition or vital signs to their physicians and receive feedback from them. Patients can also use MPHR to request appointments and receive general information about their condition (Wald et al., 2004). These capabilities are not present in paper based health records and thus represent an advantage for MPHR.

Self-management in healthcare refers to the patient capability to monitor their own condition and take part in their treatment plans (Zheng et al., 2008). MPHR enable patients to record their own vital signs and healthcare data and use these data to follow up treatment with their physicians. Smartphones can be used as hubs for patient-attached health sensors that record patient data directly in the MPHR system (Otto, Milenkovic, Sanders, & Jovanov, 2006). Health self-management is a key feature of MPHR that can utilize mobile features to enhance the value of personal health records, and hence can be considered a relative advantage for MPHR.

Patient-centered care (Bergeson & Dean, 2006) aims to provide care based on patients’ needs and circumstances and it improves the output of healthcare (Oates, Weston, & Jordan, 2000). MPHR enable providers to capture the needs and concerns of patients and hence design treatment plans to satisfy these patients. The mobility components improves patients’ capability to communicate their expectations from any place which enhance the patient-centered treatment and hence quality of care.

Mobile MPHR can play an important role in supporting patients in cases of emergencies. The location awareness capability of smartphones enables patients to locate the nearest provider and to share their health data with them (Li et al., 2012) and therefore enabling the provider to treat patients in accordance with their health condition.

H4: MPHR relative advantage has a positive relationship with attitude towards MPHR

Compatibility

Compatibility in our context refers to how using MPHR is consistent with users’ prior beliefs, values and experience (Rogers, 2010). Prior research showed a significant effect of compatibility on the acceptance of new IS innovations (Cooper & Zmud, 1990). In relation to TPB, Compatibility is positively related with attitudes towards using a new IS system (Moore & Benbasat, 1991, 1996; Plouffe, Hulland, & Vandenbosch, 2001). Compatibility of MPHR is achieved because users are already accustomed to using their mobile phones for communicating as well as for other purposes such as gaming and social networking hence they have prior experience related to MPHR and they value the use of mobile technology in MPHR.

H5: MPHR compatibility with mobile technology has a positive relationship with attitude towards MPHR

Moreover, compatibility enhances MPHR self-efficacy. This is because prior use of mobile technology enhances users’ confidence in their capabilities to use MPHR. For example, a user who has an enjoyable prior experience in using a mobile social networking application is more likely to have confidence in using her phone to access and update her personal health records. Hence:

H6: MPHR compatibility with mobile technology has a positive relationship with MPHR self-efficacy

Mobile Features

In this paper, we propose that mobile technology features are one of the driving forces behind the adoption of MPHR. These features, described below, provide enhance users’ experience of using MPHR and provide them with the tools necessary to harvest the advantages of MPHR. We propose that the most salient features of mobile communications include ubiquitous connectivity, physical attachment, viewing and authoring capabilities, and context awareness.
Ubiquitous connectivity is the ability of users to connect to their PHR from anywhere using their mobile phones. Ubiquitous connectivity is made possible through the availability of high speed wireless networks such as 3G and 4G networks. These networks transformed mobile data communications from being slow and costly to being fast and cheap, and hence provided users with enough bandwidth to access PHR from anywhere, and upload data of large size (e.g. images or lab results). Therefore, we expect ubiquitous connectivity to positively affect the use of MPHR.

We define physical attachment as the close proximity and availability of mobile phones to users. Physical attachment is an important feature of mobile phones that emerges when users perceive the role of mobile phones in their lives such as social interactions and therefore, attempt to keep their phones close by (Palen, Salzman, & Youngs, 2000). Physical attachment provides users with the opportunity to use MPHR and hence enhances their perception of control over using MPHR. Therefore, we expect mobile availability to positively affect the use of MPHR.

There are many features of mobile phones that enhance the viewing and authoring capabilities of users (Cochrane & Bateman, 2010). These features are mostly related to the development of smart phone capabilities such as processing power and storage which permitted for the development of MPHR applications. For example, MPRH applications provide mobile users with the tools to access and browse their health records as well as communicate with healthcare providers and add content to health records. The large and high resolution colored screen provides users with the ability to easily browse their records. The touch-screen input capability also provides users with the tools to update their health records intuitively and habitually.

Context awareness represents a major and unique feature of smart phones that enables them to capture and utilize user context (Emmanouilidis, Koutsiamanis, & Tasidou, 2012). Examples of context awareness tools in smartphones are the smartphone camera, microphone, different sensors and location awareness (Kofod-Petersen, Gransaether, & Krogstie, 2010) using technologies such as GPS which enables users to identify their current location and navigate to designated destinations. Context awareness can play an important role in enhancing the effectiveness of MPHR because it enables users to capture and communicate different types of health related data that can be used by the physician to understand patient’s condition. One of the prominent examples of the role of mobile capabilities is the Women’s college hospital in Toronto (Semple, 2012) which developed an application that utilize the smartphone input capabilities of touch screens to provide patients with an intuitive way to communicate their post-surgical conditions through MPHR, and utilizes the context awareness of the smartphone by using its camera to capture images of the post-surgical patient progress and communicating these data to the hospital. Women’s college hospital managed to change from an in-patient hospital to an out-patient one with a reduction in cost of 30%.

We propose that mobile features enhance both perceived relative advantage of MPHR as well as controllability. Prior research has found a significant relationship between system features and usefulness as well as ease of use (Wixom & Todd, 2005) In MPHR context, mobile features are direct enablers of the outcomes of using MPHR and at the same time, they provide patients with the tools they need to use MPHR. For example, smart phone camera and sensors enable users to capture their medical symptoms and communicate these symptoms to their physicians realizing a major benefit of MPHR. Hence we propose:

H7: Mobile features have a positive relationship with the relative advantage of using MPHR

H8: Mobile features have a positive relationship with controllability over using MPHR

DISCUSSION AND CONCLUSION

In this paper, we presented a theoretical model that attempts to explain the relationship between mobile technology and the intention to use MPHR. It uses mobile related constructs such as mobile features and compatibility between MPHR and other mobile applications to explain the adoption of MPHR.

The contribution of this paper is both theoretical and practical. Theoretically, to our best knowledge, mobile technology constructs have not been used before to explain the adoption of PHR. Using these constructs emphasize
the role of mobile technology in the adoption of PHR and encourages further research about the role of additional mobile related factors (e.g. emotional attachment) in the adoption of MPHR. This study also utilizes TPB and IDT to explain the relationship between mobile technology and MPHR adoption. Although these two theories have been used before ((Moore & Benbasat, 1996), they have never been used in PHR context.

Practically, this study provides some insights on how to overcome barriers of using PHR. For example, the use of mobile technology help in overcoming the digital divide problem since mobile phones are wide spread among society members with no gender or ethnic difference. The widespread of mobile phones enhance individuals’ self-efficacy and encourage them to adopt PHR systems. Therefore, PHR developers and vendors are encouraged to utilize mobile technology in their PHR implementations.

Finally, this paper has several limitations. First, this research should be regarded as a work in progress and as such, future research should address empirically testing the proposed model to assess its validity. The proposed model focuses on the role of mobile technology in enhancing PHR adoption and should not be considered a comprehensive model for the adoption of PHR systems.

REFERENCES


Mobile Health Information Technology and Patient Care: Methods, Themes, and Research Gaps

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Abstract: The focus of the healthcare industry on delivering Patient-Centered Care (PCC) using Mobile Health Information Technologies (MHIT) is rapidly increasing, yet this critical area is still under-researched in the IS/IT literature despite the fact that mobile devices and their applications are widely spread and are likely to change the way of using and applying healthcare services. In this study we further analyze the literature reviewed in Dadgar et al. (2013) to uncover research gaps in the area of MHIT which needs further attention. This work posits a preliminary research agenda, in forms of gaps, which can help propel future work in the field of MHIT for patient centered care.

INTRODUCTION

This paper builds on the work of Dadgar et al. (2013) on mobile health IT. Dadgar et al. (2013) conducted an extensive review of the literature which provides a broad overview of research conducted in the area of mobile IT for patient care. In this paper, we extend that work by further analyzing the findings in the literature to highlight the research gaps in each of the emerging themes uncovered in Dadgar et al. (2013). White (2013) reports that Patient centered care (PCC) has gained significant momentum in recent years where the focus is shifting from productivity and efficiency to patient care driven outcomes. The new legislation such as the Affordable Care Act and the creation of Patient-Centered Outcome Research Institute could further drive PCC related efforts. Due to the consumerization of IT, Mobile Health IT (MHIT) has a potential for being a critical catalyst for delivering patient centered care. Chatterjee et al. (2009) and Dadgar et al. (2013) argue that, although MHIT is being introduced within the healthcare industry and its use could significantly transform patient care, the scholarship in this area is at its incipient stages and thus it has been under-researched. The main objective of this paper is to analyze and discuss issues and opportunities surrounding PCC enabled by Mobile Health IT, in both the IS and Healthcare fields, in efforts to develop a research agenda for future research. Therefore, in this paper we identify the research gaps within each of the key themes revealed in Dadgar et al (2013). The paper is organized as follows. First, the paper recaptures the literature review process used to conduct the study by Dadgar et al. (2013). Second, a discussion on the methods, emerging themes, and research gaps is provided. Third, a section is dedicated to the research contribution. Finally, the paper provides a brief concluding discussion.
METHODOLOGY

Figure 1 summarizes the literature review process conducted in Dadgar et al. (see Dadgar et al. (2013) for more details). Their literature search was conducted at the intersectionality of mobile, healthcare, and IT/IS (Figure 1). The search resulted in 133 articles from 29 different journals and 14 conferences. The papers were categorized into four areas which are illustrated in figure 1. The irrelevant papers (Area 1) that were removed from the list were about mobile devices and applications but not in the healthcare industry. The most relevant papers (Area 2) included mobile, healthcare as well as IT/IS context. After removing the irrelevant papers a total of 57 papers were reviewed. These papers also included the studies which were about healthcare IT (Area 3) and mobile healthcare papers (Area 4) which were both related to healthcare. Themes and findings from Dadgar et al. (2013) are re-presented in this paper with more discussions around patient care, methods, and research gaps necessary for conducting research on MHIT for PCC.

The research gap analysis was bounded by the literature review conducted by Dadgar et al. (2013). The review looked into publications in major IT/IS and medicine journals and conferences (Figure 2). There is a possibility that other relevant papers were published in different journals or conferences were not captured in our search results. It is also evident that only few papers were found while searching the literature using the term “Patient Care”. Furthermore, the term “Mobile” was defined differently in different papers and this caused the elimination of a number of papers that defined mobile out of the context of mobile health informatics.
Research Objective
- Review of the Literature on Mobile IT Patient Care
- To examine the extant literature to understand the role mobile information technologies play in providing patient care

Boundaries/Limitations
- "Mobile" was defined differently within the papers.
- Including “Patient care” in the search, resulted in very few papers.
- Search was limited to the published papers in the major journals and conferences in IS/I healthcare.
- The papers up to 2012 were included in the

Literature Search and Selection
- Keywords: mobile, healthcare, information technology/system (and patient care)
- Field Options: Title, Abstract

Literature Search

Coding the Papers
- 133 papers from 29 journals and 14 conferences were coded
- Papers were grouped in 3 categories based on the relevancy to the research objective:
  - Category 1 (46): mobile, healthcare, and IT (and patient care)
  - Category 2 (11): IS/IT journals (healthcare and IT)
  - Category 3 (76): Irrelevant (mobile devices, technologies, and applications but not in the healthcare industry)

Databases
- CINAHL (38 papers)
- EBSCO (16 papers)
- ACM DL (14 papers)
- ScienceDirect (11 papers)
- IEEE (22 papers)
- MEDLINE (31 papers)
- SCIRUS (1 paper)

Develop the manuscript

Synthesis
- Uncover emerging themes and future research agenda.
- Cluster papers based on their:
  - Phenomena – problem addressed
  - Theoretical perspectives;
  - Methodology;
  - Findings

Step 1: Create Article Summaries
Following steps were conducted for each paper:
- Explain the phenomenon which is used as a motivation to conduct the work
- How was mobile and IT defined characterized
- State the research question, purpose, objectives
- State the guiding theory/framework
- State the research design:
  - Sampling & Data Collection: What is the unit of analysis and how are they collecting data
- State summary of key results

Step 2: Explain and Interpret each article
Following steps were conducted for each paper:
- Explain - Outline the phenomenon (Interpret: how it is similar to or different than other papers included in the lit review?)
- Explain - Outline the Research questions/Objectives/Research Statement etc. (Interpret: how it is similar to or different than other papers included in the lit review?)
- Explain - How did they go about examining or investigating the research question?
- Methods - (Interpret: Can these approaches be used to examine other related work?)
- What did they find? (Interpret: do these findings address our stated objective – explain why or why not?)
- How can this work be used to develop future work?
- Critique - Critique of this work in terms of assumptions; research questions,

Figure 2: Literature Review Process
KEY FINDINGS: DISCUSSION AND ANALYSIS

Methods

Table 1 describes the methods used in the MHIT literature. Nine different methods have been used across the nine themes discussed in this paper. The literature suggests that 32% of the papers have used conceptual methodologies and only 2% of the studies have used secondary/archival data (see Dadgar et al. 2013 for more details).

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Science</td>
<td>Testing and evaluating systems and technologies using design principles</td>
</tr>
<tr>
<td>Secondary/Archival Data</td>
<td>Using archival data such as unreported publications, magazines, multimedia</td>
</tr>
<tr>
<td>Conceptual</td>
<td>Papers with no specific data collection</td>
</tr>
<tr>
<td>Field Experiment</td>
<td>Data collection and observational studies in the field</td>
</tr>
<tr>
<td>Mathematical Modeling</td>
<td>Using predictive and analytical modeling based mathematical equations</td>
</tr>
<tr>
<td>Survey/Questionnaire</td>
<td>Distributing hard/soft copies of surveys and questionnaires to the subjects</td>
</tr>
<tr>
<td>Qualitative Study</td>
<td>Case-based studies and interviews</td>
</tr>
<tr>
<td>Simulation</td>
<td>Computer simulations such as agent-based modeling</td>
</tr>
<tr>
<td>Multi Method</td>
<td>Using mix of qualitative and quantitative methods</td>
</tr>
</tbody>
</table>

Table 1: Description of the methods

Emerging Themes

The literature review and analysis on MHIT and patient care revealed nine emerging research themes (Dadgar et al., 2013). These nine emerging themes in the MHIT literature are presented in Table 2. These themes along with methods and research gaps within these themes are discussed in the following section.

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Building and Using Healthcare Information</td>
<td>Literature on design, implementation, use, and/or adoption of IST in the healthcare industry.</td>
</tr>
<tr>
<td>Technologies and Systems for Patient Care (Build/Use HIT)</td>
<td></td>
</tr>
<tr>
<td>Communication with Patients and Health Professionals (Communication Patient/Health)</td>
<td>Literature on wireless technologies that enhance communication among healthcare professionals, patients, and their relatives.</td>
</tr>
<tr>
<td>Healthcare Data and System Integration (Health Data/SI)</td>
<td>Literature on data and systems integration issues in healthcare.</td>
</tr>
<tr>
<td>Healthcare IT Success (HIT Success)</td>
<td>Literature on HIT success and failure factors.</td>
</tr>
<tr>
<td>Healthcare IT Value (HIT Value)</td>
<td>Literature on the benefits of HIT</td>
</tr>
<tr>
<td>Mobile Healthcare Delivery for Patients (M Health Delivery)</td>
<td>Literature on the issues of physical mobility of the healthcare units for the low-income neighborhoods or aging population in the rural areas.</td>
</tr>
<tr>
<td>Patient Monitoring</td>
<td>Literature on the issues related to monitoring of aging population or patients with chronic diseases.</td>
</tr>
<tr>
<td>Patient Work Flow</td>
<td>Literature on ways mobile technologies facilitate and optimize patient work flow.</td>
</tr>
<tr>
<td>Privacy/Security of Patient Data (Privacy/Security)</td>
<td>Literature on privacy of patient health data and the security of patient care systems and technologies.</td>
</tr>
</tbody>
</table>

Table 2: Emerging Themes (see Dadgar et al. (2013))
Methods, Themes, and Research Gaps

Table 3 summarizes the methods used and research gaps revealed within each theme. In this section we will further discuss methods and research gaps by themes. Unlike Dadgar et al. work where they summarized the literature by describing each study, in this paper we analyze each theme to uncover the research gaps that can help in outlining future directions for this nascent research field.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Papers</th>
<th>Method</th>
<th>Research Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Monitoring</td>
<td>Bae et al. (2012) Berke et al. (2011)</td>
<td>Design Science (2), Secondary/Archival Data</td>
<td>Optimal ways of balancing self-</td>
</tr>
</tbody>
</table>
Build/Use HIT

This theme includes the literature that discussed the design, development, implementation, use, and/or adoption of ISTs in the healthcare area. Our analysis of Dadgar et al. (2013) MHIT review reveals that the research conducted under this theme uses a range of methodologies such as, design science, conceptual, field experiment, mathematical modeling, survey/questioners, qualitative study and/or multi method, to examine technological, design, and behavioral issues germane to the use of IT in delivering patient care. Literature review suggests that compared to other themes this theme is relatively well researched and included the largest number of papers as reported by Dadgar et al. (2013). The research in this area had focused on technology involvement in healthcare delivery but the research on the direct effects of HIT on patients is limited. No evident research was conducted to investigate the impact of healthcare technologies on patient care outcomes, such as, mortality level.
Privacy/Security of Patient Data

Papers under this theme discuss the issues involved in the privacy of patient data and the security of the systems and technologies that support patient health data. The literature included under this theme mainly examines the technical challenges of transitioning from paper-based patient records to digital records. Design science, conceptual, survey/questionnaire, multi method methods have been used to address the technology-centric security issues surrounding the digitization of patient records. Our analysis of Dadgar et al. (2013) reveals that there is a need to extend current knowledge in this area to mobile devices and technologies. We suggest that researchers study the transition from digital records to digital records on mobile devices. We believe that multi methods techniques can best address the research problems under this theme. In-depth qualitative interviews will allow researchers to uncover rich insights on patients’ values, preferences, and needs regarding the accessibility of medical records on mobile devices. Design science methods can also be used to integrate privacy concerns of the patients into the design and implementation of secure mobile technologies and systems supporting patient records.

Communication with Patients and Health Professionals

Papers under this theme looked at improving the flow of information and communication within the healthcare industry. The communication was conceptualized differently within each paper, for instance, some looked at it as a behavioral interaction among the stakeholders, or as the challenges disabled patients face when trying to communicate; other papers listed the advantages and disadvantages of using different mobile devices in healthcare facilities. A range of methods, such as design science, mathematical modeling, survey/questionnaire or multi method, were used to examine the communication and information flow issues emerging during the conduct of patient care. Our analysis of Dadgar et al. reveals that more research needs to be directed to address how the knowledge discovered in this area regarding the accessibility and free flow of information, communication, and education to empower patients can be used to by researchers to design and implement mobile applications.

Patient Work Flow

Papers under this theme examine how mobile technologies can facilitate and optimize patient work flow for treatments and quality of care. Studies in this theme are mindful of the consequences of using mobile technologies to enable patient work flow. For example, research show that using mobile devices physicians can make treatment decisions for the patients in a shorter amount of time (e.g., Bharadwaj et al. (2001)). Mobile technologies can also help to resolve the conflict between treatments and medical policies. All these benefits provide more efficient ways of delivering better quality of care to the patients. Design science, conceptual, and simulation methods have been used in the papers under this theme. We suggest the use of simulation techniques, such as agent-based modeling, for conducting future studies related to this theme. Researchers can simulate the use of mobile technologies to examine its effects on patient work flow. The nature of patient work flow and medical staff work flow can be simulated to first uncover the incongruities among these workflows and then to examine the effects of these incongruities on the quality of care. An underlying assumption in the literature found under this theme is that nurses and doctors use portable devices at work to provide better quality of care for their patients. We suggest that researchers verify this assumption in future studies. For instance, future studies should study the effects of using mobile technologies by nurses and doctors on patient work flow to explore whether the use of mobile technologies disrupts or facilitates patient care related workflow.

Health Data and System Integration

Papers under this theme have focused on the effects of promoting integration-friendly infrastructure on MHIT in terms of use, cost and scalability. None of the papers included in this theme directly addressed the issue of patient care; rather they reported the effects of integral infrastructure on the use of MHIT and explored the advantages of system integration in the healthcare industry. Dadgar et al. (2013) mention that very few studies have focused on the role of data and system integration within the context of healthcare, and no method, other than the conceptual research, was
found. We call on IS researchers to focus on data integration issues and their direct effects on patient centered care, as there is a significant dearth of research in this area.

**Patient Monitoring**

The papers under this theme study the issues around providing remote patient monitoring services mostly for the aging population or for the patients with chronic diseases. Design science, secondary/archival data, conceptual, field experiment, mathematical modeling, survey/questionnaire, qualitative study methods have been used to study this area. Considerable number of conceptual papers were found in the literature under this theme. Although these studies examine the operationalizability of the mobile technologies such as mobile sensors or wearable healthcare monitoring systems to collect data from patients, they did not study whether or not these approaches satisfy patients’ values, preferences, and needs. There are several benefits afforded by mobile patient monitoring such as instant and constant control on the patient health conditions. We suggest that the future work should design optimal ways of balancing remote and on-site care, but also study the extent the combination of face-to-face visits and remote monitoring improve the quality of patient care. Researchers should also study the long term consequences of remote monitoring on patients. In addition, the designs of these services should be guided by patients’ values and preferences.

**HIT Success**

Some papers under this theme have reported key factors that shape HIT failure while other papers have posited theoretical models that provide a consolidated view of the literature in the area of mobile work in healthcare. Papers under this theme used mathematical modeling, qualitative study or multi method while examining the factors related to the success and/or failure of HIT. Dadgar et al. (2013) found that only few papers were included under this theme and these papers have focused on all 3 components (Mobile, IT, and Healthcare). HIT success and failure research is directly related to patient centered care. Although the theme had the fewest number of papers, yet they all addressed the research gap referred to in this paper. Scholars are encouraged to provide factors that have direct impact on technology success when used by healthcare providers highlighting the relation between HIT success and patient care outcomes.

**Mobile Health Delivery**

Papers under this theme discuss the challenges of bringing mobile health services physically to the rural or low-income neighborhoods or to the elderly at their residences. Although the papers under this theme did not discuss the use of IT in detail but the combination of physical mobile vehicles and mobile technologies can be an interesting area of future research. Conceptual, field experiment, and survey/questionnaire methods have been used in the papers under this theme. Studies in this theme do not discuss the mobile technologies which can potentially be embedded in the physical mobile vehicles. The papers under this theme are mostly constrained to the physicality of mobile vehicles and medical services. We argue that IT-enabled mobile vehicles could better serve patients in the rural areas or low-income neighborhoods and could provide higher quality of care for the patients. We suggest that researchers should study how mobile technologies can affect design of the mobile vehicles or units while saving cost and time.

**HIT Value**

Research under this theme focused on assessing the value of HIT and MHIT. The key research findings in this theme suggest that current technology has significant impact on patient care and that IT can help both healthcare providers and patients themselves who wants to take more control over their health. From Dadgar et al. (2013) review we found that the methods used under this theme were: conceptual, design science, survey/questioner, simulation, and/or multi methods. Papers under this theme focused mostly on the effects of technology on the benefits generated by healthcare providers. Although the research in this theme is closely related to the patient centered MHIT, wireless and mobile devices value on health organizations has limited research in the context of MHIT. More research is needed to highlight the actual value mobility adds to the current technology and how does that impact on patient care delivery.
CONTRIBUTION

The findings of this paper show that relatively little attention has been paid to understand the direct role of MHIT on patient centered care. In other words, the use of mobile technologies to examine outcomes proximal to patients’ quality of care, values, preferences, and expectations need more attention. The nine themes uncovered in Dadgar et al. (2013) were further analyzed to find research gaps within each theme. We argue that limited, especially empirical research in this area creates interesting opportunities to conduct interdisciplinary research. This paper provides a preliminary research agenda which can help propel future work in the field of MHIT for patient centered care. Although in its initial stages, the research agenda revealed in this work in forms of gaps can fuel research at the intersectionality of mobile, healthcare, and IT to describe, predict, and prescribe the role of MHIT in patient centered care.

CONCLUDING DISCUSSION

The analyses of the nine themes reveal that the research in the area of MHIT which centers on patient care is in its incipient stages. The limited work done to examine this phenomenon, as mentioned by Poon et al. (2006), could be because the “Adoption of HIT is limited and will likely remain slow unless significant financial resources are made available.” Other reasons for the slow growth of research in this area include the complexity of the healthcare process, the high cost of implementation, the limited availability of time to build the technology, the need for developing open standards, and the management of security and privacy. The dearth of patient centered research at the intersection of mobile, healthcare and IT, (see Figure 3), creates interesting opportunities to conduct interdisciplinary research and we hope this would encourage scholars to conduct research in this area to address the research gaps discussed in this paper.

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A Balanced Perspective to Perioperative Process Management Aligned to Hospital Strategy

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Abstract: Dynamic technological activities of analysis, evaluation, and synthesis can highlight complex relationships within integrated processes to target improvement and ultimately yield improved processes. Likewise, the identification of existing process limitations, potential capabilities, and subsequent contextual understanding are contributing factors that yield measured improvement. This case study examines process management practices of balanced scorecard and dashboards to monitor and improve the perioperative process, aligned to overall hospital goals at strategic, tactical, and operational levels. Based on a 120-month longitudinal study of an academic medical center, this study investigates how integrated information systems and business analytics can improve perioperative efficiency and effectiveness across patient quality of care, stakeholder satisfaction, clinical operations, and financial cost effectiveness. Implications and/or limitations are also discussed.

INTRODUCTION

A hospital’s perioperative process provides surgical care for inpatients and outpatients during preoperative, intra-operative, and immediate post-operative periods. Accordingly, the perioperative sub-processes (e.g. preoperative, intra-operative, and post-operative activities) are sequential where each activity sequence paces the efficiency and effectiveness of subsequent activities. As a result, a hospital’s perioperative process is tightly coupled to patient flow, patient safety, patient quality of care, and stakeholders’ satisfaction (i.e. patient, physician/surgeon, nurse, perioperative staff, and hospital administration).
Implementing improvements that will result in timely patient flow through the perioperative process is both a challenge and an opportunity for hospital stakeholders, who often have a variety of opinions and perceptions as to where improvement is needed. The challenge of delivering quality, efficient, and cost-effective services affects all healthcare stakeholders. Perioperative improvements ultimately affect not only patient quality of care, but also the operational and financial performance of the hospital itself. From an operational perspective, a hospital’s perioperative process requires multidisciplinary, cross-functional teams to maneuver within complex, fast-paced, and critical situations—the hospital environment (McClusker et al., 2005).

Similarly from a hospital’s financial perspective, the perioperative process is typically the primary source of hospital admissions, averaging between 55 to 65 percent of overall hospital margins (Peters & Blasco, 2004). Macario et al. (1995) identified 49 percent of total hospital costs as variable with the largest cost category being the perioperative process (e.g. 33 percent). Given the rising cost of healthcare, the public demand for healthcare transparency and accountability, and the current economic environment—managing and optimizing a quality, efficient, flexible, and cost-effective perioperative process are critical success factors (CSFs), both operationally and financially, for any hospital.

Recently, the focus of healthcare in the United States has shifted toward monitoring and improving clinical outcomes to meet new regulatory and reimbursement requirements. Likewise, hospitals in the United States must report and improve clinical outcomes more now due to the American Recovery and Reinvestment Act of 2009 and the Joint Commission on Accreditation of Healthcare Organizations (TJC) / Centers for Medicare & Medicaid Services (CMS) core measures. These performance and reporting challenges require leveraging information systems (IS) and technologies (IT) to meet these demands. Furthermore, hospital administration could benefit by considering the strategic IS and business alignment challenges experienced in other industries over the past decades (Luftman & Ben-Zvi, 2010) as well as within the healthcare industry (Bush, 2009). With respect to hospital IS/IT alignment, this study investigates the research question of how business process management (BPM) is an applicable approach for perioperative process management as well as overall hospital’s strategic vision execution with monitored clinical outcomes.

This study highlights BPM practices of balanced scorecards (BSC) and dashboards within a hospital’s perioperative process. The case results are facilitated by empowered individuals driven by integrated internal and external organizational data. The investigation method covers a longitudinal study of an integrated clinical scheduling information system (CSIS) within the perioperative process of a large, teaching hospital (e.g. academic medical center). The implementation of an agile CSIS and subsequent contextual understanding of the perioperative process and its sub-processes prescribed opportunity for measured improvements. Specifically, the extension of business analytics into BSCs and dashboards at different levels (e.g. strategic, tactical, and day-to-day operations), coupled with internal and external best-practice benchmarks, provide the framework for targeting improvement opportunities and evoking improvement changes to the perioperative process. The planning and development of the BSCs and dashboards also provide change dynamics for evaluation and improvement to the overall perioperative process. This case study also identifies complex dynamics within the perioperative process nested in the hospital environment.

The following sections review previous literature on BPM and BPM efforts in healthcare, as well as healthcare performance indicators and quality measures. Following the literature review, we present our methodology, case study background, and a discussion of the observed results from the BSCs and dashboard efforts. By identifying a holistic framework for analysis, evaluation, and synthesis of end-to-end process measures with established benchmarks, this paper prescribes an a priori environment to support perioperative process measurement, control, and improvement aligned to hospital strategy. The conclusion also addresses study implications and limitations.

LITERATURE REVIEW

Industry competition, first mover advantage on innovations, adaptation of better management practices, and/or government regulations are examples of the many factors that drive process improvements. Traditionally, the hospital environment lacked similar industrial pressures beyond government regulations. However, hospital administration currently face increasing pressure to provide objective evidence of patient outcomes in respect to organizational quality, efficiency, and effectiveness (CMS, 2005; CMS, 2010; PwC, 2012), all while preserving clinical quality standards.
Hospital administrators and medical professionals must focus on both the patient quality of care as well as management practices that yield efficiency and cost effectiveness (PwC, 2012). To this end, industrial and operations management practices of BSC, business analytics, and dashboards borrowed from BPM provide a framework to target and measure process improvement (Jeston & Nelis, 2008; Kaplan & Norton 1996; Tenner & DeToro, 1997). Measured utilization of these practices is not a result from lack of research as a body of knowledge exists concerning their application in healthcare (Albanese et al., 2010; Fairbanks, 2007; Herzer et al., 2008; Kruskal et al., 2012; Kujala et al., 2006; Zbinden, 2002). Moreover, the literature suggests that such approaches and interventions can yield positive results with significant variations in implementation success.

Business Process Management (BPM)

Specifically, this study examines BPM applications of BSCs and dashboards to monitor and measure improvement within the perioperative process, aligned to hospital strategy. This study uses the BPM definition provided by Jensen and Nelis (2008, p. 10) as “the achievement of an organization’s objectives through the improvement, management, and control of essential business processes.” The authors further elaborate that process management and analysis is integral to BPM, where there is no finish line for improvement. Hence, this study views BPM as an organizational commitment to consistent and iterative process performance improvement that meets organizational objectives. To this end, BPM embraces the concept of continuous process improvement (CPI) aligned with business strategy.

CPI is a systematic approach toward understanding the process capability, the customer’s needs, and the source of observed variation. Tenner and DeToro (1997) views CPI as an organizational response to an acute crisis, a chronic problem, and/or an internal driver. The incremental realization of improvement gains occurs through an iterative cycle of analysis, evaluation, and synthesis or plan-do-study-act (Walton, 1986) to minimize observed variation. CPI encourages bottom-up communication at the day-to-day operations level and requires process data comparisons to control metrics. Doubt can exist as to: whether the incremental improvement addresses symptoms versus causes; whether the improvement effort is sustainable year after year; and/or whether management is in control of the process (Jensen & Nelis, 2008).

As BPM requires alignment to strategic objectives, a BSC approach (Kaplan & Norton, 1996) embraces the ability to quantify organizational control metrics aligned with strategy across perspectives of: (1) financial; (2) customer; (3) process; and (4) learning/growth. Business analytics is the body of knowledge identified with the deployment and use of technology solutions that incorporate BSCs, dashboards, performance management, definition and delivery of business metrics, as well as data visualization and data mining. Business analytics within BPM focus on the effective use of organizational data and information to drive positive business action (Turban et al., 2008). The effective use of business analytics demands knowledge and skills from subject matter experts and knowledge workers. Similarly, Wears and Berg (2005) concur that IS/IT only yield high-quality healthcare when the use patterns are tailored to knowledge workers and their environment. Therefore, BPM success through BSCs and dashboards has a strong dependence on contextual understanding of end-to-end core business processes (Jensen & Nelis, 2008).

Key Performance Indicators (KPIs)

An integral part of CPI is information about performance before and after the intervention. Thus, performance measurement is an essential requirement for purposeful BPM. Early in the IT literature, Ackoff (1967) proposed IS design should embed feedback as a control to avoid management misinformation. Other authors (Zani, 1970; Rockart, 1979; Munroe & Wheeler, 1980) proposed the selection and supervision of defined data as KPIs to assist management in qualifying measurement of CSFs and subsequently managing organizational action (i.e. business processes) through IS feedback. Similarly, hospital processes are becoming increasingly information intensive and doubt exists as to whether process management understanding can meet the increasing hospital environmental demands for value and cost efficiency (Catalano & Fickenscher, 2007).

The following scenario of operational, tactical, and strategic KPIs illustrate the complexity, dynamic nature, and nested relationships among hospital processes. Operational and tactical KPIs in managing and optimizing a
hospital’s perioperative process include monitoring the percentage of surgical cases that start on-time (OTS) and the number of first-of-the-day surgical cases (FCOD_OTS) that start on-time, as well as operating room (OR) turn times (TURNS) and utilization (UTIL) (Barnes, 2010; Herzer et al., 2008). The Thomson Group (2010) noted how OR suite TURNS between cases, along with a flexible and efficient perioperative work environment, are CSFs for physician/surgeon satisfaction, which in turn is a CSF for hospital margin. Poor KPIs on operational and tactical metrics (i.e. OTS, FCOD_OTS, TURNS or UTIL) affect strategic CSFs of patient safety, patient quality of care, surgeon/staff/patient satisfaction, and hospital margin (Marjamaa et al., 2008; Peters & Blasco, 2004).

Healthcare Quality Benchmark Standards

Healthcare industry benchmark standards focus on patient quality of care via self-reported outcome measures or patient satisfaction survey results. The CMS and the Hospital Quality Alliance (HQA) began publicly reporting inpatient quality reporting (IQR) outcomes on 30-day mortality measures for acute myocardial infarction (AMI) and heart failure (HF) in 2007 and for pneumonia (PN) in 2008 (CMS, 2010).

Patient satisfaction measures began development as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey in 2002. The collaboration effort was between CMS and the Agency for Healthcare Research and Quality (AHRQ), another federal agency under the Department of Health and Human Services. The evolved HCAHPS survey measures report patient perspectives on care received across items that encompass ten key topics: (1) communication with doctors, (2) communication with nurses, (3) responsiveness of hospital staff, (4) pain management, (5) communication about medicines, (6) discharge information, (7) cleanliness of the hospital environment, (8) quietness of the hospital environment, (9) overall rating of the hospital, and (10) whether the patient would recommend the hospital to family and friends (HCAHPS, 2012).

In 2005, CMS began a major priority to encourage improvements in the quality of care provided to Medicare beneficiaries (CMS, 2005). The result was pay-for-performance (P4P) or value-based purchasing (VBP) as a CMS payment model that rewards healthcare providers for meeting certain performance measures in quality and efficiency. In a 2007 study, hospitals reporting both public and P4P achieved modestly greater quality improvements than hospitals engaged only in public reporting (Lindenauer et al., 2007). In 2008 as an additional rule to P4P, CMS included disincentives of reducing payments for negative consequences of care that should never occur, as defined by the National Quality Forum, including hospital infections under the surgical care improvement project (SCIP) (NQF, 2008).

RESEARCH METHOD

The objective of this study is to examine BPM practices of BSCs and dashboards within a hospital’s perioperative process that target opportunities and measure improvement, aligned to hospital strategy. To this end, case research is particularly appropriate (Eisenhardt, 1989; Yin, 2003). An advantage of the positivist approach (Weber, 2004) to case research allows concentrating on specific hospital processes in a natural setting to analyze the associated qualitative problems and environmental complexity. Hence, our study took an in-depth case research approach.

Our research site is an academic medical center (e.g. University Hospital), licensed for 909 beds and located in the southeastern region of the United States. University Hospital is one of two magnet hospitals in the state and the U.S. News and World Report has repeatedly recognized University Hospital as a Best Hospital over the past two decades. Concentrating on one research site facilitated the research investigation and allowed the continued collection of longitudinal data. This study spans activities from 2003 to 2013. During the 120-month study, we conducted field research and gathered data from multiple sources including interviews, field surveys, site observations, field notes, archival records, and document reviews.

The initial perspective of this research focused on University Hospital’s perioperative process for its 32 general operating room (OR) suites. Perioperative Services is the University Hospital department that coordinates the hospital’s perioperative process across Admissions, PREP having 42 beds, Post Anesthesia Care Unit (PACU) having 45 beds, and Central Sterile Supply (CSS).
CASE BACKGROUND

Perioperative Services implemented a new CSIS in 2003, after using its prior CSIS for 10 years. The old CSIS and its vendor were not flexible in adapting to new data collection needs of Perioperative Services. Figure 1 depicts University Hospital’s CSIS architecture as of October 2004. University Hospital had six main IS: (1) a large-scale hospital materials management IS, which included pharmacy, material and medical device management (Vendor L); (2) a large scale enterprise resource planning IS (Vendor O); (3) a patient record Admit/Discharge IS (Vendor Q); (4) a cost accounting IS (Vendor T); (5) a financial budgeting IS (Vendor H); and (6) a CSIS (Vendor C) that included three modules for clinical scheduling, routing sheets, and cost data.

All IS were integrated with uni-directional constraints placed on sensitive information. The institutional intranet served as portal access to extend each of the six IS. User authentication via the intranet was single entry with particular user-IS rights and privileges negotiated upon authentication.

November 2004

University Hospital opened a new diagnostic and surgical facility in November 2004, which covers three-fourths of a city block rising 12 stories. Perioperative Services were relocated into three floors, with ORs located over two floors and CSS located separately on the third. The move expanded Perioperative Services to cover an additional floor and nine additional ORs. The new facility housed 40 state-of-the-art OR suites (32 general OR), each equipped with new standardized equipment as well as equipment by surgical specialty. Within six weeks of occupying the new perioperative facility, scheduling KPIs reflected chaos. On-time surgical case starts plunged to 18% during December 2004. Within a highly competitive hospital industry, having only 18% OTS was unacceptable as 82% of scheduled surgeries experienced delays and risked patient care and safety. University Hospital had failed to adjust its perioperative process to compensate for the introduction of radical innovations—existing perioperative processes were disparate within the new environment.

Perioperative Continuous Process Improvement (CPI)

In January 2005, perioperative concerns were laid out before a quickly convened executive council. The meeting included the chief executive officer, the chief financial officer, the chief information officer, the chief nursing officer, and top representatives of surgeons, anesthesia, and Perioperative Services. The end-result of this meeting was changed governance for Perioperative Services in the formation of a cross-functional, multidisciplinary executive team, similar to matrix-style management. The executive team consisted of a cross-section of perioperative stakeholders (i.e. surgeons, nurses, anesthesiologists, and perioperative management), chartered and empowered to evoke change.

University Hospital’s executive team launched a CPI effort to address the perioperative crisis through soft innovations (Ryan et al., 2008). The executive team and numerous task forces, formed to address specific problems and/or opportunities, were chartered to systematically identify issues and enlist working managers for solutions that focus on patient care and safety, attack difficult questions, and no issue was “off-limits.”

Given the slow learning curve associated with the OR relocation and radical innovation disruption, a new KPI was established to track surgical case OTS.

Figure 1: IS architecture (October 2004)

Figure 2: OTS KPIs Dec. 2004 to May 2007
within 10 minutes. This particular KPI provided motivation for CPI and was retired in 2008. Figure 2 represents the perioperative process improvement in the surgical case OTS through May 2007.

Since the OR relocation in 2004, University Hospital has sustained an annual 10% growth in surgical case procedures in its original 32 general OR suites (GENOR). Perioperative Services has also assumed the management and scheduling of an additional 36 ORs that include 8 cardio-vascular OR suites (CVOR), 19 OR suites at the Hygh Hospital campus (HHOR), and 9 OR suites at the Eye Foundation Hospital (CEFH). University Hospital has continued a systematic approach to perioperative CPI across all of its surgical locations and services, achieving improvement success that targeted perioperative process analysis and redesign (Ryan et al., 2010), heuristic OR scheduling (Ryan et al., 2011a), hospital-wide patient flow (Ryan et al., 2011b), preoperative clinic benchmarking and re-engineering (Ryan et al., 2012), and radio-frequency identification implementation (Ryan et al., 2013). Figure 3 depicts the improved patient flow through the University Hospital Health System (UHHS) resulting from these CPI efforts.

RESULTS AND DISCUSSION

The executive team and perioperative management consistently focus on data-driven, end-to-end CPI efforts. Initially as needed to facilitate perioperative process management and improvement, the executive team and subsequent task groups defined process control measures based on internal process data collected through the CSIS and external industry standards. Initially, these control measures benchmarked previous months’ metrics to establish trends for tracking improvement and/or targeting areas for improvement. When reviewing what could have been done better during the initial CPI efforts, the executive team and Perioperative Services management recognized the need to involve perioperative stakeholders in the entire improvement process and not just end-result to-do lists.

As a result in 2008, the executive team launched an initiative to categorize, qualify, and quantify perioperative performance measures for process management and control feedback as well as meet regulatory requirements for CMS and TJC. The initiative set out to identify and define measures associated with core perioperative processes, establish a BSC of measures, and develop a means to disseminate the process feedback to perioperative stakeholders. The following sections elaborate on the initiative’s results through May 2013.

<table>
<thead>
<tr>
<th>Outcome Category</th>
<th>Measure</th>
<th>Source</th>
<th>Operational Definition</th>
<th>Sch</th>
<th>Rpt</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>Time Outs</td>
<td>CSIS OR / Bedside</td>
<td>Mth Avg TJC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Sample Strategic Measure
Core and Operational Measures

The identification and definition of perioperative operational control measures has been an iterative evolution for University Hospital since 2005, similar to the core healthcare industry quality standards coordinated and adopted by CMS and TJC. University Hospital currently has 53 core and operational measures identified and defined at the strategic level that measure perioperative performance on a monthly or quarterly basis. Each measure maps to a process, definition, outcome, data source, data type, personnel responsible, reporting frequency, and control target. Table 1 represents a sample of the 53 strategic core and operational measures.

<table>
<thead>
<tr>
<th>Strategic Outcome</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>4</td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td>4</td>
</tr>
<tr>
<td>HCAHPS</td>
<td>3</td>
</tr>
<tr>
<td>Employee Satisfaction</td>
<td>2</td>
</tr>
<tr>
<td>Patient Throughput</td>
<td>4</td>
</tr>
<tr>
<td>Mortality/Readmissions</td>
<td>4</td>
</tr>
<tr>
<td>Financial</td>
<td>3</td>
</tr>
<tr>
<td>IQR Quality Measures</td>
<td>29</td>
</tr>
<tr>
<td>AMI–5,</td>
<td></td>
</tr>
<tr>
<td>HF–8,</td>
<td></td>
</tr>
<tr>
<td>PN–6,</td>
<td></td>
</tr>
<tr>
<td>SCIP-10</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Strategic Outcomes

<table>
<thead>
<tr>
<th>Time Outs Documented</th>
<th>Average Length of Stay (Days)</th>
<th>AMI- ACEI/ARB for LVSD</th>
<th>PN-Pneumonia Vaccinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Nosocomial Infection Marker Rate (NIM Rate)</td>
<td>Length of Stay Index (Actual / Expected)</td>
<td>AMI- PCI within 90 min</td>
<td>PN-Antibiotic Selection</td>
</tr>
<tr>
<td>NIM Benchmarking Rating</td>
<td>Percent occupancy (Inpatients Units)</td>
<td>AMI- Readmission Rate</td>
<td>PN-Blood Cultures before ABX in UED</td>
</tr>
<tr>
<td>NIM Benchmarking Rating Change</td>
<td>Discharges by Noon</td>
<td>HF- Discharge Instructions-Activity</td>
<td>PN-Readmission Rate</td>
</tr>
<tr>
<td>Nurses kept you informed</td>
<td>Mortality (Number)</td>
<td>HF- Discharge Instructions-Diet</td>
<td>SCIP-Prophylactic ABX given within 1hr of incision</td>
</tr>
<tr>
<td>Staff sensitivity to inconveinence</td>
<td>Mortality Rate (deaths / total admits)</td>
<td>HF- Discharge Instructions-Weight Monitoring</td>
<td>SCIP-Prophylactic ABX d/c within 24/48hrs (Overall)</td>
</tr>
<tr>
<td>Staff addressed emotional needs</td>
<td>Mortality Index (Actual / Expected)</td>
<td>HF- Discharge Instructions-Symptoms Worsening</td>
<td>SCIP-Prophylactic ABX d/c within 48hrs (CV)</td>
</tr>
<tr>
<td>Response to concerns/complaints</td>
<td>Re-admissions</td>
<td>HF- Discharge Instructions-Follow-Up</td>
<td>SCIP-Prophylactic ABX d/c within 24hrs (Hips &amp; Knees)</td>
</tr>
<tr>
<td>% definitely yes would recommend UH</td>
<td>Net Revenue / Adjusted Patient Day</td>
<td>HF- Discharge Instructions-Medications</td>
<td>SCIP-Prophylactic ABX d/c within 24hrs (Colon)</td>
</tr>
<tr>
<td>Pain Well Controlled (%) Always</td>
<td>CMI Medicare ONLY</td>
<td>HF-ACEI/ARB for LVSD</td>
<td>SCIP-Prophylactic ABX d/c within 24hrs (Vascular)</td>
</tr>
<tr>
<td>Nurse listened carefully to you (%) Always</td>
<td>Operating Margin</td>
<td>HF-Readmission Rate</td>
<td>SCIP-Prophylactic ABX d/c within 24hrs (GYNX)</td>
</tr>
<tr>
<td>RN Turnover Rate (%) (YTD)</td>
<td>AMI- Aspirin at Arrival</td>
<td>PN-ABX within 6hrs of arrival (overall)</td>
<td>SCIP-Post-Op Glucose</td>
</tr>
<tr>
<td>RN Recruitment Vacancy (%)</td>
<td>AMI- Beta Blocker at Discharge</td>
<td>PN-Flu Vaccinations</td>
<td>SCIP-Prophylactic VTE Assessment/Order</td>
</tr>
</tbody>
</table>

Table 3: 53 Strategic Perioperative Process Measures

Table 2 lists the specific strategic outcome categories and number of associated core and operational measures. The 53 strategic measures are spread over outcome categories that cover patient safety, patient satisfaction, patient satisfaction—HCAHPS, employee satisfaction, patient throughput, mortality/readmissions, financial, and IQR quality measures over AMI, HF, PN, and SCIP. Table 3 lists all 53 measures by financial, customer, or process BSC perspective.

Multi-level Balanced Scorecards (BSCs)

The 53 core and operational measures by BSC perspective provide an initial foundation for a BSC strategic approach to managing and controlling University Hospital’s perioperative process. However, the strategic measures are identified at a high managerial level. Many other financial, customer, and process measures are collected at lower tactical and even lower day-to-day operations levels. These lower level measures are required by perioperative stakeholders to monitor and control perioperative process performance. For example at the tactical level, performance measures are required by surgical location (e.g. GENOR, CVOR, HHOR, or CEFH) and/or surgical specialty (i.e. orthopedics). Table 4 lists all 17 surgical specialty services (SSS) performed across the four surgical locations.
Table 4: University Hospital’s SSS

University Hospital currently has 32 perioperative measures identified and defined at the tactical level to measure monthly perioperative performance by surgical location and/or specialty. The CSIS captures, stores, or derives a majority of these measures. Similarly as the strategic measures, each tactical measure maps to a process, definition, outcome, data source, data type, personnel responsible, reporting frequency, and control target.

Table 5 lists specific tactical outcome categories and the number of associated measures. The 32 tactical measures are spread over outcome categories that cover quality, satisfaction, financial, and IQR SCIP quality. Table 6 lists all 32 measures by financial, customer, or process BSC perspective.

At the day-to-day operations level, performance measures reflect more tallies, totals, and worksheets that are required by individual sub-process (i.e. PREP, PACU, CSS, etc.), surgical specialty, and/or by specific OR suite (i.e. Main OR 508). The granularity of performance measures at the day-to-day operations level allows aggregation at higher tactical and strategic levels. The multi-level BSC approach allows different perspectives (e.g. strategic, tactical, and/or day-to-day operations) of perioperative process performance as well as addressing end-to-end process performance.

The BSC for the day-to-day operations measures are more reflective of process components than end-to-end process segments as at the tactical level. The list of all day-to-day operations measures is too large to include in this paper, as most data elements within the CSIS are or are potential day-to-day operations measures. Table 7 lists examples of major day-to-day operations measures by BSC perspectives of financial, customer, and process.

### Table 5: Tactical Outcomes Measured

<table>
<thead>
<tr>
<th>Tactical Outcome</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>13</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>2</td>
</tr>
<tr>
<td>Financial</td>
<td>7</td>
</tr>
<tr>
<td>IQR Quality Measures</td>
<td>SCIP-10</td>
</tr>
</tbody>
</table>

### Perioperative Process Dashboards

Perioperative stakeholders pull BSC measures as needed. The strategic and tactical BSC measures reside on a secured, virtual drive accessible by any perioperative stakeholder who has sufficient rights and privileges within the CSIS. As previously mentioned, the majority of the day-to-day operations BSC measures reside within the CSIS with similar stakeholder access.

At the close of each monthly reporting period, Perioperative Services compiles the strategic, tactical, and day-to-day operations BSC measures into electronic dashboards that measure perioperative performance across each managerial level. These dashboards are then pushed out to update the BSC virtual drive as well as University Hospital administration, directors, and managers. Each University Hospital surgeon receives dashboards for their respective SSS and surgical locations. Team leaders also post the strategic and relevant tactical BSC dashboards in their specific areas. Therefore, BSC dashboards are pushed out monthly for stakeholder dissemination upward and downward.
there are 18 day-to-day operations dashboards. As of May 2013, all tactical dashboards use the same color sequence of green, yellow, and red as ORTHO cases are performed in the OR for the orthopedics SSS (e.g. ORTHO).

The first tactical dashboard is a composite of the GENOR and CVOR surgical locations, and 17 SSS.

Figure 5 illustrates two examples of the 22 current tactical dashboards (i.e. 1 combined for all surgical locations, 4 individual surgical locations, and 17 SSS). The first tactical dashboard is a composite of the GENOR and CVOR surgical locations. The second tactical example is for the orthopedics SSS (e.g. ORTHO). ORTHO cases are performed in the surgical OR suites of GENOR and HHOR. All tactical dashboards use the same color code sequence of green, yellow, and red as noted with the strategic dashboards.

Figure 6 contains examples of day-to-day operations dashboards. As of May 2013, there are 18 day-to-day operations dashboards used to generate the 22 tactical dashboards. The first example in Figure 6 is a summary of late and OTS cases by OR suite by OR location for May 2012. The second example is a partial listing of SSS block time utilization by OR suite by day-of-week for May 2012. The third example shows surgical case completions by OR time slots (i.e. 7AM-3PM, 3PM-5PM, 5PM-7PM, 7PM-9PM, and remaining cases after 9PM) by OR location and in total.

**Table 6 – Tactical Measures**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Category</th>
<th>Status</th>
<th>Target</th>
<th>FY 12</th>
<th>11 Jan -</th>
<th>12 Feb -</th>
<th>12 Mar -</th>
<th>12 Apr -</th>
<th>12 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes Blocked On Time Starts</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Total Cases</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Available Block Time start (12 Hrs.)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Available Block Time (Minutes)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Cases done 3PM - 9PM</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Cases done 9PM - 11PM</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Cases done 11PM - 1AM</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Cases done 1AM - 7AM</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Figure 4: Strategic Dashboard Examples**
Lastly, all dashboards are views of the original BSC data measures, stored in the CSIS or on the secured virtual drive. Perioperative stakeholders may manipulate data within each dashboard for task group analysis or graphing (e.g. data visualization), but the archived measures have read only access capabilities to ensure data integrity.

Data Visualization

Figure 7 illustrates examples of line charts representing perioperative KPI measures versus time. Charts are useful to identify trends in the financial, customer, and process BSC perspectives. The first data visualization example has four charts that show OTS, UOS-total expenses, OR utilization, and completed cases 7AM-5PM from October 2008 to June 2011. The second example is one chart that shows OTS from October 2008 to December 2012. The
third example shows Press-Ganey HCAPHS results for overall hospital and visitor/family ratings from Q3 2008 to Q1 2013.

![Graphs showing Press-Ganey Patient Satisfaction Scores from Q3 2008 to Q1 2013.](image)

Figure 7 – KPI Data Visualization

All of the BSC measures at each managerial level can be pulled into a data visualization chart to report perioperative process performance. All three of the data visualization examples in Figure 7 show positive trends for financials, customer, and process perspectives of the BSC perioperative measures.

Goal Setting and Process Improvement Aligned to the Hospital Strategic Plan

The 2008 perioperative BPM initiative established BSC (e.g. financial, customer, and process) measures and a means to disseminate process feedback to perioperative stakeholders at the strategic, tactical, and operational levels.

<table>
<thead>
<tr>
<th>AMC21 Strategic Pillars</th>
<th>AMC21 Strategic Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Quality</td>
<td>1. Delivering outstanding patient care</td>
</tr>
<tr>
<td>2. Satisfaction</td>
<td>2. Developing advancements in scientific discovery and biomedical research</td>
</tr>
<tr>
<td>3. Financial Performance</td>
<td>3. Providing a strong foundation of education and training for professionals</td>
</tr>
<tr>
<td>4. Knowledge Advancement</td>
<td></td>
</tr>
</tbody>
</table>

Table 8: UHHS’ AMC21 Strategic Goals and Pillars
However, the perioperative process is not the exclusive core process included in University Hospital Health System’s strategic vision. Updated in 2010 and labeled AMC21, UHHS’ strategic plan reaffirms the core healthcare industry standards coordinated and adopted by CMS and TJC, while complimenting core hospital process measures. Table 8 lists the foundation or strategic pillars that support AMC21 strategic goals. Furthermore, the vision within AMC21 is for UHHS to be the preferred academic medical center of the 21st century with characteristics where: a) patients want to come for care; b) employees want to work; c) faculty want to practice and conduct research; d) students, residents, and fellows want to learn; e) and donors want to give to a better future. These five characteristics in the UHHS vision exemplify the desired strategic outcomes of AMC21 goals and the four AMC21 strategic pillars reflect core BSC measures. Likewise, the perioperative BPM initiative nests within the overall execution of the AMC21 goals and vision. However, the UHHS strategic vision needed a more holistic BPM tool.

To align process improvements and stakeholder efforts with the AMC21 vision, UHHS administration also implemented an intranet-based goal setting and reporting tool to leverage existing process data via integrated IS and provide an extended business intelligence application layer across UHHS, similar to the perioperative CSIS/BPM tool, but with an entire UHHS system focus. The “Reach for Excellence” (RFE) layer provides process management capabilities for qualitative and quantitative measures, across UHHS, measurable and aligned to AMC21 pillars and goals. The purpose for the RFE layer is to provide an objective tool to measure process and stakeholder performance toward strategic, tactical, and operational goals that support the AMC21 vision. Individual employee goal setting towards achieving AMC21 is a formalized RFE activity integrated into the UHHS employee evaluation and performance review process. As a result, all hospital stakeholders (e.g., physicians, surgeons, nurses, staff, and administrators) at strategic, tactical, and operational levels have action plans, RFE goals, and resulting merit increases that align with the AMC21 pillars, goals, and ultimately vision.

Rather than identify tactics, projects, or activities, RFE goals are quantitative, objective, aggressive, and realistic outcomes, where fewer rather than more is better. RFE goals will change focus as AMC21 progress advances. Consequently, each year UHHS administration reviews opportunities for improvement and identifies the most important outcomes needed. Many RFE goals do not change annually, as they are important outcomes for success. However, the iterative nature of the goal setting process yields aggressive targets for more familiar goals. As a
result, administrators set goals so stakeholders focus on specific areas and the goal setting process aligns RFE process outcomes and stakeholder action to AMC21 strategy—a very powerful process management tool.

Figure 8 illustrates the 2012 AMC21 dashboard reflecting UHHS process measures aligned to AMC21 strategic pillars via RFE goals. The School of Medicine goals (9) are distinguishable from UHHS (15) and each goal carries a color-coated rating and indicator on performance. RFE goals use the four strategic pillars as modified BSC categories to reflect and categorize where targeted opportunities align to the AMC21 vision and goals. The color-coded performance and rating hierarchy is as follows:

- 5 — Dark Green = Stretch (achieved about 20% of the time)
- 4 — Green = Partial Stretch (achieved about 50% of the time)
- 3 — Light Green = Target (achieved about 80% of the time)
- 2 — Yellow = Partial Accomplishment
- 1 — Red = No Accomplishment

The RFE strategic goals reflect multiple core UHHS processes that are necessary to achieve the AMC21 vision. Six 2012 goals had no or partial accomplishment while 18 had 80% or more accomplishment. Perioperative processes depicted previously in Figure 7 influenced portions of RFE goals across satisfaction, quality, and finance pillars that were achieved 80% of the time or better during 2012.

