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Effectiveness of User Centered Design for Optimizing an Electronic Documentation Form

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Problem. The electronic form used by lactation consultants to document assessment findings, interventions, plans and recommendations, did not meet user's requirements.

Purpose: The purpose of this project was to evaluate the effect of optimization through a User Centered Design (UCD) process on information quality, use and user satisfaction.

Goals. The goals were to provide information technology (IT) support for the organization's *Baby Friendly* initiative and to support collaborative, consistent messaging for breastfeeding families which could, in turn, support exclusive breast milk feeding. Exclusive breast milk feeding is a population health initiative that could positively impact the triple aim of better care, lower costs and better health.

Objectives. Information quality, use and user satisfaction affect user adoption and acceptance of IT solutions. The objective of this project was to test the effectiveness of UCD on optimization by measuring the increase in information quality, use and user satisfaction after implementation of an optimized electronic lactation assessment.

Plan. Stakeholders were identified and the electronic form was optimized through UCD. A pre-test/post-test quasi-experimental design was chosen to measure the effect of optimization. Instruments included a modified version of the *System and Use Assessment Survey* (AHRQ, n.d.), a chart audit tool and an electronic data warehouse use query. IRB approval was obtained from COMIRB and Regis University. The pre and post data collection periods were each six weeks in length, allowing for a two week chart audit period and four week survey. The intervention was implemented after the close of the pre-test period. Clinical users were educated following the organization's usual methods for EHR changes. Five months after the intervention, the study timeline was repeated for the post-test period. After the post-test period, a use query was run to collect data for both pre-test and post-test periods. Data were collected, coded, and entered into electronic spreadsheets for storage and analysis.

Outcomes and Results. Although the sample as a whole showed no statistically significant increases in any parameter of information quality, use, or user satisfaction, when survey participants were divided by role, nurses and providers, there was a statistically significant increase in the post-test nursing group for two measures of information quality and one measure of information use. A Mann Whitney U test found a significantly higher perception of completeness of the lactation assessment, $U = 200$, $z = -2.11$, $p = .035$, $r = .29$ and reported frequency of accessing the lactation assessment from the EHR, $U = 233$, $z = -2.01$, $p = .044$, $r = 0.26$. A Fishers exact test found a statistically significant increase in the presence of lactation assessments in the post-test chart audit ($\square^{\square\square}$ [1, N = 39] = 11.8, $p = .001$, $\varphi = .39$). The outcomes may be explained by differences in how each role uses the EHR. Additional education for providers may be necessary to overcome these differences.

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An expectation of the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted in 2009 as part of the American Recovery and Reinvestment Act, was that the adoption of electronic health records (EHR) would improve the United States' healthcare delivery system and patient care through efficient access to patient information, support for provider decision making and coordination of care (National Learning Consortium, 2014). The envisioned benefits of a robust EHR that achieves high value health care are summed up through the triple aim of better health, better care and decreased costs (Berwick, Nolan & Wittingham, 2008). However, recent studies on the use of EHR documentation have cast doubt on the ability of the EHR to provide robust support for clinician decision making in part related to the quality of documented information as well as the ease of locating information within the EHR (Bowman, 2013; Hripcsak, Vawdrey, & Bostwick, 2011; Huryk, 2010; Keenan, Yakel, Dunn Lopez, Tschannen, & Ford., 2013; Smith, Smith, Krugman, & Oman, 2005; Stevenson & Nilsson, 2012). Checklist documentation, designed to improve the efficiency of data entry, lacks the rich narrative that illustrates the impact of nursing interventions and the overall patient story (Green & Thomas, 2008; Keenan et al., 2013). Furthermore, inefficient means of viewing information within the EHR limits the use of the EHR as a vehicle to communicate patient information to the healthcare team (Bowman, 2013; Hripcsak et al., 2011; Keenan et al., 2013; Smith,et al., 2005; Stevenson & Nilsson, 2011).

Problem Recognition and Definition

Project Purpose

The purpose of this study was to evaluate the effect of an optimized electronic lactation assessment form on information quality, use and user satisfaction. The electronic lactation assessment was contained within the Siemen's Healthcare® Soarian Clinicals EHR application. In this application, electronic forms which capture clinician documentation are referred to as assessments. This term is used throughout to describe the electronic tool.

Problem Statement

A benefit of the EHR is improved access to complete and accurate information which is expected to lead to the triple aim of better health, better care, and lower costs (Berwick et al., 2008; National Learning Consortium, 2014). Electronic nursing assessments are tools within the EHR designed to capture documentation of clinical observations and facilitate communication within the health care team for the enhancement of clinical care. The design of the electronic assessment can influence the quality of information and its usefulness for care providers (Kelley, Brandon, & Docherty, 2011; Zopf-Herling, 201l). When the design impedes the collection of complete and accurate data or limits access to information, then users' dissatisfaction may impact the use of information to support the provision of care (Stevenson & Nilsson, 2011). Electronic assessments should be optimized to increase information quality, use and user satisfaction.

PICO

P. Interprofessional clinical team: lactation consultants, Mother/Baby and NICU nurses, outpatient clinic nurses/medical support team, providers.

I. Optimized electronic lactation assessment

C. Continue current electronic lactation assessment

O. Increased information quality, use, and user satisfaction of the lactation assessment

Research Question

Is there increased information quality, user satisfaction and use of an electronic lactation assessment form after optimization using user centered design?

Project Significance, Scope, and Rationale

Project significance. Breastfeeding is a healthy behavior with benefits for both mother and infant including decreased incidence of postpartum depression, ovarian cancer and breast cancer for mother and decreased incidence of infections, asthma, childhood leukemia, and lymphoma for the child. In addition, there is a decreased risk of postpartum bleeding for the mother and decreased risk of sudden infant death syndrome for the child (Eidelman & Schanler, 2012). Exclusive breast milk feeding is a Joint Commission Perinatal Core Measure and a Meaningful Use (MU) Clinical Quality Measure (CQM). By measuring the rate of exclusive breast milk feeding in healthy term newborns whose mothers choose to breastfeed, hospitals will have data and benchmarks for quality improvement (US Breastfeeding Committee, 2013).

Hospital practices have been shown to impact the rates of breastfeeding (US Breastfeeding Committee, 2013). The *Baby-Friendly Initiative* is an evidence based program promoting ten hospital practices which increase initiation of breastfeeding in some populations and over-all rates of breastfeeding (Hawkins, Stern, Baum & Gillman, 2014; World Health Organization, 1998). Hospitals designated as *Baby Friendly* have successfully demonstrated implementation of these ten steps. Lactation consultants provide much of the education to new breastfeeding mothers that is required by *Baby Friendly*. In addition, lactation consultants develop plans of care based on their assessment of the couplet. When all caregivers are aware of

and support the lactation consultant's plan, breastfeeding mothers receive consistent communication from the healthcare team. Consistent messaging is particularly important when there are challenges in the immediate postpartum period (List et al., 2008).

Scope. The scope of the project was to implement a redesigned electronic lactation assessment as part of the optimization phase of the system life cycle. The organization implemented electronic documentation for the perinatal division in January of 2013 as part of a "big bang" simultaneous implementation of clinical documentation, CPOE (computer provider order entry) and bar-code medication administration. The implementation was problematic and resulted in significantly less functionality than anticipated, a return to paper for some specialties, and frustrated users. Users identified changes to the application that would result in better support for their workflows, including a request to adjust the lactation assessment.

Rationale. The organization was a 500 bed public safety-net integrated healthcare system with over 3,000 annual births and was recently recognized as having one of the lowest rates for Cesarean sections in the country (*The risks of C-Sections*, 2014). The organization's lactation program consisted of International Board-Certified Lactation Consultants (IBCLCs) and Certified Lactation Counselors offering prenatal classes, post-partum support, and follow up care. Because of its commitment to breastfeeding support, the organization was recognized by the Colorado Department of Public Health and Environment and the Colorado Breastfeeding Coalition with a Breastfeeding Excellence Starts Today (BEST) award for demonstrating the *Colorado Can Do 5!*, an initiative to implement five of the *Baby Friendly* Ten Steps (Colorado Breastfeeding Coalition, n.d.). A future organizational goal was to achieve *Baby Friendly* certification, which would require implementation of all ten steps.

The organization needed data retrieved from patient records to demonstrate practices consistent with the ten steps. Breastfeeding data documented in the EHR was also required to meet Meaningful Use (MU) CQM (Clinical Quality Measure) *Exclusive Breast Milk Feeding* which was part of the organization's attestation for MU Stage 2 (Centers for Medicare & Medicaid Services, 2014). Finally, patient record data was abstracted to calculate Joint Commission's Perinatal Core Measures, PC-05 and PC-05a, *Exclusive Breast Milk Feeding* and *Exclusive Breast Milk Feeding Considering Mother's Choice*.

The rationale for this project was that the EHR could lend support for the organization's *Baby Friendly* initiative and lactation program if documentation was accurate and complete. Accurate and complete documentation would allow the organization to demonstrate achievement of *Baby Friendly* and other regulatory requirements and would enhance interprofessional communication of the lactation consultant's breastfeeding plan. The previous version of the electronic lactation assessment was problematic because it lacked structured data fields specific to *Baby Friendly* requirements, did not include a specified location to document the breastfeeding plan, and was not easily viewable by the healthcare team. *Baby Friendly* documentation was entered through free text requiring manual chart audits for verification. Breastfeeding plans were inconsistently entered in any or all of up to five different free text fields contained within assessment. The breastfeeding plan was not viewable within the EHR's Interdisciplinary Plan of Care nor was lactation information available in the EHR's Clinical Summary overview of patient information.

Theoretical Framework and Conceptual Models

The conceptual model for this project includes elements from three theoretical frameworks: User centered design (Schumacher & Lowry, 2010), DeLone and McLean's information systems (is) success model (DeLone & McLean, 2003), and Donabedian's quality of care model (1988). Each of these is explained further. Then, the conceptual model for this project is presented.

User centered design. User centered design (UCD) (Figure 1) is an iterative process that seeks to understand users and their environment (Schumacher & Lowry, 2010). The process

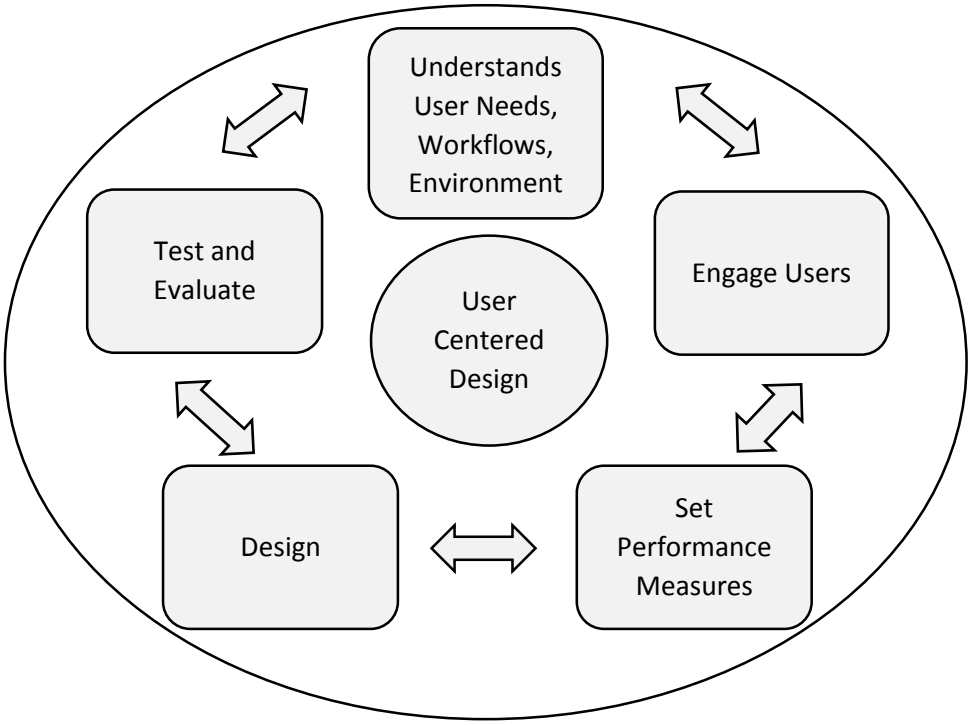


Figure 1. Model of user centered design process. The user centered design process starts with an understanding of users' needs, their workflow and their environment. Users are engaged in the design process early and participate throughout. The process can move bi-directionally, allowing for maximum user input in to the final product. Adapted from: Schumacher, R. M. & Lowry, S. Z. (2010). *NIST guide to the processes approach for improving the usability of electronic health records*. Washington, D.C. U.S.

starts with an understanding of the users' needs, workflows and environments. The next step is engaging users in the design process by setting performance measures, designing the solution and testing and evaluating the solution. The process can flow in either direction through design, testing, adaptation, and re-testing until performance objectives are met (Schumacher & Lowry, 2010). The goal of optimization is to improve the information quality of the assessment.

Information systems success model. DeLone and McLean's information systems (IS) success model, first developed in 1992 and updated in 2003, is a framework to illustrate dependent variables, or attributes, of IS success (see Figure 2). These attributes are interdependent and

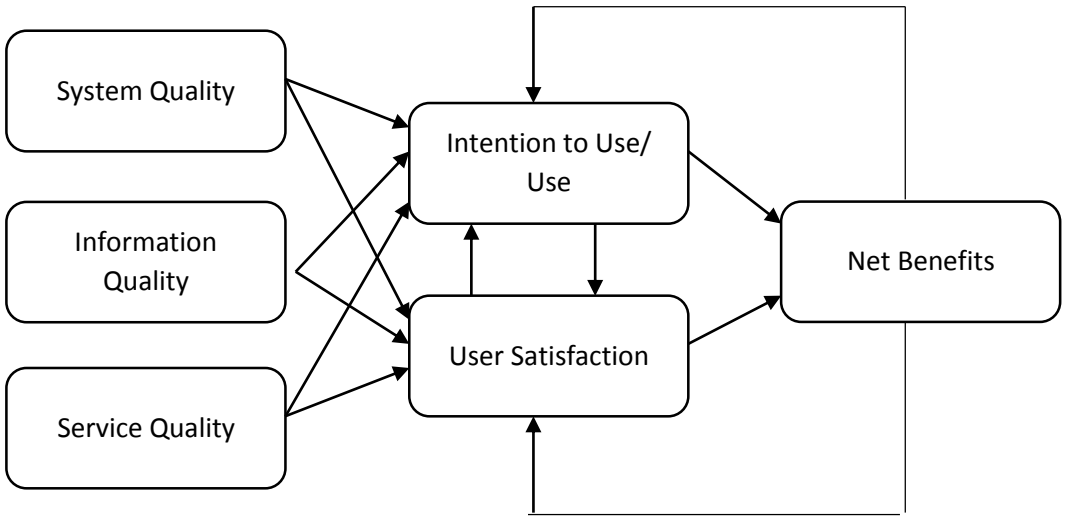


Figure 2. Updated D&M IS Success Model. The model proposes that the three dimensions of information systems success, system quality, information quality and service quality, either alone or in combination influence use and user satisfaction. The direction of the arrows indicate the flow, either positively or negatively, of influence. Adapted from "The DeLone and McLean Model of Information Systems Success: A Ten-Year Update," by W.H. DeLone and E. R. McLean, 2003*, Journal of Management Information Systems, 12*(4), p. 24. Copyright 2003 by M. E. Sharpe, Inc.

include service quality, system quality, information quality, use, user satisfaction, and net benefits for the organization (DeLone & McLean, 2003). The IS success model is a causal model; when one or more attribute(s) are impacted by an outside intervention, there is a positive or negative effect on successive attributes (DeLone & McLean, 2003). Van der Meijden, Tange, Troost and Hasman (2003) analyzed 33 studies of patient care information systems for determinants of success using the attributes of the IS success model and found the model applicable to healthcare. Booth (2012) conducted a systematic literature review of studies measuring the impact of technology on nursing, specifically examining the relevancy of the IS success model as a framework for evaluation of nursing studies. Of the 39 studies which met the inclusion criteria, the majority concentrated on measuring overall Net Benefits (Booth, 2012). Booth recommended that future studies focus on the foundational attributes of the model, such as information quality, service quality and use. Booth also recommended considering variables in addition to those in the model, such as nurse demographics. Overall, Booth found the IS success model was an effective framework for the evaluation of nursing use of healthcare information technology (HIT).

Quality of care model. Donabedian (1988) regarded quality as an improvement to the health of individuals or populations. Quality is multidimensional, encompassing technical performances, interpersonal relationships, and amenities, while acknowledging the individual's role in implementing care and the community's role in receiving care. Quality is inferred from information found within subcategories of structures, processes and outcomes. Structures are attributes within the care setting. Processes are actions associated with the provision of care. Outcomes are the effects of care on health. Quality assessment using this model is dependent on

existing positive linkages between structures and processes and between processes and outcomes. Kelley, Brandon and Docherty (2011) used Donabedian's quality of care model to develop a framework for examining the use of electronic documentation on quality of patient care. Structures were the nurses themselves and characteristics of the EHR. Processes were the use of the EHR by nurses in the provision of patient care. Outcomes were the health status of the patient and nurses' satisfaction with the EHR.

