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Beyond Meaningful Use: A Model for Evaluating Electronic Health Record Success

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Abstract

This paper presents a conceptual model for the evaluation of electronic health records. The model is grounded in IS models for evaluating system success and task-technology fit, and integrates concepts of meaningful use and outcome research to arrive at a holistic conceptualization of evaluating the success of EHR. The paper presents numerous issues and challenges to the practice of health care outcomes research, and offers practical solutions for overcoming them.

1. Introduction

Information systems (IS) have emerged in health care. Electronic health records (EHR) and health information exchange facilitate the access and sharing of patient data. Computerized provider order entry and clinical decision support systems have the potential to reduce clinical error and assist with evidence-based decision-making. These technologies have the potential to improve efficiency and quality of care [1].

Despite the potential of health care IS, there are also challenges associated with its use [2]. The failure of these information systems can have serious negative effects on patients and clinical staff. Implementation and support management can be costly, and the business case for EHR has not been well established [3, 4]. As a result, methodical, rigorous evaluation of EHR is required.

Of course, the use of IS in health care does not occur in a vacuum; systems do not use themselves, rather they require human interaction. As a result, evaluation must examine not only the technology itself but the human and organizational/social context in which use occurs. IS as a discipline is well suited to provide models of adoption, acceptance, use and success, however these models alone offer little to explain the link between use and outcome.

Similarly, health care outcomes research alone is ill-suited to examine the complex interplay of

technology and patient outcomes. Health informatics and health care IS researchers would benefit greatly from a research model that unifies IS theory and outcomes research techniques to enable the study of EHR-mediated patient outcomes.

Accordingly, the objective of this paper is to propose a conceptual framework for the evaluation of EHR. We present a holistic conceptualization that is grounded in IS models for evaluating system success and integrates concepts of meaningful use and outcome research. Issues, challenges and potential solutions will be discussed throughout the paper.

The remainder of the paper is organized as follows: Section 2 provides a review of the pertinent literature, while section 3 proposes a model for evaluating EHR success. In section 4 the model is presented in the context of a specific clinical research scenario. Section 5 discusses research design and practical guidance for implementation procedures is presented. Section 6 concludes the paper with a discussion of research contributions, limitations and future work.

2. Background

2.1 Evaluation of health care IS

Evaluation research can be of two types: formative – the goal being to improve the technology under evaluation by providing feedback to users and system designers, or summative – the objective here is to demonstrate the impact on clinical routine [5].

Typical evaluation questions deal with issues of use – such as which technical features affect utilization [6], do users accept the system, and if not why not [7, 8, 9, 10]? Other questions deal with how systems affect routines and process quality, such as data quality, clinical workflow, throughput, patient administration, etc., as well as the users (clinicians, nurses, and administrative staff) who are impacted [11, 12, 13, 14, 15, 16].

Other work has focused on outcomes such as quality of care in telemedicine [17, 18]. For example a randomized controlled trial (RCT) study design was used to evaluate the use of decision support to improve clinical outcome in asthma management [19]. A clinical reminder system was evaluated for its impact on preventative clinical services rendered to hospitalized patients [20].

Patient satisfaction has also been the subject of considerable research, including systematic reviews of patient satisfaction [21] and measurement of satisfaction in the context of a nursing documentation system [22], among others.

It has been noted by many that one of the major limitations of EHR adoption is that the business case has not been convincingly made. Researchers have explored many of these questions, for example what are the investment and operational costs of health IT implementation [23, 24, 25]? Are they cost effective [21, 26, 27], and what are the factors impacting ROI [4]?

Evaluation of health IS has been ongoing for more than 40 years [28], and there is consensus over the many problems that seem to plague it. Changing, conflicting or unclear evaluation goals represent some of the problems reported [29], as do frequently reported results that are often complex and contradictory [17].

The extensive preparatory effort needed to execute health IS evaluation is also noted as a significant barrier [30]. Uncertainty regarding the generalizability of the results is also commonplace. [21, 31].

2.2 Meaningful use

Health care IS and health informatics researchers in the U.S. presently find themselves enjoying the widespread support of the federal government for health IT research. In the Health Information Technology and Clinical Health sections of the American Recovery and Reinvestment Act of 2009, substantial economic incentives were made available to health care providers for using IT meaningfully.