CONCLUSION

Empowered individuals, integrated IS, and a holistic framework for perioperative process management allows University Hospital to take control and improve its perioperative process. The BSC approach to identify process measures gives stakeholders an end-to-end (e.g. holistic) view for financial, customer, and process perspectives. Patients are clearly customers, as well as PACU is a customer to an OR suite, or an OR suite is a customer to PREP. Also, revenue or margins are clearly financial, as well as surgical cases performed between 7PM to 9PM or cases remaining after 9PM. Moreover, the RFE goal layer affords University Hospital opportunities for process improvement aligned to AMC21 vision. The modified BSC approach to BPM gives stakeholders an end-to-end (e.g. holistic) view for AMC21 pillars, RFE goals, and hospital strategy execution.

Adopting the holistic framework for BSC measures at strategic, tactical, and day-to-day operations levels further educates hospital stakeholders on the benefits of integrated IS for process measurement, control, and improvement. The cycle of analysis, evaluation, and synthesis reinforces communication and stimulates individual as well as collective organizational learning.

Our case study contributes to the healthcare IT literature by examining how CPI, BSC, performance dashboards, business analytics, and process management are applicable to the hospital environment. This study prescribes an a priori framework to foster their occurrence. This paper also fills a gap in the literature by describing how hospital process data is both a performance measure and a management tool.

This study was limited to a single case, where future research should broaden the focus to address this issue along with others that the authors may have inadvertently overlooked. The case examples presented in this study can serve as momentum for healthcare BPM and strategy alignment methodology, comprehension, and extension. The study’s results should be viewed as exploratory and in need of further confirmation. Researchers may choose to further or expand the investigation; while practitioners may apply the findings to create their own version of process management, control, and improvement aligned to strategy within the hospital environment.

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Due to space limitations, a listing of references is available via email from Jim Ryan.
The Impact of Big Data on the Healthcare Information Systems

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Abstract: This article explores the possible impact of big data on healthcare information systems. Possible research issues include: 1). What applications in healthcare information systems are impacted most? 2). What algorithm/programs will be used for big data? 3). What privacy, security, and ethical issues are there for big data? In the biology area, big data becomes the newest technology for genomics. Other possible areas include pharmacovigilance, patient care, and medical supply chain management.

INTRODUCTION

Due to the explosion of information, big data is one of the hottest topics in data analytics and healthcare information systems today. The U.S. government announced the Big Data Research and Development Initiative for 200 million in 2012. The initiative explores the possibility of using big data or a large-scale database to solve significant problems that the government is facing. The funding will be provided to six departments/agencies which include National Institutes of Health. In a recently published Harvard Business Review article, McAfee and Brynjolfsson (2012) listed two scenarios for the application of the big data on predication and sales. The purpose of the paper is to explore the possible impact of big data on healthcare information systems.

WHAT IS BIG DATA?

Big data is similar to business analytical and business intelligence but scale of big data is much larger. Three “V” dimensions are typically used to describe big data: volume, velocity, and variability. Figure 1 illustrates the traditional relationship among healthcare information systems and business intelligences. Several reasons account for the evolution of big data. The first is the rise of in-memory computing. Traditional computers include central processing units (CPU) and secondary storage device (such as a hard drive). Data transfer occurs between the CPU and the secondary storage during data processing. Although it is an economical way to use computers, the processing speed of the computers tends to be slow. SAP Hana and Oracle design new computer systems which use in-memory systems (Monk & Wagner, 2013). Therefore, today’s computer systems are more capable of handling large-scale data than before.

The second reason for the rise of big data has been social networking. In traditional data mining and business intelligence, the data are based on the internal data generated from internal enterprise resource planning systems (ERP) or healthcare information systems. The data used in these systems are also referred to as “structured data” which is still limited. Social networking became popular merely six years ago but already generates a large amount of data. Some data are very useful for data analysis. These external data or some of the unused internal data referred to as unstructured data. As shown in Figure 2, big data analysis combines structure data and unstructured data which come from internal unused data, social media and other external data sources.

WHAT CAN BIG DATA DO FOR HEALTHCARE INFORMATION SYSTEMS?

An excellent example of a real-world case for data analysis was provided by Duhigg (2012) when he “revealed that the retail giant Target can figure out whether a girl was pregnant by tracking her consumer behavior (Trank, 2013).”
(Lee, Chen, & Kao, 2013). With these data, Target would be able to “predict her future consumption of infant-related items such as diapers.” Hill (2012) explained how Target figured out whether a girl was pregnant using data mining tools. “Since Target hired a statistician Andrew Pole to use data mining tools to predict consumer behavior, the revenue grows from 44 billion in 2002 to 67 billion in 2010.” (Lee, Chen, & Kao, 2013).

Figure 1. Traditional relationship between healthcare information systems and business intelligence

Figure 2. Relationship between healthcare information systems and big data
Clearly, there is a great deal of potential for big data in healthcare information systems. For one, such mainframe-based business intelligence (BI) or data-mining programs as SAS or SAP BW should have the capability to be upgraded to handle the big data analysis. Several ERP and healthcare systems vendors and major IT companies like IBM, Microsoft, SAP, Oracle, and SAS have already worked on various big data projects (Lee, Chen, & Kao, 2013). Research into the specific applications big data is still in the early stage and under development, but several general applications are emerging. In the biology area, big data has become the newest technological tool for genomics. Marx (2013) mentioned that biologists use big data to examine “everything from the regulation of genes and the evolution of genomes to why coastal algae bloom, what microbes dwell where in human body cavities and how the genetic make-up of different cancers influences how cancer patients fare.” It took twelve years for the Human Genome Project to collect, analyze, and interpret the huge amount of data needed to produce a map of the about 20,000–25,000 genes, but it may take just one single day to use new big data technologies to achieve the same result (Ross, 2012).

Schultz (2013) indicates big data can be used in the pharmaceutical development cycle in the following areas: 1) Genomics, 2) Clinical monitoring, and 3) Pharmacovigilance. Chawla and Davis (2013) developed a novel system called Collaborative Assessment and Recommendation Engine (CARE) for predicting personalized disease risk. Big data also facilitates the storage and processing of medical imaging data (Hay, 2011).

RESEARCH ISSUES FOR BIG DATA

We have conducted a literature study (Chawla & Davis, 2013; Jee & Kim, 2013) and make the following possible research issues for big data:

1. **What applications (modules) in healthcare information systems will be impacted most by big data?**
   In business works, marketing research, sales forecast, and finance are the most impacted areas. In healthcare, genomics, pharmacovigilance, and patient care are the most important areas.

2. **What algorithm/programs will be used for Big Data?**
   Traditional algorithms include statistics (regression analysis, time series, clustering, and sequential clustering), mathematics (neural network and Naïve Bayes), and other (decision tree and Structured Query Languages --SQL). What will be the algorithms for big data analysis? Traditional SQL is based on relational database. We will see more complex modes such as NoSQL (also referred to as “not only SQL”) and Hadoop® for big data analysis (Schultz, 2013). For example, Hadoop includes MapReduce, a software framework for writing applications, which “processes vast amounts of data in parallel on large clusters consisting of thousands of nodes of commodity hardware in a reliable and fault-tolerant manner” (The Apache Software Foundation, 2013).

3. **What the privacy, security, and ethical issues emerge for big data?**
   Several concerns and privacy issues arise from the use of big data (Hill, 2012). For one, because of the Health Insurance Portability and Accountability Act (best known as HIPAA), healthcare providers and institutions are aware of the importance of security and privacy. Ethical issues are another concern. The case of Target’s use of information mentioned earlier is an excellent example of how possible ethical issues call for the need to protect confidential patient and client information.

The growing applications of big data mean the use of more central-controlled data centers and cloud computing. For example, Cook County Health and Hospitals System (CCHHS) in Illinois has installed a unified virtual data center infrastructure to serve the operational needs of more than twenty facilities across the Chicago area (Ritchey, 2012). The European Bioinformatics Institute (EBI) in UK, one of the world’s largest biology-data repositories, presently stores 20 petabytes of data and back-ups about genes, proteins and small molecules (Marx, 2013). A security breach for data centers the size and nature of these could trigger both a financial and a non-financial disaster for the institutions, hospitals, and individuals not to mention the mental pain such disclosures could lead to.
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Digital Illness Narratives: A New Form of Health Communication

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Abstract: Social media has dramatically affected the way information is accessed and circulated. Social networking sites continue to create on-line communities where every participant plays an active role in seeking and sharing information. While social networks have profoundly impacted different industries in terms of communication between business-to-business and business-to-consumer interaction, they also have had significant impact on many stakeholders in the healthcare communication system. This report describes how a non-profit social networking site called CaringBridge can help patients communicate about their health challenges and gain support through their writings. When traditional “Illness Narratives” (a patient’s reflective writing about his/her illness) become interactive and conversational in a digital platform, the self-expression and connectivity taking place in an online social community contribute immensely to the patient’s health journey.

INTRODUCTION - “SOCIAL MEDIA ‘LIKES’ HEALTHCARE”

Today, more than 1.5 billion people around the globe have an account on a social networking site. According to a study conducted by McKinsey Global Institute, almost one in five online hours is spent on social networks—increasingly via mobile devices (Chui et. al., 2012). Undoubtedly social networking has transformed the way how information is accessed and shared, and social technologies have greatly impacted the popular culture and are being adopted across industries.

In the United States, even though there is a significant amount of debate over the use of social media in healthcare communication from manufacturers, consumers, and regulatory bodies (Popovic, Smith, & Hellebusch, 2013), social networks have continued to reshape how stakeholders in healthcare communicate with each other. As a physician, who uses a blog to communicate with her patients, claims, “Social media could transform health care. It’s already doing it” (McCarthy, 2012, Sept. 19). Indeed, the prevailing uses of social networks in health care communication have shown that social networks have become an integral part of the health care landscape.

According to a large-scale study that examines current social network applications by health care stakeholders (“Social networks in health care: Communication, collaboration and insights,” 2010), in the health care arena, social networking uses can be seen in the following areas: Maintaining health and wellness (e.g. WEGO and WebMD), disease management (e.g. PatientLikeMe and Inspire.com), clinical trial recruitment (iGUard), Personal Health Records (e.g. PatientsLikeMe and Medhelp), Health professional training (e.g. radRounds, Sermo and Ozmosis), Public health announcements and campaigns (e.g. CDC collaborated with DailyStrength and Sermo), and treatment, physician or hospital selection (e.g. DailyStrength and FacetoFace Health). This study demonstrates that more and more hospitals and medical professionals are embracing and utilizing social media as a means to convey general health information, sometimes even personalized help (Kotenko, 2013). The Mayo Clinic, known as “the gold standard for social media in healthcare” pioneered uses of Facebook, YouTube, Twitter, and blogs (Justice, 2013, May 20). Its Facebook page has over 300,000 connections, and the blog of Sharing Mayo Clinic makes it possible for patients and employees to tell their stories about the Mayo Clinic experience. Moreover, physicians now have the opportunities to submit cases for community discussion and to better practice medicine (Seda, 2013, June 17; “Social Networks in Health Care: Communication, Collaboration and Insights,” 2010). Doctors can spread good health information, address medical questions and share interesting development in the medical field. In fact,
nowadays health professionals are suggested to have a strong social media presence to establish themselves as reputable sources (Kotenko, 2013).

The benefit of using social networks also extends to the consumers. Consumers in healthcare now have places to have their voice heard. For example, some social networking sites let patients evaluate the care services provided by the hospitals they use, including clinical and nonclinical experiences. The expansive nature of social networks gives health care consumers unprecedented capacity. A patient’s comments on the service he or she receives will be able to reach 14 million followers if he or she decides to “tweet it” (Bringing the Social Media Revolution to Health Care, 2012). Also, patients now can form on-line communities through sites like PatientsLikeMe and MedHelp, which allow participants to upload detailed information about their condition and receive information from similar patients.

In addition to disseminating and sharing information among hospitals, physicians, and consumers such as patients, providing certain types of medical services is now possible through social networks. For example, virtual sessions of online therapy offering various modules that provide anxiety and depression assistance are now available (Kotenko, 2013). A small primary care medical practice, Hello Health, has been practicing “cyber-visit” whereby patients of this clinic can IM or video chat with a particular doctor to describe their symptoms and ask the doctor for advice (Hawn, 2013). E-health, the new trend made possible by social technologies, is believed to have a significant impact on the future of U.S. health care.

However, health care industry is reported to lag behind other industries in its social network presence (“Social Networks in Healthcare: Communication, collaboration and insights,” 2010). One of the major reasons may be the challenge posed by HIPAA, the Health Insurance Portability and Accountability Act. Physicians who participate in social networking avoid revealing professional and medical advice on Twitter or Facebook accounts. For example, Twitter is believed as a higher-risk environment because it basically is an open forum (Hawn, 2009; Kotenko, 2013). Also, a survey regarding consumers’ trust in information retrieved from social networks reveals that health insurance plans and drug manufactures are the least-trusted sources of health information. Despite the risks and potential downsides such as consumers’ lacking trust in information provided by certain types of organizations, social media tools have made the healthcare communication system flatter, more democratic, and presumably more effective (Hawn, 2009)

USERS CHARACTERISTICS

In the communication system in health care, both clinicians and consumers are using social networks. About one-third of Americans who go online to research their health are now using social networks to find fellow patients and discuss their conditions (“Social Networks in Health Care: Communication, collaboration and insights”, 2010). Social media has changed online dialogue from one-to-many to many-to-many at a phenomenal speed. Who are using social networking sites for their health needs? The Health Information National Trends Study that attempted to identify the sociodemographic and health-related factors associated with current adult media users in the United States demonstrates that social media are penetrating the US population independent of education, race/ethnicity, or health care access. In 2007, among the 5,078 Internet users, 5% participated in an online support group, 7% reported blogging, and 23% used a social networking site. Statistical analysis found that younger age was the only significant predictor of blogging and social networking site participation. Moreover, younger age, poorer subjective health, and a personal cancer experience predicted support group participation (Chou et al, 2009). Another study also states that in 2010, three in four American adults were online, and over 60% turned to the Internet for health information. Research also revealed that 83% of Internet users can be classified as “e-patients,” which means patients consume and share information about their health and sometimes the health of their loved ones (“Making a real impact: The CaringBridge phenomenon”, 2011). What are some health-related activities health care consumers do when they use social media? A study of 1,060 users and the health-related activities they do concluded that 27% of the users commented on other health experiences, 24% posted about health experiences, 20% join health forum or community, and 18% track and share health symptoms/behavior (“Social Media ‘likes’ healthcare,” 2012).
USING CaringBridge DURING HEALTH CHALLENGES

Social media has provided a platform for one of the stakeholders of healthcare—people who get sick—to obtain and share information. Imagine a person who, after being diagnosed with a serious illness, needs to answer 40 phone calls and tells his or her situation 40 times to people who show their concerns. Instead of making or being overwhelmed with many phone calls or e-mails, now one can use CaringBridge or some similar sites like CarePages to save a lot of time and energy, and especially ease a family’s communication burden when encountering a health challenge. CaringBridge is a non-profit web-based service that helps the families of people who have suffered a medical crisis set up a simple website and blog to keep friends informed and updated. In 1997, to help a friend cope with a life-threatening pregnancy, Sona Mehring, a software programmer, designed a website that not only kept family and friends updated but also allowed them to post words of encouragement. Today, the first single webpage of CaringBridge organization has grown considerably to over 3 million members, logging with half a billion website visits and 13 million messages (Clemence, 2008). Over 1,800 hospitals and healthcare facilities partner with CaringBridge and recommend the service to their patients (“Top hospitals go beyond patient outcomes to improve patient satisfaction,” 2011).

Social media undoubtedly changes the nature of interaction among participants. It consists of four unique characteristics: user generated content, community, rapid distribution, and open, two-way dialogue (“Social media ‘likes’ healthcare”, 2012). CaringBridge exemplifies all these four characteristics. The patient/user generated content has become a platform for patients to write about their health and feelings, thus making their journey easier, and the two-way dialogue through visitors’ signing the guestbook builds an online social community that connects people in authentic and meaningful ways.

The creators of CaringBridge personal sites more often are not the patients themselves; sites are set up by caregivers giving updates and speaking on behalf of the patients. Nevertheless, when a patient starts writing about her own experience, the CaringBridge’s blog setting has become a great way for a patient to “capture the health journey” (“Will facebook replaces CaringBridge and CarePages,” 2013). Due to its blog or journal writing format, CaringBridge is different from Facebook, which, as Mehring argues, is “for small talk” whereas CaringBridge is “where you go when you want to have a conversation”(Crosby, 2011). It is also more protective and provides value to everyone involved—the patient, the caregiver, the circle of family and friends. The ability to express oneself through writing and the opportunities to connect with people have made CaringBridge a “value-added” personal health social network (“Top Hospital go beyond patient outcomes to improve patient satisfaction,” 2011).

Many testimonials from caregivers who set up a CaringBridge site mention that Caringbridge has been a lifeline between family and friends during the time when a loved one gets sick (Mehring, 2013). Numerous users/writers who use the CaringBridge journal/blog to write about their health experiences claim that writing itself is therapeutic. As one user testified, “posting in the journal became efficient, not to mention more than just writing. It was therapy” (Mehring, 2013, p. 32).

ILLNESS NARRATIVES

The time-honored research on the therapeutic nature of writing about one’s illness including psychologically traumatic experiences proves that self-expressive writing has a profound effect on a patient’s emotional and physical health and well-being (Pennebaker, 1990; DeSalvo, 1999; Adams, 1999; Hunt, 2000; Grason, 2005). DeSalvo (1999) and Hunt (2000) have called writings about one’s physical sickness “the Wounded Body Narrative” and “Illness Narratives” respectively. In today’s persuasively digital environment, the journal writing a patient takes initiative to compose through CaringBridge allows the patient to post his or her “Illness Narrative” and deal with an ongoing illness in a new way. Following is a current and ongoing case that illustrates how a site user of CaringBridge can share her experience, voice, insight, and obtain support from friends during her medical journey.

Iris (name changed) was diagnosed a type of stage IV cancer two weeks before her 49-year-old birthday. The diagnosis, of course, came as a shock. In her “story” page (a synopsis of a patient’s situation when he or she sets up the site), Iris wrote,” From having a little pain on the lower abdomen to the diagnosis of stage 4 (type of cancer omitted) cancer, I had received one bad news after another within a short period of time. However, I have experienced the peace beyond understanding.” Iris belongs to the group of CaringBridge site authors who “tend to
be significantly active in social media activities than the average individual” (“Making a real impact: the CaringBridge phenomenon”, 2011). The average age of adult social networking site users has increased to 38 in 2010 from 33 in 2008 (“Top hospitals go beyond patient outcomes to improve patient satisfaction,” 2011). Iris is competent in using social media. She has both Facebook and Google plus presence and is comfortable with creating social media content such as uploading video or music. After her first chemotherapy, Iris set up the site and has been journaling weekly to update her health situation.

Narrative, according to Garro and Mattingly (2000), is a fundamental human way of giving meaning to experience. Research has demonstrated that journaling helps people who have physical illness create “a literature of their own” (Broyard, 1992) to articulate the experience, make sense of it, and eventually gain and share insights (DeSalvo, 1999). Audre Lorde (1980), author of The Cancer Journal, explained that she used her diary to give her illness voice. Each entry of Iris’ journal/blog was given a title and focused on one event and the insights she got from the event. In her fifth journal entry written after the third chemotherapy, Iris wrote, “Since I was diagnosed with cancer, my perspective on suffering has changed little by little. . . . The question for me becomes [this]: are the “bad things” God allowed to happen to me really bad?” In the tenth entry titled “Who Needs That Hair Brush,” Iris used humor to mention implicitly her apprehension of losing her hair in the near future: “Yesterday I went to s nursing home to visit a friend’s husband . . . .Before we walked out his room, my friend’s husband took out a hair brush from his pocket and said, “I don’t need this” and showed me his bald head with a boyish smile on the face. We met at church a couple times before, but he did not remember me at all. I said jokingly: “Well, I won’t need hair brush for long, either” and gave him a wink. My friend explained to him that I have cancer and am under chemotherapy. He said nothing but gave me a big, warm hug. Although he has lost some of his memories, he has not lost his nice personality. It is worth pondering on. . . .”

At the end of this journal entry, Iris expressed her gratitude and stated, “I don’t know which one is worse—my cancer or his Alzheimer. But I know God gave all kinds of blessings if we are going to count them.” Indeed the theme of counting blessings and accepting the reality of having cancer can be found in almost every entry of Iris’ online journal/blog.

Digital journaling has provided a new kind of writing space where writers can create words, images, and sound. Iris’ digital journal is multimodal. Oftentimes Iris uploaded a song from YouTube at the end of her journal entries. With readers in her mind, Iris intended to share the song and to encourage her readers, the site visitors.

Digital writing reaps the value of being able to make personal connections that traditional published narrative might not accomplish. In contrast to the traditional publishing mindset, narratives posted through social networking sites are framed in a social communication model, which means the writing becomes interactive and conversational, and usually open to all who wishes to participate (DeVoss, Eidman-Aadahl, & Hicks, 2010). In other words, audience members are no longer passive recipients of messages but active participants in a conversation (Lambert, 2012).

Illness narratives posted onto a social networking site creates connectivity needed by a patient who seeks to articulate and make sense of his or her health experience. According to research and medical authorities, “the most significant impact comes from personally connecting with others” (“Making a real impact: the CaringBridge phenomenon”, 2011). Connecting with someone during times of crisis or joy offers real health benefits. Visitors of a CaringBridge site can either have open access or they may be required to registered and use a password to log in. A ticker that counts visitors appears on the upper right corner of the site’s homepage. Many authors of CaringBridge praise the support they get from people who sign the guestbook and really think it is a lifesaver (Muhering, 2013). “I treat my journal as a conversation between me and my friends, and it kept me going,” stated by one of the CaringBridge users (Clancy, 2013, p. 61).

The social networking sites such as CaringBridge takes science and technology and mixes it with two fundamental human needs: communication and relationships (McCarthy, 2013 April 19). When a CaringBridge site is created, the site author make up a list of recipients, and e-mail notifications are sent to the recipients. Each time a new entry is generated, the recipients are notified through e-mails. The recipients, the intended and invited audience, can then choose to sign the guestbook where they can leave comments or converse with the site author. The author and any recipient can also click a “like this” link to show his or her appreciation of each entry in the guestbook. At the end of August, 2013, two months from its inception, Iris’ CaringBridge site has generated 13 journal entries and 331 visits. The outpouring of love shown through words of consolation and encouragement in the guestbook was
amazing. The interactive and conversational feature provided by social networking sites such as CaringBridge gives patients a platform to receive love and to be loved (Karpen, 2013).

In our networked world, the Internet, social media posts, and check-ins are a way of life. Research on social networks continues to demonstrate how social technologies create an immense amount of economic value and productivity among industries. However, social technologies can also provide individuals with significant non-economic benefits. This non-economic power stems from the innate appeal of self expression and social interaction. Users are empowered by having the pleasure and intellectual stimulation that people derive from sharing what they know, expressing opinions, and learning what others know and think (Chui et al, 2012). As demonstrated in Iris’ story, a personal health social networking site such as CaringBridge--where a patient chooses to “publish” his or her illness narrative--contributes to health communication and a patient’s health journey.

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Relationships, Caring, and Near Misses: Michael’s Story

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Abstract: Health care errors are costly to both patients, insurance companies, and put additional strain on existing resources. This research paper is a case study about a patient’s experience in health care with the electronic health care record and the information used to deliver care. This case study will demonstrate that although the electronic health care record does provide information, the information contained within it can be confusing, contribute to health care errors, near misses, and may have an impact on health provider relationships with patients. Information and systems issues are identified with recommendations to help avert health care errors and near misses in the context of the electronic health care record and health service delivery.

INTRODUCTION

Error in the provision of care is one of the top priorities and one of the deep concerns for patient safety and costs that health care organizations face (Office of Legislative Counsel, 2010; James & Bayle, 2006; Agency for Healthcare Research and Quality, 2003). Essential for patient safety and cost reduction is the accuracy of health information used for determining care. Today, the push for the electronic health record with meaningful use means that organizations will need to use effective processes to ensure that providers, caregivers, and patients are getting the right information and that the information is communicated with accuracy (Office of the National Coordinator for Health Information Technology, 2011). One positive result of the meaningful use of electronic health record (EHR) is that the patient’s information is electronically stored, retrieved, used, and care is provided based on the information contained in the EHR (The Joint Commission, 2011-2012; American Medical Association, 2007).

In the United States, more than 100,000 implantable cardioverter-defibrillators (ICDs) are implanted annually (Hohnloser & Isreal, 2013). ICDs have been used for the past 40 years to prevent sudden cardiac death for individuals with heart disease and generally have a service life of 4.4 years and cost $37,000 each to replace excluding physician and anesthesia costs (Sohail, Henrikson, Braid-forbes et al, 2011). People with ICD’s may need to have their devices replaced approximately 4-6 times during their lifetime at a cost of over $200,000.

Medication use in health care also represents large costs. More than 80% of all adult Americans take at least one medication and nearly 30% take more than five (Sline Epidemiology Center at Boston University, 2006). In the United States, 3.5 billion of dollars in health care costs are incurred because of medication related issues (Centers for Disease Control and Prevention-b, 2012). Today, there are more than 18.8 million people diagnosed with diabetes and 90-95% of those is classified as Type 2 and requires medication to manage their disease (National Diabetes Education Program, 2008). The risk of death for people with diabetes is double as compared to people without the disease.

The aims of this article are twofold. First, it is to present a real case in which a patient has encounters with an Emergency Department and examines a 15- month ordeal to identify risks where the provider assessment in the EHR could be linked to high risks tests to prevent sentinel events or near misses and to identify where a common medication given to diabetic patients can be life threatening if not managed as intended. Second, through a careful walkthrough, potential and real errors are identified, along with recommendations, for further improvement of patient care and safety in a technology-rich environment.

Our real case showed many near misses occurred due to misuse or no-use of information in the electronic health record. It was quite unfortunate that our case took place in a top rated safety hospital. These near misses will never be discovered unless organizations have a distinct plan to seek them out through some process driven strategies.
To make our case presentation easy, the real patient is de-identified as “Michael” in this paper. This article is written to benefit all people, including clinical professionals and patients, who are involved in the health care delivery to understand the importance of both the access and accuracy of information, relationships, and caring with its impacts on service outcomes. Next, the methodology, framework followed by Michael’s history and experiences are presented with each problem encountered and recommendations to minimize the problems. The ensuing discussion provides further enlightenment followed by a conclusion.

METHODOLOGY

A case study methodology is used to gain understandings of complex issues and to illuminate and extend what is known about a topic (Yin, 1984). The case study methodology is used to understand real-life contexts and has an established and extensive history. While there are criticisms regarding the validity, reliability, and generalizability of the case study methodology, it continues to be used to examine real life situations, problems and events particularly in the social sciences (Yin, 1984, Crowe, Cresswell, Robertson, Huby, Avery, Sheikh, 2011). This case study examines a patient’s experience in the health care setting over a period of 15 months. No explicit dates are provided although the experiences started in 2011. Emergency Departments and the patient’s name are not identified to protect the anonymity of the patient and hospital. The patient “Michael” shared information and documentation for the writing of this article along with in-depth discussions for optimal understanding of his experiences. At times, direct observation was used to gain information. Whenever possible, “Michael” requested copies of emergency care documentation to improve understanding and for verification purposes.

DATA, INFORMATION, KNOWLEDGE, WISDOM CONTINUUM (DIKW)

Data, information, knowledge, and wisdom are the fundamental tenets of information science (Ackhoff, 1989). Data refers to unstructured raw facts that alone have no meaning. Information is data that are contextualized to provide meaning. Knowledge is the application of what we know to the information and wisdom is knowing when and how to use knowledge and information to solve problems. This model has been used in the health care industry for years and is particularly suited for those who study health informatics and many other fields (Rowley, 2007; Ackhoff, 1989; American Nurses Association, 2008). Therefore, this study will use the DIKW continuum as the lens through which this case study is analyzed.

BACKGROUND

Michael - His Background and Health History

Michael is a young looking 62-year-old married man who stands about six foot tall with a weight of 246 pounds and has four grown children. Michael has had many experiences in the health care system due to his severe spinal degeneration, muscle weakness, and nerve damage derived partly from heavy lifting and back injuries sustained during his younger years in late 1978. He has severe spinal stenosis, nerve root compression, and a history of an attempted spinal fusion approximately 30 years ago. His mobility has progressively worsened over the past six years and has continued to be in a steady decline. During the last 18 months, three stair-lifts were installed (one on each staircase) to move him up the stairs to facilitate entry into the house, and two more to move him from the main level of the home to the second level for access to bathroom, shower, and bedroom.

Michael has had diabetes for about 20 years managed by oral medication and idiopathic dilated cardiomyopathy, which further draw upon resources - both his own and health care system. His diabetes started about age 40. After a proper diagnosis, Michael changed his diet and began monitoring fluids, fats, cholesterol containing foods, and salts. To date, he has been able to reduce his diabetic oral medications and has lost weight. Michael is faithful in checking his blood glucose every day and understands how the food he eats influences his blood glucose levels. Generally, Michael’s blood glucose range between 90-110 mg/dl consistently and his average glycosylated hemoglobin is six or less. This is considered good control.

Michael’s experience with idiopathic cardiomyopathy started in late summer ten years ago. Within about 5 months of the initial diagnosis, an implantable cardioverter-defibrillator (ICD) was implanted to avoid sudden death. During the history of his cardiomyopathy, Michael’s cardiac output (ejection fraction) has ranged from a low 12 % (almost needing a heart transplant) to 50% (almost normal).
Due to Michael’s medication regime, fluid management, and diet, he has not had an admission to the hospital for cardiomyopathy or heart failure since his original diagnosis. Michael outlived his five-year prognosis and now has surpassed the 10-year mark. Michael still has an ICD device that is not compatible with some testing devices like the Magnetic Resonance Imaging (MRI), which is used to obtain an in-depth view of human systems (bones, nerves, etc.). If Michael were to have an MRI while the ICD is still in his body, it will likely cause certain death. In addition to these health problems, Michael also has sleep apnea and a history of renal insufficiency. The following an accounting of errors and near misses that can be corrected given a technologically appropriate EHR and clinicians who are experienced with using them. The following narrative begins in the year 2011.

Month A – The Beginning of Health Needs

In early start of a new year, Michael started having incidences of severe pains, loss of muscle, and diminished strength in his legs. He mentioned these problems to his physician who prescribed pain medications to provide some relief; however, sustained relief did not come. Repeated visits to the family physician showed continued mobility issues and many limitations. Eventually, Michael was referred to a specialist and was scheduled for an electromyography (a study of the electrical activity to the skeletal muscles) that showed abnormal results. The abnormalities were simply recorded and sent to the family physician and no follow-up occurred between the patient and the physicians. Michael waited for input from the physician, barring none; he thought the results of the test were normal.

**Problem 1 Information:** Information systems and their processes are used to generate, store, retrieve and process data. While the performance of an electromyography was helpful to determine correct patient care and provided answers to the Michael’s problem, the results (information) must be processed and communicated with appropriate health care providers and their patients. The follow-up communication between the specialist, primary care physician and the patient was lacking and impaired successful relationships. Failure to notify patients of test results has resulted in a significant increase in medical malpractice (Gale, Bissett-Siegel, Davidson, & Juran, 2011)

**Recommendation 1:** Automated reminders are needed to ensure that the results from referral services are communicated with patients. The EHR must be designed to provide a method so that physicians and other providers are alerted when patients have not been informed of test results—especially those obtained by specialists and delivered to the primary physician for action. While the patient made an assumption that the test was normal due to lack of follow-up from a physician, it is necessary that patients become engaged to seek results in order to avoid delays in care through active collaboration and participation with the physicians and other health providers. Informing patients of test results and other pertinent information is known to enhance relationships and satisfaction with care.

Nine Months Later – The Epoch of a Near Miss Error

Suddenly one evening, Michael had pain that could not be relieved; it was severe, excruciating, and unrelenting. Eventually, Michael went to the local emergency department (ED2) where they took a full history including the knowledge that he had an ICD. The physician left the room to write some orders and provide treatments for Michael. When the doctor returned to the room, Michael was informed that he would have an MRI very soon. Although the physician had been told about Michael’s ICD and it was recorded in the chart, a MRI (a test) was scheduled. As Michael was waiting in the ED2 suffering in pain, a family member reminded the physician that Michael has an ICD. As a result, the MRI was cancelled and a computerized tomography (CT) test was scheduled and completed. This is a near miss because Michael should not have been scheduled for an MRI in the first place. While new research is emerging on the issue of MRI and ICDs, to date, only 700 patients with certain types of ICD’s have been successfully been administered a MRI (See & Ginzburg, 2008).

**Problem 2 Wisdom:** Wisdom is used by individuals to respond and act critically to a situation. Wisdom in decision making increases effectiveness of those decisions. In order to have wisdom the data must be processed correctly. As discussed previously more than 100,000 ICDs are implanted into individuals yearly and each of those people are at risk for death if they undergo an MRI. James recently reported that 200,000-400,000 preventable adverse events occur yearly (2013). For Michael’s case, clinicians who ordered the wrong test due to lack of attention to data shows lack of wisdom and can contribute to preventable adverse events. Patients who are subjected to near miss errors can lose confidence in their health care provider.
Recommendation 2: The EHR can be designed to prohibit the ordering of a test that is incongruent with implanted devices such as the ICD. This can be facilitated by linking the provider assessments to treatment orders. A link such as this will reduce the costs of care by eliminating wasted effort that occurs through duplication and repetition of work and will promote patient safety.

Potential Medication Complications

The CT scan showed severe stenosis and severe degeneration of the spinal disks. After the CT scan, Michael was given a Medrol Dose Pack® and a steroid injection. The Medrol Dose Pack and steroid injections will cause high blood glucose levels that must be managed with people who have diabetes. Michael did not receive any instructions to manage his blood glucose. Uncontrolled high blood glucose levels are life threatening.

Problem 3 Knowledge: While Michael received information that his blood glucose would increase because of the medication, he was not given the know-how to manage glucose. Know-how facilitates the transformation of information to instructions. Therefore, this is a knowledge problem. However, it is not clear that the provider had the know-how to instruct the patient in how to adjust his oral diabetic medications or if the provider considered glucose control as a problem he/she should manage. In the United States, 17 people out of every 100,000 die of hyperglycemic (high glucose) episodes (Centers for Disease Control and Prevention-a, 2012). Patients depend on their provider to look out for their safety. There were some misunderstandings as to who would manage blood glucose levels for this diabetic given steroid medication. This is a problem that must be corrected.

Recommendation 3: Using the capabilities of the EHR, direct links need to be provided that guide the clinician toward helping patients understand how to manage blood glucose prior to discharge from the emergency department. Patients need to be taught how to be persistent with health care providers in order to get information and know-how (knowledge) necessary for safe care. When patients are in the emergency department on weekend days, contacting the primary physician for glucose control is not routinely practiced but should be encouraged by both patients and healthcare providers.

The Next Month – An Error that Should Never Happen

In the next month, Michael underwent a minimally invasive laminectomy on a Friday afternoon at Affiliated Hospital 1(AH1). A few hours later, he was discharged and given a prescription for pain medications. Later that evening and onto the next day, Michael suffered terrible pain and discomfort that was not relieved with the pain medications. Several calls were made to the on-call physician, yet help only came in the form of reassurance to Michael and Lynn that his pain would decrease. On Sunday, another call was made and it was discovered that the physicians at AH1 forgot to give Michael a prescription for a muscle relaxer, a standard of care and a routine medication for those who have a laminectomy. Muscle relaxers such as Flexeril®, Valium® and others are generally given for short-term use to manage back pain after for operations such as laminectomy (Johns Hopkins Heart and Vascular Institute, 2012). Neither Michael nor Lynn knew that he should have been given a muscle relaxer. For two days, Michael suffered unnecessarily because an essential medication was missed upon discharge and not identified as missing with return telephone calls to the physician.

Problem 4 Information, Knowledge, Wisdom: First this is an information (what, when, how) problem because the health care provider failed to notice that Michael was not given a muscle relaxer which comes from the storage, retrieval, processing and use of data. Second, although multiple telephone calls were made, the provider did not provide the know-how (knowledge) to manage the patient’s pain, so the information was not transformed into knowledge. Lastly, the provider did not apply wisdom –the ability to increase effectiveness or add value. Michael did not receive the correct treatment or standard of care for the procedure and second, the physician failed to notice the omission. Omissions in the standard of care for patients can prolong and make recovery in certain conditions worse. Patients can lose confidence in their care provider and this will negatively influence the relationship between the patient and healthcare provider.

Recommendation 4: In accordance with the standard of care, if the discharge medication is linked to the standards of care determined by the organization, omissions or deviations from the standard can signal an alert for correction or documentation of why the standard was not followed. Standards of care are used and view as a growing methodology to provide the best care. The link between the standard and what actually occurs is necessary in the EHR to assure that fundamental mistakes or omissions in care are minimized. Perhaps it may be helpful to initiate better triage systems using the functionality available in the EHR.
Three Months Later – Another Near-Miss Error

In the early part of the next year, again Michael experienced excruciating pain late at night that could not be relieved with activity or medications. The pain was unbearable. A trip was made to ED2, and ensued with another MRI order. Again, a MRI was scheduled, which was later intervened by Lynn and Michael to avoid the life threatening error. Instead, a CT scan was ordered and compared with the previous record. This time a different level in the lumbar area was involved. For a temporary relief, Michael was given a steroid injection and oral steroid medications without instructions to prevent a potential rise of the blood glucose. Before being sent home, Michael was given an injection for pain and a prescription for pain medications for home use with instructions to follow up with his physician, if the pains resurface.

Problem 5 Wisdom and Knowledge. As noted, the repetitive nature of problem 2 (ordering inappropriate tests for a patient) and problem 3 (providing steroid medications to a diabetic without instructions to preserve health) is cause for concern. Knowledge is acquired through the synthesis of information from various sources. The occurrence of identical problems at different points in time suggests that the processing of information and transformation of that information to knowledge is lacking. As a result, the EHR in its present design is not helping the provider to use wisdom in the care and treatment of patients in certain contexts.

Recommendation 5: By identifying and attending to repeating risk patterns, improvements in care can occur. Different clinicians made exactly the same error at each ED2 visit. This is suggestive of a systematic error that can be corrected through proper integration and design of the EHR. This error was identified via this case study. Routine use of case studies of patient care delivery from the patient’s perspective may be very beneficial to catch repeated high risk errors or near misses.

Spring – A Trip Alone to ED2 with Little Help

In the spring of the same year, the identical scenario happened again, ended with another trip to ED2 at midnight. This time, since Lynn was out of town, Michael drove alone to ED2. He communicated his medical history. However, health providers at ED2 could not give Michael any pain medication injections because he had nobody to drive him home. Rather, Michael was given a steroid injection and sent him home with oral steroids and pain medication. Because of severe pains, Michael could not remember when and how much medication to take by himself and overmedicated himself.

Refer to Problem 3 –Knowledge. Again, Michael was not given the know-how (knowledge) to manage his blood glucose levels using his oral medications. Due to the repeated nature of this problem, it is likely that providers are hesitant to address blood glucose management altogether. Perhaps it is too complicated. But if it is too complicated for the provider, how is the patient expected to do the task correctly? The patient was sent home in severe pain that was not adequately managed in ED2. While pain management may be difficult, ensuring that pain is managed and effective (wisdom) prior to discharge is important. The provider and nursing pain assessments need to be linked to the discharge plan to ensure that if pain management is not obtained, options such as a short stay may be considered by the patient.

DISCUSSION

Data and Systematic Errors. This case study examined one patient’s interaction with the health care system for a consistent problem that showed disturbing results. In fact the potential errors and omissions were consistent across the visits to the ED2. As shown, health care providers repeatedly made the same mistake in ordering an MRI for a patient that cannot have one is a systematic error that can be corrected through appropriate links in the nursing and provider assessment or history to the test itself. If the systematic error can be corrected for patients such as Michael, it can be extended to other similar scenarios. Preventing systematic errors will likely improve patient satisfaction and reduce time spent in ordering the inappropriate tests for individuals with varied restrictions thereby reducing the costs of care. In this particular case study, the systematic error is related to data – simply an ICD that is not compatible with the MRI. Perhaps an algorithm can solve this issue and create a meaningful alert. Medication alerts have been established for medications and their interactions with each other. The same process could also apply to medical implanted devices.
Knowledge and Information. Michael was given steroid injections followed by steroid oral medications which have pushed Michael’s blood glucose into the 600 range, which is extremely dangerous and life threatening. There is a repeated tendency to ignore the side effect of steroid medication and the management of blood glucose for this patient when treated by the emergency department personnel. The EHR needs to be design so that the administration of this particular class of medication for a diabetic patient and management of blood glucose cannot be ignored. This means that the information (what, when, and how many) and glucose management know-how (knowledge) are distributed. Hospitals need a clear plan to determine who is responsible for guiding the patient toward glucose control. People who use insulin may have some type of scale to work with; however this is not always the case. For diabetics who are managed with oral medications glucose changes are more difficult to manage. Who will be responsible for working with the patient? Is it the primary care physician/ provider or the ED personnel?

Knowledge, Wisdom and Clinical Decision Support. Based on Michael’s experience after his first laminectomy in 2011 and the forgotten muscle relaxer, a checklist mechanism may be implemented to help physicians and/or nurses in prescribing proper medicines that will be appropriate for patients, like Michael, to meet their treatment need. Checklists in healthcare have been shown to reduce errors and omissions in care. In terms of the use of knowledge by health care providers, the environment in which they practice is filled with distractions, interruptions and high workloads. It is imperative that the systems used by health care professionals help draw that knowledge out for use, and in its absence provide the knowledge needed to both provider and patient. The day has come when an uninformed patient must change, become informed, and engaged in care, otherwise, their very life will be at risk.

Relationships between Patient and Provider. The difficulties that were experienced by Michael during this case study have profoundly affected his opinion and trust of health care providers in proving safe and satisfactory care. He identified himself as being at risk for death with each hospital and emergency department interaction. As frustration and errors become greater, it is likely we will see more people that are dissatisfied with health care delivery unless we do a better job of identifying and correcting errors and omissions in care.

CONCLUSION

This paper provides a narrative about the provider relationships, near misses, and use of information that comes from the electronic health record for medication reconciliation, patient care, and safety during ED visits. While many factors influence care, it is essential that the patient is not forgotten but rather respected and involved in care choices. This paper details fractured relationships, near misses, and medication concerns in health care that were avoidable and provides recommendations to improve them. Although errors can be eliminated with use of the EHR, it is not a time to be overly confident that the errors are actually reduced. Secondly, patients and providers need to improve relationships so together they can attend to the details of the discharge instructions and avoid unnecessary injury and adverse reactions due to errors and omissions. In this time of great change and influx of technology, it is important to remember that patient safety is expected, care is coordinated with the family, and patients are discharged with accurate and meaningful instructions and the know-how to manage their health effectively.
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What is Your Informatics Skills Level? --The Reliability of an Informatics Competency Measurement Tool

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Abstract: To determine the reliability of the nursing informatics self-assessment tool which was developed and extended from Kaminski’s assessment tool among health care students. It was hypothesized that there would be no significant difference in participant responses for a test/retest survey completed by nursing students.

INTRODUCTION

Effective use of technology among health care providers is critical to patient care quality (Havens, Vasey, Gittell, & Lin, 2010). Today, Registered Nurses (RNs) compose the largest professional group in the health care field, with approximately 2.6 million of those were actively employed in 2009 in the USA (Bureau of Labor Statistics, 2009). One of the primary roles of RNs is communication that is facilitated through the use of technology. Technology facilitates the transfer of information among patients and health care providers that takes place every single day. Communication can be complicated and overwhelming to capture and process. According to Vawdrey, about 65,000 electronic documents were created and used among two medical center campuses within four months between November 2007 and February 2008 to communicate about patient care. Nurses contributed to approximately 33.3% of the electronic documents (Vawdrey, 2008). Therefore, it is crucial for nurses to have good technology skills to support communication. Good communications will not only improve the quality of care among each unit (Havens, Vasey, Gittell, & Lin, 2010), it will also reduce medical errors and improve patient safety (Dingley, Daugherty, Derieg, & Persing, 2008). The purpose of this study is to determine the reliability of nursing informatics self-assessment tool among health care students. It was hypothesized that there would be no significant difference in participant responses for a test/retest survey completed by nursing students.

Nursing communication occurs in many different forms such as oral, written, pictorial, video, and recorded speech (Communication in Nursing, 2003). Currently, communication processing is augmented by technologies such as clinical documentation systems, monitoring systems and others (Demiris, Oliver, & Wittenberg-Lyles, 2011). The transfer of communication (information) using clinical information systems requires certain technologic skills. For example, nurses are required to have the skills to access, locate, retrieve, process information so that the best decisions can be made to influence patient care and outcomes (Eley, Fallon, Soar, Buikstra, & Hegney, 2009).

Technologies are increasingly present in the workforce environment and used to facilitate communication. However, simply using technology without a demonstration of competency does not ensure that information is effectively captured, stored, used, and transferred, and this can impact patient outcome. These are some of the important components of communication. In order to provide effective communication and use of information among nurses and other health care providers, informatics competencies (use and processing of information) for nurses are crucial (Eley et al., 2009).

The nursing informatics competencies means that nurses have adequate computer literacy and information management skills (McGonigle & Mastrian, 2012). For example, knowing how to use e-mail, manage Windows applications, search databases, and the ability to operate institution specific nursing software used for charting and medication administration are all part of informatics competencies (Barton, 2005). However, not all nurses possess adequate skills. Patients’ health outcomes are at risk when health care providers do not possess the technologic skills
required for work environment (Dufault et al., 2010). Additionally, due to the lack of informatics competencies, redundant assessments or laboratory exams frequently occur in healthcare. These redundancies increase the burden and cost for patients and healthcare providers. Furthermore, where nurses cannot transfer information or use information tools correctly, medical errors occur (Institute of Medicine, 2000). Therefore, it is extremely important to identify the nurses’ informatics skills toward the technologies that facilitate information processing, communication and its exchange.

**BACKGROUND**

According to Ackoff, nursing informatics can be examined in terms of theory surrounding data, information, knowledge, and wisdom (1989). Nursing practice begins with the use of data. In our society, more often than not, we are using technology to capture the data.

Data must be contextualized in order to become information. Otherwise data have no value (Ackoff, 1989). For example, simply having a list of blood pressure readings has little value without knowing the larger contexts about when the blood pressures were taken and who these blood pressures belong to. Furthermore, nurses need to have the knowledge to understand and be able to use the information. Information without the knowledge to interpret it is not valuable and of little use. Technology can provide direct access to additional knowledge databases to support their practice and facilitate better decision making. Having wisdom is necessary to know when and how to use the knowledge and information (Graves & Corcoran, 1989). Additionally, wisdom depends on the access to data, information and knowledge. It is important for nurses to access and to have ability to use knowledge bases and technologies related to health care system in order to use information to perform the best patient care.

Technology is ubiquitous across health care facilities (Vawdrey, 2008). Some technologies record and transfer data from monitors to healthcare record, other times they assist health care providers in their efforts to administer medications safely (Wulff, Cummings, Marck & Yurtseven, 2011). The technologies used in the delivery of information are varied and are not limited simply to computers. Many technologies such as Mobile Internet Devices (Smartphone, Personal digital assistant), USB device, and flash drive are frequently used in health care and require the user to have additional skills to use them (Sewell & Thede, 2010).

In 1988, a Commission of Nursing was created by the Secretary of Health and Human Services. The commission supported the use of the computers to improve efficiency for nurses. As a result of multiple efforts, there is an increase of presence and the use of computers in health care (Sewell & Thede, 2010). Nurses believe technologies can reduce burden related to the workflows of documentation, medication administration, and securing equipment and supplies (Bolton, Gassert, & Cipriano, 2008). Some nurses believe using technologies can save their time compare with using paper documentations (Bolton et al., 2008). Therefore nurses could use the time been saved to provide more direct patient care. Some nurses believe that the use of technologies can effectively decrease their workload, and enhance communication (Bolton et al., 2008). Along with the use of information and computer technologies by the nurses, the term “nursing informatics” was developed. The term “nurse informatics” was first used in the MED-INFO conference in Tokyo by Scholes and Barber in 1980 (Sewell & Thede, 2010).

In 1992, American Nurses Association (ANA) identified nursing informatics as a subspecialty of nursing (Sewell & Thede, 2010). Before the creation of the subspecialty, many nurses entered the nursing informatics field without any formal training. They practiced their skills and knowledge during the time of work. Now, this subspecialty is formally recognized via experienced education, and examination, communicating in board certification (McGonigle & Mastrian, 2012). The additional education improves the quality of nursing informatics and prepares nurses to be successful in their positions (McGonigle & Mastrian, 2012).

**What Nursing Informatics is and Why it is Important to Nurses**

The term “nursing informatics” means much more than its literal translation: “nursing” and “information”. According to the definition provided by American Nursing Association, nursing informatics is “a specialty that integrates nursing science, computer science, and information science to manage and communicate data, information, knowledge, and wisdom in nursing practice.” (American Nursing Association, 2008).

Nursing informatics incorporates information technologies with the skills of nurses in health care. It consists of using computer and information technologies, users, and information used during practice (Sewell & Thede, 2010). Nursing informatics also involves cognitive science, which focuses on the design of technologies and
the way nurses think and use technologies. It includes mind, intelligence, and behavior from information development perspective (McGonigle & Mastrian, 2012). Cognitive science helps bridge the gap between modern technologies and clinical practice (Falan & Han, 2011). For example, cognitive science is used to make sure that system and its components can be used and organized in a way that is useful to nurses. It uses modern technologies to help store and provide informations to assist nurses with decision-making (McGonigle & Mastrian, 2012).

For nurses, informatics competency means that certain skills in the use of technology and information management are evident. Most nurses use information technologies in the performance of their daily work (American Nurse Association, 2008). Nursing informatics competencies play a significant role in the use of technology to improve health care delivery from the aspects of quality, efficiency, and safety on a daily bases (Falan & Han, 2011). For instance, nurses perform activities using Health Information Technologies. They review and update nursing care plans and medications on the Electronic Health Record (EHR) every day (Demiris, Oliver & Wittenberg-Lyles, 2011). Competent use of technology impacts many areas of health care delivery from patient assessment to clinical documentation (Warm & Thomas, 2011). By using technologies, accessing patient information can become faster and easier (Bolton, Gassert, & Cipriano, 2008). Additionally, nurses use technologies to conduct research and education. It can help nurses to perform the highest possible quality patient care (American Nurse Association, 2008). Understanding the importance of nursing informatics skills will allow the patients to receive the best possible care (Warm & Thomas, 2011).

Nursing informatics skills are recognized as essential for nursing practice in multiple official documentation including Technology Informatics Guiding Education Reform (TIGER) and The Essentials of Baccalaureate Education for Professional Nursing Practice (American Association of Colleges of Nursing, 2008).

Technology Informatics Guiding Education Reform (TIGER) is an organization to enable nurses to use informatics tools to make health care more effective and safer in the future. It recommends that all the practicing nurses and graduating nursing students develop skills related to nursing informatics including concepts of information and communication technology, using the computer and managing files, word processing, spreadsheets, using databases, presentation, web browsing and communication (Technology Informatics Guiding Education Reform, 2009).

"The Essentials of Baccalaureate Education for Professional Nursing Practice provides curricular elements and frameworks in order to assist with nursing education directions, recommends informatics competencies as necessary (American Association of Colleges of Nursing, 2008). According to the document, “Graduates must have basic competence in technical skills, which includes the use of computers, as well as the application of patient care technologies such as monitors, data gathering devices, and other technological supports for patient care interventions” (American Association of Colleges of Nursing, 2008, p. 17).

Tools to Measure Informatics Competencies

There are different informatics competencies assessment tools including Staggers’ four level measurement tool (Staggers, Gassert, & Curran, 2002), Kaminski’s self assessment tool (Nursing-informatics.com, 2010-2012) and Schleyer, Burch and Schoessler’s five level measurement tool (Schleyer, Burch & Schoessler, 2011), and other assessment tools developed by TIGER (Technology Informatics Guiding Education Reform, 2009), Public Healthcare (O’Carroll, Yasnoff, Ward, Ripp & Martin, 2002), and AACN (American Association of College of Nursing, 2008) (See similarities and differences in Appendix A).

Staggers et al (2002) developed a four level measurement tool (Beginning Nurse, Experienced Nurse, Informatics Specialist, and Informatics Innovator) to classify nursing informatics competencies according to nurses’ ability of manipulate different technologies and information input. The competencies for first level, beginning nurses, are basic computer skills such as the ability to search for patient, access data, and documentation. Informatics Specialists which categorized as level three need to have a higher level of computer skills. For example, informatics specialists need to know how to manage projects with project management software (Staggers et al., 2002).

Kaminski created a self assessment tool to help assess nurses’ informatics competencies levels that are further subcategorized to 3 groups: Technical competency, Utility competency, and Leadership competency (Nursing-informatics.com, 2010-2012). Under each of the category, Kaminski identified different skills. For example, under technical competency, Kaminski named 17 computer applications such as word processing, keyboarding, and spreadsheets (Nursing-informatics.com, 2010-2012).

Schleyer, Burch and Schoessler (2011) divide nurses into five categories: novice, advanced beginner, competent, Proficient and expert. Each category consists of informatics competencies that nurses should be able to
perform during practice (Schleyer, Burch & Schoessler, 2011). This five level measurement tool was integrated with Stagger’s four level measurement tool with ANA’s 2001 Scope and Standards of Nursing Informatics Practice (Schleyer et al., 2011).

TIGER (2009) developed a Nursing Informatics Competencies Model which includes three components: basic computer competencies, information literacy, and information management. TIGER has identified a set of competencies for each component. The competencies were maintained by standard development organizations and evaluated by certain standards. For instance, the standard setting organization for Information Literacy component was American Library Association. Five recommendations under information literacy were made. For example, the first recommendation was that all practicing nurses and graduating nursing students need to have the ability to determine the nature and extent of the information needed (Technology Informatics Guiding Education Reform, 2009).

O’Carroll and the Public health informatics competencies working group (2002) developed a conceptual framework for public healthcare members. Three general classes of public health informatics competencies were mentioned including the use of information, the use of information technology, and development, deployment, and maintenance of information systems (O’Carroll et al., 2002).

AACN (American Association of Colleges of Nursing) emphasizes that nurses have the competences in technical skills, includes the use of computers, the application of patient care technologies such as monitors, data gathering devices, and other technological supports for patient care interventions (American Association of College of Nursing, 2008).

However, the tools they are using to determine informatics skills are either measured by yes or no questions (Staggers et al., 2002), (Nursing-informatics.com, 2010-2012), (Schleyer et al., 2011), or simply name the competencies that nurses need to have (Technology Informatics Guiding Education Reform, 2009), (O’Carroll et al., 2002), (American Association of College of Nursing, 2008). Nurses or nursing students may have difficulties to assess their nursing informatics competencies or cannot determine which part of informatics competencies they need to improve.

METHODS

This study examined the responses of students with different levels of education to determine their self-reported informatics competencies using a repeated measures design. Their responses were classified to five levels of proficiency; no experience, beginner, competent, proficient, and expert as used by Benner (1982). The next section discusses the preliminary work for the study, its design sample selection, measurement tools, and procedures for data collection and analysis.

Preliminary work

A great deal of literature exists on the importance of informatics competencies (Eley et al., 2009; Dufault et al., 2010; Institute of Medicine, 2000). In fact as previously discussed, several different authors have expressed multiple approaches to understanding informatics (Nursing-informatics.com, 2010-2012; Staggers et al., 2002; Schleyer et al., 2011; Technology Informatics Guiding Education Reform, 2009; Essentials of baccalaureate education for professional nursing practice, 2008; O’Carroll et al., 2002). The assessment tools, however, are inconsistent and somewhat vague. Kaminski has demonstrated the greatest depth in developing a self-reported informatics competency dichotomous (yes or no) list of skills. After conversation with Kaminski and permission to use her tool for this preliminary study, Falan (Personal Communication, 2010) modified the scale from a dichotomous scale to a five level scale as addressed above. This study is a preliminary report of the findings using this tool to help gain a better understanding of students’ perceived informatics knowledge.

After Institutional Review Board approval for the study was secured, the survey was given to students in health care curriculum as part of an assignment. Each student had the option to allow the results to be used for research. Those who did not want their responses used for research were removed by a graduate student. All students received course credit for completing the survey regardless of their desire to allow the responses to be used for research. The purpose of the survey was explained to the students and any questions students had about the survey were answered. A link to the survey was made available to 25 students in Informatics course that was open to all students in the university. The survey was completed electronically at the beginning of the course and again 2
weeks later. The survey consisted of five sessions. First section introduced how many questions the survey included, how long the survey takes and the confidentiality of the survey. Second section included background questions such as gender, race and how long have been practicing as a nurse. The third, fourth and fifth sections evaluated technical competencies, including user level, modifier level and innovator level competencies.

Sample and Criteria

The sample size was 25 students in nursing school. A convenience sample was used in this study. The education level of the sample population was students in an informatics course at Western Michigan University. Each participant was enrolled in the informatics course and no restrictions on age, gender, or ethnicity were used. Any student in the course was given the opportunity to complete the survey. Students were excluded from the study if they were not currently enrolled in the informatics course at Western Michigan University.

Recruitment

All students were required to complete the survey as part of a course assignment and were informed via the syllabus and grading criteria. Students were not required to share their responses for research. The professor of the course was not aware of which students allowed permission to use their responses for research. This was controlled by the graduate assistant. The graduate assistant recorded course grades for completed surveys, removed names from all surveys and deleted responses from those who did not wish to have their responses used for research. This is a pilot study.