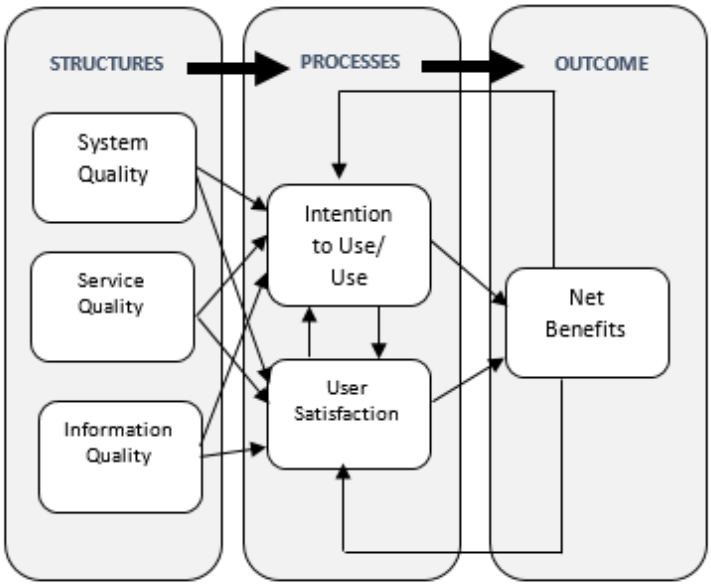


Figure 3. Alignment of Attributes of Success with Structures of Quality. This figures shows how DeLone and McLean's (2003) attributes of information systems success align with Donabedian (1988) subcategories of quality. Each model proposes that positive influences at the individual level may lead to positive outcomes. By aligning these two models, there is clarity around how improvements to technical aspects of healthcare may impact quality of care and patient health. Adapted from "The DeLone and McLean Model of Information Systems Success: A Ten-Year Update," by W.H. DeLone and E. R. McLean, 2003, *Journal of Management Information Systems, 12*(4), p. 24. Copyright 2003 by M. E. Sharpe, Inc., "The Quality of Care: How can it be Assessed?" by A. Donabedian, 1988, *Journal of the American Medical Association, 260*(12) and "Electronic Nursing Documentation as a Strategy to Improve Quality of Care" by T. F. Kelley, D. H. Brandon, and S. L Docherty, 2011, *Journal of Nursing Scholarship, 43*(2), p. 156.

Although a causal model, the IS success model is based on the processes of information systems (IS) which parallel Donabedian's subcategories of structures, processes, outcomes. The IS process begins with IS structures such as hardware, software and support systems. Structures are measured by attributes of information quality, service quality and system quality. The next step in the IS process is use of structures which is measured by attributes of use and user satisfaction. The final process step is the outcome or effect of the system measured through net benefits to the organization (see Figure 3).

Conceptual model. The conceptual model for this project was developed by combining the dependent variables from the IS success model with the processes depicted in Donabedian's quality of care model while retaining the causal properties of the IS Success Model to illustrate quality improvement effect on information quality, use, and user satisfaction (see Figure 4). The conceptual model depicts Donabedian's subcategories (structures, processes, and outcomes) aligned with dependent variables from the IS success model information quality, use and user satisfaction. The net benefits of better health, better care, and lower costs (the triple aim), although unmeasured, are depicted as the long term, desired outcomes of the project. DeLone and McLean's causal IS success model predicts any increase to information quality will increase use and/or user satisfaction which will then increase net benefits. Arrows depict the expected effect of each attribute on its successor. The independent variable, the optimized lactation assessment, is shown impacting both Information quality and use/user satisfaction. Confounding variables are the remaining attributes of the IS success model (service quality and system quality) which are not impacted by the independent variable. User characteristics are included as a confounding variable as suggested by Booth (2012).

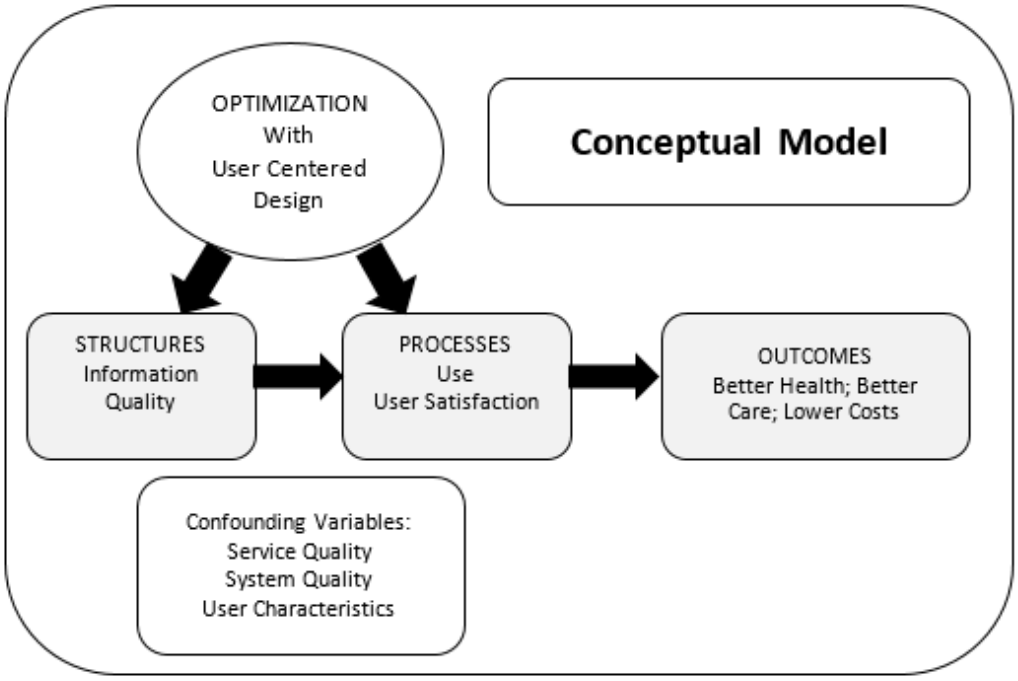


Figure 4. Conceptual Model. The conceptual model depicts the intervention of optimization using the User Centered Design process as a positive influence on both structures and processes, specifically on Information Quality, Use and User Satisfaction. By positively influencing these attributes, Net Benefits, defined as better health, better care and lower costs should be realized by the organization. Confounding variables are the attributes not directly impacted by optimization with User Centered Design. Included in the confounding variables is a suggestion by Booth (2012) that user characteristics may also impact attributes of IS success. Adapted from "The DeLone and McLean Model of Information Systems Success: A Ten-Year Update," by W.H. DeLone and E. R. McLean, 2003, *Journal of Management Information Systems, 12*(4), p. 24. Copyright 2003 by M. E. Sharpe, Inc., "The Quality of Care: How can it be Assessed?" by A. Donabedian, 1988, *Journal of the American Medical Association, 260*(12) and "Electronic Nursing Documentation as a Strategy to Improve Quality of Care" by T. F. Kelley, D. H. Brandon, and S. L Docherty, 2011, *Journal of Nursing Scholarship, 43*(2), p. 156.

Review of Evidence

Background

The Institute of Medicine (IOM) (2012) recognized the need for evaluation studies to identify possible patient risks related to the implementation and use of HIT, and there is broad

support for such studies (Nykanen et al., 2009; Talmon et al., 2009); however, there is recognition that HIT evaluation has unique challenges (Ammenwerth, Graber, Herrmann, Burkle, & Konig, 2003; IOM, 2012). The desired objectivist approach to study design in which the effect of an intervention on individual patients is objectively measured does not necessarily transfer to the evaluation of HIT projects which impact structures, processes and outcomes (Ammenwerth, Graber et al., 2003; IOM, 2012;). Challenges with HIT evaluation arise from the complexities of the object itself; HIT projects involve not just hardware or software but the use of these tools within a clinical environment composed of unique users, patient populations, work processes and organizational culture (Ammenwerth, Graber et al., 2003). Evaluation criteria may be difficult to specify based on the variety of stakeholders (Ammenwerth, Graber et al., 2003) Success to the IT department may be measured by on time delivery and functionality; whereas success for the clinician may be measured through effect on efficiency.

Defining HIT success is elusive and dependent on the user group. For clinicians, HIT success may be measured through user perceptions on impacts to their work and by attitudes and acceptance of users towards HIT. Information quality is identified as a significant contributor towards clinicians' attitudes (Kimiafar et al., 2014; Hsiao et al., 2011). Information quality can be evaluated using usability principles and can be influenced by engaging users in the design and testing of systems (Zopf-Herling, 2011, Kennedy Page & Schadler, 2014).

Systematic Review of the Literature

A comprehensive review of the literature was conducted to identify determinants of success for inpatient clinical documentation systems and to evaluate the impact of HIT on nursing care. The CINAHL, MEDLINE, PsychINFO and Academic Search Premier databases

along with Google Scholar and PubMED where searched using keywords: Healthcare IT, Clinical Information Systems, Electronic Health Record, Nursing Documentation Systems, Nursing Attitudes, Nursing Satisfaction, Quality, Success, Human Factors, Usability and Evaluation. Reference lists of pertinent articles were searched to identify additional studies. Articles included in the review were descriptive or research studies, from academic journals, published after 2003, and which evaluated HIT implementation or use in a clinical setting. The majority of HIT studies found in the literature were reports from expert committees, qualitative or descriptive studies or systematic reviews of descriptive and qualitative studies. A limitation of this body of literature is that, for the most part, these studies fall into the lower levels of evidence as described by Houser and Oman (2011). A second limitation is that HIT studies, in general, tend to lack external validity due to the small sample sizes, the unique work processes localized to a particular setting, or the specificity of the system (Ammenwerth, Graber et al., 2003; Heathfield, Pitty, & Hanka, 1998). After an initial review of studies evaluating overall HIT success, subsequent articles were limited to those which specifically addressed an impact on nursing. Additional topics for further review were identified from the initial literature review and include the impact of HIT on nursing, nursing satisfaction with and attitudes towards HIT, information quality and usability.

HIT success. Defining Healthcare IT (HIT) success is complex and dependent on the organization and the perception of the stakeholder (Kaplan & Harris-Salamone, 2009; Laramee, Bosek, Kasprisin, & Powers-Phaneuf, 2011; Spetz, Burgess & Phibbs, 2012; Van der Meijden et al., 2003). Various measures for evaluating HIT success include costs, quality, safety, system performance, morale, or user time (Spetz et al., 2012, Van der Meijden et al., 2003). HIT has the

potential to affect clinicians' workflows and how they communicate and collaborate (Kaplan & Harris-Salamone, 2009; Laramee et al., 2011; Spetz et al., 2012). When HIT disrupts established workflows, communication or collaboration patterns, users may create alternatives, or workarounds, that duplicate or bypass the application (Halbesleben, Wakefield, & Wakefield, 2008). Thus, additional measures of HIT success are user acceptance, motivation, and use (Ammenwerth, Mansmann, Iller & Eichstadter, 2003; De Veer, Fleuren, Bekkema & Francke, 2011).

Ammenwerth, Mansmann, Iller and Eichstadter (2003) examined user acceptance of a computerized nursing documentation system in a pre and post, mixed method study. The intervention (electronic nursing documentation) was developed with nursing involvement and fully supported the nursing care plan process. A clear definition of the concept "user acceptance" was not provided, although the concept was related to motivation. The pilot study was conducted on four nursing wards in German hospitals. There were three data collection time points: three months prior to implementation and three months and nine months after implementation. Results were gathered via a questionnaire and group interviews. The instrument was developed with questions drawn from validated questionnaires previously presented in the literature. Group interviews were audiotaped and content was transcribed and analyzed. The authors found overall that user acceptance of the clinical documentation system was medium to high and continued throughout the study period.

Van der Meijden, Tange, Troost and Hasman (2003) reviewed the literature from 1991-2001 to identify factors that attributed to success of inpatient HIT applications and found that defining HIT success was difficult. Thirty-three studies met the inclusion criteria. Factors were

analyzed using the six determinants of success proposed by the DeLone and McLean IS Success Model. The majority of studies evaluated information quality, system quality, user satisfaction, and individual impact. Usage and organizational impact were evaluated in fewer studies. Evaluation of HIT was limited when the design of the study failed to identify stakeholders because perception of success varies with stakeholders. When studies measured success immediately after implementation, they did not allow sufficient time for full impacts to be realized. Studies measuring success against the previous system may not have considered the limitations of the previous system which were corrected by the new system. As a multidimensional framework, the IS Success Model was useful for evaluation of HIT success and was recommended for future studies. Additional factors, such as organizational culture or user involvement in design, should be considered as antecedent or confounding variables.

Spetz, Burgess, and Phibbs (2011) conducted a qualitative study to identify success factors for implementation of inpatient HIT, specifically a patient record application and bar-code medication administration. The study targeted nurses as the primary users of these applications with the greatest impact to workflows. The setting was seven Veterans Administration (VA) hospitals representative of the inpatient VA system overall. Semi-structured interviews were conducted with participants selected by site coordinators based on their job classification. Thematic analysis was conducted and five themes impacting the success of HIT implementation emerged: leadership/organizational stability; equipment; phased implementation; training; and workflow changes. Nurses acknowledged that HIT can impact established workflows including the organization of their work, documentation processes, and

communication patterns. Addressing changes to workflow prior to implementation was identified as a success factor for HIT implementation.

Impact of HIT on nursing. Studies on the impact of HIT on nursing find that, over all, nurses described changes to communication methods, quality of care, work processes with HIT implementation. Although nurses report some positive impacts, more negative effects are described in the literature. Most of the studies are qualitative in design and lack generalizability due to small sample sizes and specificity of the system or setting.

Rogers, Socolow, Bowles, Hand and George (2013) used a case study methodology and scenario based techniques to evaluate how a system interface affected the use of a nursing information system. A purposeful sample of 12 nurses interacted with scenarios designed to test the system. Participants verbalized their thoughts throughout the interaction, while answering probing questions posed by the researcher. Violations of heuristic principles were noted. Heuristic principles are rules intended to increase usability of systems. Of note, in one scenario, a breakdown in the visibility of the system's status led to inefficiencies with interdisciplinary communication. Nurses reported that they were unsure of the ability of the system to adequately communicate information documented within the application to the interdisciplinary team. The application contained functionality to communicate with other disciplines, but there was no immediate feedback to the nurse that the message was received. Therefore, nurses took additional steps to ensure that important information was communicated such as calling the colleague. Nurses also reported difficulty retrieving information from the system once documented and relied on alternative means of communication. In both these situations, the application did not support users need for information.

Zuzelo, Gettis, Hansell, and Thomas (2008) reported on a qualitative study to describe how technology impacted daily work of nursing. Thirty one nurses participated in four focus groups. The moderator guided discussion by following a questioning sequence provided to participants at the start of the session. The sample was purposeful and participants were nurses employed at one of two networked institutions. Nurses reported both positive and negative effects of technology. In addition to computerized documentation systems, technology included a wide range of devices such as electronic devices and tools. One finding was that when technology blocked the ability to provide immediate care, nurses responded by instituting workarounds to the feature which was getting in the way of the nurse's workflow.

Zadvinskis, Chipp, and Yen (2014) evaluated nurses' perceptions of the EHR and barcode medication administration four months post implementation using a phenomenological approach. The purposeful sample included ten nurses all of whom worked on a medical-surgical unit in the same organization. Data was collected through semi-structured, private, face to face interviews. Although nurses reported both positive and negative interactions with the computer, there were greater negative interactions. In particular, nurses reported that assessments did not match their mental model of head to toe, and that the specific application had features which decreased ability to share information across the interdisciplinary team. Overall, the study findings supported a conceptualized framework of five levels of expectations related to human computer interactions, starting on an individual level (1) and expanding to an organizational level (5). At the fourth level, there is an expectation of interdisciplinary teamwork in which the computer supports collaboration, communication and the exchange of information.

Abbass, Helton, Mhatre, and Sansgiry (2012) proposed to study the impact of the EHR on nursing productivity using data collected on a national level from the American Hospital Association survey and Centers for Medicare & Medicaid Services data. One purpose of the study was to provide a more generalizable study than previous evaluations of nursing productivity which were limited in external validity due to the previously mentioned constraints: small sample size, specificity of unit and/or application. The retrospective cross sectional study hypothesized that productivity would increase in hospitals with higher levels of EHR implementation. Nursing productivity was operationalized with a formula involving the number of full time equivalent RNs who produced a defined output calculated from inpatient and outpatient days and from inpatient and outpatient revenue. EHR implementation was operationalize by the number of EHR components functioning. The study made some assumptions about staffing including that the EHR would decrease documentation time and increase time for patient care. Sample size was 3368 hospitals after excluding hospitals with outliers in any of the measured variables. Findings did not support the hypothesis and the authors concluded that expectations of decreased staffing based on implementation of EHR would likely not be met. This is an important consideration when defining HIT success.

Ward, Vartak, Schwichtenberg, and Wakefield (2011) evaluated the impact of an EHR implementation on nurses 'perceptions of workflow and patient care in a rural hospital. Using a survey developed and validated for the study, participants rated their perceptions on effects to communication, care, support/resources, and individual impacts. The survey was administered over three periods, pre training, post-implementation and post implementation. Positive responses decreased over all three study periods. From the first to the second study period, 17%

of survey items had a significant decrease and from the second to third study period 79% of survey items had a significant decrease. The greatest decrease concerned perceptions of communication, improved care and care processes.

Nurses' attitude and satisfaction. User satisfaction with clinical applications is an important component of HIT success and impacts the use of applications by clinicians (Palm, Colmbet, Sicotte & Degoulet, 2006; Ward, Stevens, Brentnall, & Briddon, 2008). Attitudes are influenced by the functionality of the system, design of content, and training (Ward et al., 2008).

Chow, Chin, Lee, Leung and Tang (2011) used a cross sectional survey design to study nurses' attitudes and satisfaction with a computerized documentation system implemented in a 450 bed private hospital. Survey questions addressed level of IT support, perceived usefulness, perceived ease of use and level of satisfaction with the application and attitude. Results indicated that although nurses had a level of satisfaction with the application, they were not satisfied that the application would improve care or efficiency.

Kimiafar, Sadoughi, Sheikhtaheri, and Sarbaz (2014) used a fuzzy analytic hierarchy process to weight factors for their degree of influence on nursing satisfaction with HIT. Based on a review of the literature, the authors selected information quality, service quality and system quality as the main factors impacting user satisfaction. Subfactors for each of the main factors were also determined. For example, a subfactor for information quality was availability and a subfactor for service quality was training. Weights for each factor were calculated through a process which presented the factors as pairs for comparison by a sample of ten experienced nurses. The highest weighted factor was information quality which was twice as impactful as service quality. The lowest weighted factor was system quality. A limitation of this study was

the small sample size; however the findings can inform future studies evaluating user satisfaction based on interventions applied to one or more of these factors.