The term “meaningful use” arose due to the concern that “use” alone would not produce meaningful results [32, 33, 34]. The law provides a process for benchmarking specifically what constitutes “meaningful”. This concept of meaningful use is central to this papers’ thesis and will be expanded and further discussed in section 3.

2.3 Health care outcomes research

Outcomes research is quite different from other types of medical research. Whereas most medical research is focused on the effects of a unique intervention, outcomes research may ask not only are individuals better off with one diabetes medication or two, but are individuals with diabetes who have their care managed through an EHR better off than others? Thus, outcomes research can provide a broader window into what impacts outcome, best practice and policy [35, 36, 37].

Outcomes can be described in different ways. They can be derived from simple measures such as blood levels, or from more complex physiological measures. Outcomes can also be expressed from data gathered directly from patients, such as the extent of satisfaction with care or with general quality of life [38].

One should not commit the error of believing that one type of outcomes research is more important than the other. As Kane notes, knowing the oxygen saturation of a patients’ big toe may be good information to have, but if the patient still can’t walk then that information may be less important [39]. In other words, patient-derived data can be as, or in some cases more valid than that obtained from machines [40].

Outcomes research uses an approach that is more complex than simple data gathering. Kane [39] suggests that the approach should be considered in terms of an outcomes information system; detailed, comprehensive data collection for the purposes of “outcomes ascertainment and risk adjustment” combined with appropriate analytical tools.

The basic formula for evaluating outcomes of care is as follows [39]:

$$\text{Outcomes} = f(\text{baseline, patient clinical characteristics, patient demographic/psychosocial characteristics, treatment, setting})$$

These factors are understood as risk factors, and the goal of such a study is to isolate the relationship between the outcomes of interest and the treatment. This is done by controlling for the effects of other factors, a process known as risk adjustment.

The types of study designs used in outcomes research include randomized controlled trials and prospective observational studies [40]. The main difference between the two is in the allocation of patients. In the RCT, the allocation of patients is accomplished randomly, whereas with the observational study, control over allocation can be under the control of either the clinician or the patient.

Selection bias is the primary risk to observational studies. For example patients may choose their practitioner or certain types of care, or clinicians may choose treatments based on differences in clinical status [39].

What is important in outcomes research is this: can some unknown, unmeasured factor be responsible for the choice of treatment? Random assignment negates this question by randomly distributing unmeasured factors between the treatment and control groups. Even still, there is no guarantee that these groups will be comparable, for either RCT or observational studies.

For observational studies, statistical techniques have been developed to address this issue. Additionally, propensity scoring techniques have become popular. Such techniques operate through the creation of homogenous risk subgroups which enable the identification of variables that may be associated with a specific treatment. Risk subgroups are created using these measured variables and the results are then compared across each subgroup. The key to convincing clinicians that observational studies have merit is by carefully controlling unmeasured factors [39, 40].

Section 5 describes the research design and implementation procedures recommended for evaluation of EHR success. Additional details pertaining to study design and analysis for the proposed EHR success evaluation model are addressed there.

2.4 IS evaluation models

Information systems evaluation research has been impacted by the theories of human and social behavior emerging from the disciplines of psychology and sociology. Social Learning Theory [42], Social Cognitive Theory [43], Theory of Reasoned Action [44] and Self-Efficacy Theory [45] have each had an important role with respect to informing early IS evaluation studies.

The Technology Acceptance Model was the first theory developed specifically for the IS context, i.e., people in business [46]. Other variations followed, including the Unified Theory of Acceptance and Use of Technology [47] and Technology Acceptance Model-3 [48], among others.

Central to models that predict acceptance and use is the notion that various contextual and behavioral factors contribute to enhanced intention to use, thereby resulting in increased use. These models seem to imply that greater utilization will result in increased performance; while system use is indeed a prerequisite to improved performance, one cannot

assume that increased use is necessarily correlated with enhanced performance [49].