RESULTS

The survey was completed by a total of 25 participants. All participants completed the same survey twice. 22 (78%) of them were females. One person (4%) was black and 24 people (96%) were white. All 25 subjects chose ‘Not Hispanic or Latino’ as their ethnicity. The mean age was 25.8 with oldest 45 and youngest 20. Among the participants, 44% (N = 11) identified themselves as ‘juniors’. 13 of them (52%) were seniors and 1 person (4%) was a graduate student. Two students (8%) were not in nursing program but currently in another program. More details please see Table 2 and Table 3.

<table>
<thead>
<tr>
<th>Years in nursing program</th>
<th>Number of students</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not in nursing, currently in another program</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>1 year</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>2 years</td>
<td>9</td>
<td>36%</td>
</tr>
<tr>
<td>3 years</td>
<td>10</td>
<td>40%</td>
</tr>
<tr>
<td>4 years</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>5 or more years</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 2. Number of people and percentage based on years in nursing program

<table>
<thead>
<tr>
<th>Highest academic degree</th>
<th>Number of students</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No degree</td>
<td>16</td>
<td>64%</td>
</tr>
<tr>
<td>Associate’s</td>
<td>4</td>
<td>16%</td>
</tr>
<tr>
<td>Bachelor’s</td>
<td>4</td>
<td>16%</td>
</tr>
<tr>
<td>Master’s</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 3. Number of people and percentage based on their highest academic degree
During the data analysis, a total of four values were found missing in the data after data cleansing. The missed values were filled with the mode of other 24 values within the same category. For example, in question 15: uses computer applications to document client care, subject 17 had a missing value in the second survey. The other 24 subjects’ responses were analyzed and the mode was used to fill in the missing value.

T-test analyzing method was used to compare the results of test reference. The responses of the repeated measures were compared for each subject. In order to determine the stability of the tool, it was hypothesized that there would be not change from time 1 versus time 2 in the subject responses.

Among the 14 questions of the section ‘overall experience’, besides presentation graphics p value = 0.016, expert data systems p value = 0.022, telecommunication devices p value = 0.10, nursing information systems p value = 0.50, p values of other competencies are all bigger than 0.05 which means the results were not significant different among those questions (Table 4). Among the 43 competencies of the section ‘technical competencies’, 26 of them had a p value that was bigger than 0.05 which means the results were not significant different. 17 of them had a p value that was less than 0.05. One was less than 0.01 (Table 5). Among the 23 competencies of the section ‘modifier level competencies’, 15 of them had a p value that was bigger than 0.05. Three of them had a p value that was less than 0.01. (Table 6). In the section “Innovator level competencies”, 19 out of 24 questions had a p value that was bigger than 0.05, two of them were less than 0.01 (Table 7).

<table>
<thead>
<tr>
<th>Competency</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Word Processing</td>
<td>-.527</td>
<td>.603</td>
</tr>
<tr>
<td>Keyboarding</td>
<td>.272</td>
<td>.788</td>
</tr>
<tr>
<td>Spreadsheets</td>
<td>-.811</td>
<td>.425</td>
</tr>
<tr>
<td>Presentation Graphics</td>
<td>-2.585</td>
<td>.016*</td>
</tr>
<tr>
<td>Databases (simple to complex)</td>
<td>-1.809</td>
<td>.083</td>
</tr>
<tr>
<td>Desktop Publishing</td>
<td>-1.661</td>
<td>.110</td>
</tr>
<tr>
<td>World Wide Web</td>
<td>.527</td>
<td>.603</td>
</tr>
<tr>
<td>E-mail programs</td>
<td>-1.000</td>
<td>.327</td>
</tr>
<tr>
<td>Expert data systems</td>
<td>-2.449</td>
<td>.022*</td>
</tr>
<tr>
<td>Multimedia</td>
<td>-1.809</td>
<td>.083</td>
</tr>
<tr>
<td>Telecommunication devices</td>
<td>-2.791</td>
<td>.010**</td>
</tr>
<tr>
<td>Nursing Information Systems</td>
<td>-2.064</td>
<td>.050</td>
</tr>
<tr>
<td>Hospital Information Systems</td>
<td>-1.599</td>
<td>.123</td>
</tr>
<tr>
<td>Peripherals (printers, CD-ROMS, DVD)</td>
<td>1.072</td>
<td>.294</td>
</tr>
</tbody>
</table>

These competencies are an expansion of Kaminski’s Self Assessment tool (Nursing-informatics.com, 2010-2012).

* Significant at .05 confidence interval   **Significant at .01 confidence interval

Table 4. Paired t-test survey results N = 25
<table>
<thead>
<tr>
<th></th>
<th>$t$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>uses word processing applications</td>
<td>-1.541</td>
<td>.136</td>
</tr>
<tr>
<td>demonstrates keyboarding skills</td>
<td>-1.549</td>
<td>.134</td>
</tr>
<tr>
<td>uses spreadsheet applications</td>
<td>-1.414</td>
<td>.170</td>
</tr>
<tr>
<td>uses telecommunication devices to communicate with other systems</td>
<td>-1.953</td>
<td>.063</td>
</tr>
<tr>
<td>uses e-mail systems to communicate with other health care professionals</td>
<td>.176</td>
<td>.862</td>
</tr>
<tr>
<td>uses presentation applications to create slides, displays, overheads</td>
<td>-1.769</td>
<td>.090</td>
</tr>
<tr>
<td>uses multimedia presentations</td>
<td>-2.400</td>
<td><strong>.024</strong>*</td>
</tr>
<tr>
<td>uses internet resources to locate client support groups, online resources</td>
<td>-1.681</td>
<td>.106</td>
</tr>
<tr>
<td>uses sources of data that relate to nursing practice and care</td>
<td>-1.365</td>
<td>.185</td>
</tr>
<tr>
<td>accesses, enters and retrieves data related to client care via available hospital or nursing information systems</td>
<td>.253</td>
<td>.802</td>
</tr>
<tr>
<td>uses database management programs to develop and access databases and tables</td>
<td>-1.000</td>
<td>.327</td>
</tr>
<tr>
<td>uses database applications to enter and retrieve data and information</td>
<td>-.618</td>
<td>.543</td>
</tr>
<tr>
<td>conducts online and database literature searches</td>
<td>-1.297</td>
<td>.207</td>
</tr>
<tr>
<td>uses decision support systems, expert systems and other aids for clinical decision</td>
<td>-.647</td>
<td>.524</td>
</tr>
<tr>
<td>uses computer applications to document client care</td>
<td>-1.549</td>
<td>.134</td>
</tr>
<tr>
<td>uses computer applications to plan client care, including discharge planning</td>
<td>-1.541</td>
<td>.136</td>
</tr>
<tr>
<td>uses computer applications to enter client data (demographic, vital signs, ...)</td>
<td>-.901</td>
<td>.376</td>
</tr>
<tr>
<td>uses information management systems for client education</td>
<td>-1.072</td>
<td>.294</td>
</tr>
<tr>
<td>uses technology based client monitoring systems</td>
<td>-2.064</td>
<td>.050</td>
</tr>
<tr>
<td>operates peripheral devices (bedside and hand held)</td>
<td>-.926</td>
<td>.364</td>
</tr>
<tr>
<td>uses operating systems</td>
<td>-2.493</td>
<td><strong>.020</strong>*</td>
</tr>
<tr>
<td>uses computer peripheral devices (CD ROMs, DVD, zip drives)</td>
<td>-1.619</td>
<td>.119</td>
</tr>
<tr>
<td>uses computer technology safely</td>
<td>-2.388</td>
<td><strong>.025</strong>*</td>
</tr>
<tr>
<td>navigates in Windows environment effectively</td>
<td>-1.769</td>
<td>.090</td>
</tr>
<tr>
<td>demonstrates basic technology skills (load paper, change toner, unjam printers, print)</td>
<td>-1.769</td>
<td>.090</td>
</tr>
<tr>
<td>applies technology support to provide evidenced based practice</td>
<td>-1.809</td>
<td>.083</td>
</tr>
<tr>
<td>synthesizes data from more than one source and applies to practice</td>
<td>-1.769</td>
<td>.090</td>
</tr>
<tr>
<td>demonstrates awareness of and ability to access data and information from multiple sources</td>
<td>-2.377</td>
<td><strong>.026</strong>*</td>
</tr>
<tr>
<td>uses decision support systems in practice</td>
<td>1.163</td>
<td>.256</td>
</tr>
<tr>
<td>accesses pertinent literature resources and incorporates into practice and professional development</td>
<td>-1.225</td>
<td>.233</td>
</tr>
<tr>
<td>creates and accesses research and other documents electronically</td>
<td>-1.155</td>
<td>.260</td>
</tr>
<tr>
<td>participates in the design and development of information systems for nursing practice</td>
<td>-1.549</td>
<td>.134</td>
</tr>
<tr>
<td>develops inventive ways to access data and interact with information systems</td>
<td>-2.138</td>
<td><strong>.043</strong>*</td>
</tr>
<tr>
<td>participates in the design and develop design and development of new applications</td>
<td>-1.445</td>
<td>.161</td>
</tr>
<tr>
<td>participates in developing new methods for data and information organization</td>
<td>-2.221</td>
<td><strong>.036</strong>*</td>
</tr>
<tr>
<td>collaborates with information technology consultants and other members of information system development team</td>
<td>-.253</td>
<td>.802</td>
</tr>
<tr>
<td>collaborates, negotiates with and directs information technology vendors</td>
<td>-1.365</td>
<td>.185</td>
</tr>
<tr>
<td>proficiency in diverse computer application programs</td>
<td>.000</td>
<td>1.000</td>
</tr>
<tr>
<td>manipulates and enhances nursing data sets</td>
<td>-1.732</td>
<td>.096</td>
</tr>
<tr>
<td>organizes and directs applications of shared data sets</td>
<td>-.901</td>
<td>.376</td>
</tr>
<tr>
<td>develops data gathering tools and processes for literature search access for nurses</td>
<td>-2.551</td>
<td><strong>.018</strong>*</td>
</tr>
<tr>
<td>develop charting and documentation templates for use in nursing practice</td>
<td>-1.769</td>
<td>.090</td>
</tr>
<tr>
<td>design and development of evidenced based practice documentation and processing within practice area</td>
<td>-2.823</td>
<td><strong>.009</strong></td>
</tr>
</tbody>
</table>

Expansion of Kaminski’s Self Assessment tool (Nursing-informatics.com, 2010-2012).

* Significant at .05 confidence interval  ** Significant at .01 confidence interval

**Table 5. Paired t-test survey results N = 25**
<table>
<thead>
<tr>
<th>Competency</th>
<th>$t$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>applies technology support to provide evidenced based practice</td>
<td>-1.809</td>
<td>.083</td>
</tr>
<tr>
<td>synthesizes data from more than one source and applies to practice</td>
<td>-1.659</td>
<td>.110</td>
</tr>
<tr>
<td>demonstrates awareness of and ability to access data and information from multiple sources</td>
<td>-0.618</td>
<td>.543</td>
</tr>
<tr>
<td>uses decision support systems in practice</td>
<td>0.000</td>
<td>1.000</td>
</tr>
<tr>
<td>creates and accesses research and other documents electronically</td>
<td>-0.972</td>
<td>.341</td>
</tr>
<tr>
<td>understands basic and complex concepts and processes of various computer systems and how they relate to practice</td>
<td>-2.092</td>
<td>.047*</td>
</tr>
<tr>
<td>accesses and utilizes multiple information sources for gathering evidence for clinical decision</td>
<td>-4.243</td>
<td>.000</td>
</tr>
<tr>
<td>upholds ethical standards related to data security, confidentiality and clients' right to privacy</td>
<td>-0.204</td>
<td>.840</td>
</tr>
<tr>
<td>evaluates internet based nursing and health materials for quality, accountability, reliability and</td>
<td>-1.541</td>
<td>.136</td>
</tr>
<tr>
<td>coordinate information flow with multidisciplinary team using information systems</td>
<td>-0.768</td>
<td>.450</td>
</tr>
<tr>
<td>analyzes patient information needs, accesses technology resources to meet needs and evaluate</td>
<td>-1.155</td>
<td>.260</td>
</tr>
<tr>
<td>awareness of role of nursing informatics in the context of health informatics and information</td>
<td>-4.042</td>
<td>.000**</td>
</tr>
<tr>
<td>participates in policy and procedural development related to nursing informatics</td>
<td>-2.138</td>
<td>.043*</td>
</tr>
<tr>
<td>participates in system change processes and utility analysis</td>
<td>-2.221</td>
<td>.036*</td>
</tr>
<tr>
<td>participates in evaluation of information systems in practice settings</td>
<td>-1.661</td>
<td>.110</td>
</tr>
<tr>
<td>analyzes ergonomic integrity of work station, bed side and portable technology apparatus in</td>
<td>-2.193</td>
<td>.038*</td>
</tr>
<tr>
<td>anticipates in design of data collection tools for practice decision making and record keeping</td>
<td>-1.541</td>
<td>.136</td>
</tr>
<tr>
<td>participates in quality management initiatives related to patient and nursing data in practice</td>
<td>-2.982</td>
<td>.006**</td>
</tr>
<tr>
<td>awareness of the impact of implementing technology to facilitate nursing practice</td>
<td>-2.138</td>
<td>.043*</td>
</tr>
<tr>
<td>evaluates security effectiveness and parameters of system for protecting client information and ensuring confidentiality</td>
<td>1.297</td>
<td>.207</td>
</tr>
<tr>
<td>participates in change to improve the use of informatics within nursing practice</td>
<td>-1.899</td>
<td>.070</td>
</tr>
<tr>
<td>encourages other nurses to develop comfort and competency in technology use in practice</td>
<td>-1.549</td>
<td>.134</td>
</tr>
</tbody>
</table>

These competencies are an expansion of Kaminski’s Self Assessment tool (Nursing-informatics.com, 2010-2012)

* Significant at .05 confidence interval       **Significant at .01 confidence interval

Table 6. Paired t-test survey results $N = 25$
was still falling into the 2-3 interval. This showed the reliability of the surveys as well. For instance, on competency 'Presentation graphics', the means for the test/retest responses were analyzed. Results showed that for the same question, the means of the retest questions were answered constantly reliable. For competencies with p values significantly different (p<0.05), the values did not jump into other categories very much. The lowest level of the Likert scale as ‘no experience’ was given 1 point and the highest level as ‘expert’ was given 5 point (as mentioned in section II Method). For instance, on competency ‘Presentation graphics’, the mean of the first time of survey taken was 2.68, and the mean for the second time of survey taken was 2.96 and it was still falling into the 2-3 interval. This showed the reliability of the surveys as well.

DISCUSSIONS

For competencies with p values bigger than 0.05, the results were not significantly different. It means these questions were answered constantly reliable. For competencies with p values significantly different (p<0.05), the means for the test/retest responses were analyzed. Results showed that for the same question, the means of the retest survey was higher than the means of the first test (Table 8). However, the values did not jump into other categories very much. The lowest level of the Likert scale as ‘no experience’ was given 1 point and the highest level as ‘expert’ was given 5 point (as mentioned in section II Method). For instance, on competency ‘Presentation graphics’, the mean of the first time of survey taken was 2.68, and the mean for the second time of survey taken was 2.96 and it was still falling into the 2-3 interval. This showed the reliability of the surveys as well.
Expansion of Kaminski’s Self Assessment tool (Nursing-informatics.com, 2010-2012).

Understands and helps to determine data structures used to organize patient information 1.60 1.92*

Table 8. *Mean results for competencies with p<0.05 (N=25)*

<table>
<thead>
<tr>
<th>Competency</th>
<th>Mean for first time of survey taken</th>
<th>Mean for second time of survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation graphics</td>
<td>2.68</td>
<td>2.96</td>
</tr>
<tr>
<td>Expert data systems</td>
<td>1.88</td>
<td>2.28</td>
</tr>
<tr>
<td>Telecommunication devices</td>
<td>2.40</td>
<td>2.96</td>
</tr>
<tr>
<td>Uses multimedia presentations</td>
<td>2.68</td>
<td>3.12</td>
</tr>
<tr>
<td>Uses operating systems</td>
<td>2.16</td>
<td>2.64</td>
</tr>
<tr>
<td>Uses computer technology safety</td>
<td>3.24</td>
<td>3.72</td>
</tr>
<tr>
<td>Demonstrates awareness of and ability to access data and information from multiple sources</td>
<td>2.68</td>
<td>3.04</td>
</tr>
<tr>
<td>Develops inventive ways to access data and interact with information systems</td>
<td>1.36</td>
<td>1.68</td>
</tr>
<tr>
<td>Participates in developing new methods for data and information organization</td>
<td>1.28</td>
<td>1.64</td>
</tr>
<tr>
<td>Develops data gathering tools and processes for literature search access for nurses</td>
<td>1.32</td>
<td>1.64</td>
</tr>
<tr>
<td>Design and development of evidenced based practice documentation and processing within</td>
<td>1.32</td>
<td>1.68*</td>
</tr>
<tr>
<td>Understands basic and complex concepts and processes of various computer systems and how they relate to practice</td>
<td>2.08</td>
<td>2.44</td>
</tr>
<tr>
<td>Accesses and utilizes multiple information sources for gathering evidence for clinical</td>
<td>1.92</td>
<td>2.52*</td>
</tr>
<tr>
<td>Awareness of role of nursing informatics in the context of health informatics and</td>
<td>2.08</td>
<td>2.80*</td>
</tr>
<tr>
<td>Participates in policy and procedural development related to nursing informatics</td>
<td>1.48</td>
<td>1.80</td>
</tr>
<tr>
<td>Participates in system change processes and utility analysis</td>
<td>1.44</td>
<td>1.80</td>
</tr>
<tr>
<td>Analyzes ergonomic integrity of work station, bed side and portable technology apparatus in</td>
<td>1.64</td>
<td>2.08</td>
</tr>
<tr>
<td>Participates in quality management initiatives related to patient and nursing data in practice</td>
<td>1.52</td>
<td>2.04*</td>
</tr>
<tr>
<td>Awareness of the impact of implementing technology to facilitate nursing practice</td>
<td>2.32</td>
<td>2.64</td>
</tr>
<tr>
<td>Develop charting and documentation templates for use in nursing practice</td>
<td>1.36</td>
<td>1.64</td>
</tr>
<tr>
<td>Ensures inclusion of nursing data and information in design of planned information systems</td>
<td>1.40</td>
<td>1.68</td>
</tr>
<tr>
<td>Synthesizes data and information for knowledge generation within practice</td>
<td>1.72</td>
<td>2.16*</td>
</tr>
</tbody>
</table>

Several factors can contribute to the significant p values. One of the reasons was that students were still in college while the survey was taken. Learning may still take place during the two week interval. For instance, for competency presentation graphics, students might have learned more skills related to presentation graphics during the test/retest period. The results may be affected by the learning process.

Also after taking the survey, the students might actually pay more attention to the competencies that they were not familiar or never realized before. For example, as a student, s/he might not be aware what “expert data systems” are or whether they have this competency or not. The student might look for answers after s/he first time of taking the survey and gave a more informed answer at his or her second time of taking the survey.

Another reason was possibly because students might realize they actually have more knowledge about certain competencies comparing with how much they think they do after their first exposure to the survey. They might change the answers for their retest.

In order to control the influences on dependent variables, a shorter interval period between the test/retest period could be suggested. For example, students could take the survey one week or three days apart instead of two weeks. Before taking the survey, the students might be able to ask questions pertaining to the competencies the survey mentioned. A broader number of students could also be conducted in this research in order to have a more accurate result.

The means for each section of the survey were also being analyzed for the purpose of being able to see where students’ competencies levels fall into (Table 9). Most of the means fall into the 1 to 2 range which were “no experience” and “beginner” (with the exception of user level competencies in the second time of survey taken which was 3.04). This showed that the skill levels fell on the lower side of the scale but they were essentially stable. The table also shows where the educators could focus on during their nursing informatics competency education due to
certain mean values were smaller than others. For instance, the mean values for innovator level competencies were 1.43 and 1.64 which is smaller than other values.

<table>
<thead>
<tr>
<th>Competency</th>
<th>Mean for first time of survey taken</th>
<th>Mean for second time of survey taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience</td>
<td>2.82</td>
<td>2.65</td>
</tr>
<tr>
<td>User level competencies</td>
<td>2.83</td>
<td>3.04</td>
</tr>
<tr>
<td>Modifier level competencies</td>
<td>2.41</td>
<td>2.59</td>
</tr>
<tr>
<td>Innovator level competencies</td>
<td>1.43</td>
<td>1.64</td>
</tr>
<tr>
<td>Modifier level technical competencies</td>
<td>2.20</td>
<td>2.36</td>
</tr>
<tr>
<td>Modifier level utility competencies</td>
<td>2.25</td>
<td>2.51</td>
</tr>
<tr>
<td>Modifier level leadership competencies</td>
<td>1.69</td>
<td>2.05</td>
</tr>
<tr>
<td>Innovator level technical competencies</td>
<td>1.39</td>
<td>1.56</td>
</tr>
<tr>
<td>Innovator level utility competencies</td>
<td>1.68</td>
<td>1.95</td>
</tr>
<tr>
<td>Innovator level leadership competencies</td>
<td>1.67</td>
<td>1.83</td>
</tr>
</tbody>
</table>

These competencies are an expansion of Kaminski’s Self Assessment tool (Nursing-informatics.com, 2010-2012).

Table 9. Mean results for each section (N=25)

CONCLUSION

Nursing informatics competencies for nurses has become crucial due to the increasing present of technologies in the workforce environment. Inefficient informatics competencies affect nurses’ ability of performing optimum health care. This paper conducted the analyzing of a newer developed nursing informatics assessment tool which further expanded from Kaminski’s self assessment tool. The study showed the tool was basically reliable. Recommendations related to the study were a one week or three days interval period between the test/retest, which may decrease variability in its means. Also a broader number of students are suggested in this research.

APPENDIX A

<table>
<thead>
<tr>
<th>Competencies</th>
<th>similarities</th>
<th>Differences</th>
</tr>
</thead>
</table>
| Communication    | Nurses need to know how to communicate and exchange information with each other and how to use technologies to communicate. | Kaminski (Nursing-informatics.com, 2010-2012): Technical competencies  
|                  |                                                                              | Staggers et al (2002): more specific computer skills- email, internet, telecommunications |
|                  |                                                                              | • Uses telecommunication devices (e.g., modems or other devices) to communicate with other systems (e.g., access data, upload, download). |
|                  |                                                                              | • Use e-mail (e.g., create, send, respond, use attachments). |
|                  |                                                                              | • Uses the Internet to locate, download items of interest (e.g., patient, nursing resources). |
| Computer skills  | Nurses need to have basic computer skills in order to successfully administer, communicate, and document information. | Kaminski (Nursing-informatics.com, 2010-2012): named specific skills:  
|                  |                                                                              | Word processing, Keyboarding, Spreadsheets, Presentation Graphics, Databases (simple to complex), Desktop Publishing, World Wide Web, E-mail programs, Blogs, Wikis, Social Media, Expert data systems, Multimedia, Telecommunication devices, Nursing information systems, Hospital information systems, Peripherals (printers, CD-ROMS, DVDs, Mp3s), Palmtops, ipods, ipads |
|                  |                                                                              | Staggers et al (2002): |
information literacy

<table>
<thead>
<tr>
<th>Nurses need to recognize when and what information is needed, conduct with critical thinking skills and evidence based practice.</th>
</tr>
</thead>
</table>

Kaminski (Nursing-informatics.com, 2010-2012): named specific nursing informatics competencies: process of applying evidenced based practice, critical thinking, accountability in the use of selected applications.

Staggers et al (2002): named specific knowledge according to different level but didn’t identify what skills nurses need to have in order to manipulate these processes:

- Beginning nurse: Informatics knowledge: data, impact, privacy/security, systems.
- Experienced nurse: Informatics knowledge: data, research, impact, privacy/security, systems.
- Informatics specialist: Informatics knowledge: data, education, impact, privacy/security, regulations, systems, usability.
- Informatics innovator: Informatics knowledge: education, impact.


Information management

<table>
<thead>
<tr>
<th>Nurses need to use information appropriately applying with accountability. Informatics</th>
</tr>
</thead>
</table>

Kaminski (Nursing-informatics.com, 2010-2012): named specific informatics competencies: process of applying accountability, client privacy and confidentiality and quality assurance in documentation in the use of selected applications in a comfortable and knowledgeable way.

Staggers et al (2002): named specific knowledge according to different level
specialists need to know how the information systems are programmed, maintained, and designed.

but didn’t identify what skills nurses need to have in order to manipulate these process:

- Experienced nurse: Informatics skills: evaluation, role, system maintenance.
- Informatics specialist: Informatics skills: analysis, data/data structures, design, development, evaluation, fiscal management, implementation, management, privacy/security, programming, requirements, role, system, maintenance, system selection, testing, training.
- Informatics innovator: Informatics skills: analysis, design, development, evaluation, fiscal management, management.

Schleyer, Burch, & Schoessler (2011): Named some examples but didn’t list all the skills, more vague: Information management skills were multifaceted, including (but not limited to) applying the data to wisdom concept continuum to support clinical decision making and tell the patient’s story; ensuring data integrity, confidentiality, and security; articulating the value of information systems and their links to improved quality, financial, and satisfaction outcomes; and mentoring peers in their acquisition of higher levels of informatics skill acquisition.

TIGER (2009): generally covered:
A process of 1) collecting data, 2) processing the data, 3) presenting and communicating the processed data as information or knowledge.
(data-information-knowledge continuum). Managed through information systems.

Public healthcare (O’Carroll, Yasnoff, Ward, Ripp & Martin, 2002):
more specific, named skills nurses need to have:

| Table 1: Informatics competencies similarities and differences. |
|---|---|
|    |    |
|    |    |
|    |    |
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REFERENCES


Standardization Needs for Effective Interoperability

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Abstract: The Electronic Health Record (EHR) has brought unique challenges in the effort to share information. How data is captured varies from institution to institution. In order for data to be well understood, data should have a definition that is consistent and comprehensively understood by all users of the data. Standardization of how data is captured is critical to allow the production and export of data needed to support quality assessment, decision support, exchange of data for patients with multiple health care providers and public health surveillance. Patient safety and quality improvement are dependent upon embedded clinical guidelines that promote standardized, evidence-based practices. Unless we can achieve standardization with terminology, technologies, apps and devices, the goals of EHR implementation won’t be realized.

Keywords: Standardization, Interoperability, Electronic Health Record, Meaningful Use

INTRODUCTION

Good data in represents good information out. Better data is critical for better health. Organizational data should be accurate, timely, well-understood, accessible, and efficiently gathered. In order for data to be well understood, data should have a definition that is consistent and comprehensively understood by all users of the data. (Glazer, 2001) Modern medicine is very complex and information about a single patient can be reported in different ways by different doctors who are treating different conditions for the same patient. Utilizing a common terminology that translates complex medical concepts into language that is both clinician and patient friendly improves the quality of care for patients and enhances efficiency.

Department of Health and Human Services (“DHHS”) Secretary Kathleen Sebelius notes that “One of the key challenges to achieving a coherent health record for every U.S. consumer is the need for consistent data across all systems and institutions”. (HHS, 2010) Lack of standardized data often creates reluctance for clinicians to use other clinician’s data. It appears to be oxymoronic that having too many standards creates a lack of standardization. The purpose of this article is to create awareness of problems lack of standardization creates and the progress to date on standardization of electronic health information data.

DOCUMENTATION FOR QUALITY AND REIMBURSEMENT

Standardization is critical to allow the production and export of data needed to support quality assessment, decision support, exchange of data for patients with multiple health care providers and public health surveillance. Private and public payers, public health departments, and independent accreditation organizations asked health care providers to report on quality measures, especially in light of the Affordable Care Act. Quality measures are now being publically reported, and in some cases tied to financial reimbursement. Developing a way to standardize and harmonize data, e.g. using a minimal data set for the universe of measures, would be helpful, especially when working toward data interoperability among many different systems. (Ahmad, 2012)

Although providing accurate documentation that an organization complied with core measure for stroke or acute myocardial infarction is required for optimal reimbursement, allowing each institution to define parameters
and develop flow sheets to capture the information could hinder a standardized method or vocabulary for capturing data. Medical professionals are mobile and practice in more than one organization at any specific period of time. Reporting standardization among Electronic Health Record (“EHR”) vendors is critical, as missing documentation may adversely affect reimbursement.

VOCABULARY STANDARDS
Vocabulary standards for electronic clinical quality measures (“eQMs”) are being developed by the Office of the National Coordinator for Health IT (“ONC”), along with the National Quality Forum (“NQF”) to develop vocabulary standards. One of their goals is to create a standardized model, i.e. the Quality Data Model, turning measure specifications into computable value sets, which can then be used for quality measurement. (Ahmad, 2012)

STANDARDIZATION AND CONSISTENCY OF DATA ELEMENTS COLLECTED
There is lack of standardization and consistency in what data elements are collected, their form and where they are placed in the computer document. Text names of data elements are often defined by the institution and differ from department to department as well as from one organization to another. (Hammond, 2005) An assessment, diagnosis, or medical problem may be documented differently in different medical records. One EHR vendor may use the term Medication Administration Record (“MAR”) where another vendor may refer to the same documentation record as an electronic Medication Administration Record (“eMAR”). One vendor may allow height in inches, others feet and inches or even in centimeters. Weight can be in pounds and ounces or just pounds or kilograms and still others will convert from one to the other automatically, or display both.

Coded Data vs. Free Text
Standardization of data is necessary to create appropriate coded data. Healthcare systems use codes in place of text in many database fields. Procedure codes, diagnosis codes, lab test codes, etc. save computer space and ensure uniform standard codes for accurate interpretation of the data by another user. Codified data allows the data to be shared easily among other users that also have access to the data fields. Text data refers to data that is not codified, and consists of words, sentences and paragraphs. Data interoperability is hindered when clinicians utilize free text documentation. Although text data can be searched with a specific word or word phrases, it does not allow for optimal data sharing. When an organization transfers data to another organization, standardized codified data allows for better data interpretation.

Definition of Terms
Developing, writing and standardizing definition of terms is not an easy task. Developing standardized language is highly complex. For example, nurses, physicians and other medical professionals may have slightly different interpretations of the same word, condition or diagnosis. As a result, each may be hesitant to adopt a defined standard not their own. In short, definitions should be as brief as possible, yet as complex as necessary. Non-standardization when defining code status can be problematic with various definitions and usage of such terms as “Do Not Resuscitate,” and / or “No Code”.

77
Units of Measure

Standardization of data not only refers to a definition of a diagnosis, but also to the unit of measure. When capturing the unit of measure, appropriate standardization should define whether milligrams will be MG, Mg, or mg. Standards, not individual vendors should establish gas or liquids flow (volumetric or mass flow) and how they should be measured.

Data Mining, Business Intelligence and the Need for Standardized Data

Standardized codified data is essential to performing data mining and business intelligence activities. Data mining is used to assist healthcare insurers detect fraud and abuse, help healthcare organizations make customer relationship management decisions and assist physicians in identifying effective treatments and best practices. Data mining can be defined as the process of finding previously unknown patterns and trends in databases and using that information to build predictive models. With the ability of computers, data mining can be used to determine which courses of treatment are effective as well as identify and track chronic diseases states and high risk patients. (Koh, 2005) However, data mining applications can only be implemented with reliability when accurate data is used. Missing, corrupted, inconsistent, or non-standardized data, such as pieces of information recorded in different formats in different data sources is a problem. “In particular, the lack of a standard clinical vocabulary is a serious hindrance to data mining”. (Koh, p.70, 2005)

Business Intelligence (“BI”) is commonly considered to be the “knowledge gained about a business through the use of various hardware/software technologies which enable organizations to turn data into information”. (Kurtyka, 2013) BI allows an organization to access and analyze data about their operations and activities. BI software allows the data to be queried, runs reports and performs what if scenarios. However, information obtained through efforts expended via BI is dependent on clean, standardized data and data formatting in databases, hence again, the need for standardization in obtaining and storing data.

Non-standardization of Laboratory Values

Lack of standardization affects more than simply data terminology and nomenclature. Even when standardized vocabulary is used, the purpose of the data may be different and may not meet the intended purpose of the additional user. One example is how various healthcare organizations define laboratory results, e.g. Within Normal Limits (“WNL”) or Within Defined Limits (“WDL”). If one organization indicates a Troponin level is WNL if the value is <0.01 to 0.5, yet when accepting a transfer patient from another facility, the same test result could have been considered a “Critical” or “Abnormal” lab value, that difference may affect patient care. Another example is the administration of insulin in managing hyperglycemia. Variations in dosing with an insulin sliding scale may exist and be especially problematic with brittle diabetics.

Abbreviations and Acronyms

The healthcare field uses many abbreviations and acronyms. Lack of standardization and misuse of abbreviations and acronyms can create problems with appropriate patient care, especially with medication errors. (The Joint Commission, 2013) The Joint Commission provides a list of approved abbreviations and acronyms as well as a “Do NOT Use” abbreviations list to standardize interpretation. Currently, The Joint Commission allows organizations to develop their own standardized abbreviation lists if using a published reference source. (The Joint Commission 2, 2013) In 2010, the Joint Commission’s “do not use” list of abbreviations was integrated into the patient safety goal requirements, but not applied to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems). However, the requirement remains under consideration for the future. (The Joint Commission 3, 2013)
“Meaningful Use” and its focus on standardization

The Health Information Technology for Economic and Clinical Health ("HITECH") Act allows doctors, health care professionals and hospitals to qualify for Medicare and Medicaid incentive payments when they adopt and meaningfully use certified EHR technology. (The US Department of HHS, 2012) Meaningful use criteria and objectives evolve in three stages over five years with Stage 1 focusing on data capture and sharing, Stage 2 advancing clinical processes and Stage 3 focusing on improved outcomes. As many health care organizations have attested to Stage 1, Stage 2 focuses on more rigorous health information exchange ("HIE"), with increased electronic transmission of patient care summaries across multiple settings. That goal will be difficult to achieve without standardization of data and data capture within standardized formats. (Health IT, 2013)

Throughout many of the Meaningful Use Stage 1 and Stage 2 measures, the thread of requiring the data captured as structured data is prevalent. For Stage 1 and Stage 2 attestation, data such as patient name, race, smoking status, medications, medication allergies and laboratory tests are all required to be captured according to published standards. Smoking status must be coded directly to a standardized SNOMED CT code. (Health IT 2, 2013)

The U.S. Office of the National Coordinator for Health Information Technology ("ONCHIT") in its Stage 2 Meaningful Use criteria address standardization among data formats in an effort to foster intersystem compatibility, allowing the facilitation and ease of sharing information across multiple disparate systems. (Zaleski, 2012)

INTERNATIONAL PROGRESS TO STANDARDIZE MEDICAL VOCABULARIES AND NOMENCLATURE

SNOMED-CT is an acronym for Systemized Nomenclature of Medicine (CT is an acronym for clinical terms). According to the International Health Terminology Standards Development Organization’s ("IHTSDO") website, SNOMED CT is the most comprehensive, multilingual clinical terminology in the world and is a vital component for safe and effective communication and reuse of meaningful health information. (IHTSDO, 2013) SNOMED CT is a standard clinical terminology with specific support for multi-lingual translation and is in use in more than 50 countries. SNOMED CT has been recommended to become the core terminology for codified EHR’s in the United States. The IHTSDO is the not-for-profit association that owns and maintains SNOMED-CT. As of June 2013, SNOMED CT has distributed its first release of the SNOMED CT International Edition.

The World Health Organization ("WHO") utilizes the International Classification of Diseases ("ICD") as their standard diagnostic tool for epidemiology, health management and clinical purposes. The ICD is utilized to assess and analyze the general health situation of population groups and monitors the incidence and prevalence of diseases and other health problems. This classification system is used for reimbursement of medical services in the United States. (World Health Organization, 2013) In 1990, the 10th edition (ICD-10) was endorsed by the World Health Assembly, but is still not used in the United States. As of July 2013, the United States has until October 1, 2014 to begin using ICD-10-CM for diagnosis coding for inpatient hospital reimbursement. Once adoption of ICD-10 is accomplished, the United States will be a step closer to achieving international medical terminology and definition standards. Additionally, IHTSDO has a formal working arrangement with the WHO to develop and assure maps and linkages between SNOMED CT and WHO Classifications. Many SNOMED CT codes have been mapped to ICD-10.

The DHHS published the 2014 EHR certification criteria designating Logical Observation Identifiers Names and Codes ("LOINC") as the vocabulary for reporting lab test results. LOINC can simplify integrating lab test results into an EHR system as structured data. RxNorm has been designated as the vocabulary for medications and is a standardized nomenclature for clinical drugs and drug delivery devices. RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. The Value Set Authority Center ("VSAC") has been designated as the repository for Value Sets that support 2014 Meaningful Use Clinical Quality Measures ("CQMs"). Routes of
Administration and Patient Assessment Instruments value sets will be added to the VSAC soon. (US National Library of Medicine, 2013)

The Unified Medical Language System (“UMLS”) is a set of files and software that brings together many health and biomedical vocabularies and standards to enable interoperability between computer systems. The open source software can be utilized when designing and developing electronic health records to assist in standardizing the processing, grouping, categorizing and release of data in a common format. Three tools used by the UMLS are referred to as their knowledge sources and include the Metathesaurus. The Metathesaurus contains terms and codes from many vocabularies including CPT, ICD-10-CM, LOINC, MeSh, RxNorm, and SNOMED CT. (US National Library of Medicine, 2013)

Medical Devices; Need for Standardization

The mobile health (“mHealth”) market continues to grow and expected to grow in the foreseeable future. Mobile devices, applications and other social media technology provide a real opportunity to help healthcare providers deliver better, more consistent and more efficient healthcare where it is needed, which is often in remote or underserved communities. Evidence from studies indicates remote monitoring and other areas of connected health may contribute to improved clinical outcomes. (Hay, 2012)

Eventually, most mHealth technology, apps and devices will need to be integrated into the EMR. Although many vendors of mHealth technology have developed interfaces allowing integration to a specific EMR vendor, at this time there does not appear to be a mHealth technology national standard for all EMR applications. When each device manufacturer develops their own interface, it stifles the creation of an interoperable device system to provide the needed standardization for use in many EMR applications. Since it is anticipated that payment for mHealth technology will eventually be paid for by insurers and / or through providers via Accountable Care Organizations, perhaps mHealth companies would be in the best position to develop standards to integrate their technology into many EMR systems. (Arnold, 2013)

A medical device regulatory position statement for mHealth,(GSMA, 2012) discusses key policy principles that provide the appropriate balance between ensuring patient safety, while providing an environment for innovation and growth. The regulatory position provides that although differences in medical device regulations vary from country to country, the use of standards has been a key element in establishing medical device regulations and includes a wide range of specifications for products, processes and services.

Organizations such as the U.S. Federal Drug Administration (“FDA”) and the WHO Global Harmonization Task Force have been working to enable interoperability for a variety of products and devices. However, first it has to be determined whether the device is a medical device or a wellness device. The FDA provided the following definition to assist manufacturers and regulatory agencies in a guidance document “Understanding Medical Device Regulation for mHealth-A Guide for Mobile Operators”. (FDA, 2013) Mobile wellness apps may include dietary tracking logs, appointment reminders, calorie counters, and posture and exercise. Whereby mobile medical apps are those intended for “curing, treating, seeking treatment for, mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition”. ABA would require a footnote/citation here for the specific quote. Manufacturers of medical apps should clarify to end users whether the app is medical or wellness as specific regulations apply to medical apps. Although many standards already exist for medical devices, additional standards are needed for current medical devices, software, network service, and mobile platforms (IT system connected to the mobile network) when developing mobile medical products. (GSMA 2, 2012)

Lack of standards is prevalent even when medical devices are supported on an open standards-based data communication like Health Level Seven (HL7). Terminology and units of measurement may not be consistent across medical devices. As discussed, medical ventilators developed by different manufacturers may have parameters that differ in definition from one to the other. Critical values and alarm settings might not have similar parameters from one vendor to another or from one organization to another. Units of measure might not be captured
in a standardized method. If medical device data is going to be relied upon by various medical providers, then standardization of the terminology, measurements and data is essential for proper patient care management. (Zaleski, 2012)

**State and National Health Information Exchange (HIE)**

A health information exchange (“HIE”) is the sharing of EMR data between institutions and clinicians involved in providing a patient’s care. Health care organizations have different EHR systems and the goal of a HIE is to allow this information to be accessed, integrated, and applied to the patient’s current needs. Ideally, all information captured in an EHR will be accessible not only nationally but around the world.

Standards are key to achieving interoperability and meeting the goals of a national HIE. In collaboration between the Office of the National Coordinator for Health Information Technology (“ONC”) and the Office of Science & Technology (“OST”), initiatives have been developed to establish the building blocks of interoperability by standardizing:

- Meaning through the use of standardized healthcare vocabularies
- Structure by leveraging standards in Health Level Seven (HL7)
- Transport using secure email protocols
- Security through National Institute of Standards and Technology (NIST)-adopted encryption standards, and
- Services through open, and accessible application programming interfaces (APIs) (Health IT, 2013)

The ONC is leading the process to establish what is needed for a national strategy on health information exchange. Each state has been provided financial incentives (total from Congress is $548 million) under the State HIE Cooperative Agreement Program to modernize how patient health information is stored and shared. (Health IT, 2013)

The vision for most state HIEs is to allow affiliated healthcare providers to exchange health information across the state. Exchanged health information includes clinical documents, laboratory results, imaging reports and demographic information. The broader vision is that the Nationwide Health Information Network would connect all of the state-based information networks. (University of Michigan, 2013)

Recent legislative developments of Accountable Care Organizations (“ACO’s”), bundled payment options and patient-centered medical homes (“PCMHs”) are motivating providers to participate in health information exchange (HIE) to better share medical information for more effective and efficient health care. (Health IT, 2013)

**CONCLUSION**

The benefits of the electronic health record can only be achieved when multiple users can look at the record and have a common understanding of what is captured in the record. Patient safety and quality improvement are dependent upon embedded clinical guidelines that promote standardized, evidence-based practices. Unless we can achieve standardization with terminology, technologies, apps and devices, the goals of EHR implementation won’t be realized.

However, such standardization is not an easy task. Capturing data in a standardized nomenclature, format and language has proven difficult for those who are developing and implementing the EHR. Modern medicine is very complex and information about a single patient can be reported in different ways by different practitioners who are treating different conditions for the same patient. Sharing of standardized data is still a goal and not a reality. Progress toward standardization is being made, but we are not there yet.
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Data Interoperability and Information Security in Healthcare

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Abstract: Interoperability represents the accurate exchange of information and the use of the information for effective decision making. For information exchange to be interoperable, it must be widely interpretable between multiple information systems. At a more granular level, it focuses on the accuracy, consistency and reliability of information exchanged between systems. The healthcare industry has defined many problems when it comes to the best practice of interoperability. Technical, financial, and managerial barriers are present that produce large scale complex problems for the whole industry. Although, a variety of potential solutions have been developed. Some have even been implemented already focusing on semantics, standardization, patient privacy and security. The private and government sectors of the economy have produced new legal and economic incentives, product innovations, along with widely available educational resources that have shown success. Overall improvements will increase quality of care, patient safety, and decrease associated costs across the entire healthcare industry.

INTRODUCTION

Interoperability in its most concise explanation is the ability of systems to exchange information and then use the information exchanged effectively (IEEE, 2013). Problems of systems interoperability are prevalent in the healthcare industry and recent regulatory changes have caused drastic business strategy shifts within the sector. In prior healthcare system implementations, vendor solutions had minimal incentive to standardize any aspects of their Health Information Exchange (HIE) and the information systems they were bound to. Overall, HIE aims to keep records, diagnosis, and treatment integrated between healthcare organizations to ensure patient data integrity along with preventing data loss (Dimitropoulos & Rizk, 2009). Marketplace dominance of specific vendors has caused defacto standardization, bringing a series of unique problems to progress in regard to interoperability, security and the business operations it supports. The need standardized models in systems design for industry technology is being demanded (Association for the Advancement of Medical Instrumentation, 2012). A key success factor brought to light is the cooperation between the practitioners, the industry and the standards bodies (Aylward, Woodhall & Lent, 2007).This preference shift is a result of regulatory compliance and is defining the need for data interoperability with best practice security measures implemented along its side.

Security concerns of the systems design are placed at a much greater priority in the healthcare industry. Privacy concerns with patient data and the high level of risk in the decisions it supports are the important factors to consider. The fear of losing patient information while exchanging data is also a high risk, promoting further importance of all healthcare stakeholders to collaborate (Dimitropoulos & Rizk, 2009). Poor security is a potential symptom of non-standardized systems that communicate. A strong need is recognized from the following perspectives of security: “authorization and authentication, user access, and audit of patient record access and modification, uniform identification of patients, security of data during transmission and at rest (Johnson & Appari, 2008)”. Through market cooperation the overall cost and efficiency of HIE can be improved, producing more timely and accurate information for decision making. From an economic standpoint, there is an untapped source of profit for companies that choose to produce standardized, integrated solutions. With proper implementation of healthcare systems interoperability, industry savings are estimated as large as $77 billion per year (Johnson & Appari, 2008).

When information is truly interoperable, it has the ability to be widely interpretable from a variety of different subjects. Doctors, nurses and all healthcare employees have reached an information access barrier, putting
a threshold on using the information available for effective decision making. The United States (U.S.) Government has promoted interoperable EHR growth through an incentive program, already shown to increase the adoption of comprehensive EHR adoptions since the year 2009 (CDC/NCHS, Nation Ambulatory Medical Care Survey, 2010). See figure 1 in the appendix for a detailed time series graph, comparisons are made between three different EHR criteria. Over half of the reporting health organizations have an EHR/EMR system in use, although only ten percent in the year 2010 have fully functional ones operating with meaningful use.

Data interoperability within healthcare was a problem produced by a variety of discontinuous industry solutions. In the 1970’s-1980 the first “practice management” software emerged to increase efficiency (Houston, 2013). No standards existed between vendors that developed this software which required people to reinterpret, input and update data manually between systems. Even if data could be exported, the potential for inaccurate or unreliable information in the transfer process was at high probability. The digital records concept was labeled Electronic Medical Records (EMR) which later on became the conceptual data component of comprehensive Electronic Health Record (EHR) systems. In 2009, the American Recovery and Reinvestment Act (ARRA) included a secondary act called the Health Information Technology for Economic and Clinical Health act (HITECH). HITECH produced a series of financial incentives for health organizations to increase overall EHR system adoption. If “meaningful use” is displayed through a successful audit of fifteen core and five menu set items, the organization is eligible for an incentive payment. More importantly, organizations that choose not to adopt will be financially penalized in the future (Wolf, Harvell, & Jha, 2012, p. 505-513).

Through our research, problems associated with HIE interoperability are categorized, analyzed and discussed while reviewing proposed solutions. Background information was obtained from a variety of accredited sources and specific case studies were chosen for their unique solution proposals of problem areas. Within the two main case study analyses our research teams own understanding, conclusions and recommendations are discussed. Healthcare interoperability is a business objective, so the financial aspects, policies and regulatory changes were reflected in our evaluation as well.

**Literature Review**

The topic of data interoperability has a short, rapid evolution within the healthcare industry. As recent as 2006, fewer than 10% of hospitals in the United States had a full intergraded Electronic Medical Record (EMR) system (Smaltz, D. H., & Berner, E. S, 2007). An EMR by itself displays patient data normally found in a “paper chart”, used for diagnostic processes (Healthit.gov, n.d.) EMR represents the first major product of change when healthcare organizations switched to digital systems. EMR’s were of the first technical components within healthcare representing major issues of interoperability. Technical standards have been created from an information systems perspective, although the variety of standards used still leaves interoperability issues with communication. The technical standards created were at first divided on an international basis. Many European countries have enforced technical standards for their information systems, such as those developed by the European Committee for Standardization (CEN). Health Level Seven (HL7) is an international healthcare informatics interoperability standards body popular with regulation changes in the U. S. Although, the standards set in place by HL7 still do not fall under “open standards” but their specifications as of 2002 have been placed into the public domain (wiki). Furthermore HL7 in 2012 decided to promote interoperability within the healthcare industry through the release of most of its intellectual property (IP). HL7 previously operated under a licensing model that required businesses that used its standards to license them at a fee. This recent choice landmarks an important issue, as HL7’s standards are viewed as defacto in much of the industry. After releasing their IP, a large component of their research and business will be available for use for free. This will potentially influence greater competition in the market place for software, hardware and technical solution vendors. The reduced barrier of implementation will result in greater quality of care and reductions in cost overall for providers. These two factors directly influence the adoption rate within the marketplace, offering a large positive change for interoperability in healthcare.

The issue of interoperability within the United States healthcare system is one of a half implementation. The topic of “semantic interoperability” is a specific reason issues of incompatibility arise. Syntactic standards exist from a purely technical point of view, although the lack of semantic compatibility causes problems of definition when data is being interpreted. Semantic interoperability is best defined as “Ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards.”(IEEE, 2013). This issue in itself promoted the creation of EHR systems, which poses unique advantages over simpler EMR based systems. EHR systems are designed with interoperability as a focus, so EMR’s are often used as data source for EHR systems. The difference between the two is important, as
they serve different purposes within the healthcare IT industry. A primary difference between them is the scope of EHR. EHR systems are designed to share patient data between health care providers. A clear definition was made by The National Alliance for Health Information Technology (NAHIT) as data that “can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization.” (Healthit.gov, n.d.) The overall goals of EHR are directly correlated with the goals of an interoperable HIE for patient data. Direct benefits of secure access to the latest information for patients are clear. Healthcare providers are businesses that rely on fast interpretation of accurate data to perform their duties most effectively. Effective EHR implementation ensures specifics such as an individual’s recent life threatening health changes, clinician’s notes and updated lab results are securely accessed and universally interpreted.

Statistical data from 2009 detailing the use of comprehensive EHR systems shows a low actual adoption rate. Only 1.5% of hospitals have comprehensive EHR systems, due largely to concerns of cost, technical support and physician resistance (Massachusetts Medical Society, 2009). Recent U. S. legal regulatory changes are directed at increasing this adoption rate. The HITECH act was signed into law shortly after this adoption rate statistic was produced in 2009. The goal is to ensure the proper implementation of EHR systems through economic incentives, if the outlined government criteria are met by providers. HITECH provides a three stage initiative, with data interoperability as the core method and tool of overall improvement within the health care industry. In stage one, providers must digitize all records and regularly use digital records for care decisions. Stage two is where interoperability is first introduced; organizations must show they can “share records with other providers, regardless of the EHR systems in use.” Stage three represents the final goal of “meaningful use”, representing a positive social externality globally. Stage three will allow better understanding of the large amounts of data collected through the use of analytics. Analytics allows for the ability to “learn from the electronic information” through data mining and other statistical computations (Blumenthal, M.D., M.P.P., 2011).

Healthcare providers take part in semantic interoperability with the use of phone, fax, email, hardcopy and, in some cases, electronic exchange. Without these communication methods, specialist referrals and procedure scheduling would be a much more difficult operation. Modern semantic interoperability requires time resource constraints and is affected by latency issues with high error probability. This is in part due to the multiple avenues of sending information. Partners in the healthcare system use a variety of access media and delivery methods. This inconsistency in their choice to send and receive information often results in information duplication. Another pitfall of varying access media and delivery methods is the unaccountable lost information during the transportation and interpretation process. Data loss remains one of the greater symptoms of non-interoperable systems (Bass, & J P Systems, Inc., 2011).

Beyond the medium the message is delivered in, the actual message can change from partner to partner. Various participants in healthcare have created systems of communication amongst themselves. Synonyms and homonyms can cause a great deal of problems between healthcare providers and their partners. A single provider may go into great detail concerning a procedure or process; whereas another has minimal information about the same procedure or process. Organizations in general may use the same name or phrase between different functional processes. Some terms may be incorrectly interpreted between providers for the same symptom, disease, illness, etc. Deciphering the terminology varying providers use and aggregating them into a standardized library is a difficult technical and managerial task. Implementation would have to work through push back from industry employees, whom may be unwilling to adapt to new terms or have issues of understanding during the changeover process (Healthcare interoperability, 2011).

On the technical side, the matching and mapping of terms can be broken down into multiple levels as well. Technical problems within semantics and syntactic design can be classified in four main area of heterogeneity. Syntactic heterogeneity comes about with differences in the language used for representing the same elements. Structural heterogeneity shows differences in the types of element structures. Model and representational heterogeneity explains the differences in database models (i.e. Relational, Object-oriented, RDF, OWL, etc.). Semantic heterogeneity defines how the terms are represented. (Nagarajan, Verma, Sheth, Miller, & Lathem, 2006). These well classified problems of semantics within the industry are the first step to obtaining solutions. By breaking the semantic and syntactic issues down into manageable levels, solutions can be created much more timely and reliably.

The next task, with the integration of terms and definitions to a standardized form, is the relation of the technical syntax to the semantic meaning. Using the proper syntax ensures the structure of information will remain intact, but there is no guarantee it will be understood universally by all parties. Web-based programming languages represent this same concept; any computer that uses the internet is able to interpret the structure of the information sent to it. However, if pages displayed are created in a foreign language, a viewer unfamiliar with that language will have interpretation problems. Semantic interoperability of person to person communication makes certain the
message is understood by the parties sending and receiving messages. Documents need to be created with standardized structure and terminology implicit to professionals in the medical field, leaving no question as to the purpose of the message communicated. A final measure in addressing problems of semantics is the creation of computable semantic interoperability. Ensuring proper delivery of straight-forward messages via electronic media used to make appropriate decisions based on the meaning contained. (Mead, n.d.). The human interpreter is the last component of the communication process. If all technical errors and standardization of the information are solved, the scope to which interoperability represents the problem has at least reached its technical boundary.

The U.S. Governments incentivized push for hospitals and medical treatment facilities to convert to comprehensive EHR systems has caused concern for the security of patient’s medical records. With the variety of non-interoperable system structures, often raw data of unsecured exports are the only means of interpretation. Once in an unsecured, unaccountable exported format, the risk a privacy breach is drastically increased. In the final ruling for the modifications to the “HIPAA Privacy, Security, Enforcement, and Breach Notification Rules” these concerns were addressed (U.S. Department of Health and Human Services, n.d). Security has been an issue since the conception of the idea for EMR’s and many statistics of breaches and problems have been well documented. In 2012, there were 154 breaches reported with 2,237,873 records lost in those breaches (Identity Theft Resource Center, 2012). The records lost, manipulated or accessed by unauthorized individuals constituted as 13% of the medical records stored by compliant reporting health agencies nationwide.

The government and military have been using EMR’s longer than the general populace due to rapid and frequent movement of soldiers internationally, along with the greater risk of health adverse situations they may encounter. Problems of interoperability and personal health information (PHI) breaches were first experienced within this sector and on person hardcopy backups were frequently ruined from environmental conditions. In addition, medical records in a physical format can be altered with no secure measure of accountability. With this thought in mind the U.S. Military started the Composite Health Care System (CHCS) in 1988. This was developed in hopes of keeping medical records intact, correct, and readily available. CHCS was combined with the Armed Forces Health Longitudinal Technology Application (AHLTA) which made it easier for doctors to add notes into medical records without having to access the entire record. This Military program has been an inspiration for the civilian health care sector to follow suite. Although no implementation has remained risk and breach free, TRICARE, the Department of Defenses (DOD) health care program has reported over 4.9 million records were compromised in a single incident (Mearian, 2012). Prior to EMR, health professionals requiring access to an individual’s medical record had physical restrictions and time constraints as influencing factors. With the removal of these two factors through advancements in technology, the balance between security and convenience must be properly aligned. An example of a technology involved in this balance is Radio-frequency Identification (RFID). A company based out of Florida in 2008 started the controversial practice of offering implanted RFID in patients who requested and consented to the outpatient surgery (Business Wire, 2008). This device is about the size of a grain of rice and can be read electronically to obtain medical record and emergency contact information. Quicker access to a patient’s medical information is the advantage, although it also gives this information to anyone with an RFID reader. Identity theft cases have been previously documented in cases of RFID credit fraud, so the same concerns for privacy of health records exist with these RFID implants.

In the Final Ruling of the HITECH for the adjustment of HIPAA, there are several new definitions and connections between any organizations involved in the transfer of patient medical information. Any Health Information Organization (HIO) that handles patient medical information on a regular basis have been reclassified as “business associates” and are accountable for information loss or breach that occurs (Gajanayake, Iannella, & Sahama, 2011). The creation of accountability for incidents promotes safer access overall, although specific technical requirements preventing data loss or attacks are absent. The updated polices in HIPAA and HITECH act largely just increase the penalty for incidents and promote a more stringent reporting procedure. The lack of outlined specifics is a burden the HIO management must handle and is also left up to individual companies providing certified EHR systems.

Analysis and Observation

From our research, the advantages of Interoperability are quite clear from a purely technical perspective. Although considerations of all variables and constraints a business operates under must be accurately evaluated to determine the benefits offered. By technical definition, Interoperability allows uniform integration and communication of information systems. Advantages derived from interoperable systems working together must also be recognized for the malicious aspects created in the process. Malicious code spreads well within environments that are predictable,
assessable, and interconnected. These three advantages can very well also become advantages of adversarial operations. If a hospital has a standardized and interconnected environment, greater security responsibilities are a burden of the business. When the security of the infrastructure and polices are not aligned, the advantages of interoperability are quick to be lost at the expense of the risk it produces. Through our research, the cost benefit of implementing government certified interoperable EHR suites must be justified alongside the security budget of the organization. This relationship is a common tradeoff when a business chooses to upgrade or add new technology to their operational model. When new technology is implemented, new and unique problems also arise alongside it.