Hsiao, Chang and Chen (2011) used a survey to gather data on nursing perspective of factors affecting acceptance of healthcare information systems. The instrument was a 39 item questionnaire adapted from a previously validated and published study. Content validity of the adapted instrument was measured using Cronbach's alpha and the tool showed a high content validity. The sample consisted of nurses working in one hospital. The study's conceptual framework suggested that satisfaction with HIT indicated acceptance and was a product of perceived usefulness and perceived ease of use. Information quality was found to significantly impact both usefulness and ease of use. Top management support and compatibility were other factors with significant impacts on usefulness.

Information quality. Nurses often serve as the central coordinators and communicators of patient information, and much of this information is entered as data into the medical record (Keenan et al, 2013). Data may include a patient's past or current condition, nursing cares and interventions provided to the patient, the patient's response to treatment, the nurse's decision making processes based on the patient's presentation and progress, and data required for regulatory agencies (Urquhart, Currell, Grant, & Hardiker, 2009; Wang, Hailey, & Yu, 2011). The patient's record should serve as a communication tool for the healthcare team; however, for the team to efficiently and effectively use nurse collected data, information must be complete and easily located, readable and actionable (Cusack, et al. 2013).

Challenges with the quality of nursing information in the EHR arise from processes of entering and accessing information. Checklist documentation is designed to improve the

efficiency and completeness of nursing documentation in the EHR; however, documentation entered via checklists may lack the rich narrative that captures the nurse's decision making in response to changing patient conditions that require nursing interventions (Green & Thomas, 2008; Keenan et al., 2013). Secondly, using the EHR to view or communicate documentation is problematic, with nurses stating that it is difficult to get an overview of the patient's story and providers not viewing nursing documentation within the application (Bowman, 2013; Hripcsak et al., 2011; Keenan et al., 2013; Smith, et al., 2005; Stevenson & Nilsson, 2011). Finally, a vision of Meaningful Use is to leverage electronic data for calculation of clinical quality metrics and thus efficiently inform clinical practices which may improve patient care outcomes (Centers for Medicare and Medicaid Services, 2014). Challenges to the efficient use of electronic data to measure quality arise from lack of structured data and from the misalignment of clinical processes with the electronic application (Dykes & Collins, 2013).

Tornvall and Wilhelmsson (2006) evaluated how providers used nursing documentation to inform patient care management and how managers used nursing documentation to assess quality of care. The cross-sectional, descriptive study was conducted in Sweden. Providers and managers were surveyed with separate instruments, using closed and open ended questions. Providers were asked about their frequency of reading nursing documentation, what they read in the nursing documentation and if they were able to find the information they were seeking. Managers were questioned about their use of nursing information for assessing resources and quality of care. The surveys were tested for content and face validity. Data was analyzed quantitatively and qualitatively. Findings were that the majority of providers indicated they always or often read nursing documentation, particularly notes about treatment or the patient's

experience with illness and the providers could generally find what they were looking for; however, providers indicated that sometimes nursing documentation was too wordy and this made it difficult to find the information the provider considered important. Furthermore, nursing information may lack specific details the provider needed, with the nurse emphasizing descriptions of care provided rather than assessment of patient condition. The authors concluded that in order to serve as an effective interprofessional communication tool, nursing documentation needs to be developed collaboratively with the healthcare team. A limitation of the study is that the findings are not generalizable due to work processes unique to the organization and to the specificity of the electronic application.

Two recent studies evaluating information quality after implementation of electronic nursing documentation showed mixed results in the perception of quality by users. Ammenwerth, Raughegger, Ehlers, Hirsh, and Schaubmayr (2010) evaluated quality of information processing after implementation of electronic documentation. A survey was administered to nurses after training on the new system and repeated one year post. The survey evaluated the quality of the hospital information system and was validated with Cronbach's alpha. Benefits perceived by users of electronic documentation were faster data entry, more complete documentation, improved communication, and improved presentation of data; however, presentation was also described as problematic, because it was difficult to identify important information. Other problems were that the electronic system was time consuming, at times required double documentation, and was missing the ability to free text in some assessments.

Michel-Verkerke (2012) evaluated the perception of information quality, ease of use and frequency of use by nurses in the Netherlands using open and closed ended questions. Validity of

the instrument was not addressed. Nurses identified that they want information that is timely, accessible, complete and accurate. With electronic documentation, nurses indicated that they did not always trust that data entered was accurate and that entering data was time consuming. A recommendation was that standardizing assessment forms could reduce the effort required to enter data.

Usability. Studies evaluating information quality frequently address the efficiency and effectiveness of data entry and retrieval. The efficiency, effectiveness and satisfaction with which users are able to "achieve specified goals" with an application is referred to as usability (National Institute of Standards and Technology [NIST], 2013, Overview). The full benefit and safe use of an EHR may not be realized unless the system is usable (NIST, 2013; Rojas & Seckman, 2014; McDowell, Dillon & Lending, 2008). Usability evaluation involves applying usability principles or heuristics (Rojas & Seckman, 2014; Rogers et al., 2013). Examples of these principles include internal and external consistency of the application; effective presentation of information, match with mental model, efficiency, flexibility, and recovery from errors (Rogers et al., 2013; Rojas & Seckman). The evaluation of usability has historically been aimed at the appearance or the functionality of systems; but future emphasis on usability evaluation of HIT should consider the impact of the system on the workflow of clinicians (Rogers et al., 2013).

The National Institute of Standards and Technology (NIST) has published guidelines for improving usability of the EHR (Schumacher & Lowry, 2010). A recommendation is to incorporate a process of user centered design (UCD) which results in EHRs that are "efficient, effective, and satisfying to the user" (Schumacher & Lowry, 2010, p. 5). UCD, or similar user

centered processes, have been used to enhance electronic nursing documentation, develop customized HIT tools, design electronic clinical handover tools, design interactive consumer health technologies, and redesign interfaces (Dabbs et al., 2009; DeVoe et al., 2014; Johnson, Johnson & Zhang, 2005; Kennedy Page & Schadler, 2014; Wong, Cummings, & Turner, 2013; Zopf-Herling, 2011). An observation in this body of literature is that poor designs have been tolerated by users of HIT, and there has been little attention to the impact poor design has on desired outcomes (Dabbs et al., 2009; Johnson et al., 2005; Wong et al., 2013; Zopf-Herling, 2011).

Zopf-Herling (2011) described a process of redesigning nursing documentation with user input and incorporating "rules of thumb" (p. 680). These rules addressed the efficiency and effectiveness of data entry. For example, one rule required consistency in presentation of data fields within an assessment: all data should be entered with checkboxes or all data should be contained within drop downs. An example of effectiveness was using triggers to guide content based on the answer to a previous question. After redesigning assessments, the number of data fields on some assessments was reduced by almost 50%, there was decreased number of clicks, and users recognized the value of the electronic health record as a tool supporting clinician efforts.

Kennedy Page and Schadler (2014) also redesigned, or optimized, existing electronic assessments using a usability checklist. The purpose of the study was to increase the efficiency, effectiveness and user satisfaction with the HIT application which would then impact patient outcomes. The process involved early and frequent engagement of users during the design and testing phases, following the UCD iterative process of engagement, design, test, and redesign.

Users rated the design with a checklist developed from usability heuristics addressing such attributes as: simplicity, consistency, naturalness, flexibility, and effectiveness. Evaluation measured user satisfaction with a questionnaire, efficiency metrics by counting keystrokes, and impact on certain patient outcomes measured for regulatory purposes. The study followed a pre and post design. Findings were statistically significant for improvements in efficiency, effectiveness and satisfaction post optimization with user engagement in the design and testing using a usability checklist.

Project Plan and Evaluation

Market/Risk Analysis

The organization is the primary safety net hospital for the region and provides both inpatient and ambulatory services through a 500 bed acute care hospital, eight community health centers and sixteen school based clinics. Trends currently influencing the provision of healthcare in the United States and impacting safety-net organizations include:

- Sustaining financial viability;
- Increasing patient engagement;
- Implementation and continued development of Health Information Technology (HIT) to meet Meaningful Use (MU) standards (Zaman, Cummings, & Laycox, 2012).

As a safety-net hospital, the mission of organization is to provide care to all; this includes the uninsured and Medicaid and Medicare populations. In 2011, the uninsured generated $374 million in billed charges, of which the organization collected five cents on the dollar (Burnett, 2011). Meeting the healthcare needs of this population within the financial constraints of limited or no reimbursement for costs is a continuing challenge for safety-net hospitals.

Strategies, weaknesses, opportunities and threats analysis. A SWOT analysis (see Table 1) identifies the strengths, weaknesses, opportunities and threats from internal and external factors which drive and restrain product implementation (Harris, Rouseel, Walters & Dearman, 2011). For this project, internal factors were the strengths and weaknesses which impact clinicians, whereas external factors were the opportunities and threats affecting the organization as a whole. The product implemented was the optimized lactation assessment. Support for the change came from the clinical informatics team and the lactation team, but the project competed for limited technical resources with other organizational initiatives.

Internal strengths included the two teams advocating for change as well as organizational support for breastfeeding. The lactation team has been described previously. The clinical informatics (CI) team was a bridge between technicians who develop an electronic application and clinicians who use the application. Without the input of clinicians on the CI team, technicians risked designing and implementing processes which did not support provider and/or nursing workflows. The CI team advocated for clinicians so that technical applications successfully added value to clinician work.

Internal weaknesses identified were that provider documentation was outside of the electronic application which decreased opportunities for providers to efficiently use the application to view nursing documentation, regardless of the quality of the information or the ease of locating information. Due to the poor functionality of the application, users were doubtful that any optimization of the current system would improve clinician work.

An opportunity, however, was to implement processes in advance of the new application to correct user's disconnect with the EHR. Ideally, the EHR would be seen as the source of

truth. Healthcare providers should be directed to find information within the EHR and should not rely on workarounds. Creating a process within the current application that provided value to

Table 1

SWOT Analysis: Strengths, Weaknesses, Opportunities and Threats

	Strengths	**Weaknesses**
Internal	• Robust Lactation Program with dedicated, certified Lactation Consultants • Organizational culture supportive of breastfeeding • Strong Clinical Informatics Team	• Provider documentation is outside of the electronic application • Current design does not support reviewing lactation information within the application • Overall poor functionality of the electronic application has caused user dissatisfaction with the entire system
	Opportunities	**Threats**
External	• Align the EHR with work processes prior to implementation of new application • Redirect users to the EHR as the source of truth in advance of implementation of new application • Implement electronic collection of Baby Friendly data to facilitate certification	• Economic Challenges • Concurrent Implementation of New Application has divided IT resources • Historically little support for allocating resources towards addressing user satisfaction with nursing documentation

clinicians who use the EHR as the source of truth could solidify these practices prior to implementation of the new application.

Threats to implementation were competing IT projects which took resources away from optimization of the current system. The organization was embarking on a multi-million dollar effort to implement a new enterprise wide system over the proceeding twenty-four months. This effort not only pulled resources that supported the current system but also demanded justification for optimizing the current state when changes would be only be temporary. A final threat was that, overall, the organization had historically put resources towards developing order sets and not towards optimizing documentation.

Driving and restraining forces. Driving forces for the project were the regulatory measures of exclusive breastmilk feeding, the *Baby Friendly* initiative, and organizational support for projects which impact patient engagement and safety and quality. Restraining forces were other projects driven by regulatory, patient safety, or economic impacts competing for limited information technology resources.

Need, resources, and sustainability. The organization's strategic plan consisted of six pillars: financial strength, workforce engagement, patient experience, growth, patient safety and quality, and community. Any new initiative within the organization would support at least one of these pillars. The lactation team requested changes to their lactation assessment to facilitate documentation requirements. Optimization of the lactation assessment directly supported the workforce engagement pillar and indirectly supported patient experience, patient safety and quality, and financial strength pillars.

The eHS (electronic Health Services) department had developed standard work for addressing EHR issues and requests. Issues or requests were identified by users and triaged by a small eHS team to the appropriate solutions group. The solutions group consisted of leaders

within the clinical area who, with the assistance of the clinical informatics team, conducted an initial analysis to identify the current state, ideal future state, and possible solutions. The solutions group then endorsed or declined the issue. Senior eHS management assigned resources for endorsed electronic health service initiatives. Work that required fewer than forty hours to complete was assigned by the team manager; when the project required more than forty hours to implement, the request was reviewed by a panel of senior leadership for approval and assignment of project resources. Because this project required less than forty hours of effort, the team manager assigned resources as available to complete the request (See Table 2).

Table 2

Project Expenses for Implementation and Evaluation

Task	Responsible Role	Effort	
		Hours	Cost (in dollars)
Analysis and Design	Clinical Informaticist; Subject Matter Experts	5	250
Build	Application Analyst	8	320
Test	Testing Office	3	60
Educate	Clinical Informaticist	5	250
Evaluate	Clinical Informaticist	4	200
Implementation TOTAL		25	$1080
Sustainability: Ongoing Support Yearly		4	$175

Changes made to any EHR are part of the ongoing systems life cycle applicable to electronic applications. Optimization is continuous and has been likened to a philosophy of continuous quality improvement (CQI) (National Learning Consortium, 2013). By adopting a CQI approach to EHR optimization, the organization continuously drives the application towards an ever moving future state. Consequently, changes to the lactation assessment itself are

sustainable only until there are new documentation requirements for implementation. An estimate of ongoing yearly costs to audit use and educate end users based on audit results is supplied in Table 2.

Feasibility, risks and unintended consequences. The requested changes to the lactation assessment were feasible within the functionality of the application and within the resources of the organization. The change management process followed by the organization for changes to the EHR was intended to identify and eliminate risks. Actively involving clinical users in the optimization process through the process of user centered design and monitoring for workarounds was a means of mitigating unintended consequences resulting from EHR change (Jones et al., 2011).

Stakeholders and Project Team

Stakeholders are members of an organization who endorse a project and advocate for support (Harris et al., 2011). Stakeholders included: lactation consultants, providers, staff nurses, support staff, the clinical informatics team and IT experts. The project team consisted of those individuals who would create the product and included members from all stakeholder groups (see Table 3). The project team identified the problem, the current state, the ideal future state, and a feasible solution. The project manager was the single source of accountability and was responsible for the overall project outcome. Resources for project completion were directed by the resource manager. The business owner was the stakeholder who had identified the problem and was responsible for the overall solution as well as aligning work process with the proposed solution.

Cost Benefit Analysis

Measuring the costs and benefits of an EHR implementation and optimization has challenges because traditional methods of calculating ROI fail to account for the potential long term benefits of EHR adoption that extend beyond the boundaries of a single organization and

Table 3

Stakeholders and Project Team Role

Stakeholder	Skill Set	Project Team Role
Lactation Consultants	Experts who assess breastfeeding couplets and develop plans of care to support breastfeeding goals for the couplet, mother or infant. The clinicians who document within the electronic lactation assessment.	Subject Matter Expert Business Owner
Providers	Responsible for the medical care for mothers and/or newborns. Practice in both inpatient and outpatient care settings. Use the lactation plan of care to inform healthcare decision making.	Subject Matter Expert
Staff Nurses: Mom/Baby Unit; NICU	Provide 24/7 care to breastfeeding mothers and or infants and use the lactation plan of care to inform healthcare decision making.	Subject Matter Expert
Outpatient Support Staff: WIC, Nurse Line	Use the lactation plan of care to inform healthcare decision making.	Subject Matter Expert
Clinical Informatics and IT experts	Use the system lifecycle to develop electronic solutions to support clinician work processes. Understands technology limitations which may impact ideal solutions.	Resource Manager Project Manager Principal Investigator Application Analyst Educator Solution Tester

could impact society as a whole (Arlotto, 2014). Traditionally, return on investment (ROI) for IT implementation has been measured through reductions in FTEs, supplies, and errors (Arlotto, 2014). Additionally, published reports of ROI for EHR implementations have not used consistent reporting frameworks which decreases the ability to make comparisons between organizations or applications (Adler-Milstein et al, 2014). Yet, the benefits to society of a robust, meaningful EHR expand beyond the ROI for a single organization (Adler-Milstein et al., 2014; Arlotto, 2014). Realizing the full benefit of a meaningful EHR will require that organizations align anticipated benefits of the EHR with "next generation" values of patient centered care coordinated between providers (Arlotto, 2014).

A model was proposed by a subgroup of the Institute of Medicine's *Roundtable on Value and Science-Driven Health Care* to assess institutional ROI by identifying expenses and benefits resulting from implementation and ongoing support of an EHR (Adler-Milstein et al, 2014). One of the expenses depicted in the model is administrative time spent optimizing the EHR. Benefits depicted in the model included improved communication to decrease office visits, reduced variability of care, reduced clinician time spent documenting, and reduced time spent obtaining paper charts (Adler-Milstein et al, 2014).

Following this model, the organization could expect to see a long-term ROI for expenses related to optimizing the lactation assessment even though these benefits are not quantifiable. Long term benefits were expected to be improved communication between the healthcare team resulting in consistent messaging to breastfeeding woman and support for exclusive breast milk feeding. Although benefits were not quantifiable, costs were calculated (see Table 2) and were in

line with similar eHS projects which are considered part of ongoing management of the application.

Mission, Vision, Objectives and Goals

The organization's mission described its role as an academic, safety net organization providing health care to all while educating future health care professionals. The outcome of the vision was the organization's mission of a healthy community. The organization measured performance against the six pillars of financial strength, growth, patient experience, workforce engagement, community and patient safety and quality. The organization asked that new initiatives align with these pillars. This project's mission and vision demonstrate alignment with the pillars and support for a healthy community.

Project mission. Optimize an electronic lactation assessment with user centered design and realize immediate positive impacts to Information Quality, User Satisfaction and Use with a goal of benefiting the triple aim of better health, better care and lower costs for the community.

Project vision. Implement user centered IT solutions to:

- Enhance the patient experience,
- Ensure patient safety and quality and
- Support work force engagement.