Unlike the models noted above that predict acceptance and use, Task-Technology Fit (TTF) attempts to explain user *performance* with an information system [49], as well as use. The premise of the theory is that individual performance can be enhanced when the functionality of the technology meets the user's needs, i.e., fits the task at hand.

TTF has been studied in a variety of contexts [50, 51]. The theory has also been extended with the Technology Acceptance Model [52, 53, 54], leading to variants with behavioral/social elements as well as the 'fit' components of TTF. Figure 1 illustrates the general TTF model.

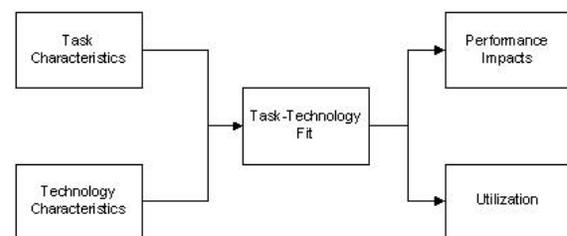


Figure 1. Task-Technology Fit Theory [49]

Driven by the need for a comprehensive model for evaluating IS/IT, DeLone and McLean [55] proposed the IS success model. This model displays a process orientation, and consists of six basic dimensions of IS success: e.g., system quality, information quality, system use, user satisfaction, and individual and organizational impacts. Figure 2 illustrates the DeLone and McLean IS success model.

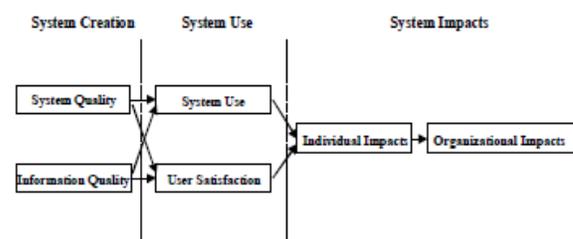


Figure 2. DeLone and McLean IS Success Model [55]

This model follows a logical sequence from system creation to utilization to system impacts. It can also be viewed from a causal perspective; system and information quality impact system use and user satisfaction. The latter two constructs are causally related to individual and organizational impacts. Overall, the model offers a broad perspective of system success.

A number of extensions to this model have been suggested. Examples include evaluation of system impacts at different levels, e.g. workgroup level [56], inter-firm coordination and impacts beyond organizational boundaries [57], as well as the concept of “Service Quality” as differentiated from information quality [58].

This IS success model is primarily focused on system characteristics, which are deliberately distinct from the human factors that also influence technology use. This point is illustrated in figure 2 above - there is no causal relationship between user satisfaction and actual use. While certainly useful when the goal is to isolate and evaluate system characteristics, we believe that a more holistic model may be helpful in the health care/EHR context.

Hu [59] extends the original IS success model [55] to the evaluation of telemedicine systems in three important ways. As shown in figure 3, this model incorporates input data quality into the system creation component, and service impact is added to the system impacts component of the model. The original IS success model [55] is primarily concerned with the output quality of the information generated by the system. However as one would expect, the quality of the data produced by the system is largely dependent on the quality of the data going into it.

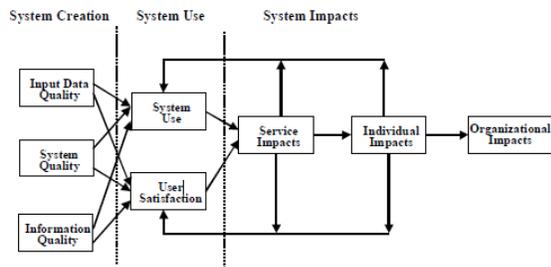


Figure 3. Telemedicine revised model [59]

In figure 3, service impact is also included as an additional dimension of system success. The key to service impact is service quality which refers to the quality of the information services available to users. Service quality can be evaluated in terms of consistency, reliability, timeliness, accuracy and completeness [59].

Hu [59] further adapts the original IS success model by adding feedback loops from service and individual impacts to system use and user satisfaction. It follows logically that the ways in which individuals and services are impacted by the system may influence both system use and user satisfaction. For example, negative service or individual impacts may reduce user satisfaction, which in turn could adversely affect ongoing use of

the system. Organizational impacts on the other hand are measured by higher order concepts such as profitability, organizational performance, or market share for example. Such impacts may not have directly observable effects on system use or user satisfaction [59] and thus a feedback loop is not included.