The financial component of businesses is the primary reason a business can continue to exist. Without positive net income, operations cease and the institutions can no longer justify their continued existence. The U.S. Government understood healthcare cost driven objectives well when in 2009 the American Recovery and Reinvestment Act (ARRA) was passed subsequently including the HITECH act. HITECH produced a series of financial incentives for health organizations to increase overall EHR system adoption nationwide. If “meaningful use” is displayed through a successful audit of fifteen cores and five menu set items, the organization is eligible for an incentive payment. More importantly, organizations that choose not to adopt will be financially penalized in the future. With the economic incentives, a relationship is shown when communicating the value in a nationwide HIE. By the U.S. Government offering immediate return on investment, the cost justification for each individual business was greatly persuaded. The comprehensive EHR system adoption rate statistics are the most influential key performance indicator available when measuring the effectiveness of the HITECH program. The adoption rate continues to increase, although as outlined in HITECH, the momentum created by incentive payments may not last in its current outlined state. The payments began in 2011 and will continue to offer a payout for the next five years, but after this time period actual penalties will be incurred. The incentive payment structure is outlined in figure 2 of the appendix. The penalties original intention is to push hesitant HIO’s to adopt, although the actual number of these has yet to be determined. Thus, a nationwide HIE loses its effectiveness if an exponential increase is not represented in a timely manner (Centers for Medicare and Medicaid, 2013).

Case Study and Discussion

Our industry research performed brought about two main categories of problems in relation to interoperability within healthcare. The first area discussed contains perspectives from the technical and fundamental focuses when reviewing semantic problems of information exchange. The second problem area addressed is the security and privacy concerns of patient records in a comprehensive interoperable system environment. Each of these two core problem areas were analyzed with a prior case study focused in the aforementioned specific problems. Each core problem area of interoperability is further discussed and defined within the scope of the case study they derived from. After proper definition is given to the problem area, the solutions are discussed and analyzed.

The issue of semantics is a primary task in solving overall communication problems of interoperability between EHR systems. HL7 is a standards body that has released effective technical whitepapers and resources on their widely used protocols and data models. Their framework is a potential overall solution to many of the technical problems experienced within HIE. The request for standardization is easy to create, but forming a government team responsible for its oversight requires resource planning and time. With the release of HL7’s standards into public domain, focus has been given at implementing their de facto standards as true standardization following all of HITECH and HIPAA regulatory principals (Health level Seven, n.d).

In the case study “Semantic Interoperability of Web Services - Challenges and Experiences” HL7’s publically available standards are discussed from an “ontological” perspective (Mendes, & Rodrigues, 2011, p. 1). The study describes the “semantic web” in relation to the widely discussed interoperability issues within healthcare EHR systems. The authors propose a contrasting view to other industry solutions. The analyses determined interoperable semantic issues are best solved by restraining from hard coded strict standards. A focus on the use of “model-based” specifications for EHR system design is discussed. In the studies model-based approach, a strict representation to promote full interoperability would exist, while remaining open enough to allow updates and revisions over time. This primary distinction separates this specific study from more common recommendations of centralized vocabulary databases, which are still discussed as a supplemental solution.

Through the design of these models, benefits of interoperability are further explained. Attaining the design and definition middle ground of the proposed HL7 based models will allow true integration of future software updates. This function based methodology is called Service-oriented Architecture (SOA) and industry wide adoption of such design methods could promote a drastic increase with interoperable software and hardware brought to
market. A root of the interoperability problem is the vendors who design and create solutions sold to health organizations. If their product design process can be influenced, the phased software and hardware upgrades will eventually fade out non-interoperable components (Mendes, & Rodrigues, 2011).

Every implementation of a solution brings unique and different problems forward. Within the systems development lifecycle, it is common for security to be implemented in a post-facto manner. Although, post-facto implementation goes against best practice principals of system design and information security. The scope size and investment risk at stake in the healthcare reform finds post-facto security as an unacceptable practice. Security and privacy concerns have been discussed greatly from top to bottom approach, formulating policy and regulations to guide the reformation process. The HITECH act brought forward updated regulations for security and privacy guidelines within HIPAA. The case study “Sharing with Care” discusses “information accountability” as an effective security and privacy strategy to follow new outlined regulatory requirements (Gajanayake, Iannella, & Sahama, 2011). Furthermore, the study focuses on “privacy by design”, a direct solution to post-facto security implementation. A proposal is made that if e-health systems are designed around proper methodologies, patient privacy will actually increase. Many websites collect general and medical information through consumer ignorance of data tracking. Consumers unknowingly waive and reveal potential ailments through publically available diagnostic sites that operate legally with debatable ethics. Data ownership of the individual is an increasing request as more information is stored in cloud based infrastructures. In healthcare, the accessibility of personal health records (PHR) is the classification term to represent this data. As for patient privacy, the problem is therefore best defined as one of accountability. Websites utilizing data mining techniques which then sell market research data are not required to be accountable for the freely available information they collect. If consumers had options of using a regulated service, with their personal standardized records this business model would prove less effective. In the updated HIPAA regulations, HIO’s are required to “provide access in electronic format” which promotes the aforementioned principles. (Blumenthal, M.D., M.P.P., 2011). Prior to this regulation, this level of patient access would likely not have been implemented in EHR systems. The ability a customer to access PHR’s anywhere and anytime is significant from a compatibility standpoint as well. Providers that forgo the economic incentive and receive penalties would still be able to view PHR’s produced by compliant organizations. Thus, this regulation promotes a global positive externality and benefits the public quality of healthcare for all individuals.

As determined in earlier analysis and observation, addressing privacy concerns of PHR’s is an influential point in overall adoption. Specific policy has not been standardized for the measures each health organization must put in place. Instead, reasonable efforts must be made by the business to protect patient data. This study addressed the concept of accountability from a top down approach to provide overall security. Accountability within EHR systems were divided into three factors. The “identification of accountable parties, issues a party is accountable for and the appropriate mechanisms for accountability make up the accountable best practices of a certified EHR system” (Gajanayake, Iannella, & Sahama, 2011). The first factor, identification of accountable parties, is best explained as a classification and segregation process. Through categorization, the parties’ level of access can be determined. The goal of secure information access is achieving the proper level of access and ensuring the correct access is given to perform a specific task. Understanding what constitutes as a privacy invasion is an important activity to define as well. If a doctor, technician or any other employee has no purpose for accessing a record and they do, a breach in privacy has occurred. The process and components of how a proper accountability mechanism works are displayed in figure 3 of the appendix. Identifying the information requested along with the information seekers required level of access leads to proper privacy protection. With proper accountability tracking, violations could be tracked and proper discipline and penalties of an individual addressed.

Conclusions and Recommendations

Interoperability represents a vital and core focus of the modern healthcare reform. Understanding why it is a problem can continue to be analyzed at an ever more granular level. If the government incentive program for healthcare organizations is able to drive the expected results, numerous positive benefits will be gained domestically and globally. The financial gain of properly implemented HIE is not derived from new and profitable income, but instead directed at cutting the overhead costs, saving time, and preventing waste from an operational standpoint. When the entire healthcare industry experiences cost reduction, the government related programs also experience benefit. Programs such as Medicare and Medicaid will require less funding to sustain their current operations, reducing the contribution to the overall United States deficit. This economic reform technique known as “cost-shifting”, showcases a unique and rapid approach to changing an entire industry. At a worldwide economic level, the movement of interoperable systems within healthcare promotes great overall positive change. The government in
many ways also operates like a business and it clearly sees the return on investment capable in a nationwide HIE project.

In addition to our economic based conclusion’s, the security and privacy aspects of a nationwide HIE were researched and analyzed. The concerns discussed specifically with interoperable systems were found to hold much less weight than added benefits of security and accountability created. The current design methodologies driving nationwide HIE are in depth, and vendors are taking due consideration from the initial design phases to incorporate security, accountability and standardized semantic meaning in new hardware and software. Furthermore, the incentives offered by the government are only for certified EHR systems. Government certified software promotes EHR vendor competition and quality control for software design influence. In the event a security exploit exists, the issue can be tracked, understood and resolved much quicker than in dispersed information system islands. From a privacy standpoint, the non-interoperable EHR systems in use offer almost little or no accountability. If a practitioner or anyone in the office wants to access information on a patient, they may do so whether it is relevant or not. A nationwide HIE will include strong aspects of accountability as a security measure for privacy. Whenever a specific record is accessed, the patient will be in complete control of knowing who accessed their record, when it was accessed and why. If the record was improperly accessed or maliciously accessed, the accountability is present to discover who is at fault for the breach. While this may not stop patient record privacy breaches, the ease of traceability certainly produces valuable follow up information to solve future problems (Gajanayake, Iannella, & Sahama, 2011).

APPENDIX

Figure 1: (CDC/NCHS, Nation Ambulatory Medical Care Survey, 2010)
## Maximum Incentive Payments for Medicaid EPs Who Are Meaningful Users in the First Payment Year

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Figure 2: (Mullin, & Hitechanswers.net, 2011)

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Figure 3: (Gajanayake, Iannella, & Sahama, 2011)
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Michigan Health Information Network (MiHIN) Shared Services vs. the HIE Shared Services in Other States

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Abstract: This paper explores selected states health information exchanges in regards to how they are implemented and used. Health information exchanges are broken down and a concise background is given for a better understanding of how states are implementing their health information exchanges. This paper not only examines states use of their health information exchange, but how they will connect to create a nationwide health information network.

INTRODUCTION

There are many different HIEs currently being implemented across the country in many different states. We will look at the similarities and differences of these, as well as explain how each one functions. Most states offer the same or similar core services, however some states offer more advanced services than others. The main goal is to eventually create a system of interoperability between all of these individual state’s HIEs to lead to the creation of one Nationwide Health Information Exchange.

History

The ultimate goal of the health information exchange (HIE) is to have a national network that enables the sharing of a patient’s electronic health records (EHRs) from anywhere across the country. The exchange of data on this health information network (HIN) would drastically improve the quality of healthcare in our country by making important medical records available in real-time whenever they are needed.

The history of HIN dates all the way back to 1990, when the Hartford Foundation gave out several grants to different cities for the purpose of building what they called a, “community health management information system.” This was the first major attempt to create a system that exchanges health information electronically (NORC at the University of Chicago, 2011).

None of these systems ultimately survived, primarily due to the lack of affordable and effective technology. Also once the grant money ran out it was difficult to find funding because it was not clear who should pay for it and that the return on investment was minimal.

During the mid-1990s another form of HIE was created—Community Health Information Networks or CHINs. Whereas the efforts in 1990 were grant funded, CHINs were mainly commercial efforts primarily aimed at reducing costs by sharing data. However most of these CHINs failed, largely because of the same problems faced in 1990.

In the early 2000’s a new type of HIE organization began to arise. These organizations, called Regional Health Information Organizations (RHIOs) were local third-party organizations that facilitated the information exchange between providers within a small geographical area. The RHIO was an attempt to achieve more efficient and effective healthcare. RHIOs continue to develop to this day.
In 2004, the Department of Health and Human Services began developing the National Health Information Network. In 2009 the Health Information Technology for Economic and Clinical Health Act, or HITECH Act was passed. The HITECH Act incentivized the use of EHR systems. In order to get bonuses from Medicare or Medicaid, doctors, hospitals, or other providers must be able to exchange EHRs with each other.

FUNCTIONS AND DEFINITIONS OF THE HEALTH INFORMATION NETWORK

The electronic movement, transfer, and sharing of health-related information is a set of national standards known as the Health Information Exchange (HIE). This allows for medical information to be shared and accessed from a secure electronic system eliminating the need for a paper-based system. HIE is a network exchange system that works to exchange a patient's critical information while keeping records up-to-date.

There are three forms of electronic medical records in place today, an Electronic Medical Record (EMR), Electronic Health Record (EHR), and a Personal Health Record (PHR). An EMR is a patient’s information within one organization. For example, if a person was admitted to Bronson Hospital, all of Bronson’s locations and entities would have access to that patient’s EMR. It would be full of all the information collected on that specific person and only shared within Bronson.

Personal Health Records (PHR) allow an individual to share, update, and control their information. However, all information conforms to nationally recognized interoperability standards. This method will be least implemented. If patient’s have access to their information, not all information could be correct and the chance of bad or incomplete information is higher.

The most important electronic record, and the most used throughout all HIE’s is the Electronic Health Record (EHR). An EHR can be defined as “any information relating to the past, present or future physical/mental health, or condition of an individual which resides in electronic system(s) used to capture, transmit, receive, store, retrieve, link and manipulate multimedia data for the primary purpose of providing health care and health-related services.” This allows for patients information to be accurate and up-to-date. Patients will not have to repeat information for new doctors or forget an important factor that is related to their health. The time to retrieve a patient’s record is diminished because a hard copy is not required. All of a patients information can be accessed, analyzed, and updated (if needed) to help formulate the patients diagnosis. An EHR is an important step and crucial element in creating a Health Information Exchange Network (HIEN).

Data Exchanged through HIE’s

Multiple information can and will be exchanged through an HIE. Some of the most prominent data exchanged will be laboratory and radiology results, as well as patient care summaries and prescription information. Other networks within the HIE include data from emergency departments, claims and insurance information, inpatient discharge summary, and pathology among others.

Benefits of HIE

Implementing an HIE has many benefits but the main ones are:

- Improved Speed
- Enhanced Quality
- Improved Safety
- Reducing Cost of Patient Care
- Greatly improved completeness of patients records

Physicians will have the ability to instantly find, view, edit, and share medical information. Access will be granted to physicians from local, state, and regional governments as well as organizations such as the Centers for Disease Control (CDC) and other federal agencies.
Value of HIE

The most valuable asset of implementing a health information exchange network is the standardization of data. Once standardized, the data transferred within the HIE can seamlessly be integrated into a patient’s EHR, thus allowing for improved patient care. Electronic signatures will be implemented. All information within an HIE organizes data from multiple sources and brings it into one standardized set of information.

Users of HIE

Physicians will be the primary users of a Health Information Exchange Network and electronic health records. Nurses, pharmacists and other healthcare providers will be able to access patient information from the local, regional, state, and/or the nationwide health information exchange network. Patients, if granted permission by the HIE within the area, will be able to update and edit their information through their personal health record (PHR).

THREE KEY FORMS OF HIE

It is important to know the different ways in which information can be exchanged throughout an HIE. The three key forms are direct exchange, query-based exchange, and a consumer mediated exchange.

Direct Exchange

“Directed exchange gives health care providers the ability to electronically send and receive secure information—such as laboratory orders and results, patient referrals, or discharge summaries—to other health care providers involved in a patient’s care over the Internet via encrypted, secure, and reliable messaging” (The 3 Key Forms of Health Information Exchange, 2013).

“Directed exchange is used by providers to easily and securely send patient information—such as laboratory orders and results, patient referrals, or discharge summaries—directly to another health care professional. This information is sent over the internet in an encrypted, secure, and reliable way among health care professionals who already know and trust each other, and is commonly compared to sending a secured email. This form of information exchange enables coordinated care, benefitting both providers and patients. For example, a primary care provider can directly send electronic care summaries that include medications, problems, and lab results to a specialist when referring their patients. This information helps to inform the visit and prevents the duplication of tests, redundant collection of information from the patient, wasted visits, and medication errors.

Directed exchange is also being used for sending immunization data to public health organizations or to report quality measures to The Centers for Medicare & Medicaid Services (CMS)” (What is HIE?, 2013).

Query-based Exchange

Query-based exchange gives health care providers the ability to find and/or request information on a patient from other providers and is often used for unplanned/emergency care.” (The 3 Key Forms of Health Information Exchange, 2013).

“Query-based exchange is used by providers to search and discover accessible clinical sources on a patient. This type of exchange is often used when delivering unplanned care. For example:
• Emergency room physicians who can utilize query-based exchange to access patient information—such as medications, recent radiology images, and problem lists—might adjust treatment plans to avoid adverse medication reactions or duplicative testing.
• If a pregnant patient goes to the hospital, query-based exchange can assist a provider in obtaining her pregnancy care record, allowing them to make safer decisions about the care of the patient and her unborn baby.’(What is HIE?, 2013).
Consumer Mediated Exchange

“Consumer Mediated Exchange gives patients the ability to aggregate and manage their health information on the Internet. When in control of their own health information, patients can help transfer information between providers, correct inaccurate demographic, medical, or billing information, and track and monitor their own health” (The 3 Key Forms of Health Information Exchange, 2013).

“Consumer-mediated exchange provides patients with access to their health information, allowing them to manage their health care online in a similar fashion to how they might manage their finances through online banking. When in control of their own health information, patients can actively participate in their care coordination by:
- Providing other providers with their health information
- Identifying and correcting wrong or missing health information
- Identifying and correcting incorrect billing information
- Tracking and monitoring their own health” (What is HIE?, 2013).

FUNCTIONS OF ELECTRONIC HEALTH RECORDS (EHR)

Electronic health records are important because they provide access to complete, up-to-date records of past and present conditions which improves patient health, quality of care, and patient safety. This is essential when EHRs are created so that they effectively communicate with each other and providers can have the latest information readily available.

Workflow of an Electronic Health Record

The picture below, Figure 1, shows a typical workflow of an electronic health record. When a patient schedules an appointment, it is entered into the computer. The patient will then update their health history, contact, and insurance information on a computer or tablet. This information is integrated with their EHR. When visiting the physician, the physician will access the patient’s information on the computer or tablet and enter the necessary data. If lab results are needed, the data will be sent to the lab electronically. This information will be uploaded into the patient’s EHR when complete.

Core Functions

An electronic Health Record (EHR) is concerned with “not just the data that is stored electronically, but what can be done with it, or its functional benefits. According to the Institute of Medicine, EHRs have eight core functions.
1. Health information and data
2. Result management
3. Order management
4. Decision support
5. Electronic communication and connectivity
6. Patient support
7. Administrative processes and reporting
8. Reporting and population health

The Computer-Based Patient Record Institute (CPRI) has three key criteria when dealing with EHRs. This provides for a better understanding and universal use of EHRs.
1. Capture data at the point of care
2. Integrate data from multiple sources
3. Provide decision support
Adoption

EHR Adoption is not only a new requirement by the United States government, but there are social forces driving adoption as well. Some of the social forces include, health and safety concerns, health care costs, and an increasing mobile and connected society via the web. When dealing with health and safety concerns, electronic health records can “improve access to a patient’s medical information, helping to reduce preventable medical errors. EHR provides access to complete, current records of past and present conditions, improving patient health, quality of care, patient safety, thereby helping to reduce costs. Today, patients typically move or change doctors more and see multiple specialists; EHR improves continuity of care by allowing practitioners to share exam records, test results” (Gartee, 2011).

BENEFITS OF ELECTRONIC HEALTH RECORDS (EHR)

Health Maintenance

“Health maintenance improves patient health through prevention and disease management, includes immunizations, patient education, counseling, and screening, and analyzes data to identify patient eligibility for clinical trials or chronic disease management” (Gartee, 2011).

Trend Analysis

Trend analysis is another useful benefit of using an EHR and can present the user with a wide range of information regarding a patient’s record. Clinicians can compare data extracted from patient’s record while allowing the provider to spot trends in the patient’s health record. An analysis can show test results (typically in real time) and vital signs from all visits. Some examples of current trend analyses are growth charts, flow sheets, graphs, and cumulative summary reports.

Alerts

Alerts are great ways to help avoid mistakes and provide a patient with accurate care. Alerts can appear automatically, alerting the physician of a special situation. Some examples of alerts are listed below.

- Drug Utilization Review (DUR). Figure 4.
- Prescribed drug is checked against the patient medication list.
- Ingredients of prescribed drug are checked against ingredients of current medication.
- Duplicate therapy: Different drugs of the same class.
- Food and drug allergies.
- Some drugs cannot be given to patients with certain condition: patient’s diagnosis history is checked. For example, many people with asthma have sensitivities to certain drugs that can precipitate an asthma attack.
- Drug might be affected by certain foods or alcohol interactions; Patient education chart is created.
- Recommended guideline for the use of drug: Too much, too little, too many days, too many refills could cause overdosing, under dosing, or abuse.
- Formulary alerts
- Preferred drugs
- Non-preferred drugs
- Non-covered drugs
  - Lab
  - Insurance alerts.
This alert shows that the patient is not covered to have a certain procedure done and/or a drug is not covered under their program. The patient would need to sign a form relaying this information. The form can then be printed or electronically sent to the patient for them to fill out and return.

**Decision Support**

Provides access to relevant, evidence-based information including:
- Defined protocols (standards plan of therapy established for different conditions)
- Results of case studies
- Standard care guidelines
- Drug formularies
- Dosing guidelines

**EXISTING MODELS AND PRACTICES OF HIE**

There are certain models that are followed by each state as they implement their HIE services. These models can be broken down into two categories. There are the governance models and the strategic and operational plan models. The governance models cover the roles for State Designated Entities driving the health information exchange within each state. The three governance models are centralized, hybrid, and decentralized. The strategic and operational plan models cover different approaches made by states to implement their health information network. The operational plan models are elevator, capacity-builder, orchestrator, and public utility.

**Governance Models**

The first type of governance model is a centralized model. In a centralized model one SDE becomes the health information organization (HIO) for the entire state. This HIO is then connected to different regional health information organizations (RHIOs) throughout the state. The SDE is at the center of this model performing core services such as ePrescribing, delivery of lab results, and computerized physician order entry (CPOE). Advantages of a centralized model include a single user interface, a single consent model, and a single sustainability model.

The second type of governance model is a decentralized model. In this model the SDE acts as a facilitator. Its role here is to set policies and regulations while creating an environment for existing HIOs to connect with each other. In this model the SDE provides no core services for the HIE. Advantages of a decentralized model is leverage against existing HIEs, support for diverse communities, and minimization of privacy or liability issues.

The third type of governance model is a hybrid model. The hybrid model combines parts from both the centralized and decentralized models. In this model the SDE creates policies and is responsible for implementing the states HIE but not the HIO. Therefore it does not hold onto clinical data. The SDE’s goal here is to create a system of interoperability between existing HIOs and hospital systems. In this model the SDE provides limited services such as master patient index, provider registry, and auditing services. Advantages of a hybrid model include leverage against existing HIEs and support for diverse communities.

**Operational Models**

The first model for operational plans is the elevator model. In an elevator model, states have a focused effort to achieve interoperability so providers can meet stage 1 meaningful use. This is level of interoperability is done through the use of a directed exchange services. One risk of this model is not having a basis for a cost-effective approach to reaching stages 2 or 3 of meaningful use.
The second model for operational plans is the capacity-builder model. The main goal of this model is to strengthen existing sub-state exchanges financial support or incentives. For this to work, a state must already have in place multiple sub-nodes which cover a large portion of the state. Then, through the use of funding, they can cover gaps between nodes. The risk with this model is that you are dependent on sub-state nodes and must deal with a potential lack of coverage in the state.

The third model for operational plans is the orchestrator model. This model contains a state level network which facilitates HIE transactions across different sub-state exchanges to create a larger network. The goal here is to create statewide interoperability. The risk with this model is the same as the capacity-builder model. There is a dependency on the sub-state nodes already in place.

The fourth model for operational plans is the public utility model. The goal for this model is to provide a wide variety of HIE services directly to end-users. This model focuses on having the state entity being the center of HIE activities. The risk with this model is that there is a single point of failure at the state entity.

CURRENT STATUS OF MICHIGAN HEALTH INFORMATION NETWORK (MiHIN)

The Michigan Health Information Network (MiHIN) Shared Services has come a long way since its creation in 2010. Currently there are seven sub-state Health Information Exchanges that will be linked through the MiHIN backbone. These seven HIEs will cover all of the approximately 29,000 active licensed physicians in Michigan. In addition to covering all physicians there are several areas that give physicians multiple choices between sub-state HIEs. The two largest of the seven HIEs are Southeast Michigan HIE and Michigan Health Connect. SEMHIE covers 51% of active Michigan physicians and Michigan Health Connect covers 45%.

The latest agreement in HIE advancement came between MiHIN Shared Services, DigiCert, and Nitor Group. This agreement means that Nitor Group will use DigiCert's federally bridged certificates for secure interstate sharing of electronic health information. This will provide Michigan residents a trusted way for their providers and insurers to exchange private medical records across state boundaries to wherever they may receive treatment. Using these new enhanced certificates allows all information to stay securely encrypted between providers in Michigan and in other states. It will shorten the times to receive electronic records while improving patient outcomes at a lower cost. This agreement will also serve as a model for other states that are trying to implement meaningful use stages of electronic health records.

As of May 26, 2011 all states have had their strategic and operational plans approved. There are currently seven trailblazer states whose goal is to support the alignment of state level HIT activities and to transform the health care delivery system. This will create models that other states can use during the implementation of their plans.

Michigan HIE Analysis

Michigan has a rather unique approach for its governance model. This is because it focuses on a public/private partnership. For Michigan this partnership is between the Health Information Technology (HIT) Commission and the MiHIN Shared Services. In this model the HIT Commission is held responsible for setting statewide policies along with monitoring HIE implementation and overseeing ongoing HIE activities. The MiHIN Shared Services is responsible for implementing the statewide HIE infrastructure, developing financing strategies, and facilitating the operational plan implementation. This approach with two separate entities promotes efficient decision making along with a system of checks and balances.

The Michigan Shared Services Network is built for performance, security, and stability. This is by maintaining few direct connections and only routing traffic that must cross to different HIEs. This network implements four core services that support a vast majority of clinical use cases. These services include security framework, messaging services, subject discovery, and document querying. The security framework allows for authentication of systems and users along with implementing security policies for auditing purposes. The messaging services allow you to push messages from one node to another. The subject discovery service allows you to perform searches for patients
across different HIEs. Then there is the document querying service which allows you to lookup data in the form of documents stored in the Michigan Health Information Network.

The biggest concern as Michigan's HIE is put into place is interoperability. This means that clinical or administrative services and applications can be shared and accessed across different HIEs. This is something that starts out with the local sub-state HIEs but must extend to other states HIEs and then onto a Nationwide Health Information Network (NHIN). That is why it is so important that Michigan supports the NHIN core functions of security, subject discovery, document querying, and retrieving documents. This system of interoperability will allow Michigan to easily exchange data between other states and federal agencies.

The following figure compares some key components of the Michigan HIE compared to other states.
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102
CONCLUSION AND FURTHER STUDY

Overall, each state has its own way of implementing their Health Information Exchanges. Some states offer the same core services while others may offer more advanced services. In the end, the main goal is to create a system of interoperability between all the states for the creation of the Nationwide Health Information Network. Further study and resources are required to dig deeper into all fifty state’s HIE implementation and analysis.

REFERENCES


A Threat Table Based Approach to Telemedicine Security

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Abstract: Information security within healthcare is paramount and telemedicine applications present unique security challenges. Technology is giving rise to new and advanced telemedicine applications and understanding the security threats to these applications is needed to ensure, among other things, the privacy of patient information. This paper presents a high level analysis of a telemedicine application in order to better understand the security threats to this unique and vulnerable environment. This risk analysis is performed using the concept of threat tables. This case study focuses on the capture and representation of salient security threats in telemedicine. To analyze the security threats to an application, we present a threat modeling framework utilizing a table driven approach. Our analysis reveals that even in a highly controlled environment with static locations, the security risks posed by telemedicine applications are significant, and that using a threat table approach provides an easy-to-use and effective method for managing these threats.

INTRODUCTION

Advances in healthcare technology, like telemedicine, will likely improve quality of care, reduce cost, and advance medicine in general. However, with technological advances comes increased information security and privacy risks. The digitization of health records, data transmission over public networks, and an assortment of client side devices increases the opportunity for privacy invasion and medical identity theft, costing patients, providers, and payers. As the very nature of telemedicine is vulnerable to security breaches, the security of personal health information in telemedicine applications is paramount.

This work-in-progress study seeks to analyze information security threats in telemedicine applications using a threat table model developed by the authors. Drawing on various techniques from the research literature, we construct a threat table that lists security vulnerabilities and potential remedies for various threats to a system or
software application. We feel that this threat table approach to modeling will prove a valuable addition to risk analysis, system analysis, or audit of any information system. To examine its usefulness, we analyzed a telemedicine application used at a Midwestern college of medicine (CoM) to provide remote clinical care for hepatitis-C and HIV patients at state penitentiaries. The CoM system has one provider location serving 22 remote locations within the state.

BACKGROUND

Telemedicine

Telemedicine is a technology-based method to provide clinical healthcare at a distance. It is considered a sub-category of telehealth, which is, generally, the remote delivery of health related services. Technological advances and the digitization of data have given rise to numerous telehealth applications. Such is the usefulness of modern telehealth that the federal government created the Office for the Advancement of Telehealth, part of the Office of Rural Health Policy within the U.S. Department of Health and Human Services, to promote the use of telehealth technologies for health care delivery, education, and health information services.

Health Information Security

With forthcoming legislation that became HIPAA, one of the first definitive works on threats to information in healthcare came in response to a request in October 1995 from the U.S. National Library of Medicine (NLM) by the Computer Science and Telecommunications Board who produced the report, For the Record: Protecting Electronic Health Information (National Research Council, 1997). Subsequently, NLM awarded projects that included the assessment of various approaches to ensuring the confidentiality of health data transmitted via electronic networks (National Library of Medicine, 2012).

A core requirement of telemedicine system analysis and development should include analysis of risk to both information security and patient privacy. Advanced risk analysis methods have long been used within many fields, such as insurance, military, finance, aviation, and others. However, only in recent years did the software industry finally develop workable frameworks to address security. This is exemplified by the development of the Open Web Application Security Project (OWASP) in 2001 and Microsoft’s development of the Security Development Lifecycle (SDL) in 2004. Additionally, other risk methods have also been applied to information systems. Such methods include CRAMM (CCTA Risk Analysis and Management Method; Central Computing and Telecommunications Agency of the U.K. government), LAVA (Los Alamos Vulnerability Assessment), OCTAVE (Operationally Critical Threat, Asset, and Vulnerability Evaluation) developed at Carnegie Mellon, and others.

Threat modeling is often done in conjunction with risk analysis. When done so, it provides a deeper quantification of risk. Indeed, this approach is seen within Microsoft’s SDL. Threat modeling of information systems or computer software is most often used for identification of vulnerabilities at entry points to a system, application, or their components. A threat model developed during the design phase can be used for verification during the test phase. A threat model may also be used to analyze existing systems and software to identify vulnerabilities.

Frameworks for information security have been proposed for decades. When information security professionals and researchers realized that the classic triad of confidentiality, integrity, and availability was inadequate to describe what security practitioners think about, they began proposing more extensive frameworks. Many have attempted to overcome the dominant technologist view of information security by focusing more holistically on security, including information assets, potential sources of loss, types of loss, controls to avoid loss, remediation selection methods, and the overall objectives in protecting information. For example, one approach included that of dividing information security into a technological component addressing logical aspects and one addressing physical aspects (Eloff, Labuschagne, and Badenhorst, 1993). Their concepts include: risk identification, risk analysis, risk assessment, risk resolution, and risk monitoring. More recently, the six security elements of availability, utility, integrity, authenticity, confidentiality, and possession have been proposed by Parker (2002) and used in his Threats, Assets, and Vulnerabilities Model. It is from the development of such frameworks that risk analysis methods such as CRAMM, LAVA, and OCTAVE arose, intending to encompass the calculation of risk in both the technical and physical aspects of risk analysis.
In contrast, OWASP and SDL focuses less on calculating risk and more on the identification of potential threats during the design and development of software. In such an environment, assigning risk to defined threats is only useful as far as prioritizing work, but not necessarily part of a calculus to determining remediation. Given the adage that information security is only as good as the weakest link in a system, the goal of system and software design is to identify all potential vulnerabilities and provide countermeasures to remove or mitigate risk.

The literature also contains numerous studies on formal approaches to threat modeling. These protocols typically employ graph-based state modeling. Some rely on UML (Kong, Xu, and Zeng, 2010; Lund, Hogganvik, Seehusen, and Stolen, 2003), and others on Petri Net notation (Mirembe and Muyeba, 2008; Xu and Nygard, 2005; Youn, Park, and Lee, 2011). Microsoft, on the other hand, developed the SDL framework utilizing data flow diagrams to identify asset entry points necessary for an attack based on their STRIDE model (Hernan, 2006). STRIDE is an acronym for the six threat categories of Spoofing, Tampering, Repudiation, Information disclosure, Denial of service, and Elevation of privilege.

Related Work

A systematic study that identified 58 published articles that in some manner concerned security in telemedicine (Garg and Brewer, 2011) reflects the scarcity of studies in this area. However, of these 58 articles, few mentioned formal standards for security. In the literature of telemedicine system development there is research that develops a secure videoconferencing system for use in diagnosis and treatment (Tulu, Chatterjee, Abhichandani, and Li, 2003), secure texting in healthcare (Bones, Hasvold, Henrikson, Strandenes, 2007), a handheld device for diagnosis and treatment of soldiers in the field (Morris, Pajak, Havlik, Kenyon, and Calcagni, 2006), a Web-based system for managing diabetic patients at home (Bellazi, Montaini, Riva, and Stefanelli, 2001), remote sensors that monitor patient health (Chowhurry 2012; Mirembe 2006; Xiao, Shen, Sun, and Cai, 2006), and applications akin to enterprise systems (Chen, Yu, and Feng, 2000; Liu, Lu, Hong, and Wang, 2008; Maji, Mukhoty, Majumdar, Mukhopadhyay, Sural, Paul, and Majumdar, 2008). Of these articles, only Maji et al. and Bones et al. devoted significant attention to threat models. Whereas, Bones et al. concentrated on demonstrating a risk assessment of approximately thirty potential threats synthesized from an ad-hoc brainstorming session utilizing the OCTAVE method, Maji et al. used OWASP and other resources to address fourteen specific threats most commonly experienced by Web applications. As such, we see that threat modeling in telemedicine has received scant attention.

A THREAT TABLE METHOD

Our approach is based on the work of Swiderski and Snyder (2004) and consists of five aspects: (1) Identification of the points at which an attack could occur, (2) identifying the potential vulnerabilities using STRIDE, (3) listing the specific attack types for the given vulnerabilities, (4) providing proposed countermeasures and, (5) classifying the goal of the countermeasure as either Prevention, Detection, Mitigation, or Elimination. Our contribution is the development of a meaningful and easy-to-use tool absent the need for learning a formal method or needing an automated tool. This table based approach captures concise information needed for threat identification and classification, and countermeasure proposal and classification. Stored electronically in a spreadsheet or relational database, the information is easily segmented, sorted, or reported in a manner conducive to the task at hand. The simplicity of the method allows those not versed in formal threat modeling, like subject matter experts, to participate in the process of threat management.

We begin with a simple listing of the conceptual tasks that a system is envisioned to perform. This listing, which can be readily achieved using a common spreadsheet, is essentially free-form, using vocabulary and terminology that is familiar to the domain for which the system is to be used. The list of primary tasks is then decomposed into component tasks until all tasks are described. For each task, potential vulnerabilities are surmised and possible countermeasures proposed. Using this simple, straightforward approach, we believe that a threat table can capture all necessary information for threat modeling while arming software developers and their managers with sufficient guidance to address security breaches to the extent possible. We note that data flow diagrams could be utilized as the starting point of constructing a threat table since they can be used to visually identify entry points into a system or application. However, our model does not require their use.

Specifically, our threat table is composed of five columns. The first column contains task information with each task described generally and its component tasks listed underneath. This process is completed when the component tasks cannot logically be reduced any further. These conceptual and concrete tasks comprise the rows of the threat
table with conceptual tasks serving as row headings. The remaining four columns are Vulnerability, Attack description, Countermeasure, and Goal of countermeasure. Vulnerability is noted used the STRIDE nomenclature described above. Attack description and Countermeasure are nominally described though a previously defined taxonomy could be used. The Goal of the countermeasure is noted as Prevention, Detection, Mitigation, or Elimination (P, D, M, or E). Noting the goal of a countermeasure is useful to later risk analysis efforts.

Once the conceptual tasks have been decomposed, each component task is analyzed for vulnerabilities in accordance with the STRIDE model. For each category of STRIDE vulnerability, potential attacks against the task are considered. Each potential attack, along with the STRIDE classification, is then listed on a separate row. For each attack listed, countermeasures are then listed in order of preference, one per row, followed by the countermeasure goal. Thus, a task may be followed by several attack descriptions, each on a separate row. Each attack may be addressed by multiple countermeasures, again with each described on a separate row.

Although the names of the goals have obvious associations, the intent of each is specific and not always apparent. Prevention refers to the idea that changes can be made in the system that prevent the possibility of a particular threat from ever occurring. For example, an interface to a system could be browser-based and use SQL statements to retrieve and store data in a database. If the code executing the SQL is not written well, an SQL injection attack is possible. By rewriting the code carefully, such as by using prepared statements, this type of attack could be entirely prevented. Of course, attacks used against certificates would be possible and would have to be addressed by other means. Detection comes into play when it is necessary for the remediation of a threat by the system, user, or some administrator. Mitigation refers only to reducing the likelihood or impact of the attack, and Elimination characterizes complete removal of the threat.

The threat table approach is arguably simpler than formal models. It is also equally capable of modeling multiple path threats due to its hierarchical nature. Each task is denoted as a starting point in the threat table, and multiple threats may be listed as being applicable to the task. As such, the threat table forms a tree but without the graphical interface. For example, an attacker might wish to obtain sensitive information about a particular patient. If a task of “View sensitive information” were listed in the table, one threat might be “Spoof identity” while another might be “Unattended screen.” Thus, the table can depict multiple threat paths to the same task. Alternatively, the table approach also permits one to list the paths separately. Hence, one task could be listed as “Logging In” and the spoofing threat identified as a potential attack on that task, while “View sensitive information” is listed as a separate task and the "unattended screen" attack listed as its potential threat. Thus, the tabular nature of our approach provides functionality that is equivalent to paths provided by formal modeling approaches.

ANALYSIS

Architecture of System

The CoM began providing remote clinical services to 22 state penitentiary locations for Hepatitis C and HIV clinical care in July 2010. This application of telemedicine serves remote and static locations using a system from Polycom to provide encrypted transmission of audio, video, and clinical instrumentation between the penitentiaries and CoM facility.

There are two examination rooms at the CoM facility designed and equipped specifically for using the Polycom system. A room contains a large high-definition screen, a remote controlled high-definition room camera mounted on top of the screen, microphones, speakers, controls for the remote (penitentiary) examination room camera, audio equalization for the stethoscope, and a PC providing access into CoM’s electronic medical record (EMR) system and a third-party laboratory. A PC-based application for connecting into the Polycom system is typically used by a caseworker and pharmacist from their respective office. A high level schematic is shown in figure 1.

When a session is initiated, the patient is accompanied by a nurse in the examination room at the prison facility. A caseworker, physician, and pharmacist are present at the CoM facility for each session. Any medical data needed from the prison are either faxed, held up to the camera to be viewed, or communicated by phone. There is no electronic interoperability between the prison and CoM EMR systems. The physician at CoM manually creates and updates an EMR record for each patient. The examination begins with the caseworker validating the identity of the patient visually and with the on-site nurse. A high-definition camera sits above the monitor at each location and is remotely controlled by the viewers. A small hand-held, high-definition camera is used by the nurse to provide close up dermatological examination of the patient. An electronic stethoscope and otoscope that plug into the Polycom system provide remote instrumentation. The physician listens to the stethoscope using headphones that are tuned
with audio equalization for optimum auscultation. Finally, the otoscope provides remote visual examination into the ears, nose, and throat.

If labs are needed, the nurse collects the appropriate sample(s) and sends to a third-party lab. Using a Citrix application on his PC, the physician has remote login privilege in order to view lab results. As with the prison EMR, there is no interoperable system connection between CoM and the third-party lab. If medication is prescribed, the pharmacist participating in the session, typically from their office, orders the medication using a CoM Hospital system. The medication is packaged from a central location and shipped overnight to the prison.

![College of Medicine to Penitentiary telemedicine system](image)

**Figure 1. College of Medicine to Penitentiary telemedicine system**

**Results**

This application of telemedicine consists of teleconferencing and digitized instrumentation. The environment is static and highly controlled, all but alleviating location privacy issues that can be problematic with telemedicine. With the Polycom system encrypting data end-to-end, any risk to information security during transmission is essentially eliminated. Furthermore, with equipment located in secure facilities and configured to use a fixed network, physical risk is minimized. Although the caseworker and pharmacist may be located in separate rooms from the physician, their data connections are on the internal CoM network and data is encrypted to their local computer. In general, the security risks to the CoM system are not as much technical as they are social.

Despite the highly controlled environment for this telemedicine application, the risk for identity theft, as well as fraud, exists. The exact procedures used during a session were not disclosed and we were prohibited from viewing a session as it would be a violation of the patient’s rights. However, without proper checks and balances several social born threats are possible. For instance, a patient and a nurse at a prison facility could collude to falsify the patient’s medical condition in order to obtain medications, such as narcotics, that could then be sold to other prisoners or on the black market. Such a scheme can work because the nurse is relied upon to identify a new patient to the caseworker and samples taken from the patient and sent to a third-party lab are also controlled by the nurse. Cross-checking of patient identity using a connection to the prison’s identification system would reduce this risk. Moreover, obtaining the patient's prior medical history by connecting to external healthcare systems would further minimize this risk.

It is also possible for the prisoner to become the victim of identity theft. Rather than the patient being examined by a physician onsite with the physician using a single EMR system, the patient’s identity is now revealed remotely to at least three people outside of the prison system, namely, the physician, the caseworker, and the pharmacist. Other personnel within earshot of a session or inappropriately in attendance of a session could also obtain the patient’s identity. Additionally, a medical record for the patient is maintained in two EMR systems, increasing the risk of unauthorized access. Though these are but simple examples of threats, our threat table demonstrates the utility of modeling both technical and social born threats to patient privacy. A partial threat table demonstrating these threats is shown in table 1.
DISCUSSION

Analyzing information security threats in telemedicine applications requires analysis at a system level and software application level. The telemedicine system analyzed for this project mostly consisted of disparate software applications and other components. From our literature review, we believe this to be generally the case in practice. As such, the need for information security and privacy analysis during the design, development, and operational phases of telemedicine applications is all the more salient given the very nature of information vulnerability in telemedicine.

Previous studies of telemedicine information security have generally discussed vulnerabilities in terms of risk. Several studies simply list threats and categorized them in a risk matrix by likelihood and consequence. Though useful for risk analysis purposes, this approach does not provide an understanding of the types of threats and potential countermeasures for specific threats to a given vulnerability. In contrast, our method of using threat tables is focused on the threat, not the risk. That is, if a goal in the design of a system or application is to minimize, or eliminate, a specific type of vulnerability then it is an understanding of all forms of attack on that vulnerability that is of interest. Simply knowing the level of risk of a given vulnerability does not provide as rich an understanding as knowledge of all forms of attack on the vulnerability. It is an understanding of threats at this level that is the contribution of our approach.

Using our threat modeling approach gives practitioners an intuitive and simple method of listing vulnerabilities, threats to these vulnerabilities, and potential remedies to these threats. This is particularly useful to those developing or analyzing applications with high concern for security and privacy, like telemedicine. Threat tables are useful as-is or as a component of some system development methodology or risk analysis method. Here, we developed an example of a threat table using functional and task dimensions to illustrate identification of threats. Use of data flow diagrams or other system modeling methods could provide useful identification of vulnerabilities and potential entry points for an attack. Compared to using formal-based methods that can require specialized knowledge and software, our method is intuitive and easily implemented.

The CoM staff was very concerned about security, although they did not describe any breaches that may have occurred. CoM had not adopted a protocol or identified a process for threat modeling. Our simple protocol of using a threat table identified all of the potential problems that had been identified by CoM staff, and more.

Notably, the physician in charge of the CoM system explained how the identity of the patient could pose a challenge and remarked that he therefore took steps to confirm the identity. This concern is readily deduced using

Table 1. Partial Threat Table Example

<table>
<thead>
<tr>
<th>Task Description</th>
<th>STRIDE</th>
<th>Attack</th>
<th>Countermeasure</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish secure data connection - Polycom</td>
<td>D</td>
<td>Denial of service (power outage)</td>
<td>Obtain backup generator or UPS</td>
<td>E</td>
</tr>
<tr>
<td>Receive call using CoM phone system</td>
<td>D</td>
<td>Denial of service (other causes)</td>
<td>Install alternate data communication links</td>
<td>E</td>
</tr>
<tr>
<td>Verify patient identity</td>
<td>S</td>
<td>Impersonation</td>
<td>Verify with official at prison or central location</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Verify through prisoner ID system</td>
<td>M</td>
</tr>
<tr>
<td>UIC's EMR system</td>
<td>I</td>
<td>Access by users of EMR</td>
<td>Highly restrictive access for remote patients</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Routine auditing of record access</td>
<td>D</td>
</tr>
<tr>
<td>Session participation</td>
<td>I</td>
<td>Identity theft</td>
<td>Have third-party verify attendees in each location</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Require all attendees to be in one location</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>Identity theft</td>
<td>Ensuring privacy of sessions</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Online ID by caseworker; no audio</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Restricted procedures for patient identification</td>
<td>M</td>
</tr>
</tbody>
</table>

STRIDE: Spoofing, Tampering, Repudiation, Information disclosure, Denial of service, and Elevation of privilege
Goal: Prevention, Detection, Mitigation, or Elimination
CONCLUSION

We performed a high level analysis of information security threats to a telemedicine application. Using a framework that utilizes threat tables developed by the authors, we demonstrated a method of defining vulnerabilities and proposing countermeasures. Our analysis of the CoM telemedicine application reveals that even a telemedicine application in a physically static and electronically controlled environment is vulnerable to some of the same threats as seen in mobile environments utilizing public communication channels, demonstrating the usefulness of threat modeling to telemedicine applications.

Because of its simplicity, the threat table approach appears to be a salient option for providers of telemedicine. The fact that telemedicine can involve a composite of systems and applications does not detract from the value that this method brings to modeling threats. Ensuring the security of telemedicine is not only necessary for legal and financial reasons but also for providing the peace of mind required for productive relationships between patients and medical professionals.

Notably, our table-based approach to modeling threats and responsive actions is intentionally open-ended; it is capable of accommodating the analysis of any type of potential threat. This flexibility is necessary when constraints such as governmental regulations come into play. In particular, security in systems that handle medical information is regulated by HIPAA and the HITECH Act. In 2013, the Department of Health and Human Services published a final rule on security measures that must be incorporated within such systems. These requirements address such fundamental security measures as user authentication, encryption, and transaction logging, among others. Threats that potentially are remediated by such measures, or, more importantly, that impact their implementation, may readily be modeled using our approach. Therefore, table-based threat modeling that relies on STRIDE is consistent with both the spirit and text of HHS regulations.

Our investigation into modeling the threats in this project was limited by our knowledge and understanding of the telecare systems analyzed. CoM was kind enough to demonstrate their system to us and discuss the details at an introductory level, but we did not have the opportunity to conduct an exhaustive audit of all elements of this system. Nonetheless, we gained enough knowledge during our visit to synthesize an initial, high-level threat model. Due to the limitations of the interview, little information was obtained about how the CoM staff views standardized approaches to threat modeling, but it appeared that the addition of a formalized protocol, such as our threat table approach, would potentially benefit their organization.

With this initial understanding we will continue exploring the identification of security threats and how the traits of these threats and their countermeasures should be represented in a threat table. Our next step is to analyze a multifarious telemedicine system and consider refinement to the structure of the threat table. Our goal is to develop a practical and useful method of addressing security threats in the design and analysis of telemedicine systems with applicability to information systems in general.

Future work could include studying threat tables in practice, as well as studying other threat modeling approaches, particularly formal methods, compared against this method for usability, effectiveness, and feasibility. Further, we could explore the utility of incorporating the threat table approach into an overall risk analysis of a telemedicine system. Finally, we would like to expand our threat analysis of telemedicine applications into unconventional environments, such as disaster relief environments, where telemedicine applications might be used with ad-hoc or hastily formed networks.

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Managing Government Regulatory Requirements for Security and Privacy
Using Existing Standard Models

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Abstract: This paper posits the use of a well-established standard approach to Federal compliance, which can be easily adapted to satisfy all legal and regulatory requirements for protection of patient personally identifiable information (PII) in health organizations. This approach is embodied in the three standards that dictate how to comply with the Federal Information Security Management Act (FISMA). These standards also provide an excellent foundation for organizing a secure operation anywhere. The discussion revolves around the application of the FIPS 199 and FIPS 200/NIST 800-53(4) standard approach to the satisfaction of the present and upcoming legal and regulatory requirements for health care PII. The outcome would provide a proven, systematically secure and cost efficient solution to those protection needs. The general approach will be explained and justified.

Keywords – PII, federal regulation, security and privacy, HIPAA, FISMA

INTRODUCTION

Public Law 109-41, which is commonly known as the Patient Safety and Quality Improvement Act of 2005 (PSQIA) is the Act that created patient safety organizations (PSOs) and their attendant patient safety databases (PSQIA, Sec.922). PSQIA establishes a voluntary reporting system to assess and resolve patient safety and health care quality issues (Clinfowiki, 2013). The aim of that Act was to “encourage the reporting and analysis of medical errors”. The primary motivator for which was the finding that most preventable errors leading to patient harm are the result of “faulty systems, processes, and conditions”(Kohn, 1999). In that respect, the Report recommended that the health care system should be “designed to improve safety at all levels”(Kohn, 1999).

PSQIA mandates privilege and confidentiality protections for patient safety information, which include any, “data, reports, records, memoranda, analyses, or written or oral statements, which could improve patient safety, health care quality, or health care outcomes”(PSQIA, 2005). All relevant data is assembled and reported to the PSO as a “patient safety work product”. The aggregated patient safety work products are the basis for the analysis of data from participating health organizations. The data is intended to be accessed and analyzed in order to identify overall trends/outcomes that can be used for the improvement of individual patient care processes.

In that respect however, the sensitivity of the information being kept and analyzed demands assurance of secure access and reporting. Care providers are understandably reluctant to report their patient care data externally for fear of liability, or the violation of regulatory requirements. Yet, if there is insufficient data to underwrite the characterization of patterns of care leading to improved patient safety, there is almost no point in having a PSO. Consequently, the Affordable Care Act (ACA) now mandates that hospitals with 50 or more beds will not be able to
provide services through the Act unless that hospital has implemented a patient safety evaluation system that reports to a patient safety organization (ACA, 2010).

THE INFORMATION SECURITY CHALLENGE

The information security challenge lies in assuring that each patient’s personally identifiable information (PII) is passed to the PSO in such a way that it does not violate the HIPAA Privacy Rule. PSOs are among the entities that fall under the HIPAA Privacy Rule (Title 45 CFR, Part 160-164, 2010). The HIPAA Privacy Rule provides federal protections for individually identifiable health information and it gives patients an array of rights with respect to that information.

Protection of the privacy of information depends in large part on the existence of measures to secure that information. Thus HIPAA has both a Privacy Rule and a Security Rule. The Security Rule specifies the need for basic safeguards, which are installed to protect electronic health information from unauthorized access, alteration, deletion, and transmission. The Security Rule stipulates administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic health information. The Privacy Rule specifies the disclosures that are authorized and the rights that patients have with respect to their health information. In concept the Privacy Rule applies to health information in any form, whereas the Security Rule applies only to health information in electronic form. However for the sake of this discussion, both Rules will apply only to electronic information.

The HIPAA Privacy Rule regulates the protection of privacy of patients' medical records and other health information maintained and processed by health plans, health care providers, and other entities involved in the processing of health care claims (45 CFR 160, 162, and 164, 2013). The HIPAA Security Rule specifies a series of administrative, technical, and physical security procedures to assure the confidentiality of electronic protected health information (45 CFR 160, 162, and 164, 2013). In addition, the procedures in the Security Rule also assure the integrity and availability of health information (HHS, 2013a). These procedures require significant control over the use and disclosure of patient information (HHS, 2013a). HIPAA compliance was required as of April 20, 2005, (HHS, 2013a). HIPAA compliance requirements were extended to cover business associates (contractors and subcontractors) of those “health care providers, health plans, and other entities that process health insurance claims” covered originally by HIPAA by the final omnibus rule released by HHS in January of 2013. The rule requires these business associates to be in compliance by September 23, 2013 (HHS 2013b).

At its core, the Security Rule requires effective risk management. The risk analysis determines which safeguards are appropriate to satisfy the Security Rule. The risk analysis assesses the likelihood and impact of potential risks and develops rational measures to reduce risk and vulnerabilities to a reasonable and appropriate level. That risk analysis is an ongoing process, where the organization regularly reviews its records to identify how adequately existing and emerging risks are addressed within the organization.

According to this Rule risk has to be addressed in three generic areas, administrative, physical and technical. Specifically, the Security Rule requires an explicit set of procedures to implement role based access control as well as enforce appropriate supervision over personnel and ensure proper training of the workforce. In addition, an organization must have procedures in place to ensure that only authorized entities have physical access to its facilities. Finally the organization has to control use of and access to physical devices and media.

All forms of control are expressed as policies and procedures. Thus, the organization must develop practices to ensure authorized access to electronic information, as well as audit controls to ensure sufficient confidentiality and integrity of the information (HHS, 2013a). In addition, there should be technical countermeasures to ensure the confidentiality and integrity of the health information that is being transmitted over an electronic network (HHS, 2013a).
CREATING A REALISTIC PROTECTION PROCESS FROM EXISTING STANDARDS

For each PSO, risk has to be mitigated by a concrete set of administrative, physical and technical countermeasures, while, at the same time, the standards that underlie HIPAA compliance for PSOs as specified in 45 CFR Parts 160, 162, and 164 are not standards in the prescriptive sense. Instead they are more a specification of generic criteria that require some form of organizationally standard response. Table 1 (below) summarizes the eight areas where these considerations need to be addressed (HHS, 2013a):

1. **Security Standards** - the organization must adopt security standards that meet statutory requirements
2. **Security Governance** – the organization must develop policies and procedures to govern the anonymization, disclosure and tracking of patient safety work product
3. **Personnel Security** – the organization must ensure that employees and contractors uphold and maintain their personal obligations regarding confidentiality of patient safety work product
4. **Secure Space** – the organization must ensure that access to patient safety work product is restricted only to members of staff that work in the defined patient safety evaluation system
5. **Physical Security** – the organization must implement physical measures to prevent unauthorized external access to the secure space (as defined in section 3.106(a)), prevent unauthorized physical access, tampering, and theft of patient safety work product within the secure space
6. **Network Security** – the organization must implement electronic safeguards against intrusion, if such controls are not implemented other measures must be taken to prevent intrusions
7. **Access Control** - the organization must formally identify, authenticate, authorize and track access by users (internally) and authorize recipients externally
8. **Assessment** - the organization must conduct periodic risk assessments to ensure adequate process security

**Table 1: Generic Areas of Consideration to Satisfy HIPAA Privacy and Security Rules**

In actual practice, in order to satisfy the HIPAA Security Rule, explicit, real-world countermeasures are required. Moreover, to ensure proper implementation these countermeasures have to be both concrete in form and tangible in effect. This requirement justifies the use of an existing set of standards for the security of Federal information systems. Federal Information Processing Standards (FIPS) 199 and 200 and the National Institute for Standards and Technology (NIST) Standard 800-53(4) work together to fully and completely specify the control objective infrastructure to satisfy the HIPAA Rules at a range of levels of security.

Structuring HIPAA compliance processes using an existing regulatory model merits discussion because of two pragmatic factors. First, where compliance is mandated, it is helpful to have a proven conceptual framework in place to guide the development of the real-world practices needed to generate tangible proof of compliance. More importantly, the regulatory models discussed in this section constitute a legitimate legal framework for ensuring comprehensive best practice in securing information in any form. Thus the three standards that dictate how to comply with the Federal Information Security Management Act (FISMA) also provide an excellent foundation for organizing a secure operation within a health care setting.

The Federal Information Security Management Act (NIST, 2013) applies to all agencies of the U.S Government. Combined into a single process, the standards that implement this Act; FIPS 199 (NIST, 2013) and FIPS 200 (NIST, 2013) and NIST Special Publication 800-53 (NIST, 2013), help ensure that sufficient security control exists for all federal information systems. FISMA implementation is based on a formal risk assessment process, which validates the initial security control selection and determines if any additional controls are needed to protect organizational operations (NIST, 2013). The resulting collection of standard security controls establishes a defined level of due diligence for the organization.
FINALLY: A COST JUSTIFICATION FOR SENSITIVITY CLASSIFICATIONS

The Federal Information Security Management Act, known officially as Title III of P.L. 107-347, authorizes the use of a compliance model for federal information systems. Unlike HIPAA, which is tailored to a particular sector and environment, FISMA is comprehensive legislation that dictates every aspect of correct security practice for every large-scale information system environment. Although this paper uses HIPAA as an example, FISMA can be applied to almost any information system in almost every type of regulatory situation. In fact one point should be kept in mind as a side note; the general applicability of FISMA standards to any information system security situation makes it a “one size fits all” solution for any regulatory situation.

The advantage of combining sensitivity classification with control deployment, as FISMA does, is easy to justify. It would be a daunting task to comply with HIPPA if every piece of information had to be protected to the same degree of sensitivity. However, since an individual’s SSN or financial account number is generally more sensitive than an individual’s phone number or ZIP code, and breaches of 25 records and 25 million records may have different impacts, organizations can categorize the PII that is maintained into levels of required protection. If this is done right, then the protection approach can be appropriately scaled based on that “level of protection” or sensitivity classification. That ensures cost efficient implementation and operation.

DETAIL OF IMPLEMENTING AN EFFECTIVE MODEL FOR HEALTH CARE FROM FISMA REQUIREMENTS

FISMA requires each federal agency to “develop, document, and implement an enterprise-wide program to secure information and the information systems that support the operations of every federal agency.” (FISMA, 2002) FISMA is implemented by two federal information processing standards publications (FIPS PUBS). These standards are issued by the National Institute of Standards and Technology (NIST) and authorized and approved by the Secretary of Commerce. The two FIPS PUBS used in the implementation of FISMA are FIPS 199 and FIPS 200.