Project objectives. The project objectives encompass the short term outcomes as depicted on the Logic Model (see Appendix A). The project objectives test the effectiveness of user centered design for increasing determinants of IS Success (information quality, use and user satisfaction) through the implementation of an optimized electronic lactation assessment within

the study period and measuring use, information quality and user satisfaction pre and post implementation. The project objectives are to:

- Increase use of information within the lactation assessment by the healthcare team from pre intervention to post intervention;
- Increase user satisfaction with the electronic lactation assessment from pre intervention to post intervention;
- Increase information quality of the electronic lactation assessment from pre intervention to post intervention.

Project goals. Project goals are the long term outcomes and the impact of the project as noted on the Logic Model. Project goals are to:

- Provide support for:
    - Collaborative, consistent messaging for breastfeeding families;
    - Baby Friendly certification;
    - Exclusive breast milk feeding.
- Positively impact the triple aim of better care, lower costs, and better health.

Logic Model

A logic model is a tool to communicate the plan for a project from resources needed, constraints to consider, activities to plan, outputs and outcomes (White and Zaccagnini, 2011). The logic model (see Appendix A) can be either a general overview or a detailed plan. This project was within the scope of the ongoing expenses associated with EHR maintenance and optimization. Inputs were consistent with these expenses. Constraints were competition with

other projects for limited EHR resources, the functionality of the current application, and undefined work process, which was also viewed as an opportunity for the organization to implement not only changes to the EHR assessment but changes to work processes that would support the new application as well. Activities for the project followed the systems life cycle for EHR projects and included the specific tasks of user centered design. The output of the project was an optimized electronic lactation assessment. Success was measured through effects on information quality, use, and user satisfaction. DeLone and McLean's (2003) causal model predicts that positive effects to these attributes of IS success will, in turn, positively impact net benefits for the organization, which are listed in the logic model under long term outcomes. The impact of IS success is the triple aim of better care, lower costs, and better health.

Design and Methodology

Research design. The design chosen for this study was a quasi-experimental, pre-test-post-test design. Randomization was not feasible due to ethical and financial considerations around withholding an intervention that was expected to improve patient care and due to increased costs related to maintenance of the pre-test application. The use of a non-experimental design increased the risk of threats to causality from confounding variables which may have offered alternative explanations (Harris et al., 2006). It was hoped that a relatively short evaluation period would decrease the threat to internal validity from alternative explanations arising from changes to the confounding variables identified within the conceptual model.

Timeline. After approval from Loretto Heights School of Nursing, Regis University, the project was submitted to the Colorado Multiple Institutional Review Board (COMIRB) and to

Regis University's IRB for approval. The pre and post-test periods covered six weeks each. The pre-test period began on October 1, 2014. The intervention was implemented on November 11, 2014. The post-test period began on April 14, 2015.

Population

Two populations were identified, one for participation in a survey and one for retrospective chart audit and documentation use query. The survey population consisted of inpatient and outpatient healthcare clinicians. Inclusion criteria were clinical employees of the organization who provided care to breastfeeding infants and/or mothers and documented in and/or accessed information from the EHR. Exclusion criteria was all who did not fit the inclusion criteria.

The chart audit and use query population was identified as postpartum breastfeeding women and newborns who received inpatient care at the organization. Inclusion criteria were newborns or postpartum patients receiving care on the Mom/Baby unit, who had a lactation consult order placed during their postpartum or newborn encounter, and whose lactation consult was documented electronically during their inpatient stay. Exclusion criteria were those who did not meet the inclusion criteria.

Human subject protection. Expedited IRB approval as a research study was received from both the organization and from Regis University. Volunteers for survey participation were solicited through invitations sent to work email addresses. The survey was completed electronically and the participant's name, IP address, and/or login were not recorded. Survey results were stored in a file on the principal investigator's password protected drive within the

organization's servers. Results will remain in the protected drive for a period of seven years from the completion of the study or until August 31, 2022.

There were minimal risks identified for survey participants and these included time to complete the survey. Risks were minimized by educating survey participants that the survey was voluntary and that they could choose to withdraw from the survey at any point. Benefits for healthcare providers were that the study could lead to improved information quality which may provide efficient and effective access to information to inform clinical decision making.

The chart audit tool and use query temporarily recorded the patient's MRN number. The data was stored on the organization's password protected computer drive in a password protected folder. At the conclusion of each data collection period, the data was de-identified and this de-identified information was stored on the principal investigator's password protected drive within the organization's server. The de-identified information will remain on the password protected drive for a period of seven years from the completion of the study or August 31, 2022. There were no identified risks to patients. Benefits for patients were identified as a potential for improved care coordination and consistent communication.

Vulnerable populations. This project did involve newborns which are considered a vulnerable population. There were no risks identified for this populations. Consideration for this vulnerable population was through de-identification of all patient data. Medical and nursing care of newborns was unaffected.

HIPAA compliance. The project complied with HIPPA regulations allowing a waiver of consent for the use of patient data by de-identifying all data collected after the fourteen day collection period. Consent for the user survey was obtained within the survey.

Setting. The setting was an integrated safety-net healthcare organization in an urban, southwestern United States location. The organization delivered over 3000 newborns annually, of which the majority were followed after discharge in the organization's outpatient clinics. The organization implemented the Soarian Clinicals application for inpatient electronic nursing documentation and CPOE in January of 2013. Electronic nursing documentation consisted of assessments and plan of care documentation. Inpatient provider documentation remained on paper. Outpatient provider documentation was in a separate electronic application. Outpatient users could access either Soarian Clinicals or a third application, the electronic data management system (EDM), to view inpatient records. EDM was the long term storage application for patient information and was considered the legal medical record. Only EDM included both electronic documentation and scanned paper documentation.

A challenge with viewing electronically documented information in EDM was that the format was not designed to provide a user friendly view of information. The presentation was in small print and veered slightly from the flow of the electronic form. For example, information that flowed vertically in the electronic version, was presented left to right in EDM. This sometimes resulted in a disjointed presentation of electronically documented information.

Newborns were scheduled for a two week follow up visit after discharge with their outpatient provider. During this visit, the provider routinely accesses EDM to view the scanned inpatient Newborn Medical Record form which contains the inpatient provider's documentation of maternal history, delivery information, and the initial and discharge exams. The electronic lactation assessment documentation was also available within this same EDM encounter. The

forms were listed alphabetically so the lactation form was close to the Newborn Medical Record in the EDM list.

The initial electronic lactation assessment, prior to optimization, was used by lactation consultants to document assessment findings, interventions, and recommendations. This assessment was designed in-house based on the previous paper form. The electronic form did not contain discrete data elements addressing *Baby Friendly* documentation requirements, making required audits challenging. In addition, the assessment did not contain a specific location to document recommendations and a plan of care. Instead, the assessment had a total of five free text boxes placed throughout the assessment following each section: the breast assessment, the infant assessment, the feeding assessment, the education documentation, and the reason for the consult. An audit of lactation documentation showed that recommendations or plans were scattered throughout the assessment in any one or more of the text boxes. This made quickly locating and reading the lactation consultant's plan challenging, particularly when accessing this information in the already difficult presentation in EDM.

Intervention

The intervention was an optimized electronic lactation assessment. Through a user-centered design process, the lactation assessment was optimized to allow users to efficiently and effectively enter and view information. One goal of optimization was to provide a lactation assessment form that allowed for discrete data entry of required *Baby Friendly* education documentation. A second goal was to clearly identify the lactation consultant's plan and recommendations within the documentation. Meeting these goals would allow for more efficient

auditing of documentation for *Baby Friendly* and provide clinicians with a focused view of the breastfeeding plan and recommendations when reviewing the documentation.

User centered design process. Optimization of the lactation assessment took place over a period of three months prior to the study period. Optimization was facilitated by a Nursing Informaticist (NI). The NI met with the lactation consultants to identify the lactation consultants' perception of documentation requirements and to engage them in the design process. The NI shadowed three lactation consultants during this time to observe their workflow and documentation. The NI also met with outpatient providers to develop an understanding of their requirements for accessing lactation information. The NI designed the optimized assessment using a tool that was part of the EHR application and allowed users to view the new assessment in a form that mirrored the electronic screens within the application. Screen shots were reviewed by the lactation consultants and changes were made based on user input until the users expressed satisfaction with the design and indicated that all requirements for documentation were met. The NI then coordinated with a technical analyst who built the assessment in the application's test environment. Once the assessment was live in the test environment, the users tested the assessment within the electronic system. No further changes were made at this time because users expressed satisfaction with the design. The test assessment then went through the organization's processes for testing prior to implementation in the live environment. This process took approximately one month. No further changes were indicated.

Dependent Variables

The dependent variables were information quality, use, and user satisfaction. Information quality was conceptually defined as the "desirable characteristics of the system outputs" (Petter,

DeLone & McLean, 2008, p. 239). Examples include completeness, accuracy, relevance and usability. DeLone and McLean (2003) do not further define usability; however, a well-accepted definition of usability is efficiency, effectiveness and user satisfaction with an application (Schumacher & Lowry, 2010). Information quality was operationally defined by the proportion of lactation assessments containing recommendations or plans, the proportion of lactation assessments indicating that patients were educated on the risks and benefits of formula, a required component of *Baby Friendly* education, and by the level of agreement users indicated with survey statements addressing completeness, accessibility, accuracy, relevance, availability and acceptability of the electronic lactation assessment. There is moderate to strong support for the causal relationship between information quality and user satisfaction, and there is insufficient data to support the causal relationship between information quality and use (Petter et al., 2008).

Use was conceptually defined as how users "utilize the capabilities of the information system" (Petter et al., 2008, p. 239). Examples include amount of use and frequency of use. Use was operationally defined as the number of completed lactation assessments accessed by users within the EHR and as the reported frequency of accessing the EHR for lactation information. There is moderate to strong support for the causal relationship between use and net benefits, and there is insufficient data to support the proposed relationship between use and user satisfaction (Petter et al., 2008).

User satisfaction was conceptually defined as the level of satisfaction with HIT products (Petter et al., 2008). User satisfaction was operationally defined as the level of agreement with survey statements addressing the impact of the electronic lactation information on quality of care, ease of job, and ability to share patient information amongst healthcare team members.

There is moderate to strong support for the causal relationship between user satisfaction and use and between user satisfaction and net benefits (Petter et al., 2008).

Confounding Variables

Confounding variables pose a risk to internal validity in quasi experimental studies (Harris et al., 2006). The interdependent relationships proposed in the IS Success Model (DeLone & McLean, 2003) that are not included as dependent variables in the conceptual model were considered to be possible confounding variables. These included system quality and service quality. System quality was conceptually defined as desirable characteristics of the system itself such as how easy it is it to use the application as a whole, how the application fits into the user's workflow or how intuitive it is (Petter et al., 2008). Two components of system quality were measured by the survey instrument. These were ease of use and integration with workflow, and were operationalized by level of agreement with survey statements addressing ease of use, integration with workflow.

Service quality, is conceptually defined as the level of support users receive from the organization. Service quality was expected to remain constant throughout the study period and was not operationally defined. There is strong support for the effect of system quality on user satisfaction, mixed support for the effect of system quality on use and service quality on user satisfaction and insufficient data on the effect of service quality on use (Petter et al., 2008).

Booth (2012) identified additional recommendations for variables that may increase generalizability of studies including the type of technology, nurse demographics and patient populations. None of these variables were anticipated to change during the study period.

Demographic data on the study sample was collected including profession, length of experience at the organization, and patient population cared for by the participant.

Data Collection Instruments

Data was collected from completed surveys, chart audits and a use query. Survey data included user demographics, self-reported use, and user's perception of system quality, user satisfaction and information quality. Chart audits gathered data on information quality of lactation assessments (see Appendix B). Use query data was the number of lactation assessments accessed by users pre and post discharge as a measure of use. An explanation of variables is given previously (see Dependent variables and Confounding variables).

Survey. The survey (see Appendix B) was modified from the Canada Health Infoway's *System and Use Assessment Survey*, publically available from the Agency for Healthcare Research and quality (AHRQ) *Health IT Survey Compendium* (AHRQ, n.d.). The *System and Use Assessment Survey* is a questionnaire focusing on satisfaction and components of usability appropriate for use across the health care system and for evaluation studies that include the EHR (AHRQ, n.d.). The survey was developed as an evaluation tool to measure components of the *Infoway Benefits Evaluation Framework*, which is closely based on the DeLone and McLean IS Success model (Canada Health Infoway, 2012). Dimensions addressed by the survey are system, information and service quality, self-reported use and user satisfaction. Survey questions were developed by evaluation of Subject Matter Experts and the organization's evaluation team (Canada Health Infoway, n.d. Benefits Evaluation Survey Process). The survey consisted of five point Likert-type response formats with answers ranging from strongly agree to strongly disagree.

The *System and Use Assessment Survey* was modified for use in this study. Some questions that did not pertain to the current study were eliminated and some verbiage was changed to include the specific assessment evaluated. Questions on *use* were added by the researcher. Permission for use of the survey in a modified form was received from the developers (see Appendix C).

Although reliability and validity of the instrument were not addressed in publically available documents, several published studies have referenced the study in whole or modified format including an evaluation study on the use of an EHR by Canadian physicians in clinic care (Paterson et al., 2010), a study on the use of technology to conduct a delirium assessment by family members of patients with dementia living in the community which modified the instrument (Steis et al., 2012), and a study on the use of the EHR in hospital settings which used the questionnaire in a modified version (Bah et al.2011).

Face validity was defined by persons with subject matter expertise. For this study, the modified survey was distributed electronically to experts with clinical, informatics or academic expertise. Suggestions for further modification were incorporated into the final version of the survey.

The survey was converted to an electronic format and hosted on the organization's account with SurveyMonkey, Inc. A link to the survey was generated and was contained in the email invitation to prospective participants. The survey was closed after the four week period. An identical survey with a new link was generated for the post-intervention survey. The survey was labeled internally as "post lactation survey" to help keep the data from the two surveys

separate; however, the name seen by participants was identical on both the pre-test and post-intervention surveys.

Survey data was collected at either the nominal or ordinal level. Demographic data was nominal and was evaluated using descriptive statistics including frequencies and percentages. Responses to questions were designed at the ordinal level and were presented on a five point scale ranging from strongly disagree to strongly agree or from never to often, depending on the question. Responses were assigned a value from 1 to 5, with the lowest values given to strongly disagree and to never. Data were evaluated with descriptive statistical tests resulting in frequencies, percentages, medians, and variances. Comparison between groups on ordinal data was analyzed with the nonparametric Mann Whitney U test.

Use query. The use query was an electronic query that counted the number of completed lactation assessments accessed from the EHR during the specified time frame. Use was operationally defined as accessing the information within the electronic lactation assessment. The query identified all patients by medical record number (MRN) with an electronic lactation assessment documented in the EHR. The query identified if the electronic assessment had been accessed and, if so, the date and time of the last access. The query was then limited to the six week period for both the pre and post groups and to patients identified for the sample by meeting the inclusion criteria. More patients than just the ones in the sample had lactation documentation in the EHR, because lactation consultants also evaluated and treated patients without a consult order placed on the patient; consequently, the need to limit the query to just those in the sample.

Reliability of the query was tested by comparing two patients identified on each period's query as positive for post discharge access of the electronic assessment form with a second

report that listed all electronic documents accessed within a patient's record. The second report was scanned for the presence of the lactation assessment. Both patients from each study period showed that the lactation assessment was an accessed document in the second report.

Use query data was at the nominal level. Descriptive statistics were used to report frequencies and percentages of access both prior to discharge and post discharge. Fisher's exact test was used to analyze differences between groups.

Chart audit. Chart audits were conducted on all patients in the pre and post intervention samples. Chart audits measured information quality of the lactation assessment documentation. information quality was operationally defined as completeness of information documented in the lactation assessment. Completeness was measured by either the presence of a specific educational requirement of *Baby Friendly*, that the risk and benefits of formula be explained, or by inclusion of a lactation plan or recommendation. Lactation consultants had identified that improving the ability to audit for the presence of *Baby Friendly* patient education requirements was a goal after optimization; thus whether this was present in the documentation was considered a measure of information quality. In the same way, a goal of optimization was to increase the visibility of the lactation plan within the documentation so that when other members of the care team needed this information, it would be easily located within the EHR. A measure of information quality was the presence of a plan within the electronic assessment.

Pre-test charts were audited for free-text stating that the risks and benefits of formula were explained to the mother. The words "risks and benefits of formula" had to be present to meet the measure. Plans were identified in pre-test charts if there was free-text indicating instructions for ongoing management of breastfeeding.

Post-test charts had discrete data fields that collected both pieces of information. Users had to check the element within the education section that stated, "Risks and benefits of formula were explained" to meet the measure. To meet the measure for presence of plan or recommendations, users had to either have selected a discrete data element within the recommendations section of the assessment or to have entered free text in the area of the assessment labeled "Lactation Plan/Recommendations."

All chart audits were performed by the principal investigator (PI). The PI is a registered nurse with thirty years of perinatal nursing experience and extensive knowledge of lactation, post-partum, and newborn nursing care. Chart audit data was collected at the nominal level. Descriptive statistics were used to report frequencies and percentages for both completeness of required education documentation and presence of a lactation plan or recommendations. Fisher's exact test was used to analyze differences between groups.

Recruitment

The chart audit population was recruited during the first two weeks of each six week study period. Participants were identified by an electronic report of all patients meeting the inclusion criteria during this time period. IRB approval was received for a full waiver of consent for the chart audit participants.

Survey participants were recruited via emails sent two weeks into each six week study period. An email from the PI was sent to organizational email list serves for general pediatrics (inpatient and ambulatory care providers/clinicians), certified nurse midwives, and clinicians working on the Mom/Baby couplet care and Neonatal Intensive Care Unit (NICU) units. The email explained the purpose of the study, an invitation to participate in the study by completing

an online survey, and the estimated time requirement for survey completion. In addition the email indicated that the survey did not collect personal, identifying information and that participation was voluntary. The timeline for survey completion, four weeks from the time of the initial email, was provided. A second identical email was sent two weeks into the four week survey timeline to the same population. Survey participants self-selected themselves for the study by opening the survey link and consenting to participate, affirming that they provided care to breastfeeding mothers or infants, and affirming that they use the EHR to either document or review patient information. If survey participants indicated that they did not consent, did not provide care to breastfeeding patients or did not access the EHR, then the survey ended and these participants were excluded from the final sample.