Based on the IS success model proposed by DeLone and McLean [55] and the extended model by Hu [59], we propose a revised model that is grounded in IS success, task-technology fit theory and outcomes research. This comprehensive approach to EHR evaluation may enable researchers to better understand the system, clinical task, individual and organizational-level facilitators and barriers to EHR success. For the proposed conceptual model, EHR success is determined by the impact on patient outcomes.

3. Conceptual Model

Figure 4 illustrates the proposed conceptual model for evaluation of EHR success. As shown, the revised model attempts to preserve the causal and temporal relationships found in the original IS success model (figure 2) as well as the telemedicine systems success model proposed by Hu [59] (figure 3).

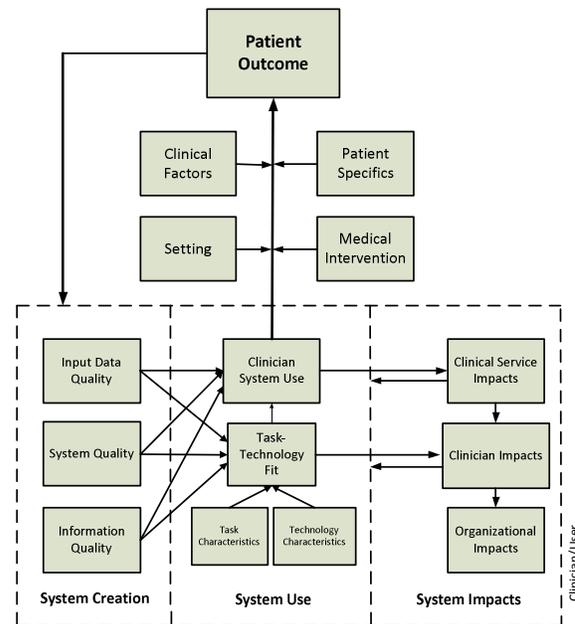


Figure 4. EHR Success Evaluation Model

We make two substantial changes to the previous models: First, the new model adds the task-technology fit construct as an antecedent to clinician

system use. This replaces the previous models' inclusion of the user satisfaction construct. While we agree that user satisfaction may be worth consideration, neither of the previous success models shows any direct causal link between satisfaction and system use. This lack of causality seems to imply that user satisfaction with the system exists in isolation from actual use, or at the very least only indirectly influences system use. Previous models suggest that user satisfaction with the system directly influences service impacts, and indirectly influences individual impacts. Despite the feedback loop to system use suggested by Hu [59], we maintain that system use not only precedes system and individual impacts, but causes them directly.

There are a few notable advantages to including task-technology fit as an antecedent to system use. First, understanding the factors that either facilitate use or act as barriers to it (see the TTF construct definition for system use in table 1) permits an objective analysis of the degree to which the technology fits the demands of the clinical task. Second, understanding fit requires that we define the task characteristics, in this case we define clinical tasks in terms of uncertainty and complexity.

Third, including TTF as an antecedent to use requires that we also define the characteristics of the technology. For this, we evaluate the system characteristics according to its capacity for information, knowledge and inferencing support. These capabilities support varying degrees of task complexity and uncertainty.

Previous models explicitly define IS success in terms of system characteristics, without accounting for the nature of the tasks that require support. The theoretical links between TTF, utilization and performance impacts have been empirically validated throughout the literature as a function of the ability of the technology to meet the demands of the task. We believe that the addition of this use antecedent offers important insight into the relationships between EHR use and patient outcome.

The second way in which we have extended previous IS success models is by including an outcome component and shown as the area outside of the dotted lines in figure 4 (see also figure 5 for this component of the model). The ultimate objective is to move beyond meaningful use and take a step closer to answering the question of whether or not EHR can positively impact clinical outcome.

The three categories contained within the dotted lines in figure 4 (system creation, system use and system impacts) can be understood as the treatment or intervention on the patient leading to an outcome. Additional factors that must be accounted for in this

intervention-to-outcome pathway include patient clinical factors, patient specifics (e.g. age, gender), current medical intervention and setting (e.g. rural, urban, ambulatory, non- ambulatory). The collection of this information permits the creation of homogenous risk subgroups that enable evaluation of treatment effects in a prospective observational study design.