FIPS Publication 199, “Standard for Security Categorization of Federal Information and Information Systems,” stipulates criteria for assigning classification levels to the information systems that fall under FISMA (FIPS, 199). FIPS 199 serves as the basis for selecting appropriate security controls based on the relative security needs of the information that is protected. Information is categorized by FIPS 199 based on three levels of risk: high, medium, and low. FIPS 199 requires federal agencies to categorize the information processed by their systems as having low impact, moderate impact, or high impact on security.

This classification is dictated by the confidentiality, integrity, and availability requirements of the information in each system. The sensitivity of the information in each system is categorized at its highest level of potential impact on security. This concept is called the high water mark. The concept is important because significant security dependencies are built into all systems. That is, a compromise in one security objective ultimately affects the other objectives as well. Because the potential impact values for confidentiality, integrity, and availability may not always be the same for every item of data in the system, the high water mark concept is used to value the overall impact level of the information that is in the system.

FIPS Publication 200, “Minimum Security Requirements for Federal Information and Information Systems,” is meant to promote the development, implementation, and operation of more secure information systems within the federal government (FIPS, 200). FIPS 200 utilizes a risk-based approach for the selection of the security controls that are needed to satisfy the minimum requirements of FIPS 199. FIPS 200 ensures minimum levels of due diligence for information security and helps federal agencies follow a more consistent, comparable, and repeatable approach to the development of explicit security controls for information systems (FIPS, 200). The 17 areas covered by FIPS 200 represent a broad-based response that addresses all aspects of management, operations, and technology. Policies and procedures play an important role in the effective implementation of enterprise-wide security and the long-term success of the resulting measures. Table 2 lists the security-related control areas are specified in FIPS 200.
1. **Access control**—Limit information system access to authorized users, processes, and devices.
2. **Awareness and training**—Ensures that personnel are adequately trained.
3. **Audit and accountability**—Ensures that actions can be traced to ensure accountability.
4. **Certification, accreditation, and security assessments**—Monitors security to ensure effectiveness.
5. **Configuration management**—Establish and enforce baseline configurations for information assets.
6. **Contingency planning**—Implement plans to ensure availability and continuity of operations.
7. **Identification and authentication**—Identify users and processes and authenticate their identities.
8. **Incident response**—Establish operations for incident handling within the organization.
9. **Maintenance**—Establish controls for maintenance techniques, mechanisms, and personnel.
10. **Physical and environmental protection**—Limit physical access to equipment and environments.
11. **Planning**—Develop plans that describe current and planned security controls.
12. **Personnel security**—Ensure that people in positions of responsibility are trustworthy.
13. **Risk assessment**—Assess risk to operations as a result of processing, storing, or transmitting data.
14. **Systems and services acquisition**—Ensure security in sourcing and acquisition.
15. **System and communications protection**—Monitor, control, and protect communications.
16. **System and information integrity**—Identify defects and protect against malicious code.

**Table 2 – The Seventeen Security Related Control Areas of FIPS 200**

NIST 800-53 Revision 4, “Security and Privacy Controls for Federal Information Systems and Organizations”, specifies a comprehensive set of control objectives appropriate to each of the FIPS 199 baseline levels of protection and each of the requisite security control areas in FIPS 200. The controls that are specified are at the discrete behavioral level and taken as a set constitute current best practice in satisfying each security control area’s requirements. In order to provide comprehensive definition of the necessary controls for each level of sensitivity, NIST 800-53 is a substantial document. However, if utilized as intended the degree of practical and detailed control specification will guarantee a proper level of security for each level of sensitivity. More important, the resulting tangible control set can be verified by audit and used as documented proof of due diligence in complying with future requirements for rigorous protection of patient PII.

**CONCLUSIONS**

The premise for this discussion is relatively straightforward and the conclusions are simple. Increased regulatory requirements for the protection of patient PII will require rigorous and well-proven methods for both implementing and auditing health care system security. The existing standard process for securing federal information provides a detailed, practical and cost effective basis for both ensuring the confidentiality, integrity and availability of patient information; as well as allowing the organization to optimize the deployment of that protection in a cost efficient manner.

Because the FISMA approach has been in place for almost a decade there are a large number of studies and reports to guide deployment and the process itself has stood the test of time. The FISMA approach also has the advantage of being based on the same type of compliance requirements that existing health care information protection regulations will impose. Consequently, the proof of due diligence is built in for Federal auditors. Given all of these factors a health organization struggling to meet mandated patient information protection laws could benefit considerably from this approach.
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Challenges of Mobile Healthcare Application Security

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Abstract: Healthcare information technology has overcome many of the Web application security challenges in the past decade. We can now access information more securely and incidents of unintentional data loss are on the decline. However, more must be done to ensure the confidentiality, integrity, and availability of mobile applications in the healthcare field. Whether it is physicians using iPads to access treatment histories or patients managing healthcare options via smart phones, the proposed CAP framework (checks, assurances, protection) adds additional security and privacy layers to our modern mobile medical needs.

INTRODUCTION

The security of Healthcare information is paramount to the success of HIT systems. Over the past decade, we have seen an increase in both research and practical application that takes into account the importance of secure transactions, information exchange, and protection of data within Healthcare systems. There is still much work ahead of us, but it is clear that more healthcare professionals realize the need for secure information exchange as the profession moves from paper to electrons.

The Challenge

Application developers and practitioners have made great strides in creating usable and secure systems that can be used to facilitate healthcare data exchange whether it be patient records, prescriptions, lab tests, or other routine daily operational data within the context of application and web centric systems. We see this best illustrated in systems and software such as EPIC (EPIC, 2013).

However, computing systems and how we use them are once again experiencing a shift. More users are now accessing, creating, and consuming information via mobile devices (Fidelman, 2012). Whether it is the teenager updating Facebook via her smart phone, or a store manager checking inventory via his tablet, more people are using always-on, connected mobile devices for play, work, research, and sensitive personal transactions.

There is much literature that looks at creating and maintaining protected transactions between mobile agents. Whether we examine the types of attacks on or among mobile agents (Jansen, 2000), the guiding principles to protect them (Burkle, Hertle, Muller, & Wieser, 2009), or the trust required to ensure sensitive transactions (Pfitzmann, Pfizmann, Schunter, & Waidner, 1997), we need to create a framework of security checks, trust assurances, and transaction protections before permitting the exchange of sensitive information. The CAP framework (checks, assurances, protections) will ensure secure interactions among mobile applications no matter what the specific platform.

CAP Framework Solution

In order to be an all-inclusive security framework malleable to the various types of attacks in order to protect transaction, as well as anticipate new attack vectors, the CAP must maintain three security tenets of confidentiality, integrity, and availability:
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Confidentiality: All data flow and stored information must be protected against those who should not have access. This includes strong authentication protocols and strong data encryption both during exchange and storage of data.

Integrity: All data must be trustworthy and any changes to the data must be valid according to set parameters. This includes concepts such as data and source integrity.

Availability: All data within an information system needs to be accessible when it is accessed. No matter how secure an information system, it should allow authorized users to access information and supporting system frameworks need to ensure that the information is always obtainable. This includes databases, servers, networks, and all parts of the information system to include mobile devices that are accessing it from external networks.

Since we are dealing with mobile transaction between software agents (e.g., server and mobile client) we must also add additional layers to support CIA, as well as transactional security and trust. These additional layers address weaknesses or gaps in the existing standards:

- Authenticity: Although CIA addresses confidentiality, in a mobile solution the communicating components (e.g., mobile device and server) need to authenticate against each other in addition to user authentication. We can address this somewhat with SSL and shared certificates, but with sensitive information we need to ensure that the participants are who they say they are. Too often certificate spoofing can result in compromised systems (Fisher, 2012) so more needs to be in place.
- Assurance: After we authenticate mobile agents and servers, we need to assure secure transactions and communications. In mobile environments, a user may move between networks in a short period of time. The system must constantly check for a secure connection before transmitting the next burst of data.
- Reliability: We must also take into account the reliability of the mobile platforms and applications (i.e., "apps") that users employ to access sensitive personal information. Without constant validation, viruses can infect apps and still maintain a coherent, healthy app signature thereby impacting data and system CIA.

By combining the standard CIA requirements with the additional components of authenticity, assurance, reliability (CIA3R) we create a multi-layered secure transactional communication that assures trusting interaction and exchange of information via mobile platforms.

FUTURE RESEARCH AND CONCLUSION

The proposed CAP framework is only one proposed solution to safeguard mobile healthcare information access and storage. More research and testing will be done within this framework which will result in developed prototypes that can be tested using, at first, sample data and later real time interactions. Additional research is needed refine the CIA3R layers before implementing them in CAP as well.

Without additional research in the area of mobile apps and healthcare information access, we will see more data leakage as more users rely on mobile devices.

WORKS CITED


Analytical Methods for Planning and Scheduling
Daily Work in Inpatient Care Settings:
Opportunities for Research and Practice

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Abstract: This article identifies current challenges in the planning and execution of daily work in inpatient care settings. Inadequate planning of the processes and resources associated with inpatient care services may negatively affect their effectiveness. It may also lead to burnout of healthcare workers when the resulting work plan is unknowingly infeasible or does not incorporate the necessary human factors considerations. This paper provides an overview of current research on inpatient care workflow planning, as well as with directions for researchers and practitioners to advance this problem using a combination of human factors engineering and analytical methods.

INTRODUCTION

Hospital efforts to shorten lengths of stay, and a higher percentage of elderly and sicker patients, have caused inpatient care workloads to increase. Nevertheless, hospital staffing levels have, at best, remained the same (Green, 2008). For example, a nurse’s workload is impacted by patient acuity, staffing levels, indirect care tasks and patient turnover (Lopez et al., 2010). Thus, fixed nursing ratios may work well on a given day but have undesired outcomes on others, depending on the patient mix (Upenieks et al., 2007; Yankovic & Green, 2011), particularly if the same methods are used to get the work done in different circumstances (Cain & Haque, 2008). Furthermore, the increase in patient acuity and the increasing demand for patient safety and quality activities evidence the need for effective work planning and prioritizing strategies (Patterson et al., 2011). Inadequate planning of the processes and resources associated with inpatient care services may negatively affect their effectiveness and the corresponding patient outcomes. It may also lead to the burnout of healthcare workers.

The national push to improve the efficiency of healthcare systems makes this trend likely to continue. Therefore, there is a need to help healthcare providers identify effective strategies to provide quality care with the resources available. Because inpatient care work at all levels (from patient care assistants to residents) involves some form of context-dependent decision-making, work planning strategies should support applicable instances of decision-making.

Analytical methods to support decisions have been widely applied in healthcare. However, most of this area of study focuses on medium and long-term decisions (e.g., weekly staff scheduling and resource allocation, respectively), while short-term decisions are seldom addressed. Operational (short-term) decision-making instances in healthcare depend on many changing variables such as patient mix, provider characteristics and available resources. Healthcare workers are often faced with the challenge of planning and adjusting their work patterns to meet actual patient demands when strategic and medium-term have been made and implemented. The success of a given strategy depends, then, on the expertise of healthcare workers to address those uncertain demands with the available resources, the most important being time. Nevertheless, even the most experienced healthcare worker can be subject to burnout and fatigue when such uncertainties are not carefully incorporated into their strategies and the resulting work plan turns out to be infeasible.

Not incorporating human factors considerations into the provider’s work plan can also contribute to burnout. Efforts are needed to understand inpatient care work and investigate strategies to support the provision of high quality care while protecting the well-being of healthcare workers. Although human factors engineering research in healthcare systems is not an entirely new concept, the use of analytical models to systematically incorporate these principles into routine inpatient care decisions is a potentially innovative approach. The use of systematic decision-making, and the ever-increasing availability of technology and healthcare information systems,
can provide a platform to support healthcare providers in making routine work-planning decisions, so that they can have more time to focus on clinical decisions that require critical thinking.

INPATIENT CARE WORK ANALYSIS RESEARCH

In manufacturing, the workflow of a product is defined as the sequence of steps that need to be carried out to accomplish such product (Damelio, 2011). In inpatient care settings, there is not a single definition of workflow (Unertl et al., 2010), so this paper will use a direct adaptation of the manufacturing definition. Inpatient care workflow is the set of services (and the corresponding activities) that need to be provided to each patient to achieve an end-goal: a satisfied patient with an improved health condition. Because of the complex nature of healthcare systems, the corresponding workflow is also complex (Clancy & Delaney, 2005; Vardaman et al., 2012) and requires the coordinated participation of many providers.

Another interesting characteristic of healthcare systems is that the work associated with patient workflow tends not to be linearly sequential or repetitive, as in manufacturing, particularly when it is viewed from the point of view of a single provider (e.g., a nurse) over a short period such as a single shift. There are many activities that a nurse needs to perform on each patient in a shift to achieve the ultimate goal (i.e., satisfied patient). Furthermore, such ultimate goal may not be accomplished within a single shift. This research is concerned with helping inpatient care providers organize their work in a single shift to ensure the provision of timely, high quality care while considering their own well-being. It is worth clarifying that this type of analysis should complementary to a systems-oriented workflow design. Once the inpatient care workflow (patient-centered) has been studied and (re)designed using a systems oriented approach, work analysis should be done to help healthcare workers plan and execute their assigned work in a manner that is consistent with such workflow. Traditional work analysis techniques from manufacturing are often not directly applicable and need to be adapted to be useful in healthcare settings.

Because nurses are the providers that most interact with patients in a hospital, most of the studies reviewed so far have been related to nursing work.

Nursing-based literature often uses qualitative research methods to understand and describe inpatient care work. These types of studies mostly focus on analyzing: tasks and sequences (Lundgren & Segesten, 2001; Potter et al., 2004), indirect care interventions (McCloskey et al., 1996), interruptions (Hopkinson & Jennings, 2013; Tucker & Spear, 2006), medication administration activities (Jennings et al., 2011; Keohane et al., 2008), and the impact of the implementation of health information technology on workflow (Niazkhani & Aarts, 2009). Some research articles focus on the analysis of nurses’ cognitive work (e.g., Wolf et al., 2006).

Some elements are common to these types of studies. Data is commonly collected from direct (field) observation and from surveys to nurses. The most common analysis methods include coding or categorizing notes obtained from observation and interviews into an existing or proposed classification system. Proportions in each category are commonly used as a measure of relevance of the corresponding category. Most studies illustrate their results using a narrative description of the work studied, while some of them propose some categorization for activities or situations of interest (e.g., categories of nursing activities, failures or interruptions). Graphical or visual representations of nursing work are scarce.

Human factors engineering (traditional work analysis) techniques have also been extensively used to categorize provider work (Battisto et al., 2009), to investigate how the time of providers is distributed (Capuano et al., 2004; Desjardins et al., 2008; Hendrick et al., 2008; Keohane et al., 2008), and to analyze the nature and distribution of interruptions (Rivera-Rodriguez & Karsh, 2010). Identification of waste, in the form of unnecessary work, motion and transport, is often an important component in human factors-based studies. For example, Capuano et al. (2004) used work sampling techniques to identify unnecessary work and implemented a series strategic and medium term solutions related to system (re)design, task (re)design and task allocation, among others. Desjardins et al., (2008) used a time-and-motion study to investigate the time spent by nurses on non-nursing activities and proposed a set of work reorganization strategies to reduce such activities. Wolf et al. (2006) and Potter et al. (2004) used link analysis and a cognitive pathway to map the physical and cognitive movements associated with tasks performed by a nurse and a patient care technician during their shift. This study can be very useful in evaluating the cognitive load of healthcare providers through a workday. Most of these studies provide strategies or recommendations to improve nursing work by eliminating waste. However, these strategies are mostly static and may become obsolete when contextual variables change (e.g., new team-members, changes in patient population).

As in any process, there are many opportunities for improving nursing work. Interesting remarks and conclusions found in the literature motivate a focus on streamlining its planning and execution. For example, Cornell et al. (2010, 2011) argues that nursing work lacks a structure that allows for the completion of care tasks
opportunities and challenges in its application to inpatient care provider work design will be discussed.

Operations Research is often referred to as interruptions in the medical literature (Tucker & Spear, 2006; Hall et al., 2010; Kowinsky et al., 2012). Unpredictable tasks range from common patients’ calls (e.g. to ask for help to go to the restroom or to ask a question) to emergencies due to unforeseen health deterioration. Tucker & Spear (2006) found that interruptions due to faulty systems, which need to be re-engineered through process improvement initiatives, represent about 5% of interruptions; while the majority of interruptions (about 95%) originate from medical work, and should be solved by designing the work to be robust to these interruptions. Cain & Haque (2008) also highlights the need for designing work so that it accommodates interruptions (about 95%) originating from medical work, and should be solved by designing the work to be robust to these interruptions. Cain & Haque (2008) also highlights the need for designing work so that it accommodates interruptions (about 95%) originating from medical work, and should be solved by designing the work to be robust to these interruptions. Cain & Haque (2008) also highlights the need for designing work so that it accommodates interruptions (about 95%) originating from medical work, and should be solved by designing the work to be robust to these interruptions.

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Computational and mathematical models are extensively used to understand problems, as well as to identify and evaluate solutions in similar situations in which decisions need to be made to accomplish a goal under limited resources. The discipline that focuses on using analytical methods to analyze complex systems is known as Operations Research (OR). In what follows, a brief description of OR in healthcare will be provided, and opportunities and challenges in its application to inpatient care provider work design will be discussed.

ANALYTICAL METHODS IN HEALTHCARE

Analytical methods, such as systems simulation and optimization models, have been used in healthcare delivery and medicine to support complex decisions (Pierskalla, 2010). This literature has increased over the years and continues to increase at a fast pace (Brailsford & Vissers, 2011). Applications include decisions in the management of operating rooms, such as the assignment of time to surgical cases, construction of surgical schedule, and patient scheduling (Guerrero & Guido, 2011) as well as identifying performance measures and incorporating uncertainty into the problem formulation (Cardoen& Beliën, 2010). Applications have traditionally focused on strategic and medium-term decisions, such as resource planning and utilization, quality management, finance, policy and regulation, workforce management, and risk management or forecasting (Brailsford & Vissers, 2011; Rais & Viana, 2010), as well as on operational decisions, such as performance monitoring, managing appointment systems, modeling patient flow and determining staffing levels.

A common application is the use of optimization techniques to support staff scheduling and rostering. In these optimization problems, the aim is to find the best schedule possible taking into consideration patient demand, required staffing levels, staff availability and, sometimes, worker preferences (Ernst et al., 2004; Hulshof et al., 2012). Models have been developed for decisions as broad as determining the number of personnel needed in a period of interest, and as detailed as determining the shifts to which each specific staff member should be assigned in a period of interest (e.g., a week). Yet, important decisions are made at the operational level, within a single shift, for which the application of OR-based decision-support models is limited.

Most of the decisions made within a shift are clinical and depend on the expertise of healthcare professionals. However, some decisions that appear to be routine (such as in which room to locate a patient or the best way to sequence patients in the next round) may have a direct impact on care quality and patient safety. Some studies have addressed these kinds of decisions. For example, Saghaian et al. (2011) used analytic and simulation models to design and evaluate emergency department triaging strategies to increase patient safety and operational efficiency under different conditions. Wang et al. (2013) proposed analytical formulas to model the processes that take place within a patient room during a patient visit to an emergency department. The model provides healthcare decision-makers with quantitative tools to investigate the impact of process changes on length of stay. Kortbeek et al. (2012) identified efficient flexible nurse staffing policies using float nurses that depend on workload prediction based on expected hourly census. Yankovic & Green (2011) used queuing models to evaluate nurse-to-patient ratios in terms of understaffing and overstaffing in different (possible) scenarios.

An important reason why these types of models are not more widely used in inpatient care work planning may be the difficulty in identifying and quantifying parameters that represent the associated processes and outcomes. Thus, these applications need to incorporate extensive reviews of relevant medical literature, use human factors principles at some level, and involve active collaboration between healthcare decision-makers and OR professionals.
to understand the processes, develop the corresponding models, quantify parameters, and evaluate the derived strategies.

**INPATIENT CARE WORK MODELING AND ANALYSIS: RESEARCH OPPORTUNITIES AND CHALLENGES**

This paper explores the potential use of analytical methods to support the planning and execution work in inpatient care systems. The vision is to develop systematic methods to understand and support decisions made by front-line healthcare workers throughout their workday that may impact patient outcomes. To that end, it is important to seek answers to the following high level questions:

- What are the types of decisions that healthcare workers make throughout their workday? Can (some of) these decisions be modeled and made systematic using analytical methods? What analytical methods are most appropriate for each specific type of decision? What information is needed to ensure that such decision support models are useful to decision-makers?

A major challenge in the use of analytical methods to support care services consists of defining and measuring system features that can be used to formulate practical models. For such models to be practical, it is necessary that the corresponding parameters can be estimated using information commonly available in hospitals.

**Understanding Healthcare Providers’ Work**

Once a patient-centered workflow has been established through a systems oriented approach (Cain & Haque, 2008), inpatient care processes should be studied from the point of view of a provider that has been assigned a set of patients to care for during a period of interest (a shift). Their objective is to provide the necessary care to those patients with the highest quality standards possible while incorporating relevant human factors considerations, such as minimizing walking time and reducing cognitive load throughout the day. The assigned patients have some specific service requirements according to key individual characteristics. The provider needs to decide when to carry out the activities associated to those services, taking into consideration the medical requirements of such services, the needs of the other patients assigned and the resources available.

Although planning helps to ensure that care plans are consistent with the appropriate guidelines, resources are used efficiently, and patients’ needs are addressed, such benefits will not be observed if the plan is not successfully implemented (Magnan & Maklebust, 2009). Because of the high variability of patient care needs from day to day, effective work planning and its implementation remain a challenge. Traditional work design methods alone are not sufficient to characterize healthcare providers’ work or to design and evaluate work planning strategies.

The first challenge in this area is to identify appropriate techniques to characterize and study inpatient care work, and that support proactive decision-making. In this research, the focus is on the decision of organizing the workday at the beginning of a shift, and modifying such plan for the remainder of the shift when unpredictable tasks disrupt its execution. In what follows, a preliminary approach to understand the problem based on optimization techniques (Taha, 2003) is illustrated.

**Example Analytical Approach: The Rounding Problem**

Healthcare providers often organize their workflow in terms of rounds. Rounds are prevalent throughout the many healthcare professions (e.g., residents’ rounds, nurses’ medication administration rounds, patient care assistants’ fall prevention rounds) because they facilitate remembering and sequencing tasks that need to be carried out in the short term. Understanding the processes and decisions involved in planning rounds, and identifying robust strategies to plan and execute such rounds, will potentially impact most healthcare-related professions, and potentially other service provider industries. Furthermore, studying the problem of rounds will provide with insights into other problems that affect front line providers, for instance: the location of patients within a care unit, the location of specialized equipment, and the provisioning of supplies to provide a specific service. Therefore understanding the rounding problem constitutes in itself a research opportunity.
A round can be defined as a set of activities to be carried out consecutively and without interruption, within a predetermined period of time. The first decision is to design a rounds-based schedule that allows for the timely completion of all activities required by the assigned patients throughout a shift. Preliminary interactions with actual healthcare workers showed that some of them plan their rounds using time slots defined by their start time. These start times usually correspond to each hour of the shift, and their duration is estimated to be the full hour. Activities are then assigned to each time slot (often using a printed schedule template) according to explicit patient needs. Following concepts from the literature on service planning and scheduling (Pinedo, 2005), the round planning decision could be represented using an optimization model that:

- assigns each predictable activity to a specific round, taking into consideration the timing requirements of the activities and the timing of the round;
- makes sure that activities assigned to a single round can be carried out within the time period of the round (often not enforced in practice); and
- provides with sufficient time to address unpredictable activities without significantly disrupting the timely performance of predictable ones.

The model could be mathematically expressed as follows:

**Parameters:**

- \( N \) number of predictable activities that need to be carried out in the shift
- \( p_j \) duration of activity \( j = 1, 2, \ldots, N \)
- \( r_j \) earliest start time of activity \( j = 1, 2, \ldots, N \)
- \( d_j \) latest termination time of activity \( j = 1, 2, \ldots, N \)
- \( T \) number of time slots available in a shift
- \( \alpha_t \) effectively available time within each time slot \( t = 1, 2, \ldots, T \)
- \( w_{jt} \) profit of assigning activity \( j = 1, 2, \ldots, N \) to time slot \( t = 1, 2, \ldots, T \)

**Decision variable:**

\[ x_{jt} = \begin{cases} 1, & \text{if activity } j = 1, 2, \ldots, N \text{ is assigned to time slot } t = 1, 2, \ldots, T \\ 0, & \text{otherwise} \end{cases} \]

**Model:**

\[
\text{max} \sum_{t=1}^{T} w_{jt} x_{jt}
\]

s.t.:

\[ \sum_{t=1}^{T} x_{jt} = 1 \quad \forall j = 1, 2, \ldots, N \]  

\[ \sum_{j=1}^{N} p_j x_{jt} \leq \alpha_t \quad \forall t = 1, 2, \ldots, T \]

\[ x_{jt} \in 0, 1 \quad \forall j = 1, 2, \ldots, N ; t = 1, 2, \ldots, T \]

The proposed objective (1) was modeled as the maximization of a profit that rewards timeliness and penalizes lateness or earliness of each task, depending on the characteristics of the task. Although earliest start and latest termination times should ideally be included in the model as constraints, in practice, these times are treated as
strong suggestions. Healthcare workers do their best to perform each activity as close as possible to the ideal time, as other activities allow and depending on their (implicit) priority.

The profit coefficients should then be a function of the earliest start time, latest termination time, and the time of the round to which the activity can be potentially assigned:

\[ w_{jt} = f(t_j, d_j, t) \quad \forall t = 1, 2, \ldots, T \quad (5) \]

Instead of profit coefficients, the decision-makers may prefer to evaluate the costs of lateness and earliness for each task assignment to specific rounds. Then, \( w_{jt} \) would represent the cost of each task assignment and the objective function would become a minimization problem.

Equation (2) represents each activity being assigned to one time slot, assuming that it is not allowed to break a task into two different rounds. Equation (3) ensures that the activities assigned to a time slot are completed within the effective time available in that time slot. Note that the parameter \( \alpha_t \) was specifically defined to denote the effective time available in the time slot corresponding to a round. This parameter is intended to address unpredictable work that needs to be carried out immediately. Therefore, it should be true that \( \alpha_t \) is less than the actual time within the time slot \( t \), providing the worker with some flexibility.

As with every model, the formulation (1) - (4) is a simplified version of reality but it triggers several interesting research questions. The first natural question that arises is if the formulation (1) - (4) is the best analytical approach to model round planning decisions or if there are other modeling techniques that could better help understand and solve this problem. Active collaboration with healthcare providers is needed to revise and validate the model. It is important that the parameters of the model selected be possible to obtain or measure using information (potentially) available in the corresponding healthcare organization.

It is also important to identify the human factor considerations that are relevant to the rounding problem. Human factors variables that may affect the well-being of providers, and in-turn the effectiveness of strategies, need to be investigated and the corresponding work-planning considerations need to be identified. Relevant human factors variables may include cognitive load (e.g., related to the use of short-term memory capacity or to shift in attention focus) and fatigue (e.g., distance walked). An example of work-planning considerations would then be the desired characteristics of the activities assigned to a single round to reduce cognitive load and to minimize transportation time. Once these considerations are identified, then they should be incorporated into the work planning model and the corresponding parameters should be estimated.

In the proposed formulation, the impact of unpredictable activities on the schedule was initially modeled as an allowance on the total time of each round. The parameter \( \alpha_t \) represents the effective time in each round, which is expected to be less than the actual time available, and equation (3) ensures that only this effective time is planned for. Therefore, each round has some flexibility to address unpredictable activities. A challenging research problem is to determine these round parameters, taking into consideration the characteristics of both predictable and unpredictable tasks as well as identified human-factors considerations. It is important to understand and quantify unpredictable tasks as well as the variability of predictable tasks to account for both in the schedule and to reduce the impact of interruptions.

Finally, an effort should be made to specify how the model can be used in practice to support decision-making and improve work. Because it is based on optimization techniques, the proposed model is in itself a decision support tool for organizing work at the beginning of the shift. Therefore, if data can be obtained or collected to estimate the proposed parameters, rounding strategies could be directly identified by implementing the model. Ideally, a model like this should interact with information in the patients’ electronic medical records, so that the plan can be updated when patient needs change (e.g., a new patient is assigned to the provider). Other situation in which the plan may have to be re-evaluated is when a substantial disruption takes place and tasks have to be deferred. In such case, a model like the proposed one could be used to revise the original plan at the time of the disruption to find the best allocation of the remaining tasks (including the deferred ones) in the remaining time.

The proposed research has the potential to result in an advanced knowledge of the work organization strategies used by providers in inpatient care settings. It could provide with an innovative modeling approach for provider work that can be tailored to different healthcare settings and different service-oriented organizations. It opens a new research area within the operations planning and scheduling field by introducing a real and challenging problem: the rounding problem. If studied and solved using information commonly available in organizations, this problem could have a positive impact on longer term decisions such as determining staffing levels and developing policies for staff scheduling.
Extensions

In addition to human factors engineering considerations, the proposed work analysis approach can be used to create a shared understanding of other qualitative considerations of importance to patients, providers and/or the organization and to incorporate some of these into work organization decisions. In the case of nursing, for example, nursing practice philosophies (Drenkard, 2008) could be investigated and modeled. One way to accomplish this would be to incorporate constraints on the maximum number of nurses assigned to a single patient in a shift, or on the total contact time of a nurse with each one of his/her assigned patients, to ensure a true healing and human caring environment.

A modeling approach such as the proposed one should be extended to incorporate uncertainty in the duration and frequency of tasks. We proposed using a time allowance to provide with flexibility to address unpredictable tasks. There are many other ways in which uncertainty can be incorporated into the decision support model. For example, if it is possible to identify probability distributions for the model parameters, then stochastic programming (Birge & Louveaux, 1997) methods could be applicable. Also, if best and worst cases of the parameter values can be estimated, then the applicability and practicality of robust optimization (Bertsimas & Sim 2003) techniques can be explored. The robustness of solutions in the face of uncertainty, regardless of the model used to identify these solutions, can be evaluated before implementation using computer-based simulation models to identify undesirable performance under certain scenarios of interest.

In general, the proposed research has application into the implementation of (new) quality practices in healthcare organizations. The implementation of evidence-based guidelines has proved challenging in many areas of clinical practice (Stacey, 2004). In particular, quality and safety practices tend to be moved down the priority of tasks when other time sensitive situations arise (Lopez et al., 2010). For instance, in pressure ulcer prevention, although it is recommended that patients be repositioned at least every two hours, a study found that about half of the patients were not repositioned for more than 2 hours. Furthermore, about 40% of the nurses surveyed believed that the recommended standard was not being met in their units (Lyder et al., 2008).

An important reason for the lack of success in implementing new practices may be the difficulty of addressing both the existing and new responsibilities when resources are not optimally allocated. In this situation, staff are often charged with closing the gaps in the system (Henriksen et al., 2008). Thus, facilitating processes by carefully designing workflow and allocating the needed resources may positively impact the adoption of new practices. The challenge is to identify the workflows, resources and other system features that may affect system performance, as well as strategies to plan for them in an efficient manner.

Workflow analysis and design using human factors engineering provide with the necessary conditions that need to be met so that interventions are implemented efficiently. The variability in healthcare processes makes this challenge particularly interesting, and traditional static/deterministic workflow analysis and resource allocation techniques inadequate. Adaptability in the strategies is key to their success. Operations research methods have the potential to help incorporate all these conditions into key decisions in the shape of constraints and objectives, so that decisions can be adapted to the context of interest.

CONCLUSIONS

A systems approach is needed to ensure that the healthcare delivery system helps providers do the right thing while caring for patients. The research opportunity lies in combining theories from human factors engineering with analytical techniques to support operational decisions that need to be made consistently and that involve conflicting criteria such as patient needs, time constraints, resource availability and ergonomic considerations. Techniques such as optimization and computer simulation have the potential to support these kinds of decisions.

This research proposes the use of modeling techniques for understanding and organizing provider work throughout a shift. Such operational model could help identify and evaluate workflow strategies, such as timing and sequencing of rounds, that take into consideration the actual patient-mix in the period of interest. Other decisions that could be potentially supported by Operations Research (OR) methods include patient location/relocation throughout their hospital stay, and the supply, location and maintenance of the physical resources of the inpatient care work-system. The current advances in information technology and data analytics have the potential to support this effort. Electronic medical records systems (computerized charts and electronic health records) allow for more data to be available to healthcare providers at different levels of care. Nevertheless, their use in planning, implementing and evaluating direct care interventions is still on the rise.
This research has the potential to directly benefit healthcare workers by helping them systematically identify and evaluate practical strategies to efficiently provide quality care to their patients. Therefore, they will be able to focus on actual care provision and medical decision-making. In turn, patients will benefit by experiencing timely, effective, equitable, and safe care.

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Predictive Modeling in Post-reform Marketplace

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Abstract: Healthcare reform changes everything. Annual and lifetime dollar limits, underwriting, and pre-existing condition exclusion will all be eliminated by 2014. Insurers must offer coverage to any individual regardless of their health status. An overwhelming majority of those who will be mandated to purchase individual insurance is currently uninsured or under-insured. Insurers have insufficient internal data to estimate costs for this new population. A study on how to apply predictive modeling to deal with risks and uncertainties facing healthcare industry in the post-reform marketplace is presented in this article.

Key Words: Predictive Modeling, Health Care Reform, Risk Adjustment, Risk Assessment, Big Data.

INTRODUCTION
As a part of strategy supporting their preparation for healthcare reform, healthcare carriers have been focused on developing high-performance risk models using advanced predictive modeling and data mining criteria to identify new potential opportunities in the post-reform marketplace. The objective is to look for tactics and strategies that can be applied by business units to maximize the margin which is defined as

\[
\text{Margin} = \text{Revenue} - \text{Cost},
\]
where, in a generic sense, the revenue represents the amount of money that a health plan expects to receive from the premium charged and the transfer under the risk adjustment, the only permanent program that applies to individual and small group markets under the Patient Protection and Affordable Care Act (PPACA, 2010), or the Affordable Care Act (ACA); and the cost includes the amount of claim liability, the administrative cost, and miscellaneous items. To put it simply, the margin is the difference between the money in and the money out. In order to maximize the margin, health plans must develop business strategies around revenue growth and/or cost reduction. However, strategies implemented for the revenue growth do not necessarily coincide with the cost reduction, and vice versa.

Historically, young and healthy members have been key drivers for profitability in the individual market. Through underwriting, health plans have the ability to know some key information about each person that is insured. The amount of premium collected from a member is the amount of money a plan will earn from that member. The health insurance industry could offer a number of plans to fit everyone’s need, and most people insured through individual policies were insured before. Healthcare reform (HCR) is changing everything. Health plans will have to find other ways to learn about their members. The revenue from members will now be more closely connected to their “coded” health status. The number of plans will be limited, and a higher level of benefits is required. There will be a large number of uninsured people entering the healthcare system.

The applications of predictive modeling have grown tremendously in recent years. It provides an advanced analytical framework to help health insurance carriers more accurately develop their business strategies to identify a niche. A useful model provides a disciplined approach for understanding the potential solutions of business problems. These solutions and outcomes give feedback to the original business problems, and the process is continuously refined through ongoing practice. There are two general purposes of fitting a model in healthcare analytics, either predicting the healthcare outcomes or exploring their relationships with various risk factors. When the attention is paid to the latter goal, one can further derive a scoring algorithm by taking the advantage of the systematic component in the model. A scorecard can then be designed for segmenting individuals into different risk groups.

The construction of a specific predictive model depends on the type of healthcare outcome. Exploratory data analysis (EDA) (see Tukey, 1977) can help modelers to identify the underlying distribution of target variable and choose a correct model and link function. When the response variable is normally distributed, linear regression models are often used to describe the linear relationship between the response and a set of risk factors. For a comprehensive review of linear regression analysis, readers are referred to Yan and Su (2009) and Fox (2002).

However, health insurance data are typically non-normal, so an extension of classical linear models is necessary. Generalized linear models (GLM; McCullagh and Nelder, 1989) extend linear models to encompass other types of responses. For example, a Poisson distribution is typically suited for modeling the number of claims over a period of time, a Gamma distribution is usually chosen for modeling the average cost of a claim. Jørgensen and Paes de Souza (1994) introduce the Tweedie distribution, a special member of exponential family, for modeling the pure premium directly. Two other general books on GLM are Dobson and Barnett (2008) and de Jong and Heller (2008).

For modeling binary outcomes, logistic regression and tree-based models (see Breiman, Friedman, Olshen, and Stone, 1984) are popular choices. In addition, there are many other tools such as boosting, random forests, support vector machine, and artificial neural networks that are available for classification problems. For more discussions of these models, one can find Hastie, Tibshirani, and Friedman (2009) very informative.

Regardless of what model is chosen, the goal is to separate “good” risks from “poor” risks and identify positive margin opportunities. In order to identify where the positive margin is, we must understand the revenue received in a risk-adjusted system and the expected cost for future prospects. In short, a risk adjuster is a predictive model in which age, gender, health status, and sometimes other factors are used to determine the amount of revenue redistributed to or from a health plan. The other half of the equation is predicting the claim costs, also referred to as risk assessment or lifestyle-based analytics (LBA). Draagtel (2011) considers the use of age, gender, and lifestyle characteristics to estimate a prospect’s future cost.

This article explains the role of predictive analytics among marketing, revenue programs, and care programs for targeted marketing, revenue growth, and cost reduction, respectively. These three entities can operate independently to achieve their own goals. However, without well-planned coordination, the margin described in (1) may not be optimized. Therefore, it is extremely important to have a dedicated team to monitor and to identify the potential risks. Section 2 gives a brief introduction of healthcare reform. Section 3 shows how a risk adjustment model is used to determine the amount of revenue an insurer will receive in the post-reform marketplace. Section 4 introduces two distinct risk assessment approaches for segmenting prospects. Section 5 discusses the use of predictive modeling focusing on marketing, revenue growth, and cost reduction. Section 6 concludes this article.
HEALTHCARE REFORM

The PPACA was signed into law by President Barack Obama on March 23, 2010. It requires insurers to offer coverage to anyone regardless of an individual’s health status, and it eliminates the annual and lifetime dollar limits. However, an overwhelming majority of those who will be mandated to purchase individual insurance are currently uninsured or under-insured. To overcome the uncertainty that concerns pooling and sharing in a new market, on March 11, 2013, the Department of Health and Human Services (HHS) published a final rule on the implementation of the reinsurance, risk corridor, and risk adjustment programs (see Department of Health and Human Services, 2013) to assist health plans with a smoother transition into this new era.

The 3 R’s

Just as our elementary school students focus on their 3 R’s (reading, ’riting, and ‘rithmatic), current health plans are focusing on their 3 R’s (Reinsurance, Risk Corridors, and Risk Adjustment) in the post-ACA marketplace. These three programs will have substantial financial impacts on insurance companies and the post-reform marketplace.

The three programs (created in Sections 1341, 1342, and 1343 of the Affordable Care Act) are generally referred to collectively as the “Premium Stabilization” programs since their inclusion was an attempt to prevent “rate shock” in individual and small group market premiums in a post-ACA marketplace.

Reinsurance

The first of the 3 R’s is reinsurance. This is a temporary program (2014-2016) that will reimburse insurers who have individual members with high dollar claims. The plans are expected to lower premiums to account for this reduction in claims liability. In 2014, insurers will be reimbursed 80% of member paid claims that exceed $60,000 up to $250,000. Most estimators have placed that to be between 8% and 15% of expected claims.

The total pool to be distributed is $10B for year 2014, which will decrease to $6B for year 2015 and $4B for year 2016. The reinsurance payments will be funded by a Reinsurance Fee of $5.25 per member per month assessed to insurance companies for each member they cover in any line of business they have during year 2014 and will decrease accordingly in subsequent years. Therefore, this effectively makes the reinsurance program a vehicle for non-individual lines of business to subsidize the individual line of business. It makes the products in the individual market less expensive and more attractive to create a better risk pool in the first years of the ACA reforms.

Risk Corridors

The second R is risk corridor, also a temporary program (2014-2016). Modeled after a similar program instituted by the Medicare Modernization Act for the creation of the Medicare Part D pharmacy benefits, it requires plans to share in gains and allows them to be subsidized on losses on “Qualified Health Plans (QHPs)”, which are defined as plans that meet the requirements to be sold on the Marketplace. It is applicable for both small group and individual QHP’s.

A loss ratio will be calculated on each issuer’s experience on non-grandfathered business, considering the impacts of risk adjustment and reinsurance on the same basis as the ACA-required Medical Loss Ratio test. That loss ratio will be compared to a specific target based on the plan’s actual administration and profit margin (or loss). If the loss ratio is better than the target by more than 3%, the company will be required to write a check to the government for 50% of the excess. If the loss ratio is better than the target by more than 8%, the company will be required to write a check to the government for 80% of the amount above the 8%, plus 50% between 3% and 8%. The opposite is also in effect, where insurers will receive payment from the government for loss ratios that are above target by more than 3% and 8%, using the same factors.

The risk corridor encouraged plans to price more aggressively for Part D. It was included in ACA since the new market rules, particularly with the guarantee issue requirement, and it may have caused insurers to avoid the market or price conservatively. The historical data will be insufficient to be confidently used to set the premiums appropriately to cover their expected claims. The risk corridor program will expire after three years with the expectation that insurers should then have enough experience to have an adequate foundation for assessing future expected risk.
Risk Adjustment

The final R introduced in ACA is risk adjustment. This is the only permanent program designed to level the impacts of risk selection by enrollees between plans. It creates a risk score for each enrollee in both the individual and small group markets and then facilitates a transfer of money from lower-than-average risk plans to higher-than-average risk plans.

Historically, in underwritten markets, financial success was often determined by risk selection. If you enrolled healthier members and maintained a healthier risk pool, you could charge a lower premium and maintain profitability. That risk selection was under the insurer’s control. With the new guaranteed issue requirement, there was concern that the sickest members might disproportionately select a richer plan (or one with more expensive specialists), and that plan would lose money not because they had higher costs or were ineffective, but due to anti-selection from the enrolling population. Risk adjustment is a method to quantify and monetize those risk disparities. It should allow plans to not be concerned about who selects them, but only about doing the best job possible in controlling costs whether through contracting or improving the health status of their enrolled membership.

The risk adjustment program established by ACA separated the individual and small group markets into separate pools. Then, on an annual basis, it scores every member based on the medical diagnosis codes they received during the year in order to calculate the necessary inter-plan transfers to normalize for member risk selection.

HHS-HCC RISK ADJUSTERS

The hierarchical condition category risk adjustment models developed by HHS (HHS-HCC) are predictive models that use the current year diagnoses to predict the current year costs, and are therefore known as concurrent models. This section provides a brief summary of HHS-HCC risk adjustment models. Interested readers can find the HHS Notice of Benefit and Payment Parameters for 2014 (Department of Health and Human Services, 2013) for more information.

HHS establishes 15 risk adjustment models, one for each combination of metal level (platinum, gold, silver, bronze, and catastrophic) and age category (adults, children, and infants). Each HHS risk adjustment model predicts plan liability for an enrollee based on that person’s age, sex, and diagnoses (risk factors); thereby, predicting a risk score. HHS proposes separate models for adults, children, and infants to account for cost differences in each of these age groups. The adult and child models are additive; that is, the relative costs assigned to an individual’s age, sex, and diagnoses are added together to produce a risk score. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups based on the infant’s maturity and the severity of its diagnoses. If applicable, the risk score is multiplied by a cost-sharing reduction adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk-adjustment-covered plan within a geographic rating area are then input into the payment transfer formula to determine an issuer’s payment or charge for a particular plan.

RISK ASSESSMENT

In this study, we apply two distinct approaches: proxy and build-up (BU). The proxy approach is designed to predict the claim cost as a whole regardless of health conditions, while the BU approach considers a claim cost as a composite of selected condition-specific costs. For both approaches, each risk assessment model is constructed with a two-stage process that consists of a prevalence model and a conditional severity model.

Proxy Approach

The proxy approach considers the claim cost as a whole. It predicts a prospect’s future claim cost through the following four steps. To avoid confusion, the final predicted claim cost from any risk assessment model is referred to the risk.

1. The claim cost will be estimated directly several times, and an ensemble model will be deployed to take the average of all possible predictions as the final outcome. That is, with k models built, the risk can be estimated as
2. In this study, these identified proxies use, for instance, the cutoffs at the 95th percentile, 90th percentile, 75th percentile, and 50th percentile of PMPM cost in the study sample. For the target variable, which defines the event of interest, individuals with PMPM greater than the cutoff will be flagged as 1 and 0 otherwise.

3. For each proxy, a prevalence model is constructed to predict the likelihood of an individual having the value of 1 or 0 on the target variable. Since the binary target defined in step 2 partitions the sample into two disjoint subsamples, we build a conditional severity model within each subsample. The risk is then determined as the expected cost by conditioning on the values of target variable, providing weights as the corresponding prevalence.

4. A wide variety of proxies were introduced in step 3. They are viewing the problem from different angles. Each model in the collection represents a tremendous amount of work. It is desirable to form an ensemble of these proxies to improve prediction accuracy (see Seni and Elder, 2010). Therefore, the overall risk is obtained using the simple arithmetic average of all proxies as shown in Figure 1.

\[
\text{Risk} = \sum_{i=1}^{k} \left( \frac{\text{Risk}_i}{k} \right) .
\]

![Figure 1: Proxy Ensemble Model](image)

**Build-Up Approach**

The BU approach, on the other hand, consists of separate prevalence and conditional severity models which are combined to develop an aggregate prediction of claim cost.

1. The BU approach selects a set of medical conditions that are costly and for which LBA is believed to have an impact. A residual category is included to capture costs attributable to all other conditions. With k condition models, the total risk can be estimated by summing over the condition risks as

\[
\text{Risk} = \sum_{i=1}^{k} \left( \text{Condition Risk}_i \right) .
\]

2. In this study, these identified risk conditions include cardiovascular disease, diabetes, hypertension, gastrointestinal disease, and musculoskeletal disease. All of the remaining conditions are combined together to form a residual category.

3. Each condition model consists of two models, a prevalence model and a conditional severity model. The prevalence model predicts the likelihood of a prospect having the condition, and the conditional severity model (severity) predicts the cost of the condition if he or she has the condition. The condition specific risk is then determined by the product of prevalence and severity.

4. The sum of the condition-level predictions results in a total cost prediction shown in Figure 2.
APPLICATIONS

Since the primary goal of marketing is introducing the right product to the right customer at the right time (see Li, Baohong, and Alan, 2011) for the right price at the micro-market level, the role of predictive analytics is to provide data-driven tactics and strategies to answer these questions. The goal of revenue growth, on the other hand, is to focus on increasing the average risk score of a health plan under a risk adjustment payment system. Every additional risk score generated by revenue programs will contribute to the revenue growth in (1). The clinical care perspective is the third crucial component to optimize the margin. By closing the care gaps and eliminating healthcare disparity, patient-centered care programs aim to improve the quality of care and to ultimately reduce the cost of medical care (see Tucker et al., 2011).

Marketing

Long ago and far away in the Far East, a little boy always has his hair cut at the same local barber shop, the VIP Barber Shop. This small barber shop was able to establish relationships with their customers. Over time, those customers became friends, which resulted in happy customers and a profitable business. That little boy grew up and moved away; now has his own family; and is working on predictive analytics in the post-reform marketplace. But one thing has not changed. His mother continues to manage the barber shop and the majority of customers continue to be loyal customers of her shop. Healthcare plans, with millions of customers, cannot form that level of personal relationship with a customer like a local small shop can. They must rely on other ways to connect with their customers. In particular, they can take full advantage of their big data.

The impact of risk modeling, based on the BU approach, can be seen from Table 1, considering a study sample of more than a half million members. After removing the effect of age and gender, the ranked adjusted LBA risk scores from the BU model were used to classify members into LBA 1, LBA 2, and LBA 3 segments.

<table>
<thead>
<tr>
<th>Loss Ratio</th>
<th>Risk 1</th>
<th>Risk 2</th>
<th>Risk 3</th>
<th>Overall</th>
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<tbody>
<tr>
<td>LBA 1</td>
<td>79%</td>
<td>73%</td>
<td>73%</td>
<td>74%</td>
</tr>
<tr>
<td>LBA 2</td>
<td>81%</td>
<td>79%</td>
<td>75%</td>
<td>77%</td>
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<tr>
<td>LBA 3</td>
<td>99%</td>
<td>93%</td>
<td>82%</td>
<td>87%</td>
</tr>
<tr>
<td>Overall</td>
<td>87%</td>
<td>82%</td>
<td>77%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Table 1: Loss Ratio Impact of Risk Modeling

Meanwhile, the HHS-HCC risk adjustment algorithm was applied to these members, and Risk 1, Risk 2, and Risk 3 segments were created to indicate the severity of HHS-HCC risk score. Table 1 displays the impact of risk modeling in terms of expected loss ratio. With the consideration of risk adjustment transfer mechanism, a Silver plan with $2,000 deductible, 80% coinsurance, $6,000 out of pocket (OOP) maximum, and an overall 80% loss ratio is assumed throughout this article.

People in LBA 1 and LBA 2 segments are more desirable than those in LBA 3 segment, having the expected loss ratio ranging from 74% to 87%. On the other hand, the HHS-HCC risk segmentation suggests that prospects in
Risk 3 have a loss ratio lower than that of Risk 1 or Risk 2. Table 2 considers the combination of the Proxy and BU approaches, with five risk segments from each model. This ensemble approach is able to provide us the range of loss ratio from 67% to 93%, which is a better risk separation than the single model.

<table>
<thead>
<tr>
<th>Loss Ratio</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>67%</td>
<td>75%</td>
<td>77%</td>
<td>82%</td>
<td>79%</td>
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</tr>
<tr>
<td>2</td>
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<td>73%</td>
<td>77%</td>
<td>80%</td>
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<td>76%</td>
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<td>73%</td>
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</tr>
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<td>90%</td>
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<tr>
<td>Overall</td>
<td>68%</td>
<td>76%</td>
<td>78%</td>
<td>83%</td>
<td>89%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Table 2: BU and Proxy Ensemble

### Revenue Growth

Predictive analytics is essential in revenue programs, where “selective interventions” – finding people and families in need of healthcare – is a must, given only limited resources available to the operational units. The use of predictive analytics is to make the management of revenue more efficient. Member-focused engagement and provider performance profiling are two areas that will benefit from predictive analytics. The member-focused engagement aims to create a rules engine to improve the quality of care based on in-home or other types of prospective health assessments (see Wilson et al., 2005). The measure of quality is based on accurate medical condition coding, care management, and efficiency. One can develop a statistically credible and focused approach for identifying high-opportunity members for prospective assessments and generating a list of members ranked by the quality of coding accuracy, efficiency, and care management in order to focus the efforts of the revenue programs with regards to member engagement.

These efforts here would include such activities as assuring the company has complete and accurate documentation of a member’s health history and health status, using member’s status and history to anticipate her/his future health needs and status, using members’ status and history to predict the healthcare resources and interventions needed to improve the health of the covered population, and forecasting the revenues under risk adjustment.

Provider performance or practice profiling (see Ash, Shwartz, and Pekoz, 2003) is another avenue to improve the quality of care and to identify additional revenue. Rather than intervene at the member level, the organization can support providers to identify and help populations and their communities to achieve better health. Ultimately, a list of providers will be identified by the accuracy of coding, the quality of care management, and the efficiency in order to focus the efforts of provider engagement.

The potential impact of these efforts can be seen from Table 1 where the expected loss ratio moves from 87% in Risk 1 to 77% in Risk 3. When considering the LBA risk segmentation together with HHS-HCC risk segmentation, the loss ratio is expected to be as low as 73%.

### Cost Reduction

With ACA’s push for an increased focus on quality outcomes, it is imperative for the organization to increase member-focused engagement strategies. Predictive modeling can help improve care and member outcome and reduce the cost. The healthcare industry is addressing this issue by developing clinical predictive models to prospectively identify members with health needs who could benefit from care management intervention, and prioritizing resources based on stratifying individuals from those with the greatest opportunity for cost reduction to those with the least likelihood (see Tewari et al., 2001).

Together with real-time and fact-checking analyses, predictive modeling gives a broader view of members that reveal their gaps in care, healthcare utilization patterns, laboratory results, and other pertinent information to help provide strategies for health improvement. In addition, an insurance company wants to determine the best
approaches for how the clinical care team can interact directly with the identified member population to not only educate them on their current health opportunities, but also to empower the member to take ownership of his/her own health outcomes.

The movement from LBA 3 to LBA 1 as seen in Table 1 indicates the potential opportunity, a decrease of nearly 13% in loss ratio overall to potential decrease of nearly 20% among people in Risk 1 or Risk 2 segments. By year 2017, the two temporary protection programs, risk corridor and reinsurance, will no longer exist. The risk adjustment is the only permanent program that will determine the premium with risk selection for the health plans. Therefore, every plan will bear the risk that is not effectively explained by the risk adjustment payment system in the post-reform marketplace. In the interim, the advantages gained from targeted marketing and revenue program management will decline over time due to the competitiveness of this market and the improvement in coding proficiently. The future success of any health plan will be its ability to reduce the cost of care of its membership in this post-ACA environment.

The enterprise efforts should be dedicated to reduce health care disparities, to enhance health literacy, and to provide culturally and linguistically appropriate services (CLAS) to improve the quality of clinical care and service for members. In summary, an organization will be evaluated on the collection of race, ethnicity, and language data from members, access and availability of language services, practitioner network cultural responsiveness, culturally and linguistically appropriate services programs, and the elimination of healthcare disparities (National Committee for Quality Assurance, 2010).

Ultimately, the healthcare carriers should provide individualized medical approaches along with a framework for identifying the minimum data needed on patient preferences for accurate medical decision making (Hornberger, Habraken, and Bloch, 1995) to their members. The concept is to customize the individual treatment care plans for members. The company must understand the variability of customers. The universal approach will not satisfy all the consumers, especially when they will have increased freedom of choice in purchasing health coverage. The expectation from the consumer will be that they understand the different treatment plans or options that are available to them. As a payer, it will be extremely important to provide the best quality of care utilizing the most efficient approach for these members.

CONCLUSION

For the health insurance industry, the purpose of predictive analytics is to proactively anticipate potential medical needs for all members and to be able to provide appropriate interventions before certain medical conditions develop or surface for these members. A dedicated team will be required to develop the predictive analytics capability that would benefit the company in the long run. The healthcare insurance environment will continue to become a more competitive and customer-oriented business. The knowledge accumulated from an effective advanced analytics team will serve the company in many areas that could impact all the elements of the margin as described in (1).

Predictive analytics allows for quantitative efforts to predict human behavior. In the context of marketing, these efforts have been helpful at “winning customers”. For political election campaign, it benefits those who apply a scientific approach to grass roots outreach. In the context of healthcare, it can help people and communities to achieve better health, increase resources and save lives.

Predictive analytics is ideally suited for a healthcare organization’s emergent business problems that the existing strategies cannot address in an evolving market where the stakes are high. These problems can be solved through advanced analysis of disparate, petabyte-scale, structured, and unstructured data sources to satisfy customers’ needs. The healthcare industry has a number of potential problems when we consider the challenges of targeted marketing, coding accuracy, revenue growth, healthcare disparity, payment integrity, quality of care, healthcare cost reduction, and ultimately personalized care management.

The reputation of advanced analytics in an organization must be founded upon solving these types of complex problems. It starts with a well-scoped process and direct engagement of the end-users. Typically, this works best on new and emerging initiatives that are identified as the top priorities. It aims on building collaborative relationships with all partners as the insurer leverages its data integration platform to help extract value from existing disparate systems, work more collaboratively with internal and external business stakeholders, create specific analytical workflows, and move the carrier from a health insurance company to a healthcare solution company that will be ready to respond to the diverse challenges of a changing marketplace.
REFERENCES


A Study on Generic Prescription Substitution Policy as a Cost Containment Approach for Michigan’s Medicaid System

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Abstract: High health care costs have left millions of people unable to buy health insurance and has broadened the state’s responsibility to protect low-income families through Medicaid programs. Increasing health care costs have created severe toll on fiscal management of federal and state governments. Prescription drugs are a significant part of Michigan’s Medicaid costs. Due to the economic recession and the downsizing of auto sector the number of Medicaid beneficiaries in Michigan has increased over the years. Thus it has increased Medicaid prescription drugs program costs at a fast pace, which creates fiscal burden on Michigan in administering the program and providing prescription drugs for its beneficiaries. Michigan has implemented several strategies for cost containment of Medicaid since 2001. These strategies have brought modest results in terms of cost containment in Medicaid prescription drugs program. This study examined whether a generic substitution policy of Medicaid prescription drugs in Michigan would be an efficient and effective cost-containment strategy. In doing so, it emphasizes three questions: First, will a generic substitution policy be an efficient strategy in containing Medicaid prescription drug program costs for Michigan? Second, if not in general, are there any “heavily used” brand drugs for which generic substitutes are available that can Michigan safely reduce Medicaid costs by implementing a higher use of generic substitution, thus saving the state in prescription drug costs through the generic substitution policy? Third, if the answer is yes for the two previous questions, then approximately how much money can Michigan save per year by implementing the generic substitution policy? This research found generic substitution policy as an efficient way in cost containment in Michigan Medicaid prescription drugs program.