Power analysis. A power analysis for sample size was conducted using a statistical calculator (Power and Precision, v.4) (Borenstein, Rothstein & Cohen, 2001). Effect size was anticipated to be small and was set at 0.2 (Cohen's d). Desired statistical power level was set at 0.8. Probability level (alpha) was set at 0.05. The minimum total sample size for a one tail hypothesis was 620 total, or 310 per group.

Sample size. The survey link was sent electronically to email lists consisting of email addresses for 319 employees within the general pediatrics division, the certified nurse midwives group, and the Neonatal Intensive Care and Mom/Baby nursing units. The convenience sample consisted of the respondents to the survey. The pre-test survey had 65 responses and the post-intervention survey 37 responses. Five surveys were removed from the pre-test data set and five survey were removed from the post data set because the participant had not completed the consent question or one of the two excluding questions addressing use of the EHR and provision

of care to breastfeeding newborns. The final sample sizes were N=60 for the pre-test group and N=32 for the post intervention group.

During the two week chart audit recruitment periods, a total of 116 newborns were admitted to the Mom/Baby unit during the pre-test period and 127 during the post-intervention period. The initial sample for the pre-test group was 44; however, four patients with lactation consult orders had no lactation documentation in the EHR so they were excluded resulting in a final sample size of N=39 for the pre-test period. The post intervention group initially had 53 patients; however, nine patients had no lactation documentation in the EHR and four patients were identified by the order report; however, upon further examination, the order was noted to have been placed outside of the two week study period so these patients were excluded resulting in a final sample size of N=39 for the post-test period.

Sample description. Characteristics of the pre-test and post-test survey participants are contained in Table 4. Information was collected from demographic questions within the survey instrument. Data was categorical and reported as frequencies and percentages. The pre-test sample (N=60) was 70% (n=42) nursing staff and 30% (n=18) provider staff; whereas, the post-test sample (N=32) was 58% (n=18) nursing staff and 42% (n=14) provider staff. The percentages for patient types which received care from participants was consistent across both groups. The post-intervention group had a higher percentage (6%, n=2) of participants employed less than six months at the organization than did the pre-test (3%, n=2). Patterns of EHR use was fairly consistent in the percentages of participants indicating that they only reviewed patient information in the EHR (15%, n=9 pre-test; 16%, n=5 post-intervention). The pre-test group did have four respondents (7%) who indicated that the EHR was only used to document information,

whereas the post-intervention group had no participants indicate they used the EHR for documentation only.

Table 4

Survey Participant Characteristics

Characteristic	Pre		Post	
	N=60	%	N=32	%
Role				
Nurse/Other	42	70	18	58
Provider	18	30	14	42
Patient Type				
Breastfeeding Infant	25	42	13	41
Breastfeeding Mother	6	10	4	13
Both Infant and Mother	29	48	15	47
Length of Employment at Organization				
< 6 mos.	2	3	2	6
6 mos. - 1 year	7	12	4	13
1 - 3 years	9	15	5	16
> 3 years	42	70	21	66
Pattern of EHR Use				
Review patient info only	9	15	5	16
Document patient info only	4	7	0	0
Both review and document	47	78	27	84

The chart audit and use query population was described as infants or mothers and reported as frequency and percentage. Orders may be placed on either the mother or the infant. Lactation consultants document on both the mother and the infant regardless on whom the order was placed. The post study had a higher percentage of orders placed on the mother (28%, n=11)

than the pre study (18%, n=7). The frequency and percentage of maternal and infant patients in the pre and post study populations are detailed in Table 5.

Table 5

Chart Audit/Use Query Patient Characteristics

	Pre N=39		Post N=39	
Consult orders placed on the:	n	%	n	%
Mother	7	18	11	28
Infant	32	82	28	72

Implementation

The intervention was implemented during the routine monthly EHR change time. Education to end users of the change was provided through the organization's usual method of emailing out an attachment produced by the instructional design department that detailed EHR changes and alerted users by role to those changes which would impact them. In addition, a nursing informaticist met with outpatient providers and staff during monthly staff meetings in the two months following implementation to educate staff on how to access inpatient lactation information from EDM. Huddle sheets specific to the lactation assessment changes within the EHR were provided one week prior to implementation and on the day of implementation to inpatient nursing units and to inpatient providers. Huddle sheets were used by the organization's to facilitate verbal updates to clinicians daily on new information impacting their workflow. The information would be shared by a charge nurse with nursing staff during specified times during the shift. After the verbal update, the huddle sheet provided a visible reminder of the new information.

Data Analysis Protocol

Data collection protocol. All survey data was collected retrospectively after the completion of the study. SurveyMonkey, Inc. data for each period's survey was exported from the website in electronic spreadsheets. The spreadsheets included raw data from all participants for each period. SurveyMonkey, Inc. had recorded the IPN for each participant; however, this was immediately deleted after the data was retrieved. Chart audit data was collected during the four weeks following each period and stored on an electronic spreadsheet. The use query was run retrospectively on each group after the conclusion of the study. Data was retrieved on an electronic spreadsheet and stored in the password protected PHI folder on the organization's server. Prior to conducting statistical analysis, data was transferred from the electronic spreadsheets into IBM's SPSS (v.23) statistical software. Data was entered on three SPSS spreadsheets, one for survey data, one for chart audit data, and one for use query data. Within each spreadsheet, the data's study period was identified as a variable. Nominal data was coded with numerals one and two. Ordinal data was codes with numerals one through five. After data was entered into SPSS spreadsheets, data was visually compared with the original electronic spreadsheets to verify accuracy.

Missing data. As a first step in data analysis, SPSS spreadsheets were reviewed for missing data. If survey questions that would have excluded the participant from the sample were not answered, the results from that respondent were purged from the data set. Otherwise, missing survey data was allowed to remain in the dataset. Missing datum for individual survey questions ranged from one to seven for the pre-test period (N=60) and from one to five for the post intervention period (N=32). Percentages were calculated using the adjusted, valid sample

size for each measure. There was no missing demographic data. For the chart review, if there was no lactation documentation in the chart, that chart was excluded from the chart audit sample and the use query sample. For the pre-test period (N=39), four charts were excluded and for the post-test period (N=39), nine charts were excluded for lack of documentation. The use query resulted in no missing data.

Data analysis. As a next step in data analysis, each dataset was split into pre-test and post-test groups using the data split functionality in SPSS. Data for each group was analyzed using SPSS's descriptive statistical tests. Results included total sample size, number of missing data per item, frequencies, percentages calculated from both N (percent) and n (valid percent). For ordinal date, median, variance and cumulative percent were also included.

Additional nonparametric statistical tests were run using SPSS software based on the measurement plan. Chi-square tests were run using the SPSS Crosstabs analysis. Fisher's exact test on nominal data from the pre-test and post-test chart audit and use query was used to report findings. SPSS was used to calculate phi (φ) as a measure of the strength of association between the variables. Effect size for phi was considered small if 0.10, medium if 0.30 and large if 0.50 (Nandy, 2012).

The SPSS legacy version of the non-parametric Mann-Whitney U test was run for analysis of pre-test and post-test ordinal data from the survey. Effect size (r) was calculated manually using the formula $r=Z/\sqrt{n1+n2}$ and the absolute value was reported (Yatani, 2014). Effect size was determined to be small if 0.1, medium if 0.3, and large if 0.5 (Nandy, 2012;

Yatani, 2014). The pre-test and post-test survey groups were then further divided by role and all statistical analysis was repeated for the provider group and the nursing group.

Project Findings and Results

The project objectives measured the effectiveness of optimization of electronic documentation forms with user centered design to increase determinants of IS success. These determinants were identified as information quality, use and user satisfaction. In addition, the survey measured a confounding variable, system quality.

Objective 1: Increase Information Quality

Information quality was measured by chart audit and by user survey. Survey responses assessed user perceptions of completeness, accessibility, accuracy, relevance, availability, and acceptability of information within the electronic lactation assessment. Median scores for all participants by pre-test and post-test samples are listed in Table 6. Medians for information quality ranged from 2.5 - 4 on the 5 point scale. All medians either increased or stayed the same from pre-test to post-test except for Available (pre $\tilde{X}$= 4; post $\tilde{X}$= 3) in the overall group and Quickly Accessed (pre $\tilde{X}$= 3; post $\tilde{X}$= 2.5) in the provider group. When medians are the same between pre-test and post-test groups, the cumulative percent at the median can give an indication of the direction of movement. A lower cumulative percent indicates that more respondents answered positively compared to the same median with a higher cumulative percent. With the exception of Available for all groups and Accessible for the provider group, all measures of information quality for which the pre-test and post-test medians were the same had a lower cumulative percent in the post-test group indicating that the movement for these indicators was positive.

Table 6

Information Quality: Medians and Cumulative Percent at the Median Pre and Post

	Provider				Nurse				All			
	Pre		*Post*		*Pre*		*Post*		*Pre*		*Post*	
Parameter	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*
Complete	3	81.3	3	66.7	4	89.5	4	68.8	3	53.7	4	78.6
Quickly Accessed	3	87.5	2.5	83.3	4	83.8	4	58.8	3	58.5	3	51.7
Accurate	3	75.0	3	66.7	4	73.7	4	52.9	3.5	64.8	4	65.5
Relevant	3	75.0	3	54.5	4	73.7	4	64.7	4	77.8	4	71.4
Available	3	81.3	3	83.3	4	76.3	4	76.5	4	83.3	3	55.2
Acceptable format and layout	3	87.5	3	100	3	52.6	4	70.6	3	63.0	3	57.1

Note: $\tilde{X}$*= Median; % = Cumulative Percent at the Median*

*When the median is the same in the pre-test and post-test groups, the cumulative percent gives information on the percent of respondents answering at or below the median. The lower the cumulative percent, the higher the number of respondents answering more positively, or greater than, the median.

In the pre-test and post-test samples overall, considering all participants, a Mann-Whitney *U* test determined there was no significant (p = .107-.831) differences between the pre-test and post-test samples for any qualifier of information quality. When the groups were divided by role, however, nurses had a statistically significantly higher perception of Completeness post-test (mean rank = 34) than pre-test (mean rank = 24.8), U = 200, z = -2.11, p = .035, r = .029. The provider group did not have any significant differences between pre-test and post-test groups for information quality (see Table 7).

Information quality was also measured by the chart audit (see Table 8). Lactation plans were present on 59% (n = 23) of pre intervention charts (N = 39) and 92% (n = 36) of post intervention charts (N = 39). Required documentation was a second measure of information quality and was measured in the chart audit. Three pre-test charts (8%) had the required education elements compared to 10 post-test charts (26%). Fisher's exact two tailed test found

Table 7

Information Quality Survey Results: Pre and Post. All Respondent Divided by Role

Parameter	Pre			Post			*U*	*Z*	*p*	*r*
	n	$\tilde{X}$ *(var)*	Mean Rank	n	$\tilde{X}$ *(var)*	Mean Rank				
All Respondents										
Complete	54	3(1.0)	38.6	28	4(0.8)	47.1	600	-1.61	.107	0.19
Quickly Accessed	53	3(1.6)	41.1	29	3(3.4)	42.2	747	-.210	.831	0.02
Accurate	54	3.5(0.9)	39.7	29	4(1.0)	46.4	657	-1.27	.203	0.14
Relevant	54	4(0.9)	39.7	28	4(0.8)	45.0	658	-1.01	.312	0.11
Available	54	4(1.1)	44.0	29	3(1.2)	38.3	677	-1.06	.289	0.12
Acceptable format and layout	54	3(1.3)	41.0	29	3(1.5)	42.6	725	-.314	.754	0.03
Nursing										
Complete	38	4 (1.2)	24.8	16	4 (0.7)	34.0	200	-2.11	.035	0.29
Quickly Accessed	37	4 (1.5)	25.7	17	4 (2.2)	31.5	247	-1.30	.193	0.18
Accurate	38	4 (1.1)	25.6	17	4 (0.8)	33.4	232	-1.75	.081	0.24
Relevant	38	4 (1.0)	26.6	17	4 (0.7)	31.2	270	-1.04	.301	0.14
Available	38	4 (1.2)	28.5	17	4 (1.4)	26.8	303	-0.40	.692	0.05
Acceptable format and layout	38	3 (1.6)	26.0	17	4 (1.6)	32.4	249	-1.39	.164	0.19
Providers										
Complete	16	3(0.7)	13.7	12	3(0.6)	15.6	83	-0.71	.568	0.13
Quickly Accessed	16	3(1.5)	15.1	12	2.5(1.5)	13.8	87	-0.45	.698	0.08
Accurate	16	3(0.4)	14.3	12	3(0.8)	14.9	92	-0.23	.873	0.04
Relevant	16	3(0.6)	13.1	11	3(0.9)	15.3	74	-0.78	.512	0.15
Available	16	3(0.5)	15.2	12	3(0.7)	13.6	85	-0.60	.631	0.11
Acceptable format and layout	16	3(0.7)	15.4	11	3(0.5)	12.0	66	-1.30	.294	0.25

that lactation plans were significantly more likely to be present in the EHR post-test (χ^2 [1, N = 39] = 11.8, p =.001, φ= .39). Although not reaching a level of significance (p<.05), a two tailed Fisher exact test found completeness of required documentation was close to significance in the post-test (χ^2 [1, N = 39] = 4.5, p = .065, φ = .24).

Table 8

Frequency Distribution of Information Quality and Use

	Pre N=39		Post N=39				*p*	Fishers Exact Test	
Parameter	f	%	f	%	*X2*	*df*	*(2 tail)*	2 tail	1 tail
Information Quality									
Lactation Plan/ Recommendations	23	59	36	92	11.8	1	.001	.001	.001
Required Education Documentation	3	8	10	26	4.5	1	.033	.065	.033
Use (Last Access)									
Accessed from EHR	35	88	39	100	4.2	1	.04	.115	.058
Post Discharge	6	15	6	15	*No change from pre to post*				

Objective 2: Increase Use

Use of the electronic lactation assessment as a way of providing information was measured by user reported frequency of accessing the EHR to view lactation information. Survey participants were also asked their frequency of accessing lactation information at all and from a source apart from the EHR. The overall group had pre-test medians ranging from 2 – 4 with wide variances (2.1 – 2.3). Post-test medians were higher for both Accessing Information Outside of the EHR ($\tilde{X}$= 5, var = 1.9) and for Accessing Information from the EHR ($\tilde{X}$= 3, var = 1.5).

A Mann-Whitney *U* test found that there were no significant differences between the pre-test and post-test groups for all users in accessing lactation information from any source or from outside of the EHR (see Table 9). There was, however, a close to significant difference (*p* = .051) between the pre-test and post-test groups for reported frequency of accessing the EHR for

lactation information. When the analysis was done considering roles, the Mann-Whitney U test found that nurses in the post-test group reported a significantly higher frequency of accessing information within the EHR (U= 233, z = -2.01, p = .044, r = 0.26) as well as from any source outside of the EHR (U= 222, z = -2.33, p = .020, r = 0.31.

Table 9

Use Survey Results: Pre and Post. All Respondents Divided by Role

Parameter	Pre			Post			*U*	*Z*	*p*	*r*
	n	$\bar{X}$ *(var)*	Mean Rank	n	$\bar{X}$ *(var)*	Mean Rank				
All Respondents										
Any source	59	4(2.3)	43.1	31	4(1.3)	50.1	772	-1.26	.209	0.13
Outside of EHR	59	4(2.2)	44.2	31	5(1.9)	48.0	836	-0.70	.482	0.07
Within EHR	59	2(2.1)	41.7	31	3(1.5)	52.7	690	-1.95	.051	0.21
Nursing										
Any source	41	4 (2.1)	28.6	17	4 (0.9)	31.6	313	-0.65	.518	0.09
Outside of EHR	41	4 (1.6)	26.4	17	5 (0.6)	36.9	222	-2.33	.020	0.31
Within EHR	41	3(2.1)	26.7	17	4 (1.4)	36.2	233	-2.01	.044	0.26
Provider										
Any source	18	2.5(2.4)	14.2	14	4(1.8)	19.4	85	-1.59	-.125	0.28
Outside of EHR	18	4(3.5)	17.1	14	3(2.2)	15.7	115	-0.43	.694	0.08
Within EHR	18	1(1.6)	14.1	14	2(1.0)	19.6	83	-1.74	.099	0.31

Use was also measured as the proportion of charts in which the completed electronic lactation assessment documentation was accessed. Proportions were reported for any access at all and for accesses post discharge. Prior to the intervention, the use query showed that 88% (n = 35) of electronic assessments were accessed at all and 15% (n = 6) were accessed after discharge. In the post intervention group, 100% (n = 39) of electronic assessments were accessed prior to discharge and 15% (n = 6) after discharge (see Table 8). A crosstabs analysis to test for

significant differences between the number of charts accessed at all in the pre-test and post-test groups was run using Fisher's exact two tailed test (χ^2 [1, N = 39] = 4.2, p = .115, φ = .04). A crosstabs analysis was not done on the number of post discharge accesses because the groups were equal (n = 6).