Table 1. Treatment categories and construct descriptions

Treatment Category	Construct	Description
System Creation		<i>Examples:</i>
	<i>Input data quality</i>	Accuracy, currency, workflow support
	<i>System quality</i>	Flexibility, ease-of-use, accuracy, reliability, response time, workflow support
	<i>Information Quality</i>	System Output – accuracy, currency, reliability, flexibility, response time.
System Use		
	<i>Use</i>	“Meaningful Use” specific benchmarks – do they support improved clinical/health outcomes?
	<i>TTF</i>	Data quality, locatability, authorization, ease-of-use, training, compatibility, timeliness, reliability, IS relationship to users.
	<i>Task Characteristics</i>	Complexity, uncertainty
	<i>Technology Characteristics</i>	Information, knowledge, inference (decision support)
System Impacts		
	<i>System impacts refers only to system users, not patients</i>	<i>Service Impacts</i> efficiency, effectiveness.
		<i>Individual Impacts</i> Performance, satisfaction,
	<i>Organizational Impacts</i>	Efficiency, cost-saving, ROI, market share

Patient outcomes can be of two basic types: condition-specific or generic [39]. Condition-specific measures are linked to specific interventions, and will vary with the condition being treated. Generic outcomes are generally understood as higher-order constructs, such as satisfaction with the quality of care or setting. These concepts are more abstract, and thus are more difficult to link causally to treatment.

The third way we have extended the original model and built upon previous work is to provide

feedback between the outcome and the treatment (note the arrow leading from patient outcome to the area within the dotted line in figure 4). Recall that Kane [39] suggested that the “outcomes approach” should be considered in the context of an *outcomes information system*. To achieve this, we have included this feedback loop from achieved outcomes to intervention as representative of a system that collects, organizes and provides analysis tools for feedback of outcomes data into the processes of system creation, use and impact. In this way, the outcomes evidence collected by the system is directly contributing to input data quality, information quality and system quality.

The final way in which we have adapted this model for EHR is to redefine “system use” in accordance with the recent development of “meaningful use” criteria. These criteria are designed to define how EHR can be used most meaningfully, the hope being that widespread achievement of the benchmarks will result in improved outcomes for patients.

In figure 4, the “clinician system use” construct is defined by recently established meaningful use criteria. System use has traditionally been a rather straightforward construct that is normally measured by simply determining if the system is being used – a yes or no answer is the extent of the information obtained. Unfortunately, simply knowing if a system is being used does not enable objective analysis of *how* system use is actually occurring in practice, nor does it provide any insight into the impact of use.

There are at least two reasons why defining use in terms of meaningful use is important. First, aligning the definition of clinician system use with meaningful use criteria gives us something to objectively measure. As an example, for the patient record function of EHR in table 2, one of the meaningful use measures is that computerized order entry is used for at least 80% of all orders (lab, imaging etc.). This represents a form of system use that can actually be measured. Use defined in such a way may enable the assessment of whether or not achievement of these benchmarks actually translates into improved patient outcomes.

Second, orienting the model toward “meaningful use” is helpful in that considerable future economic incentives are geared toward providers’ achievement of these standards. Moreover, health systems, hospitals and individual practitioners must make considerable financial investments in EHR implementation, training and ongoing support. It is critical that they have an objective method of assessing the degree to which EHR use supports the goals of improved patient safety, clinical and

administrative efficiency, better quality care and improved outcomes. Table 2 highlights a sample of EHR functions and their corresponding meaningful use measures; however it is not intended to be a comprehensive list.

In the following section, we further elaborate on the proposed EHR evaluation model as we instantiate its use in the context of evaluation of system use and type II diabetes outcomes.