INTRODUCTION

The cost of rising health care, especially Medicaid costs, have taken a tremendous toll on the fiscal management of the federal and state governments, because of the responsibility of financing the Medicaid program to ensure health care for the low-income groups of the population. Currently, states have spent almost 16% of their budget for Medicaid, which is the second largest item in the budget for most (Kaiser Foundation, 2010). This responsibility has been broadened significantly by the Patient Protection and Affordable Care Act (P.L. 111-148) commonly known as the health care reform bill signed by President Obama on March 23, 2010. In Michigan, due to the effect of the recent federal health care reform bill, it is estimated that the Medicaid expansion will add 375,000 individuals to the Medicaid program (Angelotti and Fosdick, 2010). Both federal and state governments have launched policies/strategies to control health care costs. Thus, and especially in the current economic downturn, Medicaid cost containment has become one of the focal points of federal and state governments’ fiscal policy. More and more studies are being conducted, searching for reasons for health care cost escalation and ways to contain Medicaid costs (James and Bayley, 2006; Delaune and Everett, 2008; Dalen, 2010, Kelly and Fabius, 2010).

Background - Medicaid Prescription Drug Costs in Michigan

In 2007, one and half million Michigan low-income residents received health care coverage through Medicaid at an annual cost of $9 billion (Fairgrive and Stauff, 2007). One in every seven Michigan people or 15% of the total Michigan population depends on Medicaid. More than 30% of Michigan’s 2.5 million children were enrolled in Medicaid in 2007. Seventy-five percent of Medicaid recipients are from lower income families, including pregnant women, children, and parents or other care-giver relatives (Fairgrive and Stauff,
2007). This situation has intensified due to the recent economic recession and especially due to the near-collapse of the three Michigan-based American auto giants. A large portion of the state population has historically been directly or indirectly dependent on the auto industry; moreover, employees of the manufacturing sector—such as auto industries—received good health care benefits (Fairgrieve and Stauff, 2007).

In recent years, Michigan has implemented various strategies as part of the state’s ongoing cost containment efforts. Of all the policies and strategies for cost containment, savings from prescription drugs in Medicaid has received significant attention as a potential source due to its potential advantages over any other structural or policy adjustment in this regard (Kibicho, 2006). Michigan has implemented the following four specific policies to contain Medicaid prescription drug costs: 1) in February 2002, introducing a preferred drug list for Medicaid beneficiaries known as the Michigan preferred product list (MPPL); 2) in February 2003, implementing the Michigan Multistate Pooling Agreement (MMSPA), a joint purchasing arrangement with Vermont, also known as the National Medicaid Pooling Initiative (NMP); 3) in November 2003, establishing a maximum allowable cost for pharmacy reimbursement; and 4) in May 2004, coordinating a Michigan multi-state purchasing arrangement (Kibicho, 2006). Although these cost-containment initiatives contributed a considerable savings, in reality, these cost-savings strategies achieved only modest success in limiting the escalation of Medicaid prescription drug expenditures in terms of total state shares (Grabowski, 2008).

In containing costs of prescription drugs, a generic substitution policy has received considerable attention. Research findings show that increases in the use of generic drugs for prescriptions can reduce a significant amount of costs for the Medicaid program (DHHS, 2010; OIG, 2006). Additionally, the DHHS (2010) stated that the quality of generic drugs is similar to brand-name and non-generic drugs, while generic drugs are priced much less compared to brand-name/non-generic drugs (DHHS, 2010; OIG, 2006). In recent times, ten states (Florida, Kentucky, Massachusetts, New Jersey, New Mexico, Oregon, Rhode Island, Tennessee, West Virginia and Wyoming) have implemented a generic substitution policy for Medicaid prescription drugs (Shrank et al., 2010).

In the context of Michigan Medicaid prescription drug cost containment, a generic-substitution policy becomes a viable option because Michigan has the potential to use more generic substitutions. A report prepared by DHHS determined that in 2004 55% of drugs prescribed to Michigan Medicaid patients were generic (Grabowski, 2008). According to Cox et al. (2006), the generic fill rate in Michigan was 52.7% in 2006. 2009 data of Center for Medicare and Medicaid (CMS) shows that a total of only 66% generic drugs are utilized for Medicaid beneficiaries, which, can be considered moderate. According to CMS data 2009, a 1% increase of generic drug use could potentially save the Michigan’s state share $4,616,125, and a 5% increase in generic use could save the state share over $ 23 million. Based on the CMS estimate Michigan can save nearly $64.5 million a year in Medicaid prescription drugs if it can optimize the use of 80% of generic drugs instead of the current 66% use of generic. A Lewin Group (2011) report estimated that Michigan can save a net $453.5 million over the next ten years (from 2012 to 2021) if the Medicaid pharmacy program—including increased amounts of generics in Medicaid prescription drug use—was optimally managed. All this previous research and data suggest that Michigan can increase generic substitutions at least 14% to 23% and even more to achieve the maximum limit of using generic drugs and thus, can save a significant amount of money from its Medicaid prescription drug expenditures.

The present study emphasizes two crucial issues related to Medicaid cost containment in Michigan. First, this study asks, if implementation of a generic substitution policy be an effective and efficient strategy for containing prescription drugs costs in Michigan Medicaid? Second, if yes, then what amount Michigan can save by the generic substitution policy and from which therapeutic classes?

RESEARCH APPROACH, DESIGN AND METHODOLOGY

The current study uses a cost benefit approach in examining the above-mentioned research issues and to analyze the potential savings by a generic substitution policy regarding cost containment of prescription drugs in the Michigan Medicaid program. The cost-benefit analysis is “a technique for systematically estimating the efficiency impacts of policies” (Weimer and Vining, 2005, p. 380). In the policy context “a particular matching of resources to use is efficient if and only if there exist no better alternative allocation of those same resources” (Munger, 2000, p. 32). In other words, efficiency can be defined as an effort to achieve as much public good as possible for the available dollars, and accomplish a public goal by using the fewest possible dollars (Fredericson, 1997).

Despite the criticism of cost benefit analysis in analyzing public policy, arguing that the approach ignores issues of fairness, social equity, social justice, and ethics, which are derived from constitutional, political, and judicial bases of public administration (Rosenbloom, 1983), advantage of using cost-benefit analysis in the current study is apparent. As Stokey and Zeckhauser (1978) argued “One of the great virtues of benefit-cost approach is that
the interests of individuals who are poorly organized or less closely involved are counted…” The benefit and cost accruing to all—to the highway builders, the environmentalists, the ‘little people,’ the users and providers of services, the taxpaying public—will be counted on a dollar-for-dollar basis. Benefit-cost analysis is a methodology with which we pursue efficiency and which has the effect of limiting the vagaries of the political process” (p. 151). Besides, cost benefit approach works better when policy deals with efficiency measures, as its emphasis is on the cost issue of any public policy (Weimer and Vining, 2005).

Assumptions

The current research makes the following assumptions regarding the proposed hypotheses:

1. Generic drugs are similar to single-source or brand drugs in treating diseases. The reason for this assumption is that generic drugs are chemically identical to single-source brand drugs (OIG, 2006). Additionally, the Food and Drug Administration (FDA) states that generic drugs are not only therapeutically equivalent to brand drugs but are also

…required to have the same active ingredient and the same strength, dosage form, and route of administration as the brand name (or reference) product. In addition, a generic drug must be bioequivalent to the brand drug; that is, there must be no significant difference between the generic and brand product in the rate or the extent to which the active ingredient is delivered to the patient. There can be some variability between brand name and generic drugs, but the FDA puts limits on how much variability is acceptable (DHHS, 2010).

2. Pharmacies cannot or will not increase costs of generic drugs to make up for lost profits on single-source brand drugs.

![Figure 1: Model of cost benefit analysis- status quo and mandatory generic substitution policy](image-url)
Hypothesis

Based on the research questions, the current study examined the following specific hypothesis:

In case of some brand drugs or therapeutic classes Michigan may have the potential to reduce Medicaid prescription drug costs by mandating a higher use of generic substitution whenever available by the generic substitution policy. By using the cost benefit analysis the current research analyzed the following specific policies regarding Michigan Medicaid prescription drug costs:

1) Status quo or the current policy regarding Medicaid prescription drug without mandating generic substitution.
2) Introducing a new alternative policy regarding Medicaid prescription drug by mandating generic substitution where available.
3) In analyzing the potential generic substitution policy for Michigan Medicaid prescription drugs, the program’s major components of cost and benefit are as follows: yearly costs/expenditures (for sample data set) of prescription drugs, total state share of Michigan in prescription drugs reimbursement, and potential total savings of Michigan in Medicaid prescription drugs reimbursement. A diagrammatic representation of the model is shown in Figure 1.

The main idea is to examine whether a mandatory use of higher percentage of generic drugs in Medicaid prescription drug program can benefit the state of Michigan more than the status quo or existing policy of not mandating the use of generic drugs in the Medicaid prescription drug program in terms of cost savings. If an alternative policy (policy 2) can achieve more benefits, then it is better than the status quo.

DATA COLLECTION METHOD

The current research uses State Drug Utilization data and CMS 64 Quarterly Expense data provided by the Center for Medicaid and Medicare Services (CMS). These data sets are used by Shrank et al. (2008), Shrank et al. (2010), and Brill (2011) in analyzing costs and savings issues of state Medicaid programs. For this purpose, data of 1999 and every other year from 2002 to 2010 have accessed for Michigan.

By using the descriptive measure of averages, the current research calculates percentage of state share in Medicaid, generic utilization rate, generic prescribing rate, average cost of generics, total generic scripts, percent of generic scripts dispensed, single-source drugs prescribing rate, average costs of single-source drugs, total single-source drug scripts, and percent of single-source drug scripts dispensed for Michigan.

DATA ANALYSIS

The goal of the current research is to examine if Michigan can introduce a generic substitution policy to contain its prescription drug costs. In general, a generic substitution policy refers to a policy that mandates the prescription of generic drugs when available, instead of brand drugs or single-source drugs, although states have varied ways to implement this policy. Although Michigan has improved the use of generic utilization rate over the years, still there is scope to increase the current rate of generics in its Medicaid prescription drug program. One of the crucial issues in Medicaid prescription drugs cost containment is that costs of brand drugs include major shares of total expenditure of Medicaid prescription drug programs. For example,
Table 1: MICHIGAN SAMPLE

<table>
<thead>
<tr>
<th>Year</th>
<th>MI_Units Reimbursed</th>
<th>MI_No. of Prescriptions</th>
<th>MI_Amount Reimbursed</th>
<th>MI_Medicaid Amount Reimbursed</th>
<th>MI_Non-Medicaid Amount Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>305816310.7</td>
<td>4749093</td>
<td>205047795.6</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>2002</td>
<td>579294000.1</td>
<td>9995281</td>
<td>553806427.6</td>
<td>77818723.48</td>
<td>4634298</td>
</tr>
<tr>
<td>2004</td>
<td>719217135.9</td>
<td>12738792</td>
<td>784847037.3</td>
<td>216595625.5</td>
<td>13549157</td>
</tr>
<tr>
<td>2006</td>
<td>304193547.2</td>
<td>5171836</td>
<td>368336406.9</td>
<td>263460846.1</td>
<td>2441734</td>
</tr>
<tr>
<td>2008</td>
<td>233975864.9</td>
<td>3876283</td>
<td>421436081.4</td>
<td>380880959.4</td>
<td>40555122</td>
</tr>
<tr>
<td>2010</td>
<td>650376695.6</td>
<td>11308819</td>
<td>658795004.1</td>
<td>623213699.7</td>
<td>35581304.4</td>
</tr>
</tbody>
</table>

Total: $274203372.1

Table 2: Brand Drugs with Therapeutically Equivalent (TE) Reimbursed in MI Medicaid: Unit, Amount, and Prescription

<table>
<thead>
<tr>
<th>Year</th>
<th>MI brand drug unit reimbursed with TE</th>
<th>No. of prescriptions for Brand drug with TE</th>
<th>MI Brand drug with TE amount reimbursed in $</th>
<th>Brand Drug with TE reimbursed amount in MI Medicaid in $</th>
<th>Non Medicaid Brand Drugs with TE reimbursed amount in $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>96644743.02</td>
<td>1279224</td>
<td>72,921,904.31</td>
<td>11,637,213.74</td>
<td>4,38,818</td>
</tr>
<tr>
<td>2002</td>
<td>88991515.14</td>
<td>1261508</td>
<td>47,645,639.14</td>
<td>12,469,453.9</td>
<td>10,28,217</td>
</tr>
<tr>
<td>2004</td>
<td>91553571.26</td>
<td>386506</td>
<td>16,820,737.41</td>
<td>11,710,460.61</td>
<td>12,37,590</td>
</tr>
<tr>
<td>2006</td>
<td>30153814.88</td>
<td>525216</td>
<td>39,698,035.96</td>
<td>35,228,960.96</td>
<td>44,69,075</td>
</tr>
<tr>
<td>2008</td>
<td>43394872.2</td>
<td>824309</td>
<td>39,790,835.66</td>
<td>35,759,334.02</td>
<td>40,31,501</td>
</tr>
<tr>
<td>2010</td>
<td>60138530.47</td>
<td>525216</td>
<td>39,790,835.66</td>
<td>35,759,334.02</td>
<td>40,31,501</td>
</tr>
</tbody>
</table>

Total: $274203372.1

Table 3: MICHIGAN SAVINGS

<table>
<thead>
<tr>
<th>Year</th>
<th>MI Average per unit costs of brand drug</th>
<th>MI Average costs of per TE Brand pres drug</th>
<th>MI Average per unit costs of generic drug</th>
<th>Avg. costs diff between TE brand and generics</th>
<th>Cost @ price of avg. generic $</th>
<th>Savings @ generics $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>0.754536</td>
<td>44.8132771</td>
<td>0.249658</td>
<td>24,128,086</td>
<td>48793818.05</td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>0.644176</td>
<td>37.7687966</td>
<td>0.226987</td>
<td>20,781,428</td>
<td>26864210.73</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>0.520413</td>
<td>37.7687966</td>
<td>0.182533</td>
<td>5,504,079</td>
<td>11316658.1</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>0.557831</td>
<td>37.7687966</td>
<td>0.218089</td>
<td>9,463,956</td>
<td>30234079.59</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>0.914809</td>
<td>48.2717472</td>
<td>0.233959</td>
<td>14,069,953</td>
<td>25720882.39</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>0.661653</td>
<td>48.2717472</td>
<td>0.233959</td>
<td>14,069,953</td>
<td>25720882.39</td>
<td></td>
</tr>
</tbody>
</table>

Total: $41.46 | $103,578,545 | $170624827.5

Source: Calculation is based on CMS State Drug Utilization Data 1999-2010
approximately 53% brand drugs contained almost 91.5% costs of Medicaid prescription drug programs in Michigan in 2008. In 2010, approximately 21% brand drugs accounted for almost 95% costs of Medicaid prescription drug programs in Michigan. Thus higher generic substitution policy with various provisions has received significant consideration in the Medicaid prescription drug cost containment efforts.

By employing a descriptive statistics technique, I chose to calculate the simple average of different measures as mentioned before related to brand drugs with therapeutic equivalents or generics available in the market at the prescription period (Table 2&3). In doing so, first I categorized all reimbursed drugs under the Medicaid prescription drugs program into two groups—brand or generic—as State Drug Utilization data or CMS 64 Quarterly database do not provide brand or generic classification. Using the corresponding National Drug Code (NDC) of each drug provided by the State Drug Utilization database I cross-checked two FDA databases, Old National Drug Code Directory and National Drug Code Directory, to determine if a drug is brand or generic.

After determining the drug category, I selected all brand drugs that had therapeutically equivalent or generic available at the time of prescription in Michigan Medicaid prescription drug program. Then, I calculated the average unit price of those ‘brand-to- generic’ matches, and then I calculated the price difference between the total brand drug dispensed that had the therapeutically equivalent and the price of its generic equivalents, which could be the savings. I calculated this savings as the total amount reimbursed and the Medicaid amount reimbursed in sample years.

Research findings reveal that within the sample years of 1999-2010, the Michigan Medicaid prescription drug program spent approximately $274 million for brand drugs that had generic or therapeutically equivalent drugs available in the prescription period. At the average rate of available generic drugs within the sample years, these brand drugs could cost approximately a total of $103.5 million. Thus Michigan Medicaid could save a total of more than $170.5 million by prescribing only generics instead of brand drugs.

From a public policy context, findings of these descriptive statistics appear as valuable. For example, the average cost of per unit brand drug was 90 cents in 1999 and $3.88 in 2010, whereas the average costs of per unit generic drugs was estimated at 18 cents to 33 cents within 1999-2010. Similarly, average costs of per prescription with brand drugs is estimated at $37.75 to $75.58 within 1999-2010, whereas average costs of per generic prescription contained therapeutically equivalent generics varied from $11.94 to $20.43 within 1999-2010. Thus Michigan Medicaid prescription drug program could save approximately $49million, $28 million, $27 million, $11 million, $30 million and $25 million in 1999, 2002,2004,2006, 2008 and 2010 respectively by using generic drugs instead of brand drugs used that had generic equivalent available at the time of prescription.

Findings of the descriptive analysis are similar to other recent research findings. Brill (2010) analyzed 2009 Medicaid data reimbursement of all states for a selected twenty brand drugs and found $271 million in overspending in Medicaid prescription drug programs due to the use of brand drugs instead of generic.

In quest of the research hypothesis that if there exists any specific “heavily used” brand drugs where Michigan can save costs in prescription drugs, this research identifies ten specific drugs areas of savings. In doing so, this research uses Michigan 2010 Medicaid prescription data as the reference. All brand drugs with therapeutically equivalent prescribed are identified with total number of units, number of prescriptions, total amount and total medical amount. The ten most costly and highly prescribed brand drugs with therapeutic equivalents in the market are identified. For each of these ten brand drugs with therapeutic equivalents actual prescription drug program costs, average costs of actual per unit drugs, average costs of actual per prescription for brand drugs with therapeutically equivalent drugs; average costs of per generic drug unit in Michigan in 2010 are calculated. Then average costs of per unit brand drugs with therapeutically equivalent are calculated at the rate of average per unit generic drug costs, and finally savings are calculated by deducting the amount from actual reimbursement costs of brand drugs with the therapeutically equivalent and calculated amount at the rate of average per unit generic drug costs. Then the total amount of savings are calculated by adding savings of all ten brand drugs with therapeutically equivalent.
Table 4: Brand drugs with Therapeutically Equivalent Reimbursement in Michigan Prescription Drug Program in 2010: Costs and Potential Savings

<table>
<thead>
<tr>
<th>FDA Approved drug name</th>
<th>Units Reimbursed</th>
<th>No. of Prescriptions</th>
<th>Actual Total BTE Amount Reimbursed ($)</th>
<th>Avg. cost per unit BTE ($)</th>
<th>Avg. cost per generic unit ($)</th>
<th>BTE costs @ per prescription @ per generic unit ($)</th>
<th>Savings of BTE cost @ per unit generic ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLAVIX</td>
<td>839193</td>
<td>27561</td>
<td>4,443,039.27</td>
<td>5.294419</td>
<td>0.233959</td>
<td>196,336.7874</td>
<td>7,12371784</td>
</tr>
<tr>
<td>PROGRAF</td>
<td>416732.1</td>
<td>3685</td>
<td>2,223,677.36</td>
<td>5.335987</td>
<td>0.233959</td>
<td>97,498.24959</td>
<td>26,458141</td>
</tr>
<tr>
<td>LAMICTAL</td>
<td>374526</td>
<td>4048</td>
<td>1,867,966.3</td>
<td>4.987548</td>
<td>0.233959</td>
<td>87,623.74599</td>
<td>1,780345</td>
</tr>
<tr>
<td>DURAGESIC</td>
<td>38524</td>
<td>4428</td>
<td>1,743,863.81</td>
<td>45.26695</td>
<td>0.233959</td>
<td>9,013.038231</td>
<td>1,734851</td>
</tr>
<tr>
<td>ZITHROMAX</td>
<td>1136136</td>
<td>72139</td>
<td>1,623,367.64</td>
<td>4.2885</td>
<td>0.233959</td>
<td>379,053.7799</td>
<td>1,357558</td>
</tr>
<tr>
<td>RISPERIDON</td>
<td>1620172</td>
<td>3025</td>
<td>1,374,779.71</td>
<td>0.848854</td>
<td>0.233959</td>
<td>379,053.7799</td>
<td>1,357558</td>
</tr>
<tr>
<td>TOPAMAX</td>
<td>284168.2</td>
<td>2785</td>
<td>1,312,345.86</td>
<td>4.618201</td>
<td>0.233959</td>
<td>66,483.7259</td>
<td>1,3245862</td>
</tr>
<tr>
<td>TRILEPTAL</td>
<td>1375522</td>
<td>4142</td>
<td>1,196,764.6</td>
<td>0.870044</td>
<td>0.233959</td>
<td>321,815.8161</td>
<td>77,69575472</td>
</tr>
<tr>
<td>PULMICORT</td>
<td>190546.1</td>
<td>2155</td>
<td>1,030,490.95</td>
<td>5.408094</td>
<td>0.233959</td>
<td>44,579.97458</td>
<td>1985911</td>
</tr>
<tr>
<td>DEPAKOTE S</td>
<td>547865</td>
<td>4420</td>
<td>947,883.82</td>
<td>1.730141</td>
<td>0.233959</td>
<td>128,177.9732</td>
<td>2899954145</td>
</tr>
<tr>
<td>Total</td>
<td>6823384</td>
<td>155668</td>
<td>17,764.179.3</td>
<td>1.59639234</td>
<td>0.233959</td>
<td>2899954145</td>
<td>16167787</td>
</tr>
</tbody>
</table>

Source: calculated based on CMS’s ‘State Drug Utilization data’ 2010

Table 4 shows that in 2010, Michigan Medicaid prescription drug programs reimbursed an estimated total of $17,764,179.3 for ten most “heavily used” brand drugs, which have generic equivalents. Research findings reveal that an average $0.23 per unit generic drug price in 2010 Michigan prescription drug program could save approximately $1.5 million from these most reimbursed ten brand drugs such as ‘Plavix’, ‘Prograf’, Lamictal’ ‘Duragesic’ ‘Zithromax’ ‘Risperidon’, ‘Topamax’, ‘Trileptal’, ‘Pulmicort’ and ‘Depakotes’ as shown in the table. At an average rate of generic, these top ten brand drugs could cost approximately only $1.5 million. In other words, 90% costs for these ten drugs could be offset by using generics.

FINDINGS, RECOMMENDATIONS AND CONCLUSION

This research examined if there exist any “heavily used” brand drugs for which generic substitutes are available that Michigan can safely reduce Medicaid costs by implementing a higher use of generic substitution, thus saving the state share in prescription drug costs through the generic substitution policy? In addition this research also examined if the answer is ‘yes’ for the previous question, then approximately what amount can Michigan save per year by implementing the generic substitution policy?

Findings of the research are following:

1. Brand drugs with therapeutically equivalent that are prescribed could be a potential area of savings. In the case of Michigan’s Medicaid prescription drug program, savings could be significant if generic drugs are prescribed instead of brand drugs with a therapeutic equivalent.
2. Research findings reveal that within the sample years of 1999-2010 Michigan Medicaid prescription drug program spent $274.20 million for brand drugs that had generic or therapeutically equivalent drugs available in prescription period. At the rate of available generic drugs in those respective years these brand drugs could cost a total of $103.58 million. Thus, Michigan Medicaid could save a total of $170.62 million by prescribing only generics instead of those brand drugs.
3. The more specific area for potential savings for the Michigan Medicaid prescription drug program could be using more generic drugs, instead of prescribing brand drugs such as ‘Plavix’, ‘Prograf’, Lamictal’ ‘Duragesic’ ‘Zithromax’ ‘Risperidon’, ‘Topamax’, ‘Trileptal’, ‘Pulmicort’ and ‘Depakotes’. These are the ten most expensive brand drugs, which have prescribed in the Michigan Medicaid prescription drugs program even though generic therapeutically equivalent available in the market for all these brands.
4. Research findings show that an estimated $17.5 million was reimbursed for total ten most expensive brand drugs in the Michigan Medicaid prescription drug program in 2010, which have generic equivalent. At an average rate of generic these top ten brand drugs could cost only $1.5 million.

5. Thus, Michigan Medicaid prescription drugs program could save an estimated more than $16 million in 2010 by only prescribing generic instead of those top ten most expensive drugs.

Thus the current research finds a potential relationship between ‘generic substitution policy’ and Medicaid prescription drugs costs. The costs variation between brand drugs and the brand with therapeutic classes reveals an opportunity for the Michigan Medicaid program to save a significant amount by implementing ‘generic substitute policy.’

Figure 2 is a modified schematic representation of figure 1 as shown in page 4. In figure 2, a comparative cost benefit analysis is shown between “status quo” or having ‘no generic substitution’ policy and a policy of potential generic substitution policy in Michigan Medicaid prescription drugs program. Based on the findings it reveals that a generic substitution policy depicted as policy 2 is more efficient than “status quo” or policy 1 in terms of savings or in other words cost and benefit in real monetary term between policy 1 or status quo and policy 2 or mandatory generic substitution policy. It shows that Michigan could save over $170.5 million by using therapeutically equivalent generics instead of using brand drugs through a mandating a generic substitution policy within sample years of 1999-2010.

Figure 2: Model of cost benefit analysis in real monetary term- status quo and mandatory generic substitution policy
Cost increase in prescription drugs is a complex phenomenon. Many factors contribute to the cost escalation, which includes high cost of research and development, advance treatment, promotional and advertisement costs, growing groups of an aging population with more needs for prescription drugs, and higher insurance coverage for prescriptions. These factors and many others influence in escalating drug price and its utilization and thus overall costs for Medicaid prescription drug programs (Kreling, Mott, and Wiederholt, 2001). Thus, cost containment in Medicaid drug programs also needs multifaceted policies and actions. As already mentioned, Medicaid costs have appeared as the second largest expenditure for Michigan, and created severe pressure on state and local government. In the midst of cost escalation of Medicaid prescription drug programs, the Michigan state government must implement appropriate measures to tackle this issue. Implementation of a generic substitution policy could be a viable policy option for the state government of Michigan. Implementation of a generic substitution policy could be an effective and efficient measure to address the issue.

In containing costs of the Michigan Medicaid prescription drug program, implementing a generic substitution policy has some distinct advantages over any other strategies proposed for controlling Medicaid prescription drug programs from a public policy context. For example, implementing a generic substitution policy does not need to make huge fundamental structural change such as creating a new bureau for Medicaid cost control. Implementation of a generic substitution policy most probably has the lowest potential as a political challenge for state government than any other policy implementation, which includes such huge numbers of beneficiaries (Kibicho, 2006). One of the most intriguing advantages of implementation of a generic policy is that its outcomes are not uncertain, as some other states have already been implementing the same policy for years.

Thus analysis of this research provides a basis of the implementation of a potential generic substitute policy as an efficient approach in containing prescription drugs expenditure in the Michigan Medicaid program. This research, therefore, strongly suggests implementing a generic substitution policy without a prior consent provision for Michigan in containing costs of its Medicaid prescription drug program.

REFERENCES


Shrank, W. H., Choudhry, N. K., Agnew-Blais, J., Federman, A.D., Liberman, J. N.,


Theoretical, Methodological and Practical Challenges in Designing Formative Evaluations of Personal eHealth Tools

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Abstract: This article describes the challenges experienced in designing a formative evaluation of a mobile personal eHealth tool for disease symptom tracking, in the context of Inflammatory Bowel Diseases management. As this unique context is characterized by regular visits with physicians, and the need to report disease activity to the physician, a mixed methodology is used to assess the fit of the technology to the context, and a multilevel model is used to evaluate theoretical links between patient and physician. Other issues include selection of sampling techniques, recruitment, and preventing study attrition by participants.

INTRODUCTION

Advances in technology are increasingly applied to healthcare processes, in particular, those that enhance and empower the care received by patients (Eysenbach, 2001). Personal eHealth tools (PETs), such as personal health records (Archer, Fevrier-Thomas, Lokker, McKibbon, & Straus, 2011), entail the delivery of healthcare services and resources via technology directly to patients. The capabilities afforded to the patients through devices that are affordable, available, and versatile, and have provided health benefits in the context of diabetes self-management (Glasgow, 2011), and aided in maintaining general personal medical documentation (Tobacman et al., 2004). Further, the PETs can be applied in a way that can enhance the connection between patient and provider, through capabilities such as communication of symptom data (Johansen, Henriksen, & Berntsen, 2011; Johansen, Henriksen, Horsch, Schuster, & Berntsen, 2012).

As the benefits to using these technologies needs to be clearly documented, they require careful evaluation. The Randomized Controlled Trial (RCT) experimental design is regarded as the “gold standard” for the evaluating the efficacy of medical interventions (Kaplan, 2001), essential for adoption of the technology. However, the RCT and other experimental designs may not be sufficient for evaluating PETs, in particular before a widespread implementation takes place, for several reasons (Easterby-Smith, Golden-Biddle, & Locke, 2007; Kaplan, 2001). First of all, experiments are a costly and complicated undertaking. Second, experiments are better suited for interventions that are simple in nature. For instance, a drug and a mobile application differ greatly in how it will be used by the user. A PET application requires more learning to use in an effective manner, and is usually contingent on many more factors than those purely biological. Third, as the purpose of an experiment is to test the viability of an intervention to produce a significant outcome (Cook, Campbell, & Peracchio, 1990), it often ignores the context of use due to a high focus on quantitative methods, which is important in answering questions as to how the intervention is used, what its barriers to use are, and what features are important. These reasons compel researchers to conduct formative evaluations (Campbell, 2000; Craig et al., 2008), which tend to focus on informing the development process, and are thus conducted earlier on in development, informing subsequent experimental studies.

In order to conduct formative evaluations on complex interventions such as PETs, it is important for researchers to consider the context in which it is used, in order to generate knowledge and build theory for PETs, despite the impracticalities with using experimental design. One way to further the wider field of technology in healthcare applies here (Kaplan, 2001); research that asks the question of how a particular technology is used in a certain context can be used to build knowledge as to how the technology relates to or impacts the existing care processes established by the patient. Specifically, it can ask the question as to what factors are important in the context, be they psychological, behavioural, social, cultural, relational, related to workflow, institutional influences, or other
pertinent factors. Further, it can help us understand how an intervention is implemented (Oakley, Strange, Bonell, Allen, & Stephenson, 2006). Researching information systems in such a way is referred to as the “fit” (Easterby-Smith et al., 2007; Kaplan, 2001) that an information system has with these and other factors in the environment. It is argued that researching the fit of technology with its environment is the direction best suited to generate knowledge in this area, but the question remains as to how the theory and protocol is configured. Given the multitude of unique environments in healthcare that can benefit from technology, guidance is valuable for researchers in this area.

The purpose of this paper is to present theoretical, methodological and practical challenges experienced when designing formative evaluations to assess the fit of patient-centric eHealth tools to their context of implementation. Drawing on several established approaches, it is the goal of this article to provide guidance to researchers in constructing theoretical frameworks for their research, as well as designing a suitable methodology, so that the product of their endeavours is scientifically rigorous, valuable to practitioners, and efficiently executed. To this end, this paper will first describe PETs as a complex intervention, the degree to which they must fit their context, as well as how they can be evaluated to improve fit. Following, challenges in determining design for an evaluation will be described, including selection and integration of theoretical frameworks, choice of methodology, and issues associated with selecting and managing participants. The experiences designing an evaluation of a PET, specifically to record and report gastrointestinal related symptoms to physicians, within the context of Inflammatory Bowel Diseases (IBD) care, will be used to illustrate how these challenges can be addressed when designing a study protocol.

BACKGROUND

PETs as Complex Interventions

It is difficult to provide an exact definition of a complex intervention, although guidelines are used for their identification (Campbell, 2000; Craig et al., 2008). Complex interventions are deemed so as they contain several interacting components (Campbell, 2000; Craig et al., 2008). For further elaboration, they provide several characteristics of a complex intervention. These include, but are not limited to, number of components of the intervention, interactions between the user and intervention, groups targeted by the intervention, number of outcomes, and degree of flexibility of the intervention (Campbell, 2000; Craig et al., 2008). Further, it may be difficult to identify exactly what components contribute to the outcomes of the use of a complex intervention (Campbell, 2000; Craig et al., 2008), yet containing the components into one intervention would have a synergistic effect where the sum of the components is less than the entire intervention (Casti, 1997). A “stroke unit” is provided as an example of a complex intervention (Campbell, 2000). A stroke unit may provide several services, contain many workers, and produce several positive outcomes, yet it is hard to define what the actual components of the stroke unit are, which are beneficial, or even if the benefit would still exist if the components were provided elsewhere.

Personal e-health technologies (PETs) is defined broadly for this article as technologies targeted to patients, healthcare consumers, or the population at large, for a health related purpose. This includes electronic personal health records (ePHRs, Archer et al., 2011) or any other intervention used for health-related data collection and management that predominantly involves the patient. As many of these interventions are comprised of several components, serve several purposes, and can be implemented on various technologies, such as the web, or mobile phones of various platforms, they can be considered complex interventions. Further, some interventions may involve integrating users with other healthcare professionals or healthcare system processes. One case is that of Electronic Symptom Reporting (ESR, Johansen et al., 2011, 2012), where patient technology is used to collect data on disease activity, which is subsequently transported to a physician or other healthcare practitioner. Mobile devices themselves afford benefits to users that are not necessarily tied to any software feature, and can be considered a component of an intervention in themselves. Generally speaking, a large amount of PETs will certainly be considered complex interventions, attaching with them implications of their evaluation.
Fit

Due to the issues with complex interventions, a different and varying approach must be taken in their evaluation. Unlike simpler interventions, such as a medicine in pill form, experimental designs such as randomized controlled trials (RCTs) do not account for much of the contextual information associated with the intervention. This can include existing processes, approach to implementation, socio-cultural and other environmental factors that may impact uptake of the intervention. This can be illustrated by comparing a pill to a PET implemented on a mobile phone, for the purpose of helping a patient manage their chronic disease. The former typically requires easily understandable, clearly defined instructions and outcomes for the user (“take twice a day with food”, for example). The latter may require the user to learn how to use mobile devices, learn how to enter, interpret and act upon symptom data and reports, respond to alerts, enter personal information, and integrate or synchronize with other systems, to various benefits to the user and other people. Given the relative complexity of the latter intervention, more knowledge may be necessary in its implementation that will be used to ensure adoption, long term use, and long lasting benefits. This knowledge will typically be used to discover the requirements for the intervention, barriers to implementation and to guide further development of the technology in question (Craig et al., 2012). Use of a purely experimental research design typically is employed to demonstrate that use of intervention has a significant positive impact on the sample, and that the benefit is generalizable to a defined population (Woolard, 2004). Although it is important that any medical or healthcare intervention demonstrate such a benefit, a purely experimental methodology is poorly equipped to address these important aforementioned issues.

Health technology researchers have addressed the difficulties of evaluating complex interventions through focusing on the “fit” of technology to its context. As termed by Kaplan (2001), the “fit” refers to the compatibility of a technology with the context that it is implemented in, and there are many possible aspects of the context which may be relevant when determining fit. For instance, the technology may have to fit with workflow (Yusof et al., 2008; Ammenwerth, Iller & Mahler, 2006), or culture (Kaplan, 2000), for example. Indeed, a substantial amount of frameworks have been developed to attempt to explain the fit of systems in their respective environments. These studies often take a sociotechnical (ST) theory (Edwards, 1972) approach. ST theory has focused on the fit of systems to their context has been imperative in the success of systems in various contexts. Each respective context may require the system to fit the context on a unique set of dimensions, as reflected in each of the ST models. For instance, Sittig and Singh (2010) propose that healthcare information technology must fit the context on the following dimensions – computing infrastructure, clinical content, system interface, relevant people and roles, workflow and communication, internal policy and culture, external rules, and performance measurement. As systems typically implement their own processes, procedures and other various relevant factors, they must be in congruence to the context on all of these dimensions, or there is a risk that the users will not adopt the system, resulting in wasted efforts on building the system. In other words, systems are not guaranteed to meet the goals they intend to; it is entirely possible that they have no effect, or worse yet, exacerbate the problems they intend to address. Care must be made in ensuring that the system will be effectively used, and contribute to positive outcomes that it intends to address.

Formative Evaluation of Complex Interventions

As elaborated on before, experimental designs on their own are insufficient to determine the fit that a system has with its context, rather experimental research is largely used to establish that an intervention has had a significant benefit on an outcome through quantitative methods. Following a call for a variety of methodologies to be used in evaluating health technologies in order to ensure sufficient knowledge of the context (Kaplan, 2001), qualitative methods (Lee, 1999; Bachiochi & Weiner, 2004) can be employed for this purpose, and mixed methods research (Johnson, Onwuegbuzie & Turner, 2007) can be used to combine performance measurement and contextual description into one study. However, the use of qualitative methods alone cannot ensure that an intervention will be successful. There must be a mechanism to inform those responsible for crafting the intervention on the shortfall between the context of application and the qualities of the intervention, so that a change may be implemented in the intervention. Having such will mitigate the risk of an intervention falling into disuse.

Determining fit of a healthcare technology intervention with the intended context can be performed with a formative evaluation (Campbell, 2000; Craig et al., 2008). As formative evaluations are largely used to inform developers of an intervention, they typically take place early on in the implementation process, before a larger implementation or evaluation takes place. The developers then can act upon the results of the formative evaluation by improving the
artifact before it is implemented. In the case of technology, they may find out that the inclusion of a certain feature is a crucial requirement of the user, or what outcomes the users expect from the use of the technology (Flagg, 2013; Scriven, 1967; McClintock, 1984). A formative evaluation can uncover this requirement before a large scale rollout, and the developers can choose to improve the application (Brown & Kiernan, 2001). A formative evaluation is often conducted under a larger implementation framework, where subsequent summative evaluations will report on performance, such as cost, and outcomes, such as relevant health outcomes (Patton, 2008).

As formative evaluations are regarded as an important activity in crafting successful complex interventions (Craig et al., 2012), it is important that they are conducted. Although these types of evaluations are typically smaller scale than summative interventions, they still present several unique conceptual, methodological, and practical challenges that must be addressed by the researcher. The remainder of this article will discuss some of these issues for consideration by researchers involved in formative evaluation of PETs in a healthcare context. An illustration will follow on how these issues can be addressed in a formative evaluation of a smart phone application for the purpose of Electronic Symptom Reporting (ESR) of a chronic disease patient symptom data to a healthcare practitioner.

CONCEPTUAL CHALLENGES

Developing a Theoretical Model

A theory is an organization of knowledge, an attempt to describe a defined context in the real world, but it based on a behavior, situation, or outcome of a process (Dubin, 1976). A theoretical model consists of two components, at minimum. First, it specifies the units important to the theory as variables, as well as descriptions of relationships among the various variables. Second, it describes the context in which the theory is relevant to, for which it is proposed that this theory will be supported. If the theory is to be empirically tested, an empirical indicator is assigned to each of the variables, which, when data has been collected, can be used to test the relationships between variables, referred to as hypotheses. A theory can be used to predict events, explain why events occur, gain a deeper understanding of a context, or to describe an ideal situation (Dubin, 1976; Gregor, 2006). There are several qualities that good theories possess. First, as it is impossible to explain every phenomena in every situation, it must be falsifiable, so it can be tested and possibly refuted (Popper, 1963). Stronger theories are tested, with the purpose of falsifying it, but each time the author fails to falsify the theory it adds strength to the theory. Good theories are supported by existing empirical evidence. Second, a theory must be parsimonious, in order that can be easily and simply communicated and understood (Cohen, 1990). As well, good theories are appealing and make sense to the practitioner (Dubin, 1976). A theoretical model should be useful when applied to the real world, and fulfilling to practitioners in guiding the endeavors (Dubin, 1976; Gregor, 2006). It must be parsimonious, and focused. As well, it must be generalizable, or useful in other situations to explain, predict, or gain understanding there (Gioia & Pietre, 1994).

Healthcare is very rich and diverse in context, therefore there are many opportunities and efforts to explain behavior and develop theory. There are many specialties, many diseases, many healthcare system functions, disciplines and professions, payers, research traditions, and cultures represented in healthcare, making for a diverse system. It can explain clinical and organizational behavior, select or tailor interventions given a certain problem or context, evaluation of implementations. In public systems, the taxpayer is relevant, whereas shareholders and other stakeholders are relevant in private systems. Theory in healthcare hasn’t been widely employed as they have in other areas (Walsh, 2007). Hence, there has been an influx of theories developed outside of healthcare, such as complex adaptive systems theory (McDaniel, Lanham & Anderson, 2009), actor-network theory (Greenhalgh & Stones, 2010) and technology adoption theory (Gallant & Boone, 2009). Indeed theories are important in healthcare, yet their development poses a challenge. The evidence based medicine approach espouses the importance of theory development if innovations and research are to be implemented in healthcare systems (Walsh & Rundall, 2001; Guyatt et al., 1992). One way of ensuring that theory is used in healthcare is to ensure that it contains a practical or strategic element. Also, the link between theory and practice must be clear. That way, it is more likely that it will eventually be applied. This can be accomplished by including both manager and health researchers in the theory development process, in particular during initial phases of research.

The researcher may see it necessary to integrate several theories in the interest of seeking a higher understanding of the context, thereby creating a unique theory for use in a highly unique context. Further, when applying theory from outside of healthcare, the research may find that there is little empirical evidence to support its use within healthcare.
Even in an early formative assessment, preferably during development, it is important to adhere to a theoretical perspective (Craig et al., 2012), but a suitable theory, or sufficient empirical support, may not exist. In the case that researchers are attempting to utilize a theory where none exists before in this context, it is advisable to start with an exploratory phase in order to determine the important factors and outcomes to the context being studied, and to start on a smaller scale study, to start with preliminary support for the theoretical model (Power et al., 2004; Rudolf et al., 2006).

Multilevel models can be used where there is a relevant hierarchical component to a context (Hoffman, 2004; Dixon & Cunningham, 2009). For example, a physician can have many patients, but a patient can only have one physician. This entails that the relationship between patient and physician may have an impact on certain outcomes of care, such as patient satisfaction (Barr et al., 2003). Indeed, a tenant of patient centered care (Wagner et al., 2005) is to foster a relationship with the patient so that the physician gains a higher understanding of the personal situation, preferences and knowledge held by the patient, for the purpose of enabling the patient to participate as a decision maker in their own care decisions. In some contexts, especially those where long-term chronic disease management is relevant, the use of PETs may enhance or otherwise augment the relationship between patient and provider. For instance, an attribute of the group of patients of a certain physician can impact the individual physician in some way (Dixon & Cunningham, 2009), or the individual physician can impact the group of patients (Hoffman, 2004). Other hierarchical structures can include physicians within a department, hospitals within a region, or medical students within a school. As multilevel theories have been applied successfully in understanding healthcare contexts (Piatt et al., 2006), the researcher must consider the contribution of using them when evaluating healthcare technology (Kaplan & Harris-Salamone, 2009).

METHODOLOGICAL CHALLENGES

Selection of Methodology and Design

In formative assessments, the target outcome of the intervention is not always necessarily known. In complex interventions, this challenge is exacerbated, as different stakeholders of the intervention may have their own goals, or a user may have two outcomes in mind. For example, if a single complex intervention is implemented for both a physician and a patient, the patient may want to increase their ability to cope with a chronic disease, whereas the physician may want to increase efficiency in the delivery of care to a population of patients. A purely quantitative evaluation of this intervention will measure only a limited number of outcomes for economic reasons, but other outcomes may be appropriate to the user, context, or system, and would not be measured or otherwise detected. The use of quantitative methods (Creswell, 2009) function to construct a rich description of the perspectives, attitudes, experiences, and goals of the users of the complex intervention, otherwise lost to the purely quantitative study. Results of these types of studies serve to inform future summative evaluations, and develop theory in these particular areas.

Mixed methodologies offers an enhancement over pure qualitative studies (Creswell, 2009). Two general categories of pragmatic research exist: sequential, with each part executed as a phase, and concurrent, with both parts being executed at the same time (Creswell, 2009; Easterby-Smith et al., 2012). The sequential can take one of three forms: explanatory, exploratory, and transformative. In the sequential explanatory form, the results of a quantitative phase are enhanced by qualitative data from participants in the first. This configuration is valuable for enhancing unexpected results (Morse, 1991), or for further interpretation by outliers in the first phase. In the sequential exploratory configuration, the results of a qualitative phase are followed by a quantitative phase, which is quite useful when a researcher wishes to develop a concept and an instrument in the same project. The sequential transformative strategy employs a critical theory lens to guide the project, and may employ quantitative or qualitative in any order. In any of the sequential strategies, an a priori theory may or may not be employed, and dominance is usually given to the first phase. The concurrent strategy can take the form of triangulation, embedded, or transformative. Concurrent triangulation strategy entails the integration of quantitative and qualitative data after both datasets are collected. Concurrent embedded strategy prioritizes one result set over another, which uses the secondary result set to enhance the results from the primary. Concurrent transformative strategy uses any of the configurations above, with the researcher adhering to a critical theory lens to guide the research.

The value of conducting mixed methods research exists in the fact that results are enhanced to a level greater than any of the individual components on their own (Farquhar, 2011). For instance, if an outcome of use of a PET is
found to be lower than expected, an exploratory phase in the same study can be used to determine why this is, what barriers exist to effective use of the PET. As mixed methods research is significantly more complex than purely quantitative or qualitative, justifying mixed methods research projects is important, despite the clear benefits of these methodologies. These research projects can consume more resources, take longer to complete, and tax participants to a higher degree. Further, they may not readily be understood by reviewers of conferences, journals, and granting agencies, restricting opportunities for the researcher. With this in mind, the reason to use mixed methods must be clearly demonstrated.

Recruitment of Participants

The acquisition of potential participants in formative evaluations presents challenges for the researcher, although the difficulties with recruitment associated with experimental designs, such as randomization or blinding (eg. Shcherbatykh, 2008), are less of a concern for smaller scale, non-experimental evaluations. Although PETs can be integrated with the system of the healthcare provider to several degrees (Tang et al., 2006), this discussion will be limited to integrated PETs, as patient-physician interaction is much less relevant with standalone PETs (ie PETs that in no way interact with a healthcare provider’s system). Tethered PETs would allow healthcare providers to grant read-only access to certain data to the patient, whereas interconnected PETs allow for richer data interchange between patient and provider (Tang et al., 2006).

An example of an integrated personal healthcare tool is DiaMonD (Wickramasinghe, Troshani, & Goldberg, 2010). DiaMonD is a smart phone application for the purpose of sending symptom data of patients with diabetes directly to the healthcare provider. In this sense, the tool is an intervention that involves several people (patient and physician), each with their own activities (patient must enter symptom data, and physician must receive it) and each user can perform several main functions. In this case, the patient can either enter or view their own data, and the physician can view the data of one person, or aggregated data of their patient list. When developing this complex intervention, it is important to involve all people in the care process. In this case, it will be both the diabetic patient, and their physician. It is clear to see that, since DiaMonD can potentially benefit both diabetic patient and their doctor, that both could be targeted for research, whether in the same project or not.

For studies that are not intended to gain insight into a larger population, the use of non-probability sampling methods, such as convenience, self-selection, or snowball sampling, can be acceptable (Small, 2009). If access is granted, patient registries has been identified as a valuable sampling frame for recruiting patient participants in healthcare studies (Snyder et al., 2009) although these are not available for every patient group. Other outlets may be of value, such as patient associations, newsletters, websites, social media groups, local associations and foundations. Of course, physicians may allow access to their patient population, in particular if a physician is a partner in the research project. Also, out-of-date registries pose a problem. If patients do not suffer from the disease anymore, they are unlikely to keep in touch with a patient registry (Patel, Doku & Tennakoon, 2003). If the researcher is studying a condition with a high death rate, the registry may be full of records of deceased people. As well, if the budget allotted for the study is low or non-existent, the researchers may require the patients to own their own technology, which may reduce the number of potential participants.

Apart from patients, there may be a need to recruit a significant number of physicians, which presents some difficulties (Johnston et al., 2010). First, a sampling frame for physicians of a certain specialty may not be kept accurate and up to date, potentially resulting in unplanned time and effort spent assessing participants for eligibility, or changing the definition of eligible participants. Second, clinic staff may have to be engaged to perform some duties associated with the study, such as recording participant data, or advertising for the study. Facilitators to recruiting physicians to studies included to have a rapport with the clinic staff, employ clinicians to recruit other clinicians, as well as various incentives. Incentives may include a payment of a very high sum of money, continuing medical education credits, and provision of other clinical resources. As well, the physician participant must perceive that the study is important and relevant to their practice, in order to achieve buy-in. Personal connections between the researchers and physician participants is regarded as important as well.

Retention of Participants and Addressing Attrition

In research, attrition refers to the reduction of the number of participants in a study. When conducting a longitudinal study, researchers will typically require the participants to use an intervention for a period of time, and submit data
after the time period has elapsed. When the time period has elapsed, it is probable that a fraction of the participants that have not completed the study, divided by the total number of participants at the start of the study. Attrition rate then refers to the number of people that have not completed the study, divided by the total number of participants at the start of the study. Attrition hurts the generalizability of a study, for several reasons. First, if the number of participants is reduced to a level that is below the minimum sample size dictated by a power calculation (Dupont & Plummer, 1998), the ability to report that a study made inferences on a population is compromised. If the number of participants sinks low enough, the ability to perform certain statistical analysis techniques is removed. For instance, both Structural Equation Modelling (SEM) (Klem, 2000) and regression (Licht, 1995) have a minimum sample size specified in order for any analysis on the data to be considered valid. From a practical standpoint, the time, effort and resources in recruiting and signing on participants to a project is wasted when a participant quits the study (Cotter et al., 2005). For these reasons, it is in the researchers’ best interests to try to retain their participants through until the end of the study.

Several approaches exist to help ensure that the attrition rate is as low as possible. First and foremost, the research design certainly can impact the attrition level of a study, such as length of an instrument (Hoerger, 2010). Beyond that, retaining participants in the study can be aided by making regular contact with the participant, scheduling callbacks, establishing a good rapport with the participant (MacLachlan, 1988; Nagler et al., 2013), and “cultivating subject loyalty” (Probstfield, 1986) in the participant, to the study and researcher. It may also help to schedule contact as part of routine healthcare, such as regular appointments (Meinert, 2012). When data must be collected, not limiting the number of times that researchers can contact participants to encourage them to complete the study will improve results (Woolard et al., 2004; Cotter et al., 2005). Limiting the times that researchers are allowed to contact the participants may negatively impact post-intervention contact with participants. In very long studies, as participants move and fall out of contact, researchers may need to employ strategies in finding lost participants, such as web searching, and multiple contact methods (email and telephone, etc.). In doing so, contact is made with the participant in order to determine any reasons for withdrawal or barriers to participation. It has also been suggested that, in conducting clinical trials, that a dropout participant can be “re-recruited” back into the study (NHLBI, 1998). Dropout participants may be valuable source of qualitative data for this same purpose, although the need to re-enroll the participant may not exist. Other approaches include collecting much of the data up front (MacLachlan, 1988).

Studying the nature of research retention is the focus of some research projects. In a study of an online weight loss intervention, it was found that younger participants and participants with higher levels of self-efficacy for weight loss would remain with the 12-month long study (Glasgow et al., 2007). In a similar study, engagement of the online intervention, measured by several website usage variables, was found to be a predictor of study retention after 3, 6 and 12 months (Couper et al., 2010). The condition of the participant studies may also affect attrition. It has been found that people with the ADD condition were easier to retain than those with CD and OCD (Cotter et al., 2005). Other factors such as mistrust of researchers, community involvement, incentives, and cultural adaptation of studies have been found to impact study retention, in particular with minority populations (Yancey, Ortega & Kumanyika, 2006). Another approach is to look at determinants of attrition that are variables related to the person, such as their beliefs and attitudes (Wojtowicz, Day & McGrath, 2013). In implementing a depression, anxiety and stress module, student participants who were more likely to adhere to the study the longest had higher perceived behavioral control in completing the prescribed tasks, use phone instead of email for their chosen method of communication, and were older in age. Further, people who dropout may be experiencing a negative outcome from use of the intervention (Ladouceur et al., 2001), resulting in a systematic bias in the results.

PRACTICAL CHALLENGES

Creating Value for Developers

Developers of technologies rely on interaction with the users to ensure acceptance of the technology by its users (Ries, 2011). In fact, close interactions are an integral part of newer software development methodologies such as Scrum (Rubin, 2012) and Agile (Beck et al, 2001). One method of communicating with users is via prototyping, where a partially functional or representative version of the system is showcased to a user, or the user is asked to use the system, with the intent of eliciting judgments on the system to inform its further development, including
features, usability, function and congruence to workflow. Formative evaluations and prototyping are similar in purpose, yet differ in aspects such as scale, stage, use of theory and formality.

A more focused explanation of how developers require feedback is described with the concept of validated learning (Ries, 2011; Rubin, 2012). Features in software are built on an assumption held by the developer that the user will find it useful. The assumption turns out to be false when it is discovered that the user will not find this feature useful. If much time has been spent building a feature that is not considered valuable by the user, the time and effort that is used to build this feature is considered waste, as it does not contribute to the user’s goals in using the software. The longer that the development team uses unvalidated assumptions to inform their development, the larger the risk that efforts will be considered waste if the user does not adopt these features. This reasoning underlines the importance of validating these assumptions as early as possible, in order to ensure that development efforts are directed towards features that are more likely to be adopted by the user. Formative evaluations, pilot studies and other early evaluations should seek to validate assumptions held by the development team, in order to direct development. In order to do this, researchers may want input from developers when designing formative evaluations.

Conveying Value of the Study to Reviewers

Although the formative evaluations will primarily serve to improve the complex intention by informing its design, there are important reasons why researchers will want to communicate the research protocol and results to parties external to the research and development processes. First, the research team may want to apply for funding from a foundation, industry or government organization, such as the Agency for Healthcare Research & Quality (AHRQ) or the Canadian Institutes of Health Research (CIHR). Second, the research team may want to communicate the results of their research, including any valuable theoretical contributions, to various conferences and journals. As research in the area of eHealth is relevant to several fields, including medicine, healthcare, management, information systems, and engineering, the writing of proposals and articles must be tailored to their respective audience. The challenge arises when reviewers from one area are not familiar with languages, concepts and approaches from another. This challenge is inevitable, given the diverse number of researchers and areas contributing to eHealth research.

An example of this challenge will exist when those from the medical field review material for a formative evaluation. Problems may manifest if the reviewer is not aware that an evaluation is a formative evaluation, or the purpose of such an evaluation is largely to provide feedback for refinement of the intervention, or the value of these reviews to the developers and future researchers of an intervention. In this case, the reviewer may assume that the evaluation is indeed an experimental design, due to the popularity of RCTs in medicine, and conduct the review as such. As discussed, a formative evaluation is not suitable for demonstrating a significant positive outcome due to the use of an intervention, nor is it suitable to do so. This is accentuated when evaluating complex interventions, as a formative evaluation is essentially a precondition for experimental research. To address this challenge, the researchers must clearly communicate the definition of a formative evaluation, its purpose, its relation to other experimental evaluations, and its value, so that the reviewer does not assume that the evaluation is experimental. As well, reviewers may attempt to convince researchers to stick to more established theories. There is value in looking at a context in a new perspective, yet a reviewer may believe otherwise. For this reason, rationale for the use of this theory must be clearly provided, and communicated in such a way that can be understood by researchers from all applicable areas.

DISCUSSION – FORMATIVE EVALUATION OF “THE CDHF GI BODYGUARD”

The research proposal in question is for a formative evaluation of The Canadian Digestive Health Foundation’s (CDHF) Gi BodyGuard (“Gi BodyGuard”), a smartphone application used for recording and tracking symptoms related to digestive health, in the context of Inflammatory Bowel Diseases (IBD) care, a group of chronic diseases that manifest as inflammation or ulcers within the gastrointestinal tract (CCFC, 2008; Carter, Lobo & Travis, 2004). In the absence of a definitive cause and cure, IBD patients are compelled to cope with their chronic disease in the long term (Carver, 1997), and treatment is focused on achieving remission and improving the quality of life for its patients. Gi BodyGuard is a smartphone application that is used by users to record, view and share data clinically relevant to IBD care - namely stool qualities, episodes and severity of pain, diet, medication and water intake (Robinson, 2001; Kennedy et al., 2004; Lakatos, 2009) – which can be shared with a physician during a regularly
scheduled appointment. The physician can then use the data to assess disease activity over a historical time period, and draw inferences on the efficacy of the treatment prescribed to the patient. In this sense, this can be considered an application of Electronic Symptom Reporting (ESR; Johansen et al., 2012; Dohan & Tan, 2014), where electronic means are used to report patient symptom data to physicians, so that they may gain some knowledge about patient experiences. The application is currently available on iTunes and Google Play as a free download.

Developing a Theoretical Model

A theoretical model should reflect the context of its application. In this case, the context is IBD care. Among IBD patients, the clinical features of Crohn’s Disease (CD) and Ulcerative Colitis (UC) include the defecation of blood, mucus, and pus, as well as the occasional sudden need to empty the bowels (Baumgart & Carding, 2007; Wilson & Greco, 2012). Whereas CD can manifest anywhere on the digestive tract, including mouth, esophagus, stomach, and small intestine, UC is isolated to the rectum and the entire colon or portions thereof (Lennard-Jones, 1989). Although UC’s symptoms are more homogenous than those of CD, symptoms of UC may include abdominal pain, diarrhea, and weight loss (Carter, Lobo & Travis, 2004). During the IBD patient lifetime, disease activity is intermittent, occurring at different times and with varied levels of severity (Munkholm, 1995). Hence, many patients seek ways in which they can better cope with their disease (Casati et al., 2000). Without a cure, the goal of IBD treatment is to reach remission and improve patient quality of life. Treatment generally involves monitoring disease activity, and accepting various drug therapies, laxatives, and topical treatments (Robinson et al., 2001). Adherence to this treatment, as well as dietary adjustment, periodic physician office attendance and active management of symptoms remain an important part of coping with IBD patients to attain remission and improve their quality of life (Robinson et al., 2001; Kennedy et al., 2004; Lakatos, 2009).