Objective 3: Increase User Satisfaction

User satisfaction was measured as the reported agreement with survey statements about the impact of the lactation assessment on quality of care, job ease, and ability to share information with the healthcare team. For the overall group and provider group medians for

Table 10

User Satisfaction: Medians and Cumulative Percent at the Median Pre and Post

	Provider				Nurse				All			
	Pre		*Post*		*Pre*		*Post*		*Pre*		*Post*	
Parameter	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*	$\tilde{X}$	%*
Quality of care	3	81.3	3	63.6	3	56.8	4	81.3	3	64.2	3	51.9
Ease of work	3	87.5	3	63.6	2	52.6	3	58.8	3	74.1	3	60.7
Sharing of information	3	80	3	72.7	3	52.6	4	82.4	3	60.4	4	89.3

Note: *$\tilde{X}$ = Median; % = Cumulative Percent at the Median*

*When the median is the same in the pre-test and post-test groups, the cumulative percent gives information on the percent of respondents answering at or below the median. The lower the cumulative percent, the higher the number of respondents answering more positively, or greater than, the median.

quality of care ($\tilde{X}$ = 3 pre and post) and ease of work ($\tilde{X}$ = 3, pre and post) did not change between the pre-test and post-test groups; however, the cumulative percent did decrease indicating movement of scores in the positive direction from pre to post (see Table 10) The medians for Sharing of Information increased in the overall group and nursing group (pre $\tilde{X}$ = 3, post $\tilde{X}$ = 4). For the provider group, the median for Sharing of Information was unchanged, but

the cumulative percent decreased from pre to post). The nursing group also showed increases in medians from pre to post for Quality of Care (pre $\tilde{X}$= 3; post $\tilde{X}$= 4) and Ease of Work (pre $\tilde{X}$= 2; post $\tilde{X}$= 3).

Table 11

User Satisfaction Survey Results: Pre and Post. All Respondent Divided by Role

	Pre			Post						
	n	$\tilde{X}$ *(var)*	Mean Rank	n	$\tilde{X}$ *(var)*	Mean Rank	*U*	*Z*	*p*	*r*
All respondents										
Quality of care	53	3(1.3)	38.5	27	3(1.2)	44.4	612	-1.10	.274	-0.12
Ease of work	54	3(1.4)	38.1	28	3(1.0)	48.1	572	-1.86	.063	-0.21
Sharing of information	53	3(1.3)	38.6	28	4(0.9)	45.5	616	-1.31	.191	-0.15
Nursing										
Quality of care	37	3 (1.6)	26.4	16	4 (1.7)	28.5	261	-1.18	.638	-0.16
Ease of work	38	2 (1.7)	26.4	17	3 (1.2)	31.7	223	-1.79	.238	-0.24
Sharing of information	38	3 (1.4)	25.5	17	4 (0.8)	33.5	261	-1.18	.074	-0.16
Providers										
Quality of care	16	3(0.7)	12.5	11	3(0.5)	16.2	64	-1.42	.251	-0.27
Ease of work	16	3(0.9)	12.1	11	3(0.7)	16.8	58	-1.70	.134	-0.33
Sharing of information	15	3(1.1)	13.7	11	3(0.8)	13.7	80	-0.15	.919	-0.03

A Mann-Whitney U test was run on measures of user satisfaction to test for statistically significant differences between pre and post groups. No significant differences between pre-test and post-test were found for any measure or in any group (see Table 11).

System Quality

System quality is an attribute of IS success and has been found to be correlated with user satisfaction (Petter, Delone, & McLean, 2008). In this study, system quality was identified as a confounding variable. System quality was measured with the survey instrument through user's

level of agreement with statements addressing ease of use and integration with workflow. Medians ranged from 2 – 4 for all measures and all groups.

There were no significant differences between pre-test and post-test groups for any indicator of system quality for the all participant group or for the provider group. A Mann-Whitney U test did find that nurses reported a significant (p = .022) difference between the pre-test and post-test for ease of use, $U = 201$, $z = -2.29$, $p = 0.22$, $r = 0.32$ (see Table 12).

Table 12

System Quality Survey Results: Pre and Post. All Respondents Divided by Role

	Pre			Post						
	n	$\bar{X}$ *(var)*	Mean Rank	n	$\bar{X}$ *(var)*	Mean Rank	*U*	*Z*	*p*	*r*
All Respondents										
Ease of use	54	3(1.0)	39.3	28	4(1.3)	49.8	635	-1.23	.220	0.14
Integration with workflow	54	3(1.7)	41.9	28	4(2.0)	40.8	735	-0.21	.834	0.02
Nursing										
Ease of use	38	4(1.7)	24.8	17	4(1.0)	35.1	201	-2.29	.022	0.31
Integration with workflow	38	3(1.9)	26.3	17	4 (2.0)	31.8	259	-1.21	.227	0.16
Provider										
Ease of use	16	3(0.6)	14.6	11	3(0.6)	13.1	78	-0.64	.645	0.12
Integration with workflow	16	3(1.3)	16.2	11	3(0.9)	10.8	53	-1.90	.080	0.37

Reliability and Validity of Findings

Several threats to reliability and validity of results are identified. These threats primarily arise from the methodology of the study and sampling.

Methodology. In the timeline of the study, the survey period overlapped the use query period. Use was operationalized as electronically accessing information documented on the

lactation assessment. Exposure to the survey may have encouraged users to access electronic lactation information. If users were prompted by the survey to increase their access of the EHR for lactation information, then findings from the use query may demonstrate higher use rates than had the design not had this overlap, potentially leading to a Type 1 error. To reduce the possibility of error, the survey period could come after the chart audit and use query are complete.

A second threat to reliability of results based on methodology was that the intervention may not have been implemented in a way that every participant received the same exposure. When the implementation is delivered differently to participants in the study, then there is a lack of intervention fidelity (Polit & Beck, 2012). Although the protocol included training users, there was no standardization of training, no measurement of who did or did not receive training, and no measurement of level of understanding. If users were not exposed to the intervention, then answers to the post-test survey would not reflect their interaction with the optimized form potentially causing a Type II error. To reduce this threat to reliability, the protocol could have included a post-test measure of the participant's exposure to the intervention and understanding of how to access the intervention.

Sample. The pre-test and post-test survey samples were recruited from the same population but were assumed to be independent groups. The Mann-Whitney U test assumes that the samples are independent and without duplication (Laerd, n.d.). A threat to the reliability of the results was that some of the participants in the pre-test may have also been represented in the post-test sample. If participants from the pre-test were represented in the post-test, then the data would not have met the assumptions for the Mann-Whitney U test. An alternative non-

parametric test was considered, the Wilcoxon signed-rank test. The Wilcoxon signed-rank test is a nonparametric test that is the equivalent to the paired-samples t-test and compares dependent samples of paired or matched observations (Laerd, n.d.). The samples can be the same participants or can be matched on a characteristic (Laerd, n.d.). Because the sample size of the second group was half the size of the sample size of the first group, and because it was unknown if any of the participants were duplicated in the two samples, the Wilcoxon would have had similar threats to the reliability of the findings. To reduce this threat to reliability, the research design could either identify a dependent sample for before and after testing; or include an identifier in the survey to eliminate participants from the second sample who had participated in the first.

A second threat to reliability from sampling is the low sample size which did not reach power. When sample size does not reach power, then the relationship between the independent and dependent variables may be found statistically insignificant when there is, in fact, a significant relationship that was not measured because of small sample size (Polit & Beck, 2012). Unpowered sample size also reduces the generalizability of the findings (Polit & Beck, 2012).

Although online surveying as a data collection tool is convenient, selection bias may lead to threats to the reliability of findings. Self-selected survey samples may not represent the overall population (Khazaal et al., 2014). Bias resulting from self-selection may also impact generalizability of findings (Cusack et al., 2009; Eysenbach & Wyatt, 2002).

Discussion

What makes an HIT implementation successful? For clinicians, HIT success is achieved when the application supports workflows, allowing effective and complete documentation of information and efficient communication of information (Ammenwerth, Mansmann, et al., 2003; De Veer, Fleuren, Bekkema & Francke, 2011). Based on the conceptual model for this study, improved information quality would lead to increased user satisfaction which would result in increased use. The vehicle for improving information quality was the UCD process, which engaged end users in the design process. By engaging users in the design, the result would be a product which satisfied users, both those entering information as well as those reviewing information. Satisfied users would continue to use the application. With increased use, clinicians would have more complete information, documented by lactation consultants, to inform care provided to breastfeeding mothers and infants.

When survey participants were considered as a whole, this study did not find any statistical differences between pre-test and post-test groups on any determinants of IS Success. When survey participants were divided by role, this study did find significant differences for two measures of information quality and one measure of information use.

Nurses in the post-test sample had a significantly higher perception of completeness of the lactation assessment, a measure of information quality. Furthermore, the post-test chart review showed a statistically significant increase in the presence of lactation assessments, a second measure of information quality and completeness. Finally, nurses in the post-test sample indicated a significantly higher frequency of accessing the lactation assessment from the EHR, a measure of use. Although no statistically significant differences between pre-test and post-test were found on measures of user satisfaction, every measure of user satisfaction for every group

(overall, providers, and nurses) showed either an increase in the median or a decrease in the cumulative percent at the median, if the median was unchanged, indicating more positivity in responses post-test.

The differences in findings for measures of information quality between the two groups, nursing and providers, may be related to the differences between their use of the Soarian Clinicals application. Electronic lactation assessments are entered into Soarian Clinicals by the lactation consultant. Nurses use Soarian Clinicals to both document and review information. Because of their familiarity with the application and because it is within this application where they do their own documentation, nurses may be more comfortable than providers using Soarian Clinicals to review information, including the lactation assessment.

Providers could access information entered into Soarian Clinicals in either of two ways. They have access to Soarian Clinicals and use this application to review vital signs, medications, and notes. They also enter CPOE (computerized physician order entry) orders into Soarian Clinicals. Accessing assessment data is possible, however providers may not be familiar with navigating the application to access information entered by other clinicians.

A second method providers could use to access lactation information is within the electronic data management system, EDM, which is used as the legal medical record. All paper forms completed during the inpatient stay are scanned into EDM, and providers do routinely access EDM during newborn outpatient provider visits for the scanned copy of the form containing the newborn's admission and discharge exam. All electronic documentation from Soarian Clinicals is also converted into forms that are accessible in EDM.

A provider was consulted during the UCD process to identify which information from the lactation assessment was most important to providers. Documentation fields that captured this information were positioned in the electronic assessment so that, when converted to EDM, the information would be found at the top of the EDM form when reviewed by the provider. Although providers do access EDM for scanned inpatient paper forms, they may not know that assessment information documented within Soarian Clinicals is also available in EDM. Two providers wrote comments on the post-test survey indicating that they did not know how to access lactation information within EDM.

Each user group reported an increased frequency of finding lactation information within the EHR from pre-test to post-test. The median value for this measure increased by a value of one for each group, although, as previously discussed, the difference from pre to post was only significant for the nursing group. For providers, the pre-test median ($\tilde{X} = 1$) corresponded to a value of never, and the post-test median ($\tilde{X} = 2$) corresponds to rarely. If providers routinely did not access the EHR for lactation information, even post-test, then the survey would not accurately reflect their perceptions of information quality of the electronic assessment or their degree of satisfaction with the lactation assessment. Providers were given education on how to access lactation assessments from EDM post implementation; however, the effectiveness of that education was not measured.

Overall, providers gave more negative scores than nurses for every measure of IS Success except Ease of Work, as measured by median or the cumulative percentage at the median when medians were equal. Because providers were unfamiliar with the EHR application, their lower scores overall may have been indicative of their lack of knowledge on how to use the application

to find information within the EHR application rather than their frequency of use, perception of information quality or their satisfaction with either the information or the system.

It is important to note that nurses, which include the role of lactation consultant, did access the application to both enter and review documentation, and had a significantly higher perception of completeness post-test, as measured on the survey. In addition, the chart audit results, measuring the presence of lactation plans/recommendations and required education within the electronic assessment, also had a significant increase in completeness of information post-test. The chart audit measure of completeness corresponds to entry of information, was the user able to enter all required information, whereas the perception of completeness on the survey corresponds to review of information, did the user find all the information needed. These findings may be point towards a degree of success in meeting the goal of optimizing the assessment to allow efficient and effective documentation as well as to provide users with efficient and effective review. If providers had accessed the lactation information, they may have also found that the information was more completed.

The optimized lactation assessment was designed to facilitate discrete documentation by creating checklists to capture lactation consultant recommendations and plans as well as required education topics. The checklist for recommendations and plans was compiled by the consultants to include the phrases they most frequently entered as free text into the previous assessment. The checklist for education topics included those topics that were required by *Baby Friendly* as well as other topics that the lactation consultants routinely taught. Because the optimized lactation assessment included an opportunity to discretely document education, it was somewhat surprising that the number of charts meeting the measure of required education documentation

was not higher. One reason for this may be that the statement chosen to operationalize this measure addressed both risks and benefits of formula. Although this is required education, lactation consultants may be hesitant to explain benefits of formula to their breastfeeding patients. Many charts had checkmarks by every topic in the education checklist except for *risks and benefits of formula*.

The use query was able to supply the date and time of electronic access of the assessment. Interestingly, for assessments that were accessed while the patient was still an inpatient, the time was often around change of shift, particularly the day to night shift change. This may indicate that nurses were reviewing lactation consultant plans prior to beginning their night shifts when the lactation consultants were not on site and when breastfeeding babies and mothers may face additional breastfeeding challenges. When the use query indicated a date and time post discharge, this was assumed to be by an outpatient clinician. The time was during the workday and on weekdays. Although no further analysis was done to see if the date and time of a post-discharge access to the electronic assessment corresponded to any outpatient documentation, either an office visit or phone call, this may be an area for further study. It would also be informative to implement structured education for providers on accessing electronically entered inpatient information through EDM and measure effect on use post discharge.

A goal of this project was to increase provider access to electronic lactation information by improving the overall design of the assessment so that important information, relevant to providers, would be easily located within the EDM documents accessible to providers. This was particularly challenging. Unlike applications where all clinicians access the same electronic

application to review all clinical information, at this organization, providers did not access clinical assessments within the electronic application where they were entered. Instead, this information was translated into a PDF document that was then stored in EDM. Providers accessed EDM routinely during the first newborn outpatient clinic visit to review am electronic copy of the paper form where the newborn's history and physical and discharge information was hand written during the inpatient stay. However, providers were not used to accessing the documents in EDM that converted electronically entered assessment information into a PDF document. This project was unable to overcome this limitation of the organization's overall dichotomy of electronic documentation that divides users by application.

Limitations, Recommendations, Implications for Change

If the EHR will serve as a patient safety and quality tool, then the EHR must be continuously adapted as new information is known (National Learning Consortium, 2013). Optimization is the process though which implemented EHRs are adjusted to better meet existing safety and/or quality initiatives. Optimization is also the process by which the EHR is configured to meet new safety and/or quality initiatives. It may be difficult for organizations that have invested a significant amount of resources in the implementation of the EHR to commit additional resources to continuous improvement of the EHR. McAlerney et al. (2010) found that the distinguishing factor between organizations with "good" EHR implementations and those with "great" EHR implementations was a focus on optimization (p. 45). This focus included the commitment to invest additional time and resources beyond implementation to allow the EHR to be used as a tool for quality improvement.

The conceptual model for this project theorized that if structures which impact IS success, such as information quality, are improved through a process such as User Centered Design, then user satisfaction with the application and processes, such as use of the application to obtain information, will increase. This will lead to achievement of long term outcomes and net benefits to the organization.

A long term outcome of this project was to support quality initiatives through the short term goal of increasing the success of the EHR to support users' needs for efficient and effective capturing and communicating lactation information. The significant findings that nurses did perceive information to be more complete, and that information within the assessment was measured as more complete, lend a degree of confirmation that optimization of the EHR, through a user centered process, may have long term benefits for patients by increasing clinician access to information. The findings of this study lend themselves to recommend future studies and suggest ways that the findings impact clinical practice.

Limitations. Several potential limitations of this study have been identified. Many of these were have been discussed previously as threats to the validity or reliability of the findings. Additional limitations of the study are that the complexity of the model and multiplicity of variables, both dependent and confounding, as well as the study design, limits the identification of correlational relationships between variables. The causal nature of the DeLone and McLean (2003) IS success model assumes that such relationships exist; however, the study design did not allow further confirmation.

A second limitation, previously identified, is that the size of the sample did not reach power thus limiting the generalizability of the findings. A third limitation was the ability of the

use query to identify information that would better inform objective use of the electronic assessment by identifying the role of the user accessing the assessment as well as the number of times the assessment was accessed. Without these additional pieces of information, the value of the use query was minimal.

The most significant limitation, however, as previously described, was the impact of the organization's three separate electronic applications: Soarian Clinicals, where inpatient clinicians other than providers documented patient information; EDM, which served as the legal medical record and contained all documentation, but did not present electronically documented information in a user-friendly view; and an outpatient application where outpatient clinical information was documented.

Recommendations. Despite the limitations of the findings, several recommendations arise from this study. For clinical users of electronic clinical documentation systems, the User Centered Design process, built on principles of usability, is a valuable process for ensuring that EHR applications meet the needs of users. Nursing Informaticists should follow UCD processes when implementing or optimizing electronic documentation forms.

A second recommendation is to ensure that end-user education of new EHR processes is heard and understood. Auditing and re-educating, as appropriate, is recommended to hardwire new processes. Findings in this study may indicate that providers were not adequately educated on the new features and added value of the optimized assessment. Lack of education, rather than lack of user satisfaction, may have been the reason for lack of use. Nursing Informaticists should implement closed loop education processes for any new or changed EHR processes.

Eight months after the optimized assessment was implemented into the Soarian Clinicals application, the PI met with lactation consultants during the analysis stage of a new, enterprise-wide, EHR implementation project. The purpose of the meeting was to validate content of the lactation assessment that would be implemented in the new application. That the organization would be implementing a new EHR application was known throughout this study and was a focus of the design process for the Soarian Clinicals lactation assessment. The PI had access to clinical documentation assessments used by organizations which had implemented the new EHR system. These were shared with the participants in the UCD process and helped inform the design of the optimized electronic lactation assessment. Having used the assessment for eight months, the users were in an ideal position to identify if there were content changes to make before implementing in the next EHR. Except for minor changes, the lactation consultants indicated that the current, optimized lactation assessment was efficiently and effectively meeting their documentation requirements. Because the design of the lactation assessment will be unchanged in the next EHR application, there will be an opportunity to study the effect of increased user access to the application on use of the application to review lactation information. A limitation of this study was that providers did not use the same clinical documentation application as nursing and lactation consultants. In the future EHR, all clinical users will document in the same application, thus increasing the opportunity to share information electronically. A third recommendation is to consider studying the effect of the new application on user satisfaction, information quality and use of the electronic lactation assessment.