4. Model Instantiation

To illustrate how the proposed model may be used in a real-life scenario, this section describes its use in evaluating example diabetes outcomes given the use of EHR technology. Referring to figure 5, only the patient outcomes section of the model will change for the evaluation of different condition-specific or general outcomes. For example, assessment of the elements of the model enclosed in dotted lines (see figure 4) will remain the same whether the outcome of interest was diabetes or congestive heart failure, or if the outcome was condition-specific or general in nature. That is not to say that system creation, system use or system impacts will not change, rather the variables used to measure these constructs remain the same over time. In contrast, the outcomes section of the model (figure 5) will vary according to the patient outcomes of interest.

Table 2. EHR Functions and Meaningful Use Measures [60]

EHR Function	“Meaningful Use” Measure
Patient Record	
<i>Rx lists</i>	At least 80% of patients have at least one entry as structured data
<i>Problem lists</i>	At least 80% of patients have at least one entry as structured data
<i>Rx orders</i>	CPOE used for at least 80% of all orders
CDS (Clinical Decision Support)	
<i>Rx Warnings</i>	Drug-drug, drug-allergy, drug-formulary checks enabled
<i>Guideline-based care reminders</i>	Implement at least 5 CDSS rules relevant to applicable quality metrics for clinician specialty

Information Exchange		
	<i>Images returned electronically</i>	Perform at least one test of capacity to exchange key clinical information.
	<i>View lab results</i>	At least 50% of all clinical lab tests ordered whose results are pos/neg or in numerical format and recorded as structured data.
Public Health Reporting		
	<i>Notifiable diseases sent electronically</i>	Perform at least one test of capacity to provide electronic submission of lab results and syndromic surveillance data.

The four categories shown interacting with the pathway to outcomes are 1. Clinical factors, 2. Setting, 3. Patient specifics and 4. Medical intervention. The clinical factors include those specific to diabetes, including the patient’s A1C value, LDL cholesterol level, blood pressure (BP) and fasting glucose level. Additional clinical factors should be considered, including patient co-morbidity factors.

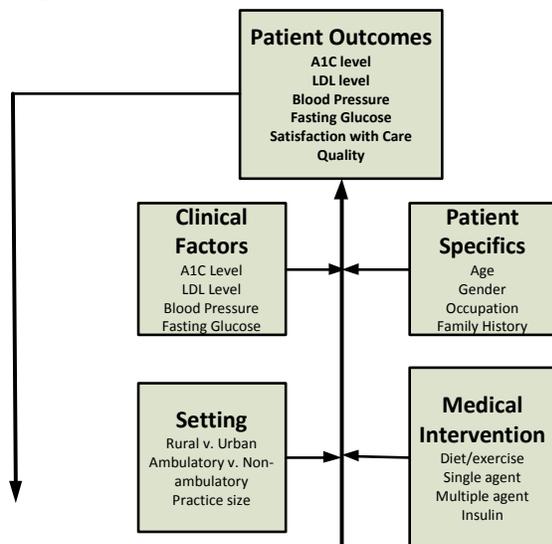


Figure 5. Outcome section of EHR evaluation model

Setting should differentiate between rural or urban location, and ambulatory versus non-ambulatory settings. Patient specifics including age, gender and occupation should be considered. The medical intervention should also be defined according to the

type the patient receives. One patient may be managing their diabetes with diet and exercise alone, while another may require multiple drugs to manage their disease.

For the prospective observational study design outlined in section 5, the collection of this data will permit the creation and use of homogenous risk subgroups. Because such study designs do not offer the same degree of internal validity protections as RCT-type designs, the use of this data for subgroup creation and assignment is needed to minimize the possibility that unmeasured variables will impact the outcomes of interest.

5. Issues with Study Design, Implementation and Analysis

The choice between a RCT and an observational study design (experimental v. quasi-experimental) requires a tradeoff between internal and external validity. Random assignment of patients does not guarantee group comparability; it simply means that any differences are due to chance. Of course the main problem with highly controlled experimental designs is that the results may not be generalizable to the wider population due to the tight controls in place.

On the other hand, observational designs are subject to the risks of selection bias. This bias has the potential to confound the treatment-outcome relationship. Despite the fact that observational, quasi-experimental designs more accurately reflect the greater population and are thus potentially stronger with respect to external validity concerns, selection bias remains perhaps the greatest threat to health outcomes research [39].