As no known theoretical framework specifically addresses ESR in the context of chronic diseases, this presented several challenges to the researchers. First, IBD patients who are likely to adopt an application for recording, viewing, and sharing data relevant to coping with IBD disease activity likely have some knowledge of the disease before they start using the application. This application will have to offer some sort of benefit over and above their established disease coping processes. Second, as the chronic nature of the disease entails periodic visits with a clinician spanning a long period of time, their perspective on patient use of the application will likely influence whether the patient uses the application or not. Third, as the impact of self-management on disease activity of IBD is not yet known (Barlow et al., 2010), it can’t be certain that use of the application will impact disease activity, but there still may be some other benefit to use. Lastly, the perspective held by the patient on the specific technology, as well as their general ability to learn how to use technology, will likely influence its use. In addition to these challenges, and although the Gi BodyGuard technology has undergone some formative evaluation in its development (Mulvale, 2013), it has not been particularly evaluated in the described clinical context. For these reasons, the purpose of this research is to better understand how the use of particular smartphone application is used to assist coping with disease activity within the normal process of IBD care.

The theoretical background of this formative evaluation is constructed by integrating three relevant theoretical perspectives, namely Self-Regulation Theory (SRT) (Diefenbach & Leventhal, 1996), Information System Continuance (ISC) (Bhattacherjee, 2001), and Information Quality and Satisfaction (IQS) (DeLone & McLean, 2003; Wixom & Todd, 2005; Nelson, Todd & Wixom, 2005). SRT offers an approach to understanding how people with chronic diseases process environmental and somatic stimuli in relation to their condition to learn how to cope with their long-term illness. As the need to study the fit of technology into a context is clearly articulated earlier, the authors argue that the context for the patient experiencing the disease is one in which the appraise disease-related stimuli and environmental factors in relation to their disease, and how it can be better managed. ISC provides a framework for understanding long-term use of information systems. For the patient, as they are appraising stimuli against their ability to cope with a disease, therefore technology is considered one among many stimuli to the patient. Further, IQS involves the appraisal of the beliefs and attitudes associated with the information produced by a system, as a result of its use, as is planned to be received by the physician. Considering the persistent nature of IBD, and degree to which many IBD patients generally consult periodically with one physician (Bernstein et al., 2010), the ability for ESR tools to provide long-term support for both the patient and the physician, may be informed by integrating both perspectives into a multilevel model, with many patients nested within each physician. As this model is quite novel, it was necessary to consult several physicians and academics in its construction.
Choosing a Methodology

A sequential explanatory mixed methods approach will be employed (Creswell, 2009; Johnson, Onwuegbuzie & Turner, 2007), which is used when the objective of the research is to understand phenomena and to gain conceptual insight on a pre-existing model. As the model used in this research is new and unvalidated, there is certainly a need for gaining this insight. As well, the benefit of using a qualitative phase will inform the researchers more on the context being studied, and the “fit” of the technology to this context. This research will consist of two phases, a quantitative followed by a qualitative. In the quantitative phase, the impact of Gi BodyGuard as an ESR tool on the ability of the IBD patient to cope with their disease will be assessed. Participants will use and evaluate Gi BodyGuard in conjunction with their physicians. Quantitative data will be collected via an online questionnaire from participants before use at an appointment with their physician, and then again after their next regularly scheduled appointment, typically after one- to three months. In the qualitative phase, issues with including patient symptom data from Gi BodyGuard used as an ESR tool in clinical workflow will be explored. Qualitative interviews will be used to explore the determinant themes to facilitation or inhibition of long-term adherence to Gi BodyGuard as well as the ways in which data from Gi BodyGuard was used by the physician within their workflow. Results of the second phase will be used to update the model from the first phase, contributing to developing a general theory for ESR.

Recruitment of Participants

As the first phase of this study involves the use of a multilevel model integrating the perspectives of physician and patient, two populations must be defined, and two sets of sample frames sought. The physician population will be inclusive of physicians who care for IBD patients regularly, for example, gastroenterologists, family practitioners, as well as other relevant physicians. Nurse practitioners may also be included in this population. The sample frame will be sought from among membership listings, personal networks and events related to the Canadian Association of Gastroenterology, the Canadian Digestive Health Foundation, the Crohn’s and Colitis Foundation of Canada, and the College of Family Practitioners of Canada. Physician participants will be self-selected; that is, they will volunteer. The sample will be further restricted to clinicians who are capable of communicating with their patients in English. To be eligible, physician participants will be screened based on the criteria described above. Physician participants must also be willing to recruit patients for the study in their clinic. Physicians that agree to participate will be asked to refer other potential physician participants. Patients that agree to participate will be compensated $100 for every patient they bring into the study.

The patient population will comprise individuals who have been diagnosed with a form of IBD, including but not strictly restricted to those diagnosed with CD and UC. As disease activity can change over the course of time, patients who are experiencing remission will also be permitted to participate. The sample frame is “defined English speaking patients who attend a participating physician clinic.” As such, consenting and volunteering patients will be recruited through their physician offices. As this is a low-budget study, patients must also own a mobile device (e.g., an iPhone or Android device) capable of running Gi BodyGuard.

Retention of Participants

In order to retain physician participants, a separate strategy is formulated for physicians and patients, as their duties as participants in this study are quite different. As the physician is responsible for recruiting patients out of their own clinic, they must display the appropriate recruitment material as well as verbally attempt to recruit patients at their regular appointments. Either before or during patient follow up appointment, they will be expected to inspect the Gi BodyGuard data in conjunction with the patient, once for each patient they have successfully recruited in the study. They will then have to fill out their own questionnaire after the last patient has reported their results. As this involvement is substantial, and to encourage recruitment of many patients, the physician will be compensated with a fitting incentive of $100 per patient. They may also be selected for an in-depth interview, for the qualitative portion of the study, which will be compensated separately. As well, physicians will receive medical education credits as applicable. A rapport will be developed with the clinic staff as well as the physician, as they will need to prominently display the recruitment material, as well as schedule periodic telephone meetings and provide information when the physician is too busy. In the event that a clinic has not recruited participants in some while, a phone call will be arranged with the physician in order to assess any barriers to participation in the study experienced by patients. Physicians who are contacted that say that they wish to drop out of this study will be asked to participate in a brief telephone interview, concerning their barriers to participation in the study, their disuse of the
application, or any negative outcomes experienced. Physicians must explicitly drop out of the study before contact attempts will cease.

Patient involvement in the study consists of the following. They are to fill out a questionnaire at the start of the study, which will capture a majority of the data concerning their current disease activity, disease perception and coping strategies, perceptions of their physician, and perceptions to technology in general. They are then to download the Gi BodyGuard application on their phone, and use the application to log details concerning any disease activity or disease exacerbations, as well as undergo their regular routine. They are then to produce the data to the physician at their next regularly scheduled appointment. They are free to experiment with functions in the application, or to use the data themselves. After their appointment, they are to fill out another questionnaire, same as the first, but including questions on their perspective of the Gi BodyGuard application. They may also be selected for an in-depth interview, for the qualitative portion of the study, which will be compensated separately. In order to increase retention of the patient, their personal contact information, including email address and phone numbers, will be asked for at the beginning of the study. As well, the date of their next regularly scheduled appointment with their physician will be asked. Leading up to this date, the patient will be sent reminders to bring their symptom data into the appointment. After this date, patients will be sent reminders that they must fill out the final questionnaire. Patients who are contacted that say that they wish to drop out of this study will be asked to participate in a brief telephone interview, concerning their barriers to participation in the study, their disuse of the application, or any negative outcomes experienced. Patients must explicitly drop out of the study before contact attempts will cease. Participants that complete the final questionnaire will be compensated $100. If the rate of attrition is significant, a post hoc analysis will be conducted to see if any knowledge can be discovered from the existing data as to why participants dropped out of the study.

Creating Value for Developers

As future phases of Gi BodyGuard are planned (Mulvale, 2013), this formative evaluation is expected to inform the development team to current needs and future improvements. Although some validation of assumptions has occurred in the development of this technology concerning its use by IBD patients (Mulvale, 2013), this study is a formative evaluation within a clinical context. This study will serve to validate various assumptions the developers have in sharing symptom data from Gi BodyGuard with physicians.

Conveying Value to the Reviewers

As it is likely that reviewers from many areas related to eHealth will review this proposal, the purpose and value of the review must be communicated clearly. In particular, reviewers from the medical and healthcare areas view RCTs as the “gold standard” in research, therefore they may not be aware of the value of other types of research such as formative evaluations. In writing this research proposal, the researchers have communicated the value of formative evaluations in the following ways. First of all, the title of the research will explicitly contain the words “formative evaluation”. To add to this, formative evaluations will be characterized in the body text of the proposal, along with describing the value of formative evaluations, their distinction from summative evaluations, and the reason why evaluations like this are performed at this time. As well, the contribution to the theory must be conveyed to the reviewers, as well as the developers in further developing this technology.

CONCLUSION

This article described the design of a formative evaluation of a smartphone application, applied for ESR within the context of IBD care. The goal of this application in the context of IBD care is to facilitate the recording and transmission of patient symptom data to healthcare providers, so that they may incorporate the data into their workflow. Theoretical challenges include integrating theories from outside of healthcare, and use of theories with insufficient empirical support. Methodological challenges include integration and utilization of exploratory methods into research projects. Practical challenges include producing value for developers, and communicating clearly the value of formative evaluations for reviewers that may not be familiar with this type of research.

REFERENCES

References available on request from Michael S. Dohan.
The Principles of Good Health Care in the U.S. in the 2010s

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International Society for the Comparative Study of Civilizations
President (2007-2013)

ABSTRACT

The purpose of this investigation is to define the principles of good health in the U.S. in the 21st century. The interdisciplinary, civilizational methodology is applied to establish roots of this health care at the national level. Among findings are; well-being of Americans” is the constitutional opportunity of an American, good health of Americans is a constituent of their well-being, basic health care should be perceived as the controlled right of a citizen. Human and societal wisdom requires mentally healthy people. Human and societal wisdom requires well educated citizens. The state of health care of the Americans is in a state which is not appropriate for the most richest and powerful country in the world. The quality of health care is at the level of 54 percent. Vision of American society has been defined as well as its goals and strategies for the next 17 years, till 2030. Practical implications: If the integration of well-being, health care, and information infrastructure-oriented components into one comprehensive solution is not provided and if each one is treated in isolation, the improvements in health care won’t be lasting and positive. Social implications suggest: political will and leadership at all levels of the nation must reach agreement; otherwise the society will be declining in its physical and mental health.

Key words: constitutional well-being, health care, health care principles, health care rights, health care vision, health care goals, health care strategy, health care implications.

INTRODUCTION

In order to pursue the universal reform of health care in the U.S. one must define the principles and aims of this reform. The principles of 2010s Reform of Health Care in the U.S (known as Obama Care) should include the following:

1. The basic laws of the U.S. should be the foundation for the concept of health care:
   a. The Declaration of Independence of the U.S. (1776) states that “We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of happiness.
   b. The United States Constitution (1787) is also the base for the concept of health care. In the Constitution’s preamble is stated: “We the People of the United States, in order to form a more perfect union, establish justice, insure domestic tranquility, provide for the common defense, promote the general welfare, and secure the blessings of liberty to ourselves and our posterity, do ordain and establish this Constitution for the United States of America.”
   c. The concept of “Happiness” and “Welfare” in the 18th century were slightly different than today. We can assume that both terms currently mean “Well-Being of Americans.” This value is the constitutional opportunity of an American. Well-being is a very time and process-oriented value that cannot be guaranteed forever. Once accomplished, it can be lost to many internal and external factors. On the other hand, the American constitution supports this value by providing tools that help in pursuing this opportunity.
   2. Good health of Americans is a constituent of their well-being. In other words, good well-being is usually a determinant of good health. Without good well-being, Americans may not have good health.
3. Good health care is the constitutional opportunity of Americans. Today health care is very expensive. If it is free, it certainly will not satisfy the high expectations of Americans. Do they often perceive death as an option? The choice is between the right and privilege of having health care. It depends on the state’s economic situation and societal and political support. In this respect today, Americans are divided almost equally between the right and privilege. Due to almost 16.3% percent of the population not having health insurance (49.9 million) in 2012\(^1\) and high inequality (for 2010, 40.8 % are below perfect distribution, according the GINI index, comparable to Morocco’s and in contrast to Norway ’s 25.8% in 2000 (2007 World Development Indicators, World Bank, pp.67 -68), in times when 10 percent is unemployed and another 5 percent is out of statistics, to have a privilege of health care it may lead to the lack of social tranquility which is expected by the U.S. Constitution (too long, break it down, put information in parentheses in separate sentence). Therefore, basic health care should be perceived as the controlled right. It means that certain medical help is secured but its use is controlled and if it is abused by unwise life styles, it can be suspended.

4. The strong effort to improve the American Health System is the number 1 in the political agenda of President Barak Obama’s administration (2009-16). The implementation of the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act under the American Recovery and Reinvestment Act of 2009 (signed in February 2009) and of the Patient Protection and Affordable Care Act (ACA) – coupled with $30 billion in funding - have led to significant changes in the adoption of electronic health records by eligible providers (EP) and eligible hospitals (EH). However, its first year of whole Act implementation, which began in October 1, led to the profound political crisis, resulted in shutting down the federal government due to the budget dispute at the Congress. This crisis is mostly caused by the lack of agreed principles of the American Health Care System and limited to the insurance issues.

5. Some positive changes have been implemented in 2009-2013 as the result of the mentioned Acts in p. 4, namely in quality reporting, population health monitoring, electronic health record (EHR) certification for Meaningful Use and adoption and the start of major healthcare practice and payment reforms\(^2,3\). The Obama Care Act triggered many positive changes in the improvements of the American Health Care System; among such improvements one can notice; (1) vendor investment in the healthcare sector has grown significantly since 2009-2010. (2) there are created; Federal Advisory Committees (FACA) for HIT Policy and HIT Standards guiding development of standards and working to improve interoperability and reduce cost, improve quality reporting and increase transparency. However, many individual physicians implementing EMR reduced their productivity and lowered health quality by limiting good bedside manners (looking in patients’ eyes) by replacing them by a look at the screen of a computer.

6. Well-being of Americans means an equal access to sustainable economic vitality with minimized inequality, based upon a sustainable environment which delivers healthy food, fresh water and air, and culture-oriented activities.

7. Well-being of Americans is achievable through human and societal wisdom, meaning prudent choices made in economic, cultural, and technology-oriented processes.

   a. In particular, political wisdom is very important, since it leads the whole regions and nation.

   b. Human and societal wisdom requires mentally healthy people.

   c. Human and societal wisdom requires well educated citizens.

8. Good health is possible if the Americans’ life styles are wise and good.


THE STATE AND AIMS OF THE HEALTH CARE REFORM IN 2013

The U.S. state in 2013:

- **The state of the Americans** is below its peak in 1960 (so-called fabulous years). In the 20\textsuperscript{th} century America towered over its rivals. At the end of the Second World War, America’s dreams were collectively ambitious but individually modest. Nowadays, the collective ambitions of America have shrunk but the individual aspirations of its citizens – their dreams of prosperity, freedom and happiness (2013)\textsuperscript{4} – are undiminished (Brands, 2010). The question for the future is whether the relative decline of America (due to unregulated globalization) means that the dreams of individual Americans will need to be downsized as well.

- **The state of the well-being of the Americans** is low. The service economy is too weak to support the American Way as used to be. The off shore outsourcing of manufacturing is the permanent cause of high unemployment. The Americans borrow too much money and capital and soon may be internationally bankrupt. The 2008-13 financial crises indicate that the Managerial Revolution (executives intercept dividends under a form of huge bonuses) is at the peak. Wall Street turned the American financial system into casino. Bad economy limits taxes at all levels and as the result, schools are closing (ex. 44 in Detroit in 2009) and colleges are in financial crises. The national IQ of 98 is far behind too many countries. In terms of social-civilizational wisdom the U.S. is not the first, as its level of Academia could indicate. Mass culture lowered standards of social taste and behavior, which is reflected in this statement: “no logic, be nice and have fun.”

- **The state of health care of the Americans** is in a state which is not appropriate for the most richest and powerful country in the world. The quality of health care is at the level of 54 percent\textsuperscript{5}. The cost of health care per capita is twice bigger than in some developed countries and life expectancy is lower (e.g., Japan and Sweden). Even in the U.S. the same difference is among northern (New England) and southern states (Louisiana and Texas) as between the U.S. and leading countries.\textsuperscript{6}

- **Vision of American Society.** Americans achieved the highest standard of living among large nations in the second part of the 20\textsuperscript{th} century and should strive to maintain it throughout the 21\textsuperscript{st} century. It can be achieved if manufacturing will return to the U.S and business will secure jobs for the Americans as its best well-being customers. Schools and colleges should shift from education based on the knowledge to wisdom inquiry and rise national IQ from 98 to 105. This will lead to the shift from the fun to a wise, good, and healthy society. Mental health should be meaningfully improved. Such society should practice wise life styles and pursue of happiness as it is aimed in the Declaration of Independence, 237 years ago. Furthermore, Americans play a role of a stabilizing force in the world affairs in the last almost 100 years (since 1914). Despite of declining their economic ability in the 21\textsuperscript{st} century, there is no other state in the world which could play this role instead of the U.S. Americans are perhaps the only nation which is interested in almost all countries’ state of affairs which means that Americans’ well-being in general defines well-being of other countries.

**Creed:** Wise Americans are healthy.

**Goals:** are defined in the scope of Well-Being (Table 1), Health Care (Table 2), and Information Infrastructure (Table 3). These goals are defined first at the big-picture of the national level and when is necessary they are also defined at the small-picture of levels below the national one.

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\textsuperscript{4} Smile: USA ranks 17th among world's happiest countries. *USA Today*. September 9, 2013.
<table>
<thead>
<tr>
<th>AREAS</th>
<th>GOALS</th>
<th>2013-2020</th>
<th>2020-2030</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENHANCE EDUCATION</td>
<td>WBG1. Shift for knowledge to wisdom inquiry</td>
<td>10% of schools and colleges</td>
<td>60% of schools and colleges</td>
<td>Wiser graduates, future professionals, managers, leaders, and politicians</td>
</tr>
<tr>
<td></td>
<td>WBG2. Enhance national IQ</td>
<td>From 98 to 101</td>
<td>From 101 to 105</td>
<td>More able citizens</td>
</tr>
<tr>
<td>ESTABLISH SUSTAINABLE ECONOMY</td>
<td>WBG3. Minimize statistical and structured unemployment</td>
<td>From 10%+5% to 8%+4%</td>
<td>From 8%+4% to 6%+3%</td>
<td>Middle class restored</td>
</tr>
<tr>
<td></td>
<td>WBG4. Regulate food business ‘s products and consolidation</td>
<td>Increase the number of food making companies by 200%</td>
<td>Increase the number of food making companies by 500%</td>
<td>More local versus global food production and services</td>
</tr>
<tr>
<td></td>
<td>WBG5. Reduce Inequality</td>
<td>From 0.40 to 0.35 (of GINI index)</td>
<td>From 0.35 to 0.25 (of GINI index)</td>
<td>Larger middle class developed</td>
</tr>
<tr>
<td>GREEN-UP ENVIRONMENT</td>
<td>WBG6. Increase fresh water availability</td>
<td>Expanding the scope of sources by 5%</td>
<td>Expanding the scope of sources by 5%</td>
<td>Healthier consumption</td>
</tr>
<tr>
<td></td>
<td>WBG7. Increase availability potential of timber, fiber, and fuel</td>
<td>By 5%</td>
<td>By 5%</td>
<td>Maintaining sufficiency of civilization</td>
</tr>
<tr>
<td></td>
<td>WBG8. Increase availability of fresh air by reduce C2O emission</td>
<td>By 20%</td>
<td>By 30%</td>
<td>Slowed warming of climate and healthier air</td>
</tr>
<tr>
<td></td>
<td>WBG9. Increase recycling</td>
<td>By 20%</td>
<td>By 30%</td>
<td>Better use of unrenewable resources and better management of waste</td>
</tr>
<tr>
<td>INCREASE SOCIAL AWARENESS</td>
<td>WBG10. Implement curriculum (or electives) of</td>
<td>In 25% of schools and colleges</td>
<td>In 95% of schools and colleges</td>
<td>More aware graduate</td>
</tr>
</tbody>
</table>
environmental study and civilization study

WBG11. Increase the number of green organizations (campuses, enterprises, institutions) By 25% By 50% More social awareness in promoting green workplaces

WBG12. Establish prestigious awards systems for best practices in sustainability of civilization Several Several More inspirational ruling and society

WBG13. Reduce super-consumerism Expand the education curricula in the area of secular spirituality (virtues and values) Intensify the education curricula in the area of secular spirituality (virtues and values) More wiser and ethical business and consumers

Table 2. The Goals of Improving Health Care of the Americans in the 21st Century

<table>
<thead>
<tr>
<th>AREAS</th>
<th>GOALS</th>
<th>2013-2020</th>
<th>2020-2030</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>POPULATION</td>
<td>HCG1. Stabilize the growth of American population</td>
<td>Reduce the annual growth rate of population from 0.89 to 0.75</td>
<td>Reduce the annual growth rate of population from 0.75 to 0.50</td>
<td>Better use of strategic resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stabilize population in 2050 below 400 million.</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>HCG2. Reduce the number of mentally ill to the level of leading countries</td>
<td>To the level of the Czech Republic</td>
<td>To the level of Japan</td>
<td>Better decision-makers within the society</td>
</tr>
<tr>
<td>PREVENTION---LIFE STYLES</td>
<td>HCG3. Popularize healthy diets</td>
<td>Reduce the obesity of population from 60% to 50%</td>
<td>Reduce the obesity of population from 50% to 25%</td>
<td>Reduce rate of mortality and cost of health care of diabetic and heart-born patients</td>
</tr>
<tr>
<td>QUALITY</td>
<td>HCG4. Implement Wellness Programs</td>
<td>Increase the number of participants by 20%</td>
<td>Increase the number of participants by 30%</td>
<td>Healthier people</td>
</tr>
<tr>
<td></td>
<td>HCG5. Increase quality of health care</td>
<td>From 54% to 65%</td>
<td>From 65% to 75%</td>
<td>Healthier patients and lower curing cost</td>
</tr>
</tbody>
</table>
HCG6. Increase life expectancy

From 78 to 80
From 80 to 82
Pleasure of living and the sign of well-being and health

**COST**

HCG7. Reduce the cost/capita

From $6,000 to $5,500 (in 2010 dollar)
From $5,500 to $5,000 (in $2020 dollar)
The containment of cost growth

**INSURANCE**

HCG8. Improve insurance system

Develop the national system of controlling rights to basic health care at the level of individual patient (NBHCS)
Improve the NBHCS according to issues of practice
Less abuse basic rights for health care by those who do not care about their lives styles

HCG9. Improve the 2010 Health Care Law
Remove errors and misuse solutions
Implement the universal health care insurance law
Insurance system more suiting the right of basic health care

HCG10. Improve mal practice insurance system
Remove solutions which abuse the health care system
Implement the universal mal practice mal practice insurance

**Table 3. The Goals of Improving Health Information Infrastructure of the Americans in the 21st Century**

<table>
<thead>
<tr>
<th>AREAS</th>
<th>GOALS</th>
<th>2013-2020</th>
<th>2020-2030</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMR-Electronic Medical Records</td>
<td>HIG1. Increase the use of EMR</td>
<td>From 7% to 25% of medical practice</td>
<td>From 25% to 85% of medical practice</td>
<td>Higher throughput of the entire health care system for the sake of patients and administration</td>
</tr>
<tr>
<td>HIE-Health Information Exchange</td>
<td>HIG2. Make it operational in all 50 states</td>
<td>At the level of basic services of a region</td>
<td>At the level of knowledge management systems (Data warehousing and Data Mining)</td>
<td>The right regional information environment for providing better and less expensive health care</td>
</tr>
<tr>
<td>NHIE-National Health Information Exchange</td>
<td>HIG3. Make it operational</td>
<td>At the level of basic services</td>
<td>At the level of regional knowledge management systems (Data Warehousing and Data Mining)</td>
<td>The right national information environment for providing better and less expensive health care</td>
</tr>
<tr>
<td>Global- Health Information Exchange</td>
<td>HIG4. Make it operational at the level of standardization</td>
<td>At the level of basic services</td>
<td>At the level of regional knowledge management systems (Data Warehousing and Data Mining)</td>
<td>The right global information environment for providing better and less expensive health care</td>
</tr>
</tbody>
</table>
Strategies:

1. The implementation of 10 well-being-oriented goals of Americans for the next 20 years requires top-down leadership at the federal, state and local governments’ levels and bottom-up engagement at the level of schools, colleges, civic organizations, and citizens. Special coordination offices should be created and supported by updated well-being indexes and information systems for reporting and analysis.

2. The implementation of 10 health care-oriented goals of Americans for the next 20 years requires top-down leadership at the federal, state and local governments’ levels and bottom-up engagement at the level of local health care providers. Special coordination offices should be created and supported by updated health care indexes and information systems for reporting and analysis. The critical issue of improving the quality of health care can be solved in the following approaches (by each one or their combination):
   a. Strong public reporting on quality (using The Quality Assessment and Analysis Systems) and pay for quality-driven performance.
   b. By increased market-oriented competition among providers. The Quality Assessment and Analysis Systems at local, regional, and national levels should be available for the public and serve in supporting their judgment and choices of the most suited providers.
   c. Increased number of physicians from 2.3 (2000) to 4.0 per 1,000 people.
   d. Physicians can be reimbursed by pay rate per day.

3. The implementation of four information infrastructure-oriented goals of Americans for the next 20 years requires top-down leadership at the federal, state and local governments’ levels and bottom-up engagement at the level of local health care providers. Special coordination offices (ONC-Office of National Coordinator for Health IT, OLC- Office of Legal Counsel, and other) should be created and supported by updated indexes and information systems for reporting and analysis.
   a. The critical issue of the successful Health Information Infrastructure is in implementing EMR at the physicians’ level. The major improvements in the health care delivery cannot occur without physicians making transition from paper medical records to EMR (Lee and Mongan, 2009:76).
   b. The biggest barriers that prevent most American physicians from adopting EMRs are in their cost ($15,000 to $50,000 per physician) and their probable loss in productivity (due to slower data entry in comparison to quick notes on paper). According to a popular doctors’ opinion, this system raises costs, without increasing revenues. On the other hand, those physicians who implemented EMRs never gone back to paper charts (Lee and Mongan, 2009:86).
      i. Part of the federal economic stimulus package that passed in February 2009 included a provision for physicians who accepted Medicare patients to earn $44,000 over five year if they prove they are “meaningful users” of a certified EMR system. The rule also includes a 1 percent penalty on Medicare reimbursements for physicians who don’t adopt records by 2015.
      ii. Being electronic and connected to the Internet allows physicians to access records on an iPhone or Blackberry. The mobile system does not contain all functions available in the office, but physicians can view patient summary information in real time for active problems, allergies, current medications and immunizations, social history, and values from the most recent lab tests.
   c. Perhaps the user unfriendliness of some EMR software packages is the reason that physicians do not want to use this solution. It is a room for nation-wide standardization and acceptance rules for EMR software. Then the best solutions (certified) would be more successfully applied.
CONCLUSION

The implementation of this comprehensive concept of goals and strategies leading to better well-being and healthy Americans requires:

1. The integration of well-being, health care, and information infrastructure-oriented components into one comprehensive solution. If each one is treated in isolation, the improvements won’t be lasting and positive. (Figure 1).

2. Political will and leadership at all levels of the nation
3. Professional leadership at all major professional associations (ex. AMA)
4. Academic leadership at selected schools and colleges, at the preparatory phase of the program
5. Business leadership of this program-oriented health care providers
6. Media’s support in developing and implementing this program
7. Other necessary initiatives.

At the time of publishing this paper (Fall 2010), the author is rather pessimistic about possibility of successful implementation of this program. The American national political and societal climate is negative for large-scale and innovative initiatives. The status quo is the most popular policy among established political and professional leaders. This is because the 19th century attitude was supposedly very successful in developing of Americanism (efficient way to wealth and “happiness”). Unfortunately, after the passing of almost two centuries, today we enter a new epoch of new societal issues and required solutions, which require bold conceptualization and tough choices, through the 21st century.

Perhaps, the American Medical Association (AMA) and medical schools should take the lead in promoting professional and political ways of wise and good health care in the U.S.

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Health Information Technology in American Medicine: A Historical Perspective

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Abstract: Medical care has had great advances during and especially after the 19th century. With these advances has come the moral imperative to provide care to all in a nation regardless of the ability to pay. One of the great dilemmas of our time is how to provide this care without consuming other national priorities. There exists a debate between government-centered or patient-centered models of care and how electronic medical records could facilitate this process.

INTRODUCTION – GOVERNMENT-CENTERED VERSUS PATIENT-CENTERED CARE & COST

Aneurin Bevan was the Minister of Health in the Labor Government in Great Britain, which was elected into office in 1948. He is credited with the design and formation of the National Health Service. His motive was that all in Great Britain regardless of economic standing should be able to obtain health care free at the point of service. To do this he thought the only solution was to nationalize the health care industry putting a centralized bureaucracy with price controls in charge of the industry. With price controls set by “experts” there is no market determination of the true value of any service. Those who could afford care on their own were allowed to participate in a distinctly separate system with private insurance and co-pays. Bevan believed so strongly in free service paid for by the government that when the Prime Minister opted for the participants in the health service to pay for false teeth and some medicines, Bevan resigned in protest. Apparently Bevin was unaware that people are much more careful spending their own money than everybody else’s. The British National Health Service has been plagued with problems of quality and cost since its inception and to this day (History Learning Site, 2013; Black, 2013).

Could the same goal of universal coverage have been accomplished in a somewhat different fashion? Could a system be developed whereby all citizens would have the funds necessary to obtain health care through simple market forces? The labor government could have empowered individuals with health savings accounts (HSAs) along with high deductible insurance (HDHP) using tax policy. For instance those with no or limited income could have funds deposited directly into their HSA and a HDHP policy bought in their name and paid for by the central government. Insurance bought in the patient’s name would eliminate the problem of non-coverage for pre-existing conditions and other health insurance issues when changing employment. The HSA funds could be used to fund direct care contracts with a physician, thus allowing the poor the same access to care as all others. Those with significant incomes could fund their HSA along with a HDHP via tax credits (Fisher, 2013). With these arrangements market forces determine the value of services; individuals with their physicians develop individualized health plans conserving resources whenever possible. These plans have been extremely successful in Singapore, Switzerland, the state of Indians and function with efficiency, eliminating the need for a large government bureaucracy (Goodman, 2013; Roy, 2012). Despite the belief by some that the United States has a market driven health care system that belief is false. As the largest insurer Medicare drives pricing for health services in the U.S. However, Medicare uses an artificial pricing system, the Resource Based Relative Value Scale with a special interest controlled update committee (The American Medical Association, 2013).

In the United States a major federal and state commitment to health care took place in 1965 with the creation of Medicare and Medicaid. The situation was somewhat different than Great Britain in 1948 because during World War II employee health insurance was initiated and paid for by the employer with tax free dollars. Thus the
uninsured were mostly those over 65 y/o and the unemployed. Again there was a choice: a centralized, bureaucratic system or one with savings throughout a person’s lifetime deposited in a protected health savings account. The latter would have to be phased in for future generations. Our nation chose the government controlled, bureaucratic and in short order a price fixed option, as did Great Britain. History has shown that government centered, price fixed, bureaucratic systems produce distortions in market forces and are invariably unsuccessful (Rockoff, 2013).

Although most Western industrial nations have had problems controlling the cost of their centralized, price fixed, bureaucratic healthcare systems, the cost increases in the U.S. have been astronomical (The H.J. Kaiser Family Foundation, 2013). This is in large part due to the success of lobbying by special interests and crony capitalism with their expertise in obtaining wealth from the Federal Treasury. The more dollars at stake and the larger the bureaucracy the more the special interests are able to extract federal and state dollars. This is certainly true with Health Information Technology (Israel, 2013). There have been many attempts over the past forty plus years to control runaway Federal and State spending on health care; so far all have failed (Roy, 2013).

GROPING TO CONTROL COSTS- THE ELECTRONIC MEDICAL RECORD

Sold as a cost containment mechanism and jobs program, the HITECH ACT as part of the 2009 Obama Administration economic stimulus package, uses Medicare penalties and rewards as incentives to computerize all Medicare patient records (ARRA, 2009). Since almost all health care facilities care for Medicare patients, in effect these ‘incentives’ were in reality compulsory. These programs were designed to: 1) provide ready access to patient information regardless of location or hospital, even though hospitals would be using different commercial products, (2) collect aggregate health data for the nation, and (3) most importantly control costs. There were no controlled studies to determine if any of these laudable goals would be obtained with the commercial products available at the time. Also, there was no consideration of the possibility of far superior products that could be created by independent entities in the future. Because there were not detailed trials of these programs with their varied new requirements of such things as meaningful use, many unintended consequences are now being observed.

As of this time there is an apparent failure to accomplish success in any of these three major goals. (1) To-date there is NO interoperability between these various commercial health information technologies. It is not possible to share information for a patient cared for in one facility with electronic medical record (EMR) X now being cared for in a hospital with EMR Y; thus a major goal for patient safety and cost control is not being met. Demonstrating the difficulties involved is the Department of Defense and the Veterans Administration which has been unable to provide interoperability of their medical records despite the investment of approximately $1 billion (Branz, 2013). In Kalamazoo Michigan there are at least four distinct EMRs. Borgess and Bronson hospitals, Kalamazoo Center for Medical Studies and the Family Health Center. To date there is no ability while using one program to access any other (Personal Communication, 2013). (2) The value of the collection of national aggregated health data has also not undergone rigorous testing. It is not hypothesis driven and thus does not follow the scientific method. Its usefulness above and beyond controlled clinical trials and present day epidemiological information is unproven. (3) The ease of up-coding for more payment of services is widespread and thus instead of a cost containment device today’s EMRs are actually increasing costs (Hirsch, 2013).

Many unintended consequences are beginning to emerge over the past few years while using these programs. (1) The impact on the training of young physicians in residency programs has been dramatic (Block, 2013). This study found that excellent first year residents were spending approximately four fold more time entering data into the EMR than with their patients. This time restriction with patients compromises obtaining a quality history and performing an excellent physical exam. This does not bode well for the future of medicine as history taking and physical exam skills are fundamental components of being a physician. (2) Privacy concerns are many; the security of the state Affordable Care Act exchange information has been severely questioned by the Inspector General of the department of Health & Human Services (Roy, 2013). Internet accessible hospital patient records have been compromised in many instances (Gerstein, 2013). (3) The cost and complexity of using these HITECH ACT
approved programs has forced many physicians to forgo their practices and be employed by hospitals. This change has proven extremely expensive as the same procedure done in the hospital owned facility cost considerably more than when previously billed in a private office (Mathews, 2013). There is also concern that a hospital employed physician may have more loyalty to the hospital’s bottom line than to the patient’s best interest (Pathology Education Consortium, 2013). (4) The concern for the validity of physician notes remains a problem (Hartzband & Groopman, 2008).

CONCLUSION

There is no doubt that electronic medical records have an important place in American medicine. However, the Federal imposition of unproven, extremely complex, vendor driven systems that preclude newer more innovative programs, is in my opinion extremely unfortunate. I expect that if a voluntary market driven approach were adopted, financial incentives would induce the introduction of many more user and patient friendly systems. I personally favor computer programs that put the patient’s medical information on a pass word protected portable device that would stay in the patient’s possession. The only internet portion would be information needed to pay for expensive care by their high deductible insurance.

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Monitoring and Assisting Maternity-Infant Care in Rural Areas (Mamicare)

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Abstract: We present our project called MAMICare that is motivated by the alarming number of maternity and infant deaths in rural areas due mainly to a poor monitoring of pregnancy progress and lack of appropriate alerting mechanism in case of abnormal gestation evolution. We are proposing an information technology solution based on mobile devices, and health sensors such as ECG (electrocardiogram), stethoscope, pulse-oximeter, and blood-glucose meter to automatically collect relevant health data for a better monitoring of pregnant women. In this paper we address the current status of the maternity infant death problem especially in rural areas of Mexico. We review some applications of IT in health systems (known also as Electronic Health or simply e-Health) and discuss how these are related to our proposal and how they differ. In the paper we present our proposed solution and discuss the current status of our work.

INTRODUCTION

The lack of appropriate maternal and child health in rural areas results in an alarming number of maternity and infant deaths (World Health Organization, UNICEF, UNFPA and The World Bank, 2012). In Mexico, although the infant and maternal mortality has been declining (maternal mortality fell from 89.0 to near 50 per 100 000 live births between 1990 and 2010), the states of Chiapas, Oaxaca, and Guerrero have high rates, with mortality rates highest among indigenous children. The leading causes of death continue to be associated with hypertension, hemorrhages, and other complications of delivery (World Health Organization, 2006) that could be avoided. It has been demonstrated in other countries that by means of an information technology approach several medical conditions such as maternity care can be intelligently monitored, managed and treated on a long term (Blank et al., 2013, Mougiakakou et al., 2010). Such approaches can be studied and technology can be adapted to the particular conditions of maternity care and information technologies access in the rural areas of Mexico.

Current health conditions in Mexico present a downward trend in overall maternity and infant mortality. However it is highly remarkable that unequal access to healthcare services prevail as a challenge in the country (World Health Organization, 2006). More specifically rural areas are the ones lacking the high quality services needed to reduce maternal and infant mortality in the whole region. According to a study, health services and human health resources (such as equipped hospitals and well trained personnel) are more valuable for rural communities (Jennett, Yeo, Scott, Hebert, & Teo, 2005), thus the delivery of these services remotely using accessible technology could help to level up the unequal access to health services. Electronic health records, risk assessment systems, and remote monitoring are just some examples of how technology can be applied in the healthcare field.

The objective of our proposed work is to reduce maternity and child mortality rates in rural areas using information and communication technology (ICT) to strengthen the current health delivery practices for both the mother and child during pregnancy. The goal of this effort is to develop an integrated IT solution similar to our Emergency Remote Pre-Hospital Assistance (ERPHA) project (Muñoz, Avila, Lavariega, González, & Grote 2012). A solution that is suitable for rural areas, focused on the maternity care conditions and considering the technology limitations that prevail in the area are key elements to be considered.

The remainder of the paper is organized as follows: Section 2 presents and discusses current e-Health approaches on which we based our work, including our previous project called ERPHA. In Section 3 we introduce our project to alleviate the maternity infant death situation in rural Mexico. Finally, in Section 4 we establish our current status and discuss future work in the short and middle term.

RELATED WORK

In the past 10 years Information technology (IT) has been used to improve the accuracy of patient records, and health monitoring. Benefits and challenging unsolved problems continue to be the outcomes of such attempts (Bates,
2003), such as electronic health records, remote monitoring, tele-health, health data collection and processing, and clinical decision support systems, to name a few. Groups interested in the IT-Healthcare efforts have gathered and exchanged opinions to identify technological areas with the highest benefits. These groups integrated by members of the public, health care provider and private sectors selected tele-health and electronic health records, in this order, as the most valuable IT approaches. The groups of interest also identified as a disadvantage the changes in the current practices and processes in the delivery of health services (Jenett et al., 2005).

The use of electronic health records (EHR) is one of the most successful examples of the application of IT to support health care services. Research efforts state that EHR is a solution with great potential as EHR strengthens the collaboration between public and primary care (Calman et al. 2012). Electronic health records offer additional benefits such as improving public health surveillance by documenting patient data, real-time guiding of the physician interventions using statistical data to generate clinical alerts, improving surveillance and management of a communicable disease, etc. (Calman et al., 2012).

Other research effort focuses in supporting the treatment of patients with type 1 diabetes mellitus. This decision support system (Mougiakakou et al., 2010) provides risk assessment for long-term complications. Data exchange between a unit for the patient and a unit for the management of the patient occurs, and data is also stored in a web server. By combining database technologies, simulation algorithms and data mining, the system provides an advanced processing of the stored data to support the decision making for the physician. Although a study to evaluate the user requirements satisfaction, the cost and the effectiveness of the solution is needed, this work has allowed a proper risk assessment for long-term diabetes mellitus complications. Other risk-assessment technologies have been developed allowing the physician to do a smart diagnosis of the patient.

In Ghana, a software solution was designed in response to the rapid expansion of community health workers in Africa and Asia. This was made taking as an advantage the proliferation of mobile devices. The Mobile Technology for Community Health (MoTeCH) offers features such as calculating the schedule for each patient; and notifying both patient and community workers when care is due. The system automates the delivery of information for routine reports and integrates with existing software applications for mobile data collection. The presented project is the initial part of an iterative process and still requires advanced software development skills, attention to standards and configurable design to make it more readily available to groups of interest within the research (MacLeod, Phillips, Stone, Walji & Awoonor-Williams, 2012).

From Brazil and Peru, a Windows-based application called “TeleConsult” proposes to reduce the high mortality on rural areas in Latin America. TeleConsults proposes the establishment of a medical network that communicates using satellite. The system acquires images from ultrasound examinations, electrocardiogram and blood imaging and pretends to cover disciplines such as cardiology, gynecology pediatrics and infections from the region (Sachpazidis, Rizou & Menary, 2008).

An effort in the maternity and prenatal care is the ‘Prenatal Risk Calculation (PRC)’. PCR is a software solution based on a previously introduced system known as JOY. PCR and JOY work using chromosome data information (aneuploidies), through this analysis prenatal risk could detect symptoms such as Down syndrome and potential cancer cells on the product. The test performance between PCR and JOY gave higher significant results while detecting aneuploidies in the first trimester trial; testing alone, the test performance results of JOY were better than the results of PRC. PRC demonstrated to be a good tool to detect prenatal risk but it still needs to be improved (Hörmansdörfer et al., 2008).

A clinical decision support system on maternal care field was created and implemented for rural health care centers in Africa. The QUALMAT CDSS provides guidance for antenatal, delivery and post delivery care. This guidance is possible by incorporating features such as an orientation process based on set of routinely actions, algorithms to detect situations of concern, and electronic tracking of perinatal and postnatal care. CDSS is a java-based application that incorporates the World Health Organization (WHO) guidelines for pregnancy and childbirth care. The CDSS was first developed in English for the use in Ghana and consist of four parts: a user interface; an XML-database for patient data, a set of algorithms to screen entered values; and a set of training documents. Decision support is implemented by offering guidance through routine action in maternal and perinatal care, detection of critical situations using clinical data and electronic partograph for observation on the progress of delivery up to 24 hours. This system requires an equipped site with a laptop computer. Staff members in charge receive general software and QUALMAT training and are left in charge of user administration. The implementation presented limitations in complex medical environments leading to a different conclusion than expected. Another challenging issue was the implementation of the system in a resource-poor environment, leading to hardware insufficiencies and user frustration (Blank et al., 2013).

In general, as we have seen in this section, a great deal of effort in applying IT to health systems is based on keeping records and monitoring patients through a network. However, little effort has been set to use mobile
technologies for a better diagnostic in remote areas. One example of applying mobile and wireless computing in health remote health assistance is our previous work called ERPHA.

ERPHA (Emergency Remote Pre-Hospital Assistance) is an example of a IT solution based on mobile technologies to improve remote monitoring under emergency situations like car accidents. ERPHA is an Information Technology solution that enables the continuous monitoring of a patient’s condition during the pre-hospital period. ERPHA enhances the pre-hospital care quality by allowing early intervention of specialist physicians with key data such as video, audio and visualization of patient’s vital sings. ERPHA collects key health data form patient using body sensors that transfer their data to a mobile device (usually a smartphone) creating a body-sensor-network (BSN). The mobile device processes, displays and forwards the collected data to a hospital or medical center where a specialist physician can remotelly assist paramedics in the diagnosis. Additionally, at the medical center the data sent by de mobile device is stored into a database for maintaining historical records of the patient. These records can be later used for identifying patterns for a more effective treatment or for classifying the severity of injuries. The mobile device can resend all collected data from the BSN plus video to a medical center where a physician can provide a better diagnostic of the patient being monitored. The BSN is built with Bluetooth-enabled sensors for vital sings such as ECG, stethoscope, pulse-oximeter, and blood glucose-meter. The mobile device has been implemented using smartphones running Windows Mobile and Android as operating systems. The mobile device currently transmits video, GPS location and data from the BSN to the hospital via Wi-Fi and 3G. Besides the smartphone a tablet can be used as alternate mobile device. At the hospital, the transmitted video, vital sign and patient information are stored and managed using dedicated database and video servers. The hospital front-end is implemented using Microsoft Visual Studio 2010 (ASP.NET) and Microsoft SQL Server 2008 R2. Further ERPHA details can be obtained at (Muñoz, Avila, Lavariega, González, & Grote 2012).

RESEARCH METHODOLOGY

Our research is based on a real case that will describe in the following sections. In the following description some identities have changed to be anonymous. The intention is to highlight the improvement of healthcare quality and accessibility using wireless technology in a rural area.

Our research is in its initial state. A team of colleagues in the demographic area have already performed an evaluation study of the needs and requirement of the people in the selected rural area. From that study several projects were identified; some related to rainwater harvesting; dignified dwelling; reforestation and better use of natural resources; and of course, health improvement. For health improvement we have identified as the key problem maternal and infant care.

In this initial part of the project we will develop, based on our in-site observations, an information technology solution for assisting the monitoring and evolution of pregnancy in the area. Then, we will perform a pilot evaluation of the IT solution and make the required adjustments. As a result, we expect to see a progress in the quality of the information during pregnancy monitoring; an improvement in the quality of the health care services and eventually a downfall in the maternal and infant death indices.

DESCRIPTION OF THE PROJECT

Existing healthcare support systems have been proved to be efficient in the improvement of medical services. Most of these systems are applied in controlled environments like hospitals. Other systems are implemented to be used at home, where patients have access to such technologies and can follow the health recommendations that an expert or experts provide remotely. Also, as shown in the related work, aiming the healthcare problem in rural areas seems to be a growing concern, particularly in less developing countries such as Mexico, Peru, or Brazil in Latin America or Ghana in Africa. However, direct application of similar technologies would result in an inefficient solution for the Mexican communities included in the scope of this proposal. This is mainly because of the limited communication technology to which those rural areas have access. Our project is focused on the Magdalena Peñasco community, a rural area in the state of Oaxaca, Mexico. In that region, the communities lack of current communication systems such as Internet or Cellular Networks. Most of the time, the only communication service to which they have access is civil band radio communication.
Background

The current process for maternity-infant care attention in the community of Magdalena de Peñasco is a manual process. Because primary attention is performed by volunteers, enough documentation exists about the attention protocols to follow. However, it is hard to identify if everyone involved has a full knowledge of the steps to follow when immediate attention is required. Medical assistance, in particular Maternity-Infant assistance, is based in a hierarchy of levels of attention. Attention levels range from the most elemental home visit performed by a social worker (called Rural Volunteer Promoter or PRV) to the most equipped but expensive trip to the Zone Hospital at the capital of the state. In between the PRV and the Zone Hospital there are the Health House, the Rural Medical Unit (UMR), the Basic Services Hospital(HSB) and the Rural Hospital.

In order to understand what those levels of attention represent for anyone in the community a brief description of each level is given. The Social worker has a basic follow up equipment, accordingly to the Mexican Social Security Institute (IMSS). Health houses are a base for the social workers, vaccine campaigns, and have access to a basic medical kit. The UMR is conformed by a medicine practitioner or a general physician as well as an auxiliary worker. The HSB is considered to be fairly similar to an UMR with some additional equipment such as an ambulance and a delivery room, although much of the information is not clearly defined. Only the Rural Hospital and Zone Hospital have all the basic services (pediatric, internal medicine, general surgery, and gynecology) with the difference that the Zone Hospital in Oaxaca also has more special services. However, Oaxaca’s Zone Hospital gives services to patients from the whole state and most of the time is over capacity.

In general terms, attention in the rural communities, in particular in Magdalena de Peñasco is very limited. Health services are hard to reach, personnel are sometimes undertrained and most of the time hospitals or health centers are overcapacity or can’t cover the full needs of the community. In order to provide a better understanding, a case scenario is described.

Original Situation Scenario

This scenario illustrates in a fair amount the current state of maternity-infant attention in the community of Tlaxiaco. Names and fictitious characters have been developed to illustrate the case.

Maria is a voluntary Social Worker (or PVR) in the region of Chalcatongo; Rosa is a mixteco woman that lives in a settlement 700m far from Chalcatongo. Rosa is 7 month pregnant, this is her fourth pregnancy; her children are 7, 4 and 2 years old. She is a healthy 36 years old woman. Her husband left 3 months ago to continue working in Los Angeles, California (USA); Maria lives 500m away from Rosa’s home.

A Health House is 3km away from Rosa’s home. UMR is 6km away from the Health House and 12km away from Rosa’s. The closest HSB is 48km away. The orography of the zone makes travelling really slow and hard for all those distances.

As part of her duties as rural promoter, Maria performs a home visit to Rosa to check her pregnancy evolution. Maria following her basic training takes the recommended vital sings from Rosa such as blood pressure, cardiac rhythm, and belly size. However, Maria does not remember how to properly use the sphygmomanometer and is hard for her to interpret the attached instructions. Maria skips some measurements, mainly because the form where data is registered does not indicate them. Also, Rosa has been working hard at home moving some heavy objects, and Maria does not know about that. Maria fills the form with normal data and proceeds to finish the evaluation. At that moment, Rosa begins to feel pain in her belly and turns pale. Maria interprets those symptoms as abnormal and proceeds to make Rosa rest while she seeks for help. Rosa’s older son runs to the nearest home (100m away). A neighbor goes to the nearest Health House seeking for help, 20 minutes passed, and the place is closed. Meanwhile, Rosa is feeling worse. People in the community find the kid and decide to help him by driving him to Rosa’s home in order to take her to the nearest UMR. 1 hour and 15min has passed since the first symptom appeared on Rosa; she has not gotten any sort of expert medical attention yet. As situations gets worse, they decide to go straight to the HSB looking for better facilities and the possibility of having an ambulance. Thirty minutes of traveling hurt on Rosa’s situation because of the ground conditions. Rosa’s evaluation takes longer than expected because the doctor was not notified on time about the emergency. He wasn’t ready to receive Rosa. Maria stayed and did not travel with Rosa, moreover the forms with information of Rosa’s evaluation were missing. Therefore, there is no information that allows the doctor to make a smart decision. Rosa’s critic situation forces her to be transferred to the hospital in Tlaxiaco. Fortunately the ambulance was in good conditions, but still it takes 1.5 hours to take Rosa to Tlaxiaco. It was too late by then; unfortunately both Rosa and her baby die on arrival.
This case scenario illustrates that failing to communicate fast and efficiently is a critical factor to solve any emergency of this type on time and effectively. Also the incomplete information is a really big factor in the final outcome of the maternity-infant attention.

MAMICare System Description

It is believed that by using information technology, the above-described problem could be mitigated. The e-Health solution that is proposed aims to generate a positive impact in the community by improving the communication channels and offering the possibility of having reliable information about the patients at the time when it is most needed.

There are special characteristics in the highest needed rural areas that challenge the implementation of a simple healthcare solution. Currently, most of the monitoring is done by social workers without any special preparation and that belong to the same community. In the zone, there is no telecommunication infrastructure (Wi-Fi or cellular networks) - the most advanced technology is civil band radio. Due to the lack of sufficient communication technologies, the proposed solution is an asynchronous support system to assist the social workers in the monitoring process and the physician with reliable information. Also the system aims to work as a data center for patient’s information.

MAMICare is the proposed system to cover three mayor setbacks currently present over rural communities in Mexico. First, the proper monitoring and control of the patient’s evolution by storing adequate information and following up data required in basic maternity-infant care; second, the failure to detect risk situations on-time due to the lack of a proper knowledge under those circumstances; and finally, the communication gap within the rural communities in relation to the healthcare problem. Those three issues will be covered by MAMICare under different use conditions. The eventual availability in the future of communication infrastructure in the different rural areas would make possible to extend the MAMICare functionalities to forward the recorded information in a live stream fashion to the nearest hospital or medical facility. This functionality provides an additional tool for the social worker by allowing a health professional to check on the patient and a remote physician to give complete feedback on time. Data in the MAMICare will be locally stored and used to properly follow up the patient’s record. At the same time and when available, data will be shared to a centralized database in the community center in which data will be properly analyzed for statistics and in-depth knowledge of the illness under medical treatment. MAMICare will have a risk-condition assessment tool that will identify situations and alert the social worker of critical conditions.

MAMICare is integrated by two parts: MAMITA and MAMI Server, as illustrated in Figure 1, each will handle part of the previously described functionality. The first part (MAMITA) is a tablet device that will be used by the social worker or physician to record, store and analyze information of the patient. The MAMI Server is a system that allows wireless communications between the tablet (MAMITA) and the community center in which a database system will be implemented for the storage and administration of the data. This paper focuses on the MAMITA part of the project; although MAMI Server may be briefly discussed it is only considered to be part of the long-term solution.
Following ERPHA architecture as a reference, the MAMITa system is a software solution that integrates different sensor devices (as shown in Figure 1) such as pulse-oximeter, ECG, Doppler, and glucometer. MAMITa is expected to keep valid track records of patients by aiding the social worker in her job through a visual interface. Such interface includes a step-by-step process to be followed in order to avoid any missing information. MAMITa will also include support video on how to use the sensors and follow the exploration protocols in order to avoid missing critical information. MAMITa will consist of a risk assessment tool that will alert if measurements are out of a healthy range and possibly become a risk situation for the patient. The application will incorporate the definition of system priorities to alert the social worker of any maternity-infant risk such as hypertension following norms and standards as the Mexican Official Norm NOM-007-SSA2-1993. This Mexican norm specifies prenatal, during and after labor attention for women and newborn children (Secretaria de Salud del Gobierno Mexicano, 1995). Also the WHO “Pregnancy, childbirth, postpartum and newborn care - A guide for essential practice” provides recommendations to guide health-care professionals in the treatment and management of women during their pregnancy, childbirth, postpartum period or any complications that may arise (World Health Organization, Department of Making Pregnancy Safer, 2006). When the system has been input with some conditions and considers a risk situation, MAMITa gives feedback to the PRV to communicate with and pass the system to the physician. The doctor is then informed by the system on the patient’s current condition allowing him/her to make a smart decision by fully knowing all the details. As described in the original situation scenario, the patient, the social worker and the doctor are the ones that should be in direct contact with MAMITa system.

The proposed MAMITa solution includes a specific list of medical devices such as ECG (electrocardiogram), stethoscope, pulse-oximeter, and blood-glucose meter. Such devices will be synched with the tablet and used for the proper monitoring of the patient. Those devices are considered part of the basic medical kit included with the tablet; other devices will be selected in order to fulfill the requirements in the rural communities. Devices properly synched with MAMITa system allow the system to keep track of the patient’s situation and at the same time to keep an electronic record of patient’s health. Figure 2 illustrates the way in which MAMITa reads the patient measurements through the devices. Also it shows the way in which interaction occurs between the Social Worker, the patient and the device (D). System allows the social worker to input data as well as to receive readings and instructions from the system in order to aid in the process of recording information.
MAMITa interface will be allowed to interact with multiple devices (D’s in Figure 2 and Figure 3). It is expected to use an internal database as well as an internal control layer that interacts with the view layer. View layer is in charge of communications and the tablet to be used is expected to have as well at least one of the Wi-Fi/3G/4G communication protocols that will be used for some external communication activities in a further stage of the project. All these are shown graphically in Figure 3.

While readings are being stored locally in the MAMITa, MAMITA Server complements the functionality by allowing communications between tablets and a data center. Local MAMITa data is synch with the community center database via Wi-Fi whenever communication is allowed or connection is achieved. This scenario happens locally within a single health community center such as the Rural Hospital. MAMITa will be later extended to a wireless environment, when communications are allowed between medical centers. By allowing having patient’s information centralized in one place the doctors or other social workers will have better accessibility to the patient’s information without the original social worker or the tablet being required to travel. Storing the data will also allow further data processing for having statistics or applying algorithmic solutions that allow improving the risk assessment evaluation process.

Figure 4 illustrates the whole MAMICare system interactions. First, the MAMI Server in which different tablets from different patients are being synchronized and data is being centralized in order to be accessible from any workstation. Secondly, the MAMITa system in which medical measurements are input and stored locally in the tablet device.
For the short-term, the Denis cheap CDMA 450/800 Mhz 7 inches Android 4.0 CDMA tablet has been defined as a base development environment due to its inclusion of the CDMA450 communications protocol which has been chosen by Mexican telephone company TELMEX (2008) to be used for expanding the communications services to the rural areas since 2007. However at the moment or writing this paper, there are no communication services yet in the rural area of our attention. The Denis CDMA tablet will also enable a later process of synching the data with a central database, which will help to keep track records of the patient’s evolution.

It is important to highlight, that even though MAMICare is a full solution, having only MAMITa available does help to reduce the problems of data accuracy. Of course, current communication limitations still does not allow to have centralized data, but MAMITa still keeps valid track records of patients information. While MAMI Server is unavailable, it is expected that MAMITa will be transported with the patient in case of an emergency; this allows the physician to have access to the patient’s information and a proper assessment of conditions and a quick decision-making. In order to have a better understanding of the expected impact of this system, our original use-case situation will be exposed next, this time under the assumption that the MAMITa system is already implemented in the community.