A fourth recommendation is for nursing informaticists to develop carefully designed, robust studies to inform EHR usability. Although the objectivist design may appear to be more

valuable, based on its historical use as a gold standard of research, methodological challenges of controlled studies arise from the dynamic nature of technology and may impact the validity and reliability of findings when measured against objectivist ideals (Moehr, 2002). Instead, nursing informaticists should consider a subjectivist approach where findings will provide information that is desired to be known, that describes effects on users, and that leads to better understanding (Moehr, 2002). This study may have added more value to the body of knowledge on HIT success if a subjectivist design had been used that explored the reasons why providers did not access lactation information electronically and what attributes of IS Success, such as information quality or system quality, may increase provider access.

A fifth recommendation is for organizations to support continued research in HIT and application of evidence, particularly around usability, when implementing or optimizing EHRs. The findings of this study support the application of usability principles of efficiency and effectiveness to the design of electronic assessments to ensure completeness of documentation. More research to inform usability principles supporting inputting and exporting of information within the EHR are needed to ensure the EHR can impact better care, lower costs, and better health.

In order for HIT research to flourish, a sixth recommendation is to encourage terminal degrees for practicing nursing informaticists. When educated at the doctoral level, Nursing Informaticists can develop a body of evidence to drive optimization and use of the EHR in order to achieve the goal that the EHR will be a learning system to inform clinical practice while supporting quality and safety initiatives.

A final recommendation is to engage legislators to develop policy that will fund future research and development of usability around clinical electronic documentation tools. Concerns about the usability of EHR applications was the impetus behind the formation of a bipartisan working group to identify ways to improve the ability of the EHR to meet expectations that the application will support quality of care, patient safety, exchange of information, and patient engagement (Monegain, 2015). The findings of this study support funding of legislation to develop policy around ensuring that usability principals are included in EHR design, implementation and optimization. When principles of usability, such as efficiency and effectiveness, are a focus of optimization, then use of the application and information quality may increase, resulting in improved outcomes from increased access to clinical information.

Implications. Findings from this study support an optimization process that includes User Centered Design to develop documentation tools to support clinicians when entering information into the EHR or retrieving information from the EHR. When information quality is improved, then clinicians may find information to be more complete. When information is complete, clinicians may use the EHR to access and review patient data to inform clinical practice. Limitations of the application, however, such as system quality or access, may decrease user satisfaction with the application and result in workarounds. When members of the healthcare team have challenges in accessing electronically documented patient information, they may develop workarounds to accessing the application. When workarounds are in place, then clinicians may not increase use of or access to the application even when information quality is increased.

References

Abbass, I., Helton, J., Mhatre, S., & Sansgiry, S. (2012). Impact of electronic health records on nurses' productivity. *Journal of the Association of Occupational Health Professionals in Healthcare*, *32*(3), 33-37**.**

Adler-Milstein, J., Daniel, G., Grossmann, C., Mulvany, C., Nelson, R., Pan, E., . . . Perlin, J. (2014). Return on Information: A standard model for assessing institutional return on electronic health records. *Digital Learning Collaborative of the IOM Roundtable on Value & Science-Driven Health Care*. Institute of Medicine. Retrieved from: http://www.iom.edu/Global/Perspectives/2014/ReturnOnInformation.aspx

Agency for Healthcare Research and Quality (AHRQ) (n.d.) Health IT survey compendium. *Health IT Tools and Resources.* http://healthit.ahrq.gov/health-it-tools-and-resources/health-it-survey-compendium

Ammenwerth, E., Gräber, S., Herrmann, G., Bürkle, T., & König, J. (2003). Evaluation of health information systems—problems and challenges. *International Journal of Medical Informatics*, *71*(2/3), 125. doi:10.1016/S1386-5056(03)00131-X

Ammenwerth, E., Mansmann, U., Iller, C., & Eichstädter, R. (2003). Factors affecting and affected by user acceptance of computer-based nursing documentation: results of a two-year study. *Journal of the American Medical Informatics Association*, *10*(1), 69-84.

Ammenwerth, E., Rauchegger, F., Ehlers, F., Hirsch, B., & Schaubmayr, C. (2011). Effect of a nursing information system on the quality of information processing in nursing: An evaluation study using the HIS-monitor instrument. *International Journal of Medical Informatics*, *80*(1), 25-38. doi:10.1016/j.ijmedinf.2010.10.010

Arlotto, P. (2014). Accelerating the ROI of EHRs. *HFM (Healthcare Financial Management), 68*(2), 72-79.

Bah, S., Alharthi, H., El Mahalli, A., Jabali, A., Al-Qahtani, M., & Al-kahtani, N. (2011). Annual survey on the level and extent of usage of electronic health records in government-related hospitals in Eastern Province, Saudi Arabia. *Perspectives in Health Information Management / AHIMA, American Health Information Management Association, 8*1b.

Berwick, D. M., Nolan, T. W., & Whittington, J. (2008). The Triple Aim: cares health, and cost. *Health Affairs, 27*(3), 759-769. doi:10.1377/hlthaff.273.759

Booth, R. (2012). Examining the functionality of the DeLone and McLean Information System Success Model as a framework for synthesis in nursing information and communication technology research. *CIN: Computers, Informatics, Nursing, 30*(6), 330-345.

Borenstein, M., Rothstein, H., & Cohen, J. (2001). *Power and precision.* Englewood, NJ: Biostat, Inc. Retrieved from: http://www.power-analysis.com/pdfs/power_precision_manual.pdf

Bowman, S. (2013). Impact of electronic health record systems on information integrity: Quality and safety implications. *Perspectives in Health Information Management,* 1-19.

Burnette, P., (2011). Denver Health and Hospital Authority. *Healthcare Business News.* Retrieved from: http://www.modernhealthcare.com/article/20110131/NEWS/110129981

Canada Health Infoway (n.d.). *Benefits evaluation survey process*. Retrieved from: https://www.infoway-inforoute.ca/index.php/resources/toolkits/change-management/national-framework/monitoring-and-evaluation/resources-and-

tools/doc_download/1139-benefits-evaluation-survey-process-system-use-assessment-survey

Canada Health Infoway (2012). *Canada Health Infoway benefits evaluation indicators technical report. Version 2.0*. Retrieved from: https://www.infoway-inforoute.ca/.../544-benefits-evaluation-indicators- technical-report-version-2-0

Centers for Medicare & Medicaid Services (2014). *Clinical quality measures basics*. Retrieved from: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html

Chow, S., Chin, W., Lee, H., Leung, H., & Tang, F. (2011). Nurses' perceptions and attitudes towards computerization in a private hospital. *Journal of Clinical Nursing*, *21*(11/12), 1685-1696. doi:10.1111/j.1365-2702.2011.03905.x

Colorado Breastfeeding Coalition (n.d.). *The Colorado Can Do 5*! Retrieved from: http://www.cobfc.org/2014-03-06-17-22-52/co-can-do-5

Cusack, C. M., Byrne, C., Hook, J. M., McGowan, J., Poon, E. G., &Zafar, A. (2009). *Health information technology evaluation toolkit: 2009 Update*. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from: http://www.healthit.gov/unintended-consequences/sites/default/files/pdf/ModuleIIpdf1.5.pdf

Dabbs, A., Myers, B., Mc Curry, K., Dunbar-Jacob, J., Hawkins, R., Begey, A., & Dew, M. (2009). User-centered design and interactive health technologies for patients. *CIN: Computers, Informatics, Nursing*, *27*(3), 175-183. doi:10.1097/NCN.0b013e31819f7c7c

De Veer, A., Fleuren, M., Bekkema, N., & Francke, A. (2011). Successful implementation of new technologies in nursing care: a questionnaire survey of nurse-users. *BMC Medical Informatics and Decision Making*, *11*67. doi:10.1186/1472-6947-11-67

DeLone, W. H., & McLean, E. R. (2003). The DeLone and McLean Model of Information Systems Success: A ten-year update. *Journal of Management Information Systems*, *19*(4), 9-30

DeVoe, J., Angier, H., Likumahuwa, S., Hall, J., Nelson, C., Dickerson, K., & … Cohen, D. (2014). Use of qualitative methods and user-centered design to develop customized health information technology tools within federally qualified health centers to keep children insured. *Journal of Ambulatory Care Management*, *37*(2), 148-154. doi:10.1097/JAC.0000000000000016

Donabedian A. (1988). The Quality of Care: How Can It Be Assessed? *Journal of the American Medical Association, 260*(12), p. 1743-1748. doi:10.1001/jama.1988.03410120089033

Dykes, P. C., & Collins, S. A. (2013). Building linkages between nursing care and improved patient outcomes: The role of health information technology. *Online Journal of Issues in Nursing*, *18*(3), 1-17. doi:10.3912/OJIN.Vol18No03Man04

Eidelman, A. K., & Schanler, R. J. (2012). Breastfeeding and the use of human milk. *Pediatrics*, *129*(3), 598-601. doi:10.1542/peds.2011-3552

Eysenbach, G., & Wyatt, J. (2002). Using the internet for surveys and health research. *Journal of Medical Internet Research*, *4*(2), e13. doi:10.2196/jmir.4.2.e13

Green, S., & Thomas, J. (2008). Interdisciplinary collaboration and the electronic medical record. *Pediatric Nursing*, *34*(3), 225.

Halbesleben, J. R., Wakefield, D. S., & Wakefield, B. J. (2008). Work-arounds in health care settings: literature review and research agenda. *Health Care Management Review, 33*(1), 2-12.

Harris, A., McGregor, J., Perencevich, E., Furuno, J., Zhu, J., Peterson, D., & Finkelstein, J. (2006). The use and interpretation of quasi-experimental studies in medical informatics. *Journal of the American Medical Informatics Association*, *13*(1), 16-23.

Harris, J. L., Roussel, L., Walters, S. E. & Dearman, C. (2011). *Project planning and management. A guide for CNLs, DNPs, and nurse executive*s. Sudbury, MA: Jones & Bartlett.

Hawkins, S., Stern, A., Baum, C., & Gillman, M. (2014). Evaluating the impact of the Baby-Friendly Hospital Initiative on breast-feeding rates: a multi-state analysis. *Public Health Nutrition*, 1-9. Electronically published ahead of time.

Heathfield, H., Pitty, D., & Hanka, R. (1998). Evaluating information technology in health care: Barriers and challenges. *BMJ: British Medical Journal (International Edition)*, *316*(7149), 1959-1961.

Houser, J. & Oman, K. S. (2011). *Evidence-based practice. An implementation guide for healthcare organizations*. Sudbury, MA: Jones and Bartlett.

Hripcsak, G., Vawdrey, D., Fred, M., & Bostwick, S. (2011). Use of electronic clinical documentation: time spent and team interactions. *Journal of the American Medical Informatics Association, 18*(2), 112-117. doi:10.1136/jamia.2010.008441

Hsiao, J., Chang, H., & Chen, R. (2011). A study of factors affecting acceptance of hospital information systems: a nursing perspective. *Journal of Nursing Research (Lippincott Williams & Wilkins), 19*(2), 150-160.

Huryk, L. A. (2010). Factors influencing nurses' attitudes towards healthcare information technology. *Journal of Nursing Management, 18*(5), 606-612. doi:10.1111/j.1365-2834.2010.01084.x

Institute of Medicine (IOM). 2012. *Health IT and patient safety: Building safer systems for better care.* Washington, DC: The National Academies Press

Johnson, C., Johnson, T., & Zhang, J. (2005). A user-centered framework for redesigning health care interfaces. *Journal of Biomedical Informatics, 38*(1), 75-87.

Jones, S. S., Koppel, R., Ridgely, M. S., Palen, T. E., Wu, S., & Harrison, M. I. (2011). *Guide to reducing unintended consequences of electronic health records*. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from: http://www.healthit.gov/unintended-consequences/#sidebar

Kaplan, B., & Harris-Salamone, K. (2009). Health IT success and failure: Recommendations from literature and an AMIA workshop. *Journal of the American Medical Informatics Association, 16*(3), 291-299. doi:10.1197/jamia.M2997

Keenan, G., Yakel, E., Dunn Lopez, K., Tschannen, D., & Ford, Y. (2013). Challenges to nurses' efforts of retrieving, documenting, and communicating patient care information. *Journal of the American Medical Informatics Association, 20*(2), 245-251. doi:10.1136/amiajnl-2012-000894

Kelley, T. F., Brandon, D. H., & Docherty, S. L. (2011). Electronic nursing documentation as a strategy to improve quality of patient care. *Journal of Nursing Scholarship*, *43*(2), 154-162. doi:10.1111/j.1547-5069.2011.01397.x

Kennedy Page, C., & Schadler, A. (2014). A nursing focus on EMR usability enhancing documentation of patient outcomes. *Nursing Clinics of North America*, *49*(1), 81-90. doi:10.1016/j.cnur.2013.11.010

Khazaal, Y., van Singer, M., Chatton, A., Achab, S., Zullino, D., Rothen, S., ... & Thorens, G. (2014). Does self-selection affect samples' representativeness in online surveys? An investigation in online video game research. *Journal of Medical Internet Research*, *16*(7), e164. doi:10.2196/jmir.2759

Kimiafar, K., Sadoughi, F., Sheikhtaheri, A., & Sarbaz, M. (2014). Prioritizing factors influencing nurses' satisfaction with hospital information systems: a fuzzy analytic hierarchy process approach. *Computers, Informatics, Nursing: CIN*, *32*(4), 174-181. doi:10.1097/CIN.0000000000000031

Laerd Statistics (n.d.) *Mann-Whitney U test using SPSS*. Retrieved July 19, 2015 from: https://statistics.laerd.com/spss-tutorials/mann-whitney-u-test-using-spss-statistics.php

Laramee, A., Bosek, M., Kasprisin, C., & Powers-Phaneuf, T. (2011). Learning from within to ensure a successful implementation of an electronic health record. *CIN: Computers, Informatics, Nursing*, *29*(8), 468-477. doi:10.1097/NCN.0b013e3181fc3fc7

List, B., Ballard, J., Langworthy, K., Vincent, A., Riddle, S., Tamayo, O., & Geraghty, S. (2008). Electronic health records in an outpatient breastfeeding medicine clinic. *Journal of Human Lactation*, *24*(1), 58-68.

McAlearney, A. S., Song, P. H., Robbins, J., Hirsch, A., Jorina, M., Kowalczyk, N., & Chisolm, D. (2010). Moving from good to great in ambulatory electronic health record implementation. *Journal for Healthcare Quality*, *32*(5), 41-50.

McDowell, D., Dillon, T., & Lending, D. (2008). Perceived quality benefits influenced by usefulness and documentation accuracy of information systems. *Computers, Informatics, Nursing: CIN*, *26*(6), 350-357. doi:10.1097/01.NCN.0000336463.72069.7c

Michel-Verkerke, M. B. (2012). Information Quality of a Nursing Information System depends on the nurses: A combined quantitative and qualitative evaluation. *International Journal of Medical Informatics*, *81*(10), 662-673. doi:10.1016/j.ijmedinf.2012.07.006

Moehr, J. R. (2002). Evaluation: salvation or nemesis of medical informatics? *Computers in Biology & Medicine*, *32*(3), 113.

Monegain, B. (2015, April 30). Senate panel to look into EHR usability. In *Healthcare IT News.* Retrieved from: http://www.healthcareitnews.com/news/senate-panel-look-ehr-usability

Nandy, K. (2012). *Understanding and quantifying effect sizes*. Retrieved from: http://nursing.ucla.edu/workfiles/research/Effect%20Size%204-9-2012.pdf

National Institute of Standards and Technology (NIST) (2013). *Usability.* Retrieved from: http://www.nist.gov/healthcare/usability/upload/Usability-Fact-Sheet-SEPT2013.pdf

National Learning Consortium (2014, March 19). *Health care quality and convenience. Benefits of EHRs*. Retrieved from: http://www.healthit.gov/providers-professionals/health-care-quality-convenience

National Learning Consortium (2013). *Continuous quality improvement (CQI) strategies to optimize your practice*. Retrieved from: https://www.healthit.gov/sites/default/files/nlc_continuousqualityimprovementprimer.pdf

Nykänen, P., Brender, J., Talmon, J., de Keizer, N., Rigby, M., Beuscart-Zephir, M., & Ammenwerth, E. (2011). Guideline for good evaluation practice in health informatics (GEP-HI). *International Journal of Medical Informatics*, *80*(12), 815-827. doi:10.1016/j.ijmedinf.201.08.004

Palm, J., Colombet, I., Sicotte, C., & Degoulet, P. (2006). Determinants of user satisfaction with a Clinical Information System. *AMIA … Annual Symposium Proceedings / AMIA Symposium. AMIA Symposium*, 614-618.

Paterson, G., Shaw, N., Grant, A., Leonard, K., Delisle, E., Mitchell, S., & … Kraetschmer, N. (2010). A conceptual framework for analyzing how Canadian physicians are using electronic medical records in clinical care. *Studies in Health Technology and Informatics*, *160*(Pt 1), 141-145.

Petter, S., Delone, W., & McLean, E. (2008). Measuring information systems success: models, dimensions, measures, and interrelationships. *European Journal of Information Systems*, *17*(3), 236-263. doi:10.1057/ejis.2008.15

Polit, D. (2010). *Statistics and data analysis for nursing research* (2nd ed.). Upper Saddle River, NJ: Pearson, Inc.

Polit, D. F. & Beck, C. T. (2012). *Nursing research* (12th ed.). Philadelphia, PA: Wolters Kluwer

Rogers, M., Sockolow, P., Bowles, K., Hand, K., & George, J. (2013). Use of a human factors approach to uncover informatics needs of nurses in documentation of care. *International Journal of Medical Informatics, 82*(11), 1068-1074. doi:10.1016/j.ijmedinf.2013.08.007

Rojas, C., & Seckman, C. (2014). The Informatics Nurse Specialist Role in Electronic Health Record Usability Evaluation. *Computers, Informatics, Nursing: CIN*, *32*(5), 214-220. doi:10.1097/CIN.0000000000000042

Schumacher, R. M. & Lowry, S. Z. (2010). *NIST guide to the processes approach for improving the usability of electronic health records*. Washington, D.C. U.S. Department of Commerce. Retrieved from; http://www.nist.gov/itl/hit/upload/Guide_Final_Publication_Version.pdf

Smith, K., Smith, V., Krugman, M., & Oman, K. (2005). Evaluating the impact of computerized clinical documentation. *CIN: Computers, Informatics, Nursing*, *23*(3), 132-138.