The study design suggested for this evaluation of EHR technology is observational in nature, due primarily to the challenges of instituting a RCT in the rural, primary care setting of South Dakota. The study will take place over a three year period, with baseline data gathered in a pre-test fashion during year one, EHR implementation during year two, and post-test data collection at the end of year 3.

To address the issues of selection bias, patients will be assigned to homogenous risk subgroups as previously discussed. Other threats to validity include statistical conclusion validity, internal and external validity, and construct validity. Low statistical power means that the study design is unable to detect a true effect. The solutions are to increase the sample size and the responsiveness of the outcome measure. Fishing and error rate problems refer to the increased risk of a type I error due to multiple comparisons. The goal here is to

develop primary and secondary hypotheses, and if necessary, make ad hoc adjustments for multiple comparisons.

Violated assumptions of statistical tests and inappropriate statistical tests can be rectified by using methods that take into account the correlated nature of outcomes research. Reliability of measures refers to measures that are unreliable and or unstable. To address this issue, only measures based on sound psychometric properties should be used. Finally, inconsistent treatment implementation is caused by a lack of standardization and clarity regarding the implementation process. Taking corrective measures is possible through careful monitoring of system implementation. In this case, EHR technology implementation must be standardized across subgroups.

Another concern with health outcomes research is internal validity. Validity threats here include selection, regression to the mean, attrition and missing data and history. A selection threat refers to the differential selection of patients to treatment and control groups, and arises when treatment is not randomized. Possible solutions include risk adjustment or propensity scoring.

Regression to the mean refers to the selection of sicker or healthier patients for the study, and can be addressed by careful evaluation of recruitment criteria and outcome measures. Another solution is to use a control group with similar characteristics to the treatment group.

Attrition and missing data occurs when subjects leave the study before its completion. A focus on adequate follow-up can ease this threat; however patient death due to unrelated causes cannot be preemptively controlled for. Finally, history is a threat to validity. This happens when events occur during the study that impact treatment implementation and outcomes. The solution in this case is to carefully monitor external factors such as medication, reimbursement and patient management changes.

Threats to construct validity include poorly defined constructs, mono-method and mono-operation biases and treatment diffusion. It is likely clear why poorly defined constructs are problematic; however mono-method and mono-operation threats arise from the use of single methods during data collection. This threat can be minimized by using multiple measures for treatment and outcome. The primary challenge here is that multiple measures are costly to implement. The final threat to construct validity is treatment diffusion. This threat is understood as the spill-over of treatment to groups not intended to receive the treatment. One way to

address this issue is to appropriately segregate treatment and control groups. Another is to blind subjects to the treatment or give control subjects a pseudo-treatment.

The final threat to the validity of health outcomes research is the threat to external validity. External validity is understood as the representativeness of the results to person, place and time. Many researchers understand this as a threat to generalizability. The solution here is to replicate studies across different populations, settings and points in time.

Ultimately, implementation of the proposed study design must address these challenging threats to validity. The guidelines discussed here help to ensure maximum validity of the findings.

Methods include survey and interviews. System users will be evaluated by survey method and the results analyzed by SEM techniques, namely latent path analysis (partial least squares regression). Patients will be interviewed for higher order questions such as satisfaction with care. Such methods should produce valuable information regarding the information input and output, and system and task characteristics that impact the meaningful use of EHR.

6. Conclusion

This paper presents a conceptual model for evaluating EHR. The model is based on IS success, task-technology fit theory, and outcomes research, and is focused on the extent to which “meaningful use” impacts health care outcomes.

The conceptual model presented here contributes to IS theory, health/medical informatics and outcomes research by suggesting a unified approach for evaluating EHR. The new model captures the antecedents to meaningful use, and establishes a research design suited to assessment of EHR-mediated patient health care outcomes.

Some limitations apply to this work. First, although we propose a quasi-experimental design, there may be clinical situations in which RCT-type designs are more appropriate. Second, while well-grounded in theory, the model has not been empirically verified. A third limitation is that our model assumes the feedback loop from Patient outcomes to system creation (see fig. 4). This capability, described by Kane [39] as an *outcomes information system*, may not be present in current iterations of EHR. Clearly, these limitations offer opportunities for future work.

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