Expected Impact of Health Information Technology Scenario

Considering the same characters, distances, orography and characteristics originally described in the original situation scenario. This time Maria has her full kit including the sensor devices and the MAMITa system.

During her scheduled visit to Rosa’s home, Maria activates the MAMITa system. MAMITa guides her thoroughly during the metrics process. Maria uses the stethoscope as required by the system and data is stored in the system using wireless communication. MAMITa shows Maria a set of images/video on how to use the sphygmomanometer properly, the system receives the data and detects an abnormality in Rosa’s health. MAMITa asks Maria to write down the anomaly in the form. Maria is asked by the system to make some follow up questions such as what her activities have been during the past days. MAMITa uses a microphone to record and store Rosa’s description. Using a Doppler ultrasound, MAMITa stores data being sent by the device, in that moment the system detects another anomaly and asks the social worker to use her radio communication system to notify the Health House, UMR and HSB that a patient in critical situation has to be transferred to the HSB. One of the neighbors with vehicles comes to help move Rosa. Eight minutes later, Rosa is at the HSB, the physician practitioner in charge makes her diagnosis based on the tablet information. Data allows him to decide to move her to Tlaxiaco Hospital. In Tlaxiaco Rosa is timely attended; both Rosa and her baby are safe.

Expected Impact

As shown in the previous use cases, expected impact of implementing MAMICare in the rural areas include having truthful information and thus reducing diagnostic errors. The PVR will be better prepared to act under any circumstance. Another great advantage is the preservation of data. At the UMR, data could remain active from a few hours up to three days. In the Rural Hospital, data could remain relevant from one up to four days. Also inside the Hospital, communication and data transfer occurs immediately between tablets and workstations. MAMITa expects
to reduce the time of capturing the medical records by giving proper instructions, as well as by having available truthful information that allows physicians and social workers to have the best possible scenario for decision-making and even highlighting any considered risk situation.

**RESEARCH LIMITATIONS AND FURTHER STUDY ISSUES**

As we mentioned before in our research methodology section, our work is based on observation of a real case, therefore there exists some limitations which can reduce our expected impact. First of all the communication issue: the lack of proper communication means is considered in the initial phase of MAMICare, but further versions depend on the availability of communication technologies in the region (WiFi, 3G, or 4G). Availability communication technology depends on federal agencies and findings, which are out of scope of influence. In addition, the adoption or rejection of MAMICare depends on the approval of the state and federal health agency. This approval however is not only based on the technical merit of our project, sometimes, political reasons have more impact that technical benefits. These findings and validity remain to be verified in additional/future research, that we will be reporting as the project evolves.

**CONCLUSIONS**

MAMICare System is a work in progress that is expected to make a positive impact once it is implemented in any of the rural areas in Mexico. Research demonstrates that MAMICare is a viable solution to the maternity-infant problem that is currently present among the rural community areas in the states of Chiapas, Oaxaca, and Guerrero. Also the use of electronic healthcare services makes possible to reduce attention issues associated with the main causes of death (hypertension, hemorrhages, and other complications of delivery) that are much higher in maternity-infant care. The MAMICare System is a two-part system to be developed both in the short, medium and long term. For the short term, the MAMITa – a tablet system to aid the social workers in the patient’s assessment process will be developed. In the medium term MAMI Server should begin development with the possibility of being expanded to become a wireless system in the long-term, when such communication technology is made available in the communities.

**ACKNOWLEDGEMENTS**

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**REFERENCES**

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An Empirical Study of Home Healthcare Robots Adoption Using the UTAUT Model

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Abstract: Home healthcare initiatives are aimed to reduce readmission costs, transportation costs, and hospital medical errors, and to improve post hospitalization healthcare quality, and enhance patient home independency. Today, it is almost unimaginable to consider this initiative without information technology. Home healthcare robots are one type of the emerging technologies that hold promise for making clinical information available at the right place and right time. Several robots have been developed to facilitate home healthcare such as remote presence robots (e.g., RP2) and Paro. Most previous research focus on technical and implementation issues of home healthcare robots, there is a need to understand the factors that influence their adoption. This research aims to fill this knowledge gap by applying the UTAUT model. The model was tested using survey questionnaire. The empirical results confirm that performance expectancy, social influence, and facilitating condition directly affect usage intention of home healthcare robots, while effort expectancy indirectly affects usage intention through performance expectancy. Several practical and theoretical implications are also discussed.

INTRODUCTION

One of the most notable and well-established streams of research in Information Systems (IS) over the past four decades has been focused on how and why people adopt information technology. The need to investigate the factors influencing successful adoption arises, in part, due to the complex interplay between people and technology. Technology adoption research, therefore, seeks to clarify the factors that contribute to the success and failure of information systems and technologies (Wills, El-Gayar & Bennett, 2008).

Recently, healthcare has been transferred from hospitals and nursing facilities to the patient home, which leads to what is commonly known as home healthcare. This initiative has been undertaken broadly by healthcare industry in the U.S. to reduce readmission costs and transportation costs, and to improve post-hospitalization healthcare quality and finally increase patient independency (The Joint Commission, 2011). Moreover, the rapid increase of the older adult population, which is expected to reach 21 percent in the U.S. by 2030 will create new challenges for our society. The growing population of those with disabilities will also create the need for more nursing and home-care services from the healthcare industry (U. S. Census Bureau, 2005).
Today, it is almost unimaginable to consider this home healthcare initiative without information technology. Clinical decision support systems, mobile health systems (mHealth), sensor based monitoring systems (SMS) and longitudinal electronic medical records (EMR’s) promise to make clinical information available at the right place and right time, thereby reducing error and increasing safety and quality.

One of these promising technologies is home healthcare robots, which is the focus of this study. It is critical that we understand the factors that influence their adoption. Home healthcare robots that are perceived negatively by stakeholders are no longer applicable like any product or service, customers must be satisfied or they will look elsewhere to fulfill jobs they are interested in completing. Most previous research focused on technical, implementation and algorithmic design issues (Advait & Kemp, 2010; Choi, Anderson, Glass, & Kemp, 2008; King, Tiffany, Jain & Charles, 2012; Fan, Chen, Fan, Glass & Kemp, 2010). Limited research has focused on user perceptions, needs and requirements of such technology. Thus, this research fills this knowledge gap by leveraging the UTAUT model.

The research makes several contributions to the literature. First, it enables robot designers and service providers to understand what influence stakeholders’ decision to adopt home healthcare robots; second, it enriches the literature on technology adoption by extending the related theories to the home healthcare robots domain; third, it enhances the theoretical foundation of home healthcare robots research by innovatively applying technology acceptance models to explain the adoption of this technology.

The remainder of this paper is organized as follows: the next section reviews the related literature. The third section introduces the research model and hypotheses. Section four describes the research method. The fifth reports the analysis of the results and followed by discussion and conclusion in section six, and section seven, respectively.

LITERATURE REVIEW

Home Healthcare Initiative

In this first decade of the 21st century, great attention is being devoted to U.S. society’s needs for access to health care and health care delivery. To date, there has been increasingly focus on the transition of care into the home. Health care is coming home. Health care is increasingly occurring in residential settings rather than in professional medical settings (National Research Council, 2010). The Centers for Medicare and Medicaid Services (CMS) estimates that 8,090 home health care agencies in the United States provide care for more than 2.4 million elderly and disabled people annually (Alaiad & Zhou, 2013). By 2020, 70 million elderly people will increasingly need to stay at home rather than in nursing home (Hughes, 2008), technology is helping 80% of seniors to live independently at home out of institutions.

This change in the locus of care needs to be seen in context. In the United States, health care devices, technologies, and care practices are rapidly moving into the home. This transition, which is likely to accelerate in the future, has raised a host of issues that have received insufficient attention in the past such as very few homes have been designed for the delivery of health care, and technologies that are designed for hospitals and clinics can be ill suited for use in the home. However, researchers indicated that many health care treatments that were once offered only in a hospital or a doctor’s office can now be done in home. Home health care is usually less expensive, more convenient, and just as effective as care you get in a hospital or skilled nursing facility (National Research Council, 2011).

Home health care is a system of care provided by skilled practitioners to patients in their homes under the direction of a physician. Home health care services include nursing care; physical, occupational, and speech-language therapy; and medical social services. The main goals of home health care services are to help individuals to improve function and live with greater independence; to promote the client’s optimal level of well-being; and to assist the patient to remain at home, avoiding hospitalization or admission to long-term care institutions. Common diagnoses among home health care patients include circulatory disease (31 percent of patients), heart disease (16 percent), injury and poisoning (15.9 percent), musculoskeletal and connective tissue disease (14.1 percent), and respiratory disease (11.6 percent) (Hughes, 2008).
In summary, a number of factors are driving the migration of health care practice from professional facilities to the home and, as a result, significantly increasing the numbers of people who must receive health care in the home (National Research Council, 2011):

- The costs of providing health care at formal medical facilities are increasing. Advanced medical technologies and procedures, as well as the training of medical professionals to employ them, can be very expensive.
- Hospitals are discharging patients, including premature infants, sooner into home care, sometimes with complex care regimens.
- The U.S. population is aging, and consequently the demand is growing for various health services (particularly related to conditions associated with aging). At the same time, people are focusing increasingly on overall wellness and quality of life, even into advanced age.
- The prevalence of chronic conditions across the entire age spectrum is growing (particularly conditions related to obesity, such as diabetes), and growing along with it is the demand for health care. More people are living longer with increasingly complex medical and social needs.
- Larger numbers of veterans are surviving military conflicts and returning home to live with disabilities.
- People who may have had a rapidly fatal illness years ago, such as a heart attack or AIDS, are instead now living with longer chronic illnesses, such as congestive heart failure or HIV.
- Some types of health care professionals are in short supply, which shifts the burden of some types of care onto lay caregivers to fill the gap.
- Consumers want to be independent in their health management and are seeking more home-based services.
- Innovations in information technology, along with consumer demands for more health care quality and personal independence, are shifting the focus from health care providers, procedures, and prescriptions onto consumers and how they can manage care at home.

**Home Healthcare Robots**

Robots can be defined as machines that can be used to do jobs, according to NASA. Some robots can do work by themselves. Others must always have a person telling them what to do. When these jobs are related to home healthcare, then it is called home healthcare robot. Robots are being used for a wide range of jobs in home healthcare. Table 1 provides a summary of these jobs.

<table>
<thead>
<tr>
<th>Monitoring personal health and safety such as monitoring blood pressure, blood sugar, and body temperature, monitoring of injuries, following-up with the family, and detecting people lying on the floor and call doctor for help.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing medication management and scheduling such as medicine preparation and reminder</td>
</tr>
<tr>
<td>Helping in physical therapy such as rehabilitating from leg/hand illness through the use of a wearable leg robot for mobility enhancement.</td>
</tr>
<tr>
<td>Facilitating communication with doctor/physician and enable submission for the medical data into a centralized medical IT system over wireless network (WLAN) so that doctor can access and see the data remotely.</td>
</tr>
<tr>
<td>Helping in cognitive and occupational therapy (e.g. Paro improves the bad mood).</td>
</tr>
<tr>
<td>Helping in nurse tasks such as keep monitoring the blood pressure and bed bath.</td>
</tr>
</tbody>
</table>

**Table 1. Common Home Healthcare Robots Jobs and Tasks**

In the last few years, home healthcare robots have started helping professionals including nurses, doctors, therapists and physicians provide home health cares and services to their patients in several forms. Our research focuses on two main popular home healthcare robots, namely; remote presence robots RP (Intouch, 2013) and Paro robots (Wada, Shibata, Musha & Kimura, 2008). Professionals (e.g. physicians) at one location are able to take care of remote patients at different locations (e.g. home) by using remote presence robot which provides direct access to the patient in emergency cases especially in rural areas and provides diagnostic capabilities through the use of camera, remote control, speaker, light, ultrasound and EMR access. For those patients who are suffering from cognitive disabilities, a paro robot (friendly looking pet robot) can be used to increase positive mood, decrease the feeling of
loneliness, alleviate stress and the feeling of social connectedness. Such a robot can respond to petting by moving its tail and opening and closing its eyes. It can show emotions such as happiness, getting surprised and even anger. It can produce sound similar to a real baby seal active during the day and asleep at night. Doctors/Therapists can teach patients on how to use the Robots at home to achieve better cognitive skills instead of using traditional therapies.

Technology Acceptance Theories

Technology acceptance is defined as “an individual’s psychological state with regard to his or her voluntary or intended use of a particular technology” (Gattiker 1984). Technology acceptance research has been profoundly impacted by the theories of individual human and social behavior emerging from the disciplines of psychology and sociology. With its origin in the area of social learning, Social Cognitive Theory (SCT) is focused on the process of knowledge acquisition through observation (Bandura, 1986). This theory was expanded and became known as SET, or Self-Efficacy Theory (Bandura, 1977). (Fishbein & Ajzen, 1975) publish their research on the Theory of Reasoned Action (TRA). The theoretical basis for TRA lies in the tenets of social psychology, and has been widely accepted as a foundational theory of human behavior.

Theory of Planned Behavior (TPB) emerges as an extension of TRA with perceived behavioral control from SET as an additional determinant of intention (Ajzen & Fishbein, 1980). (Thompson and Howell, 1991) published an alternative to TRA and TPB, the Model of PC Utilization (MPCU). This theory too has its roots in psychology. The Technology Acceptance (TAM) model represents the first theory developed specifically for the IS context, i.e. people in business (Davis, 1989). A few years later, (Taylor & Todd, 1995) put forth their theory, known as Combined TAM-TPB, or C – TAM – TPB. This theory of technology acceptance combined the predictive elements of TPB with the concept of perceived usefulness from TAM. TAM was further extended to TAM2, and included subjective norm as a predictor in settings where use is mandatory (Venkatesh & Morris, 2000).

The most recent model to emerge from this long line of study is known as the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh, Morris, David & Davis, 2003). The UTAUT has been studied in at least six organizations and found to explain roughly 70% of the variance in user intention to use information systems. The UTAUT integrates eight user acceptance models: TRA, TPB, TAM, TAM2, IDT, MM, PCI, MPCU, and finally, social cognitive theory (SCT). Each of these models has usage intention or actual usage as the dependent variable.

RESEARCH MODEL AND HYPOTHESES

The UTAUT attempts to explain usage intention, as well as subsequent usage behavior. The theory suggests that four key constructs: performance expectancy, effort expectancy, social influence, and facilitating conditions are direct determinants of usage intention and behavior. In addition, gender, age, experience, and voluntariness of use will mediate the impact of the four constructs on usage intention and usage behavior (Venkatesh, 2003). The comprehensiveness, suitability, validity, reliability and a accuracy of the model have been demonstrated in different contexts (AlAwadhi & Morris., 2008). Thus, our research model for determinants of usage intention is shown in figure 1.
Usage intention is the dependent variable, which relates to the way(s) stakeholders intend to use home healthcare robots. Usage intention is a predictor of actual use, which is in turn influenced by performance expectancy, effort expectancy, social influence, and facilitating condition.

**Performance Expectancy**

Performance expectancy can be defined as the extent to which stakeholder believes that using home healthcare robots will help him/her improve job performance. The following five constructs, taken from the eight models, capture the concept of performance expectancy: perceived usefulness (TAM/TAM2 and C-TAMTAB), extrinsic motivation (MM), job-fit (MPCU), relative advantage (IDT), and outcome expectations (SCT) (Venkatesh, 2003). In addition, it has been demonstrated that performance expectancy is the strongest predictor of usage intention of IT (Venkatesh, 2003). Adapting performance expectancy to home healthcare robots suggests that stakeholders think home healthcare robots are beneficial in that they can help them get better/ a raise, improve overall productivity and perform tasks/ treatments quickly and flexibly, or access services effectively. There is also extensive empirical evidence that supports the significant effect of performance expectancy on usage intention (Alshehri & Drew, 2012; Wills, El-Gayar, & Bennett, 2008). Thus, we put forward the following hypothesis:

**H1**: Performance expectancy has a positive effect on stakeholders’ usage intention of home healthcare robots.

**Effort Expectancy**

Effort expectancy is defined as the degree of ease stakeholder feels with respect to the use of home healthcare robots (Venkatesh, 2003). The three constructs that relate to effort expectancy are perceived ease of use (TAM/TAM2), complexity (MPCU), and ease of use (IDT) (Venkatesh, 2003). We believe that stakeholders adoption of home healthcare robots depends on whether home healthcare robots are easy to use. There is also extensive empirical evidence that supports the significant effect of effort expectancy on usage intention directly (Kijsanayotina,
Pannarunothaib & Speediec, 2009) or indirectly through the performance expectancy (Chaua, & Hu, 2002). Thus, we posit the following hypothesis:

**H2a**: Effort expectancy has a positive effect on stakeholders’ usage intention of home healthcare robots.

**H2b**: Effort expectancy has a positive effect on stakeholders’ performance expectancy of home healthcare robots.

**Social Influence**

Social influence is defined as the extent to which stakeholder perceives that significant others believe he or she should use home healthcare robots (Venkatesh, 2003). Three constructs capture the concept of social influence, namely, subjective norm (TRA, TAM2, TPB and C-TAM-TPB), social factors (MPCU), and image (IDT) (Venkatesh, 2003). Prior studies suggest that social influence is significant in shaping an individual’s intention to use new technology (Taylor, 1995; Thompson, Higgins & Howell, 1991). We believe that other people such as friends, relative and peers in the society may influence the stakeholder’ decision to use home healthcare robots. Therefore, we propose the following hypothesis:

**H3**: Social influence has a positive effect on stakeholders’ usage intention of home healthcare robots.

**Facilitating conditions**

Facilitating condition can be defined as the degree to which stakeholder believes that an organizational and technical infrastructure exists to support use of home healthcare robots. This definition captures concepts embodied by three different constructs: perceived behavioral control, facilitating conditions, and compatibility. Each of these constructs was operationalized to include aspects of the technological and/or organizational environment that are designed to remove barriers to use (Venkatesh, 2003). (Thompson, Higgins, & Howell, 1991) stated that providing support for PC users may be one type of facilitating condition that influences system utilization. By training users and assisting them when they encounter difficulties, some of the potential barriers to use can be alleviated or eliminated. There is also extensive empirical evidence that supports the significant effect of facilitating condition on usage intention (Zhou, 2012). Thus, we expect that stakeholders’ perceived facilitating resources, including technical, organizational, time and money, will influence their intention to use the applications of home healthcare robots.

**H4**: Facilitating conditions have a positive effect on stakeholders’ usage intention of home healthcare robots.

**METHOD DESIGN**

**Data Collection**

A questionnaire is employed in this study to collect empirical data. The questionnaire instrument is one of the most common tools of technology adoption as it uses a set of specific questions to cover the study topic and to target a large number of participants in a practical and efficient way. The proposed model includes five constructs and each construct is measured with multiple items. All construct items were adapted from Venkatesh (2003). The questionnaire instrument collects additional information such as gender, education, age and robot knowledge. All questionnaire items were measured using a 7-point Likert scale, ranging from “strongly disagree” to “strongly agree”.

The sample for this study consists of potential stakeholders of home healthcare robots: patients and professionals. The professionals include nurses, doctors, physicians, technicians and therapists, please see Table 1. Two online versions of the questionnaire were developed relevant to the target stakeholders (one for patients and the other for professionals). Each questionnaire has four main parts: introduction to home healthcare robots, demographic information, robot opinion questions and robot knowledge level. The patient questionnaire items are listed in Appendix A. The questionnaires were distributed to the participants randomly selected from a mid-sized university on the east coast and online healthcare communities. A total of 90 questionnaires were returned, and 64 (71.1%) were considered complete and valid.
Data Analysis

Partial least squares (PLS) was selected for data analysis in this study applying smartPLS software. A number of recent technology acceptance studies have utilized PLS, such as (Wills, El-Gayar & Bennett, 2008; Kijsanayotina, Pannarunothai & Speediec, 2009). To evaluate the measurement model, PLS estimates the internal consistency for each block of indicators. PLS then evaluates the degree to which a variable measures what it was intended to measure. This evaluation is comprised of convergent and discriminate validity. Following Gefen and Straub (2005), convergent validity of the variables is evaluated by examining the t-values of the outer model loadings. Discriminate validity is evaluated by examining item loadings to variable correlations and by examining the ratio of the square root of the AVE of each variable to the correlations of this construct to all other variables. For the structural model, path coefficients are interpreted as regression coefficients with the t statistic calculated using bootstrapping, a nonparametric technique for estimating the precision of the PLS estimates. To determine how well the model fits the hypothesized relationship PLS calculates an $R^2$ for each dependent construct in the model. Similar to regression analysis, $R^2$ represents the proportion of variance in the endogenous constructs which can be explained by the antecedents.

RESULTS

Sample Profile

Table 2 provides a general demographic overview of the stakeholder subjects who participated in this study in terms of gender, age, education level, and stakeholders category.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>42</td>
<td>65.6</td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
<td>34.4</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 - 33</td>
<td>51</td>
<td>79.68</td>
</tr>
<tr>
<td>34 - 49</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>50 +</td>
<td>4</td>
<td>6.25</td>
</tr>
<tr>
<td>Education Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school degree or equivalent (e.g., GED)</td>
<td>8</td>
<td>12.5</td>
</tr>
<tr>
<td>Some college but no degree</td>
<td>4</td>
<td>6.25</td>
</tr>
<tr>
<td>Associate degree</td>
<td>7</td>
<td>10.93</td>
</tr>
<tr>
<td>Bachelor degree</td>
<td>15</td>
<td>23.8</td>
</tr>
<tr>
<td>Graduate degree</td>
<td>30</td>
<td>46.8</td>
</tr>
<tr>
<td>Stakeholder category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td>43</td>
<td>67.18</td>
</tr>
<tr>
<td>Professionals (doctor, physician, nurse, technician and managerial)</td>
<td>21</td>
<td>32.81</td>
</tr>
</tbody>
</table>

Table 2: Sample Characteristics

As shown in Table 2, the majority of the participants is male (65.6%), 18-33 old (79.68%) and have a graduate degree (46.8%). About 67.18% of the participants are patients and 32.81% are professionals. All the participants use the Internet and computer several times a day. Table 3 summarizes the participants’ knowledge levels on robots. It is shown that most participants have heard about robots, but few have actual experience of using them.
### Table 3: Level of Robot Knowledge

<table>
<thead>
<tr>
<th>Robot Type</th>
<th>Not sure what it is</th>
<th>Never heard about</th>
<th>Have only heard about or seen this robot</th>
<th>Have used or operated it only occasionally</th>
<th>Have used or operated it frequently</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home healthcare robot (e.g. Paro)</td>
<td>19.4%</td>
<td>29%</td>
<td>50%</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td>Surgical Robot (e.g. daVinci surgical system)</td>
<td>19.4%</td>
<td>21%</td>
<td>51.6%</td>
<td>8.1%</td>
<td></td>
</tr>
<tr>
<td>Robot lawn mower</td>
<td>16.1%</td>
<td>32.3%</td>
<td>46.8%</td>
<td>4.8%</td>
<td></td>
</tr>
<tr>
<td>Space exploration robot (e.g. Mars Rover)</td>
<td>9.7%</td>
<td>12.9%</td>
<td>71%</td>
<td>4.8%</td>
<td></td>
</tr>
<tr>
<td>Manufacturing robot (e.g. robotic arm in factory)</td>
<td>4.8%</td>
<td>16.1%</td>
<td>71%</td>
<td>3.2%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Entertainment/toy robot (e.g. Aibo, Furby)</td>
<td>8.1%</td>
<td>17.7%</td>
<td>40.3%</td>
<td>30.6%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Unmanned Aerial Vehicle (UAV)</td>
<td>9.7%</td>
<td>24.2%</td>
<td>62.9%</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>Military Robot (e.g. search and rescue)</td>
<td>6.5%</td>
<td>12.9%</td>
<td>79%</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td>Robot security guard</td>
<td>12.9%</td>
<td>40.3%</td>
<td>45.2%</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td>Domestic/Home robot (e.g. Roomba)</td>
<td>9.7%</td>
<td>30.6%</td>
<td>54.8%</td>
<td>3.2%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Personal Robot 2 (PR2)</td>
<td>22.6%</td>
<td>37.1%</td>
<td>35.5%</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td>Autonomous Car</td>
<td>14.5%</td>
<td>14.5%</td>
<td>66.1%</td>
<td>1.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Research robot (e.g. at university or company)</td>
<td>17.7%</td>
<td>24.2%</td>
<td>54.8%</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>Remote presence robot (e.g. remote doctor)</td>
<td>9.7%</td>
<td>25.8%</td>
<td>58.1%</td>
<td>6.5%</td>
<td></td>
</tr>
</tbody>
</table>

### Measurement Model Validation

Table 4 summarizes the results for the items comprising the model. The results show acceptable convergent validity to all the constructs except facilitating condition. All item loadings are significant. Except for facilitating condition, all AVEs are above 0.5, all CRs are above 0.7 and all alpha values are larger than 0.7, showing good reliability. Therefore, the results support the convergent validity of all the scales except facilitating condition but we will keep it for the purpose of this study since its values close to the minimum (Gefen & Straub, 2005).
<table>
<thead>
<tr>
<th>Item</th>
<th>Individual Item</th>
<th>Item Loading</th>
<th>AVE</th>
<th>Composite Reliability CR</th>
<th>Cronbachs Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Expectancy</td>
<td>PE1</td>
<td>0.9054</td>
<td>0.8112</td>
<td>0.945</td>
<td>0.9225</td>
</tr>
<tr>
<td></td>
<td>PE2</td>
<td>0.8687</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PE3</td>
<td>0.9312</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PE4</td>
<td>0.8962</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effort Expectancy</td>
<td>EE1</td>
<td>0.8423</td>
<td>0.7329</td>
<td>0.9163</td>
<td>0.8809</td>
</tr>
<tr>
<td></td>
<td>EE2</td>
<td>0.9185</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EE3</td>
<td>0.8653</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EE4</td>
<td>0.7935</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Influence</td>
<td>SI1</td>
<td>0.8891</td>
<td>0.6639</td>
<td>0.886</td>
<td>0.829</td>
</tr>
<tr>
<td></td>
<td>SI2</td>
<td>0.908</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SI3</td>
<td>0.7874</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SI4</td>
<td>0.6485</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitating Condition</td>
<td>FC1</td>
<td>0.2152</td>
<td>0.3757</td>
<td>0.5666</td>
<td>0.5464</td>
</tr>
<tr>
<td></td>
<td>FC2</td>
<td>0.3832</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FC3</td>
<td>0.9665</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usage Intention</td>
<td>UI1</td>
<td>0.9439</td>
<td>0.8771</td>
<td>0.9554</td>
<td>0.93</td>
</tr>
<tr>
<td></td>
<td>UI2</td>
<td>0.9354</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UI3</td>
<td>0.9302</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 4: Item Loadings, AVE, Composite Reliabilities (CR) and Alpha**

Discriminate validity is confirmed if the square root of AVE are significantly higher than correlations between constructs in the corresponding rows and columns. As shown in Table 5 the instrument demonstrates adequate discriminate validity as the AVE (bold) are greater with respect to the corresponding correlation values in the adjoining columns and rows.

<table>
<thead>
<tr>
<th>Performance Expectancy</th>
<th>Effort Expectancy</th>
<th>Social Influence</th>
<th>Facilitating Condition</th>
<th>Usage Intention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Expectancy</td>
<td>0.9006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effort Expectancy</td>
<td>0.4968</td>
<td>0.8560</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Influence</td>
<td>0.6059</td>
<td>0.4493</td>
<td>0.8148</td>
<td></td>
</tr>
<tr>
<td>Facilitating Condition</td>
<td>0.3431</td>
<td>0.2984</td>
<td>0.4521</td>
<td>0.6129</td>
</tr>
<tr>
<td>Usage Intention</td>
<td>0.6313</td>
<td>0.6645</td>
<td>0.6163</td>
<td>0.3119</td>
</tr>
</tbody>
</table>

**Table 5: AVE Scores and Correlation of Latent Variables.**

**Testing the Structural Model**

Figure 2 depicts the structural model showing path coefficients and $R^2$. The $R^2$ value for the usage intention indicates that the model explained 50.8% of the variance. $R^2$ for performance expectancy indicates that effort expectancy explained 44.2% of the variance. The bootstrap method was used in smartPLS to assess the statistical significance of the path coefficients.
As shown in Table 6, performance expectancy (PE) positively predicted usage intention (0.3564, p < 0.001); therefore, H1 was supported. Second, social influence (SI) significantly predicted usage intention (0.3036, p < 0.001); therefore, H3 was supported. Third, facilitating condition positively predicted usage intention (0.2397, p < 0.05); therefore, H4 was supported. In summary, four hypotheses representing the relationship between performance expectancy, effort expectancy (indirectly), social influence, facilitating condition, and usage intention were supported in this study. However, the proposed direct effect of effort expectancy on usage intention was not supported. In other words, effort expectancy was not found to have a direct impact on usage intention of home healthcare robots, but have an indirect effect through performance expectancy (.6645, p< 0.001).

### Table 6: Structural Model Results

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Standardized path coefficient</th>
<th>T Statistics</th>
<th>Supported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Expectancy -&gt; Usage Intention</td>
<td>0.3564</td>
<td>3.8967</td>
<td>Supported</td>
</tr>
<tr>
<td>Effort Expectancy -&gt; Usage Intention</td>
<td>-0.0098</td>
<td>0.1003</td>
<td>Not Supported</td>
</tr>
<tr>
<td>Effort Expectancy -&gt; Performance Expectancy</td>
<td>0.6645</td>
<td>9.226</td>
<td>Supported</td>
</tr>
<tr>
<td>Social Influence -&gt; Usage Intention</td>
<td>0.3036</td>
<td>3.4791</td>
<td>Supported</td>
</tr>
<tr>
<td>Facilitating Condition -&gt; Usage Intention</td>
<td>0.2397</td>
<td>2.1507</td>
<td>Supported</td>
</tr>
</tbody>
</table>

### DISCUSSION

This study sought to identify factors that predict the stakeholders’ usage intention of home healthcare robots by applying the UTAUT model. The results show that usage intention of home healthcare robots is a function of the perception that home healthcare robots are useful (i.e., performance expectancy), that important others believed that he/she should use them (i.e., social influence) and the perception that one has the sufficient knowledge and...
technological resources (i.e., facilitating condition). The predictive power of these factors was substantial and accounted for more than half of the variance in the usage intention of home healthcare robots.

Among these four influencing factors, performance expectancy was by far the strongest predicting factor. This result is consistent with that of a number of prior studies (Kijsanayotina, Pannarunothaib & Speedie, 2009; Venkatesh, 2003). Performance expectancy is likely to exert a great influence than effort expectancy and social influence on a stakeholders’ usage intention of home healthcare robots. Stakeholders apparently tend to be pragmatic in their technology acceptance decisions, focusing on usefulness in technology assessment. That is, a stakeholder is likely to adopt the technology when it is considered to be useful to his or her practice. For professionals, the technology may help to increase their job productivity, gets a raise and finish tasks quickly. For patients, the technology may enable them to get treatment more quickly, get better soon and improve daily life effectiveness.

Effort expectancy seems to have no direct effect on usage intention of home healthcare robots. This is consistent with the results of some prior studies (Zhou, 2012, Chau & Hu, 2002). One explanation is that our sample is composed of a large percentage of knowledgeable stakeholders with the robot technologies, as showed in Table 1. They have relatively high self-efficacy and working with home healthcare robots poses no difficulty to them. The professionals have relatively high general competence and mental/cognitive capacity and thus may comprehend the use of the technology quickly; that is, become familiar with its operations without going through the intense training. Furthermore, professionals in many cases have relatively strong staff support for operating medical equipment and related technologies. Together, these factors might have contributed to less weight on effort expectancy. However, effort expectancy indirectly affects usage intention through performance expectancy. Thus, performance expectancy mediates the effect of effort expectancy on usage intention.

Social influence was also found to have a significant effect on usage intention. This shows that stakeholders will conform to important peers’ opinions when considering the adoption of home healthcare robots. They are likely to develop dependent evaluations and consequently may place high weight on others’ opinions. The finding suggests that home healthcare agencies can encourage early adopters to invite their friends and colleagues to adopt the technology. They can use incentives such as awards and membership levels to promote these early adopters’ recommendation.

Facilitating conditions, which measure whether stakeholders have resources and knowledge necessary to use home healthcare robots, have a significant effect on usage intention. Thus home healthcare agencies need to reduce the cost of using robots and equip the potential stakeholders with the knowledge necessary for leveraging such an emerging service. For instance, home healthcare agencies can use propaganda, training sessions and online help tutorial to increase stakeholder understanding of the technology. On the other side, professionals responded to this study generally seem to have the competence, learning capability, and access to the technical support, which paves the way for robot adoption.

This research has multifold theoretical and practical implications. Theoretically, the research provides a model that explains the adoption of home healthcare robots, which not only enhances the theoretical foundation for the home healthcare robot research, but also expands the applicability of technology adoption theory to the domain of home healthcare robots. Further, we provided empirical evidence for the efficacy of the constructs in home healthcare robot adoption.

In practice, the knowledge acquired from this study can potentially benefit both robot designers and the service provider. The strong influence of performance expectancy on the adoption of home healthcare robots suggests that work-related benefits of implemented robots must be perceivable, identifiable and substantial, and favorable perception of the robots’ usefulness is crucial, whereas the ease of use might not be of equal importance to robot adoption. Once deciding to adopt robots technology, service providers should strongly emphasize, demonstrate and communicate the technology’s usefulness for routine tasks and services. Thus, initial information sessions and training programs should focus on how the technology can improve the efficiency or effectiveness of stakeholders. An awareness of these effects on the robot adoption can help develop and accelerate the process of implementation. Social influence does affect the adoption of home healthcare robots. Therefore, it is important to identify individuals with strong personal influence (formal and informal) and work with them to become advocates for home healthcare robots’ use in order to facilitate the implementation process. Adequate facilitating conditions (continuous training and technical support to users) also play an important role in home healthcare robots adoption. Fostering an
environment, both from top-down and bottom-up perspectives, where use of technology is desirable, and that maintains the perception that use is a choice, could do much to facilitate the implementation process.

This research has several limitations, including small sample size, moderate AVE, CR and Alpha of the facilitating condition construct, and lack of consideration of unique characteristics of healthcare robots in introducing research constructs. In the future, more samples will be incorporated into the research such as more actual users, and domain-specific constructs such as trust will be introduced into the research model. In addition, possible mediating effects of gender, age, and culture warrant future investigation. Exploring the differences in the adoption between professionals and patients.

CONCLUSION

This research is attempted to explain stakeholders’ usage intention of adopting home healthcare robots. The research model is developed based on UTAUT. The results show that performance expectancy, social influence, and facilitating condition are directly associated with, and effort expectancy is indirectly associated with, stakeholders’ usage intention of adopting home healthcare robots. These findings have implications for the design and implementation of home healthcare robots.

APPENDIX A

The following is part of our survey questionnaires.

<table>
<thead>
<tr>
<th>Questionnaire Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I would find home healthcare robots useful in my home.</td>
</tr>
<tr>
<td>2. Using home healthcare robots would enable me to get treatment more quickly.</td>
</tr>
<tr>
<td>3. Using home healthcare robots would increase my effectiveness in the life.</td>
</tr>
<tr>
<td>4. Using home healthcare robots would increase my chances of getting better.</td>
</tr>
<tr>
<td>5. My interaction with home healthcare robots would be clear and understandable.</td>
</tr>
<tr>
<td>6. It would be easy for me to become skillful at using home healthcare robots.</td>
</tr>
<tr>
<td>7. I would find home healthcare robots easy to use.</td>
</tr>
<tr>
<td>8. Learning how to use home healthcare robots would be easy for me.</td>
</tr>
<tr>
<td>9. People who influence my behavior think that I should use home healthcare robots for better health.</td>
</tr>
<tr>
<td>10. People who are important to me think that I should use home healthcare robots for better health.</td>
</tr>
<tr>
<td>11. People whose opinions that I value prefer that I should use home healthcare robots for better health.</td>
</tr>
<tr>
<td>12. I will have the technological resources necessary to use home healthcare robots at my home (e.g. internet connection).</td>
</tr>
<tr>
<td>13. I will have the knowledge necessary to use home healthcare robots (e.g. IT background).</td>
</tr>
<tr>
<td>14. Home healthcare robots are compatible with other technologies I use in my house (e.g. internet).</td>
</tr>
<tr>
<td>15. A specific person (or group) should be available when I have difficulties using the robots.</td>
</tr>
<tr>
<td>16. Given the chance, I intend to use home healthcare robots in the near future.</td>
</tr>
<tr>
<td>17. Given the chance, I predict I would use home healthcare robots in the near future.</td>
</tr>
<tr>
<td>18. Given the chance, I plan to use home healthcare robots in the near future.</td>
</tr>
</tbody>
</table>

REFERENCES


HDQM\textsuperscript{2}: Healthcare Data Quality Maturity Model

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Abstract: Data Quality is a central issue within the development of Healthcare Systems, for both the delivery of the service as well as for the establishment of public policies. Public and private Healthcare Systems in Latin America do not have a framework of reference which allows them to have knowledge of the level of Data Quality (DQ). In other frameworks found within literature the evaluation of DQ has been centered within the dimensions. The intention of this research is to build an evaluation model for DQ based on maturity. This research contributes an innovating and comprehensive model, based on the data life cycle and maturity models, applied to the Health Sector, mainly because it contributes to the switch from the traditional physical mediums to Electronic Medical Records. This article presents the advancements of the research that is being conducted in some hospitals of the Healthcare Cluster of Monterrey, Mexico.

INTRODUCTION

There has been an increase in the interest for Data Quality because during the last fifty years the economy has centered around information as one of its main resources (Eckerson, 2002). According to the TDWI (The Data Warehouse Institute), intellectual capital, which is built from data and information, and know-how are now more important assets than tangible infrastructure is (Eckerson, 2002).

The growth of health organizations has gone hand in hand with the growth in collected, transported and stored data. This has created problems and new challenges which allow securing that the most important asset—the data—has an acceptable level for the delivery of health services. DQ can degrade quickly as its volume grows and moreover with the uncontrolled exchange allowed by the interconnectivity of the Infosphere.

Information is the product which will allow for decision making within a determined context. In other words, both Data as well as Information must satisfy (or exceed) the requirements of those making their use. J. M. Juran states that there could be a high level of DQ "if the same adjusts to what is expected from its use within operations, decision making and planning" (Juran, 1964).

The area intended to be addressed in this research is the Assessment of DQ. Within the revised literature there was a reoccurrence with a key element for the Assessment of DQ: the dimensions of DQ. The dimensions are criteria which qualify an aspect of the group of data to be evaluated. This aspect can be intrinsic and extrinsic to the data and is instrumented through one or more metrics associated with each dimension (Batini & Scannapieco, 2006). In the literature there is an extensive list of dimensions to be considered, however, there is a consensus with regards to the main dimensions and these are: Accuracy, Completeness, Timeliness and Consistency (Batini & Scannapieco, 2006).

DQ is a process of continuous improvement and not a project, and its evaluation must be comprehensive, considering all of the factors affecting it and showing its evolution over time. This is the reason why this research intends to build an assessment model for DQ based in the maturity of its capabilities, given that these models have gotten excellent results in industries such as Software and is widely accepted within the academic community. Philip Crosby was the first to propose a model for maturity management (Crosby, 1980). Afterwards these ideas were adopted by IBM and SEI for quality within Software Engineering, an area where they had wide acceptance and which still continues evolving. Within the literature, there has been found a number of references of maturity models applied to DQ and no reference specifically related to data management within the Healthcare area.

The construction of the maturity model for DQ will be conducted taking as basis models found within literature, considering the peculiarities of the Health Sector and the characteristics of the local context. It is expected that the model, once validated, can serve as a reference and starting point for other DQ evaluation initiatives within national or international Health entities.
This research presents the progress achieved within the Framework Construction for Data Quality Evaluation, based on the Maturity Model approach.

For the construction and validation of this model we will have the participation of the hospitals which form the Healthcare Cluster of the State of Nuevo León in Mexico.

**MOTIVATION**

Health is a current and critical topic within the development of the communities and constitutes as an indicator of the development of a country (SECRETARIA DE SALUD, 2012).

The low quality of DQ within the health sector has already generated problems (Al-Hakim, 2007) (SECRETARIA DE SALUD, 2012). In developed countries, according to the WHO, one of every ten patients is affected while being hospitalized; it is possible for the medical errors to be related, directly or indirectly, with the level of DQ.

One of the factors which contributes to the mitigation of risks within the Medical Attention Service, is the implementation of Electronic Health Record (EHR), which is the evolution of the traditional medical file in a physical format (SECRETARIA DE SALUD, 2012). The Health System in Mexico, although lagging with regards to the EHR in other developed countries, has made significant efforts within the public and private sector for the implementation of this technology which will noticeably improve the Health service.

There is already a regulation of the Mexican State, through a norm (SECRETARIA DE SALUD, 2012) which pretends to set the foundation for the implementation and standardization of the EHR within public and private health entities. As is mentioned in the justification to the implementation of this norm of EHR, problems have been found in DQ related with Health service processes. These problems would mean a non-quantified expense for medical errors, rework, inefficiency in the delivery of States’ resources to the Health System and degradation within the medical service. Without a doubt this will have an impact over the Quality of Life of all Mexicans.

The norm establishes the DQ dimensions which are expected to be fulfilled by the EHR. The norm is a new official regulation, promulgated in 2010. Given that this is the first time trying to regulate the topic of the EHR, there are several loopholes with regards to the instrumentation of the norm, which only mentions the “what” but does not define the “how”. One of these loopholes is the one regarding the tool that will serve to conduct the DQ evaluation. This lack of instrumentation is an area of important opportunity which this research intends to include with the construction of a Framework, which allows to take cognizance of the level of maturity of the DQ and to size the existent gap in order to mitigate it in the future.

The DQ evaluation has been conducted, until now, in aspects inherent to the data, in other words only considering the qualification criteria of the group and its syntactic and semantic intrinsic characteristics, without considering the level of maturity of the practices guided towards achieving a high level of DQ.

In order to provide an example of the low DQ problem within the Health area, a group of data is presented (see Table 1), which corresponds to some variable taken from the medical records of “Patients”. This example is a typical dataset which can be found in a hospital that has not established an evaluation and improvement mechanism for DQ.

<table>
<thead>
<tr>
<th>No</th>
<th>Gender</th>
<th>BirthDate</th>
<th>BloodGroup</th>
<th>Gravida</th>
<th>Allergies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>05/09/1979</td>
<td>A+</td>
<td>0</td>
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</tr>
<tr>
<td>2</td>
<td>M</td>
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<td>0-</td>
<td>0</td>
<td>NO</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>03/12/1956</td>
<td>B+</td>
<td>NGOUNGO</td>
<td>NO APLICARA</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>NULL</td>
<td>A Rh+</td>
<td>1</td>
<td>ANESTESICOS</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>05/04/1989</td>
<td>AB-</td>
<td>NULL</td>
<td>NO APLICARA</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>24/05/1988</td>
<td>NULL</td>
<td>1</td>
<td>NULL</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>19/04/1979</td>
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<td>0</td>
<td>PENICIL</td>
</tr>
<tr>
<td>8</td>
<td>NULL</td>
<td>05-may-76</td>
<td>O-</td>
<td>3</td>
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</tr>
<tr>
<td>9</td>
<td>F</td>
<td>12-34-5678</td>
<td>B NEG</td>
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<tr>
<td>10</td>
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<td>05-12-6785</td>
<td>NULL</td>
<td>NULL</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Table 1. Low Data Quality Recordset**
From the analysis of this group of data from the perspective of the DQ Dimensions, we can evidence a series of deviations which can mean low DQ. These deviations can go from what is simple: incomplete cells, to what is complex: inconsistent information.

Even though all of the variables of the Table 1 example are critical, some can originate errors that could affect human lives. Such is the case with the "Blood Type" that a case of emergency could result in a delay in the treating of a patient due to not having the specific type, or even worse, administering an incompatible blood type. Both are examples that the level of data within one single variable can result in fatal errors.

Each element which contributes and impacts DQ must be analyzed and placed over a maturity scale. This will help to have a benchmark for each element that comprises the evaluation model for DQ.

This causes motivation to search for a manner to evaluate DQ where the maturity level held by the health institutions within the practices, processes and the application of tools and methodologies for DQ evaluation can be established. The knowledge of DQ maturity level would give certainty with regards to the governing of this data within the health entities. The proposed DQ maturity level starts from the scenario that an information system is composed of basic and fundamental elements for its characterization. These are: People, Processes, Data and Technology (Figure 1).

With this context we can represent that:
- DQ is a current and relevant topic for scientific research.
- A low level of DQ is cause of problems for people, organizations and society.
- There is evidence that some problems within medical attention are related with low DQ level.
- No DQ Evaluation model exists for the Health Sector of Mexico or Latin America.
- According to the revised literature there is a need for DQ evaluation models to be validated in a more rigorous manner and that more study cases be developed in order to give them validity.
- DQ evaluation that considers only characteristics of data is insufficient and there is a need for a holistic vision of the DQ problem.

**Figure 1. Holistic Vision of DQ**

**BACKGROUND**

The concept of Quality has been used in different areas of knowledge in order to assure a better quality of life for society. Norm ISO 9000 defines Quality as “the degree in which a group on inherent characteristics fulfills the requirements”. In order to state that a service or product is of Quality, an evaluation has to be conducted, which allows us to have knowledge of the degree of deviation of the expected characteristics, to later analyze the causes and execute preventive or corrective actions.

Having a deficit within data quality, as with any resource of the company, would provide a reason to not achieve the objectives in a greater or lesser degree. Fisher states that there exists a clear relation between the achievement of the objectives of a company and how they manage their data (Fisher, 2009).

The awareness that the data consists in an important asset for the organization forces the adoption of the necessary measures in order to secure their governance and quality. On the contrary, there would exist an
uncertainty that could be the root of difficult problems to explore and that depending on their urgency could go from simple to fatal.

Data Quality

According to Juran: “Data is of high quality if the same fulfills the purpose of its use within operations, decision making and planning” (Juran, 1964).

English, on the other hand, suggests that the fitness for use concept of the data is limited, because the data could be useful not only for the “desired” use, but also for other potential uses (English, 1999).

McGilvray extends this concept and suggests DQ as the level or degree of trust offered by the data, for the use or uses that want to be taken advantage of (McGilvray, 2008). In a simple manner “correct data, at the right place, at the right time, by the right person and which is used for the better performance of the business”.

An important point to highlight is that DQ is related with its use and exploitation. So, as such, it cannot exclude the data consumer, because the same forms part of the evaluation and improvement (Strong, Lee, & Wang, 1997). To this it can be added that the consumer is part of the evaluation and its system, in other words, the organization.

Redman adds that to comply with the quality of fitness for use the data must be accessible, exact, timely, complete and consistent with other relevant and comprehensive sources, they must provide a level of detail that is easy to read and interpret (Redman, 1997).

In this definition, reference has already been made to the multi-dimensionality of DQ, given that there are no sole criteria to be able to define it. Emphasis is made that DQ is more than just accuracy and is not only a technological problem.

With this context we can conclude that DQ:

- Is multi-dimensional.
- Reflects the level of trust attributed to a group of data by its consumers.
- Is the degree of satisfying or exceeding the requirements of a Data consumer.
- Is a holistic concept which not only includes data but also its consumers.
- Is not static and can change through the time and usage of the data.
- Not only relates to accuracy, it must consider the dimensions which are adequate to each specific problem.
- Is not only a technological problem or of processes.
- It is evidenced when somebody accesses data which has a potential use, for a useful purpose.

Data vs. Information vs. Knowledge

Data consists on the representation of event of diverse nature such as text, sounds, images, etc. Data represents an abstraction of the real world, limited to the characteristics or properties of interest (Dama International, 2009).

The data on its own is not more than a symbolic representation and in order for the same to have meaning it must have a context. From the data as an atomic unit, Information and Knowledge are built. This hierarchic relation makes DQ to be reflected at higher levels.

Information is the product of data processing within a determined context, turning it into a decision making instrument. Knowledge if Information put into perspective, with the acknowledgement, understanding and familiarity of a situation with its complexity (Dama International, 2009). Knowledge is constructed with basis on the significance of the information and is also a valuable asset and resource for organizations.

Maturity Models

The first maturity model was suggested by the quality guru Philip Crosby in his book “Quality of Free” (Crosby, 1980). He declared it as the “Quality Management Maturity Grid” (QMMG). It came from ample experience and livelihood within the implementation of quality management systems. At that time, companies were reluctant to the adoption of quality systems because they perceived it as a pointless expense of resources and in the case of there being any benefits they came in the long term.
One of the contributions of the Crosby model is that it can be used as a self-evaluation of the current situation which will serve as reference to know the gap dimension of the desired maturity state. The possibility of seeing the maturity improvement over time is what gave it its recognition in front of the already known quality systems. This model is a table, as a manner of rubric which describes the five stages of maturity. These are: 1. Uncertainty, 2. Awakening, 3. Enlightenment, 4. Wisdom and 5. Certainty.

This model is generic and is used as the basis for all types of maturity models. Due to its acceptance and usefulness, it is without a doubt the cornerstone for the conduction of this research.

At the end of 1986 the US Government made a request to Software Engineering Institute for the development of a maturity model for software processes. Later this model evolved to the SW-CMM.

The CMM model is founded over a group of key practices and processes, included in Key Process Area (KPA). The KPAs are added within five levels of maturity, which qualify their evolution in the adoption of better practices. The qualification is obtained when demonstrating that the organization has adopted and institutionalized all of the practices of the corresponding level and of the inferior levels.

The levels of the CMM model are: 1. Initial, 2. Repeatable, 3. Defined, 4. Managed and 5. Optimizing.

METHOD

The research will be conducted in three main phases (Figure 2).

Exploratory Phase

The first activity of this phase is the revising of the Literature, which will provide all of the theoretical basis and the foundation for the construction of the model. Although it is located at the beginning, this activity is continuous.

The focus group will involve the personnel of the hospitals in the following areas:

- People: Human Resources, Training.
- Processes: Responsible of Quality and Continuous Improvement
- Medical Area: Medical Director
- Technology: CIO, Responsible of TIC’s.

Another activity that is important is the evaluation of the DQ in datasets obtained from the health entities that participate in the research. There has not been an antecedent methodology detected that allows the measurement of the level of DQ in Mexican hospitals, and this prevents having an objective measurement for the current level of DQ. Knowing the level of DQ in the exploratory phase reinforces the motivation behind this investigation and it helps detect areas of opportunity in the life cycle of Data.

For the purpose of this investigation, information will be taken from demographic data as well as identification of the patients that are considered “Clinical Information” according to the Official Mexican Norm (SECRETARIA DE SALUD, 2012)
Construction of the Model

This is the central part of the project because it will give as a result the model as well as the generation of the theory. For the first activity a hybrid research strategy of Action-Research and Design Science (AR+DS) will be used, inspired in Lee’s framework published in (Kock, 2007).

**Constructs:** Domain vocabulary.
**Model:** Group of prepositions or statements which express the relation between constructs.
**Method:** Group of steps to execute a task.
**Instantiation:** The realization of an artifact within its surroundings.

Form the research activities are expected:
- Process Areas of the Data Quality Maturity Model
- Indicators for each Process Area
- Evaluation criteria for the indicators (Appraisals)

The theory is obtained from the evaluation of the model and the results of the instantiation of the artifact. It is expected that part of the theory be generalized to other areas.

As the second activity, a technic of interviews will be used to conduct the mapping of the model to the criteria of “Value Creation”. The interviews will be conducted to the personnel of strategy and tactics. The goal is to cognizance the impact that maturity has over DQ within value creation for health entities.

Finally, an instantiation will be conducted within a selected unit, where the model will be applied and all of the evidence for the case study will be generated. At the end of the application of the model we will have the maturity evaluation of the entity where the pilot test will be held. This pilot test will be carried out using an audit guide, which will be part of the model as well as a concept test of an artifact of software for the automation of the DQ maturity evaluation.

RESULTS

Data Quality Assessment

To identify the dimensions there was a focus group used where the evaluation criteria was defined. Here there was a description of the principal dimensions that appear in DQ literature defined and afterwards there was a tool used to obtain the following dimensions:

A. Accuracy/Correctness
B. Completeness
C. Uniqueness
D. Duplicates

Although there was success in the consistency of the dimensions selected in the hospitals where the cases were studied, it was noted that in the second case there was a mention of duplicated registered patients as an important problem to detect. This finding was due to empirical and anecdotal evidence of problems in the service due to duplicated records.

In consulting the root cause of these problems, there was no establishment of a unique cause for the problem of evidence to support it. There was also no evidence to be accounted for to confirm and establish the quantity of duplicated records.

In order to evaluate this establishment, clustering techniques were used in the total of the records given, which totaled approximately 600K records. The rate of duplicated records can be confirmed with the records that were analyzed. In presenting the results to the focus group, there was a consensus that the level found was not admissible for the hospital (the confidential agreement does not allow to report the rate of duplicates).

Deviations of other measurements evaluated were also found like:

- Completeness: incomplete e-mail addresses, incomplete addresses, incomplete dates of birth.
- Correctness: incorrect e-mail addresses, incorrect dates of birth, incorrect geographical names

The results were presented to the participating hospitals and there was a general consensus about the results which were also shared with two experts in order to validate them.
Metamodel

From the elements of the Research model, a metamodel was obtained that will help with the conceptualization of the framework, as well as for the construction of the artifact with which concept tests of the Maturity Model will be conducted. This model is formed by the following elements: Levels of Maturity, Practices, Process Areas and Value Creation. The Metamodel was represented using the UML notation (see Figure 3).

For areas of process of the Maturity Model the phases of data life cycle were considered (McGilvray, 2008). The phases were presented in the focus groups and there was a successful consensus in validating the health service delivery. All the phases are presented within the chain value of the health service.

The consensus regarding the maturity model for DQ was that it should be continuous and not staggered due to the fact that it can have different levels of maturity during different phases of the data life cycle.

Focus Group

Very interesting and revealing data was obtained from the focus group during the exploration phase. The most important findings are as follows:

Data
- There is awareness of the value of the data as a main asset.
- There is evidence of low quality data within the health entities.

People
- There is awareness that DQ is not the solely responsible in the Information Technologies area.
- There is awareness that people can contribute to the improvement of DQ.
Processes
• There is no procedure to share data among hospitals.
• There are processes for some of the phases of the Data Life Cycle.

Technology
• Technology helps to reduce the potential errors of DQ.
• There are errors due to processes which are magnified with the use of Information Technologies.

DISCUSSION AND CONCLUSION

The relevance of data for the Health Sector during the advancement of the research has been evident, both for the clinical processes as well as for the establishment of public policies.

The research contributes an innovating and comprehensive model, based on the data life cycle and maturity models, applied to the Health Sector, particularly because the same contributes to the switch from the traditional physical mediums to Electronic Medical Records.

The contribution of this research is the design and validation of metrics within focus groups to calibrate the evaluation process within value creation in terms of compliance with the norms of world class practices, of sustainability of the quality of life within Health, and in the economic benefits derived from the elimination of reprocesses and deviations within clinical diagnostics and in support of decision making through Health Intelligence.

There is an overwhelming amount of existing evidence that DQ in registered patients contains deviations and errors that should be evaluated and improved. If improvement does not happen, these problems could generate adversity in the provided health service.

It was evidenced within the focus groups that there are problems in all perspectives (people, processes, technology and data) which could be the cause for low DQ.

The Health Sector (public and private) does not count with the capabilities for the evaluation of the DQ level with which it operates, so there is uncertainty with regards to the level they have. Because there is no mechanism of evaluation, there will not be one to improve.

LIMITATIONS AND FUTURE WORK

The research is concentrated over some institutions from the Health Cluster of the State of Nuevo Leon; the inclusion of more private and public institutions will contribute with findings which will sustain an external generalization of greater trust.

The Health institutions in Mexico have not adopted a culture in terms of certifying their processes of:
• Data Quality
• Data Life Cycle Maturity
• Holistic Models for DQ Assessment.

The research for the plan of the construction and refining of the model will continue. An instantiation of the artifact to an application to allow for the automation of the evaluation activities and that show the results in a graphic manner will be conducted afterwards.

For the implementation of the evaluation of DQ, identification and demographic data, which partake in the collection of information in a clinic, was taken into account. It is suggested that the research is extended to clinical data that details cases of medical service delivery. It was found that part of this evaluation is performed by the evaluation committee (EHR committee) or the area of health quality.

In fact, due to the volume of the information, there is a need for an analysis to determine what strategy to follow. The restrictions of this suggestion are given by the limited access to these types of data since it is not easy to access all of the EHR databases. To further solidify the evaluation of the capability of maturity of DQ, it is suggested that long-term studies are done to verify the casualties and the impact in the long-run of adopting DQ practices.
REFERENCES


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11th Western Michigan IT Forum

Information Security and Privacy

Friday, November 7, 2014
Fetzer Center, Western Michigan University, Kalamazoo, Michigan

The Western Michigan IT Forum hosted by the Department of Business Information Systems at the Haworth College of Business provides an important forum for the exchange of ideas and information for educators, students, professionals, employers, and state and local governments.

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Suggested Topics (but not limited to)
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- Innovative Ways of Teaching Information Security and Privacy
- Curricular Issues Related to Teaching Information Security and Privacy
- Student Projects and Papers on Information Security and Privacy
- Industry Experience Papers on Information Security and Privacy
- Cases on Information Security and Privacy
- Technology Demonstrations on Information Security and Privacy
- Posters on Information Security and Privacy

If accepted, refereed research papers will be published in the Proceedings and will be scheduled for presentation during the meeting. Acceptance of papers and abstracts are subject to final approval by the track chairs.

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