Spetz, J., Burgess, J.F., & Phibbs, C. S. (2012). What determines successful implementation of inpatient information technology systems? *The American Journal of Managed Care, 18*(3), 157-162.

Steis, M. R., Prabhu, V. V., Kolanowski, A., Kang, Y., Bowles, K. H., Fick, D., & Evans, L. (2012). Detection of delirium in community-dwelling persons with dementia. *Online Journal of Nursing Informatics*, *16*(1), 6-20.

Stevenson, J. E., & Nilsson, G. (2012). Nurses' perceptions of an electronic patient record from a patient safety perspective: a qualitative study. *Journal of Advanced Nursing*, *68*(3), 667-676. doi:10.1111/j.1365-2648.2011.05786.x

Talmon, J., de Keizer, N., Nykänen, P., Rigby, M., Brender, J., & Ammenwerth, E. (2013). STARE-HI – Statement on Reporting of Evaluation Studies in Health Informatics: explanation and elaboration. *Applied Clinical Informatics, 4*(3), 331-358. doi:10.4338/ACI-2013-04-RA-0024

The risks of C-Sections. What hospitals don't want you to know. (2014). Consumerreports.org. Retrieved from: http://consumerreports.org/cro/2014/05/what-hospitals-do-not-want-you-to-know-about-c-sections/index.html

Törnvall, E., & Wilhelmsson, S. (2008). Nursing documentation for communicating and evaluating care. *Journal of Clinical Nursing, 17*(16), 2116-2124. doi:10.1111/j.1365-2702.2007.02149.x

United States Breastfeeding Committee. (2013). *Implementing The Joint Commission Perinatal Care core measure on exclusive breast milk feeding* (2nd ed.). Washington, DC: United States Breastfeeding Committee. Retrieved from: http://www.usbreastfeeding.org/Portals/0/Publications/Implementing-TJC-Measure-EBMF-2013-USBC.pdf

Urquhart, C., Currell, R., Grant, M., & Hardiker, N. (2009). Nursing record systems: effects on nursing practice and healthcare outcomes. *Cochrane Database of Systematic Reviews,* (1), doi:10.1002/14651858.CD002099.pub2

Van der Meijden, M., Tange, H., Troost, J., & Hasman, A. (2003). Determinants of success of inpatient clinical information systems: a literature review. *Journal of the American Medical Informatics Association, 10*(3), 235-243.

Wang, N., Hailey, D., & Yu, P. (2011). Quality of nursing documentation and approaches to its evaluation: a mixed-method systematic review. *Journal of Advanced Nursing, 67*(9), 1858-1875. doi:10.1111/j.1365-2648.2011.05634.x

Ward, R., Stevens, C., Brentnall, P., & Briddon, J. (2008). The attitudes of health care staff to information technology: a comprehensive review of the research literature. *Health Information & Libraries Journal, 25*(2), 81-97.

Ward, M., Vartak, S., Schwichtenberg, T., & Wakefield, D. (2011). Nurses' perceptions of how clinical information system implementation affects workflow and patient care. *CIN: Computers, Informatics, Nursing*, *29*(9), 502-511. doi:10.1097/NCN.0b013e31822b8798

White, K.W. & Zaccagnini, M.E. (2011). A template for the DNP scholarly project. In K.W. White & M. E Zaccagnini (eds.) *The Doctor of Nursing Practice essential* (pp. 451-493). Sudbury, MA: Bartlett and Jones

Wong, M., Cummings, E., & Turner, P. (2013). User-centered design in clinical handover: exploring post-implementation outcomes for clinicians. *Studies in Health Technology and Informatics*, *192*253-257.

World Health Organization Division of Child Health and Development (1998). *Evidence for the ten steps to successful breast-feeding*. Geneva, Switzerland: World Health Organization. Retrieved from: http://whqlibdoc.who.int/publications/2004/9241591544_eng.pdf

Yantani, K. (2014). *Mann-Whitney's U test.* Retrieved July 25, 2015 from: http://yatani.jp/teaching/doku.php?id=hcistats:mannwhitney

Zadvinskis, I., Chipps, E., & Yen, P. (2014). Exploring nurses' confirmed expectations regarding health IT: a phenomenological study. *International Journal of Medical Informatics, 83*(2), 89-98. doi:10.1016/j.ijmedinf.2013.11.00

Zaman, O. S., Cummings, L. C., & Laycox, S. (2012). *American's safety net hospitals. Results of the annual NAPH hospital characteristics survey.* Washington D. C.: National Association of Public Hospitals and Health Systems.

Zopf-Herling, K. (2011). Enhancing usability in EMR screen design. *CIN: Computers, Informatics, Nursing*, *29*(12), 679-691. doi:10.1097/NCN.0b013e31823ea54e

Zuzelo, P., Gettis, C., Hansell, A., & Thomas, L. (2008). Describing the influence of technologies on registered nurses' work. *Clinical Nurse Specialist: The Journal for Advanced Nursing Practice*, *22*(3), 132-142.

Appendix A

Logic Model

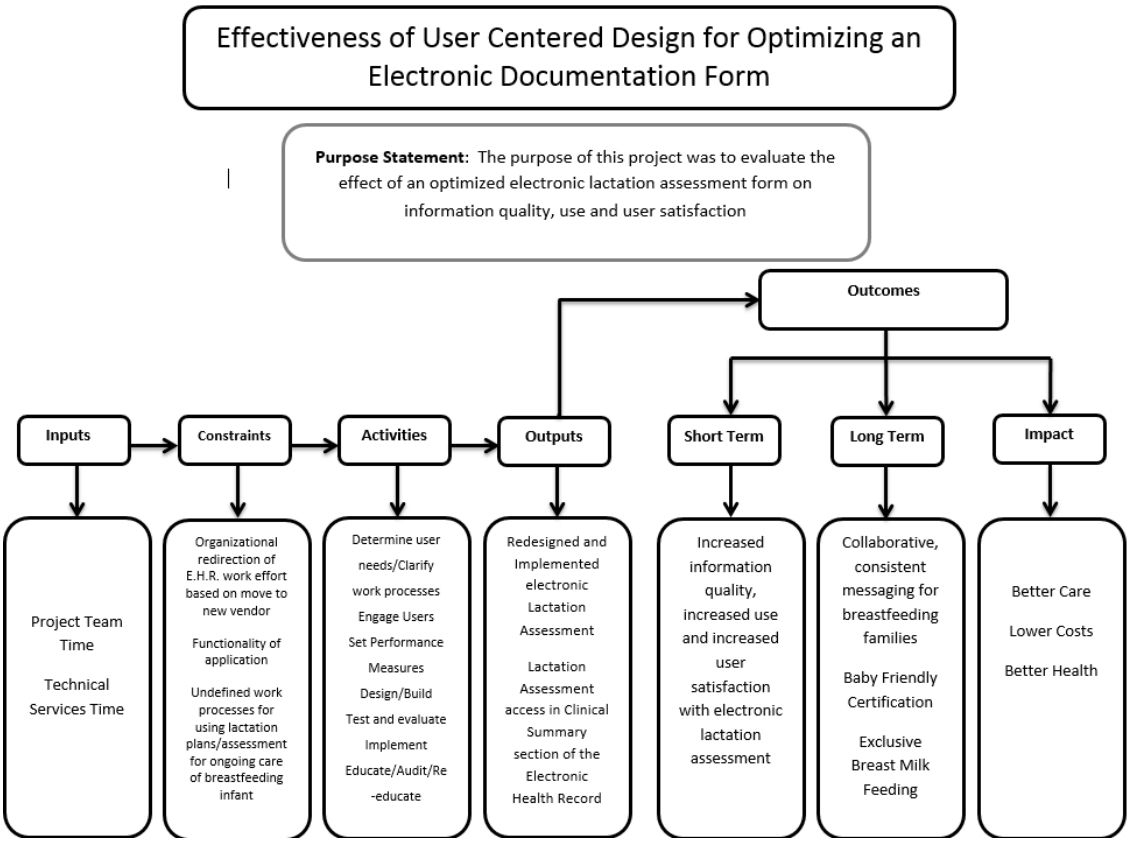


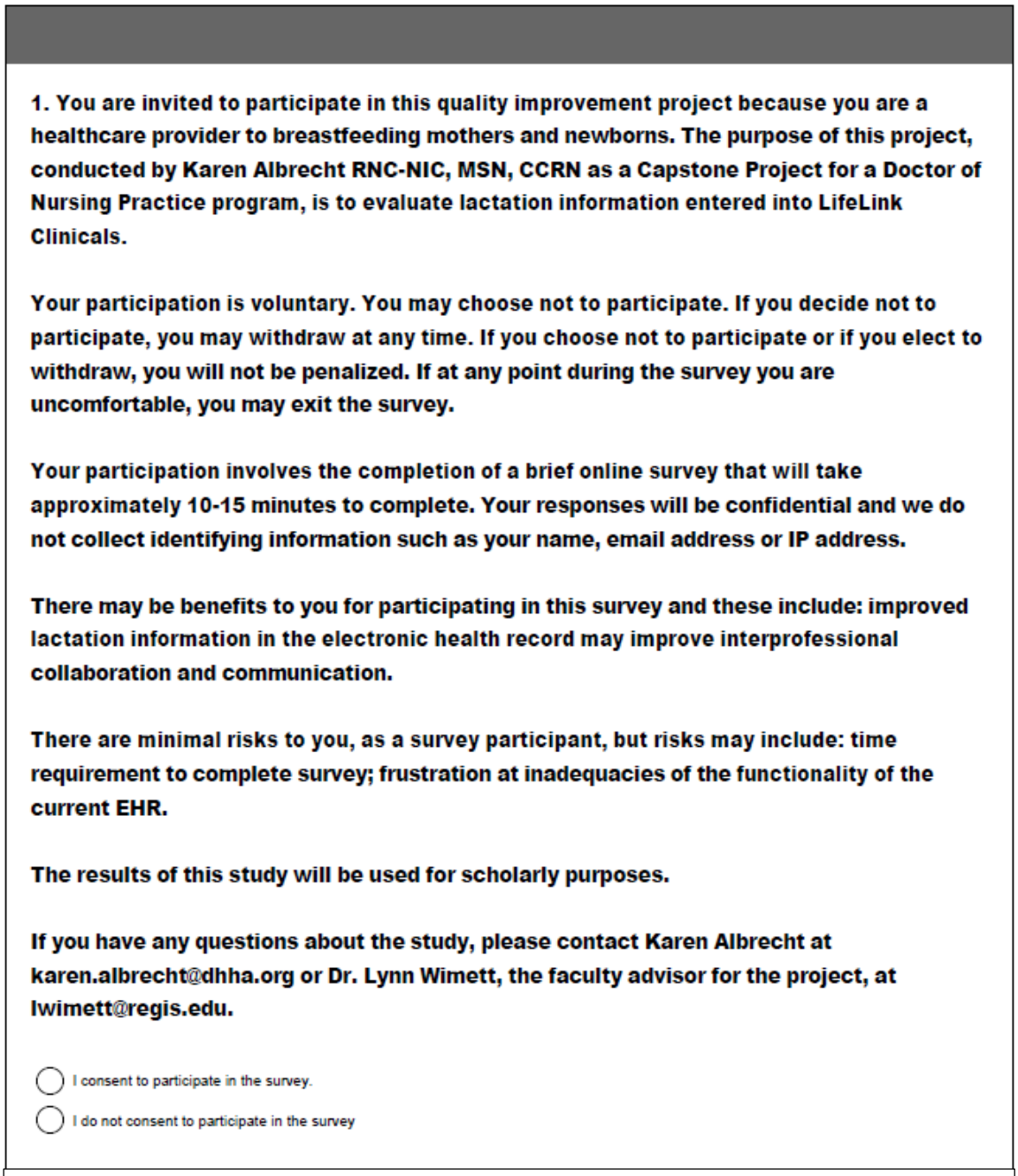
Figure D1: Logic Model. The logic model is based on a model from White & Zaccagnini, 2011, p. 481.

Appendix B

Instruments

			Patient Type		Type of Documentation		Required Baby Friendly Documentation		Lactation Recommendations Narrative located in designated Textbox	
Number	Date of consult	Date/Time of Assessment	Mother	Infant	Initial	Follow Up	Yes	No	Yes	NO
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										

Figure A1: Chart Audit Tool. The chart audit tool was used for compiling data from chart review.



1. You are invited to participate in this quality improvement project because you are a healthcare provider to breastfeeding mothers and newborns. The purpose of this project, conducted by Karen Albrecht RNC-NIC, MSN, CCRN as a Capstone Project for a Doctor of Nursing Practice program, is to evaluate lactation information entered into LifeLink Clinicals.

Your participation is voluntary. You may choose not to participate. If you decide not to participate, you may withdraw at any time. If you choose not to participate or if you elect to withdraw, you will not be penalized. If at any point during the survey you are uncomfortable, you may exit the survey.

Your participation involves the completion of a brief online survey that will take approximately 10-15 minutes to complete. Your responses will be confidential and we do not collect identifying information such as your name, email address or IP address.

There may be benefits to you for participating in this survey and these include: improved lactation information in the electronic health record may improve interprofessional collaboration and communication.

There are minimal risks to you, as a survey participant, but risks may include: time requirement to complete survey; frustration at inadequacies of the functionality of the current EHR.

The results of this study will be used for scholarly purposes.

If you have any questions about the study, please contact Karen Albrecht at karen.albrecht@dhha.org or Dr. Lynn Wimett, the faculty advisor for the project, at lwimett@regis.edu.

◯ I consent to participate in the survey.

◯ I do not consent to participate in the survey

Figure A2: Survey. Survey was modified from the *System and Use Assessment Survey,* Canada Health Infoway. Used and modified by permission. Retrieved from: http://healthit.ahrq.gov/health-it-tools-and-resources/health-it-survey-compendium/canada-health-infoway-system-and-use

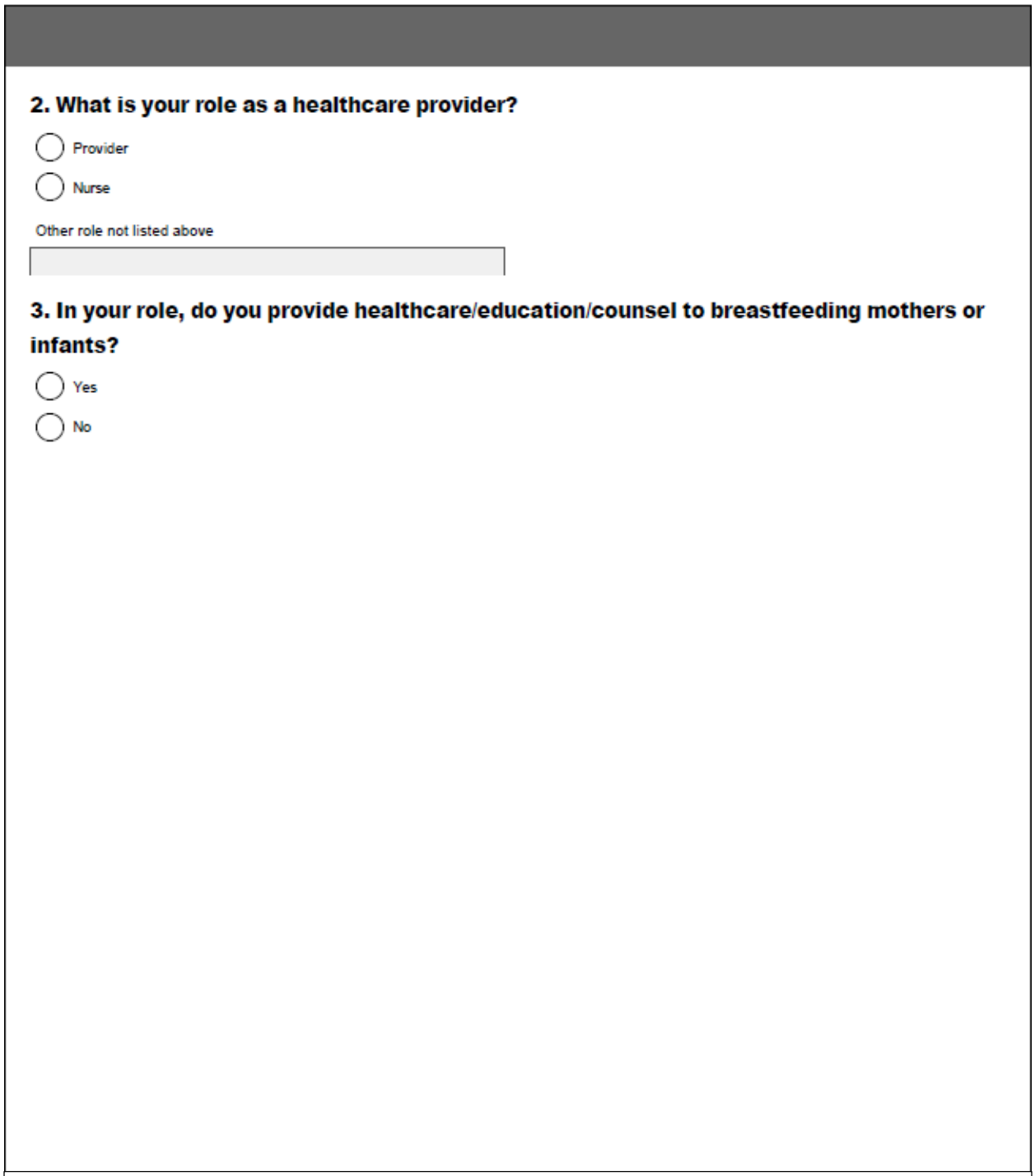
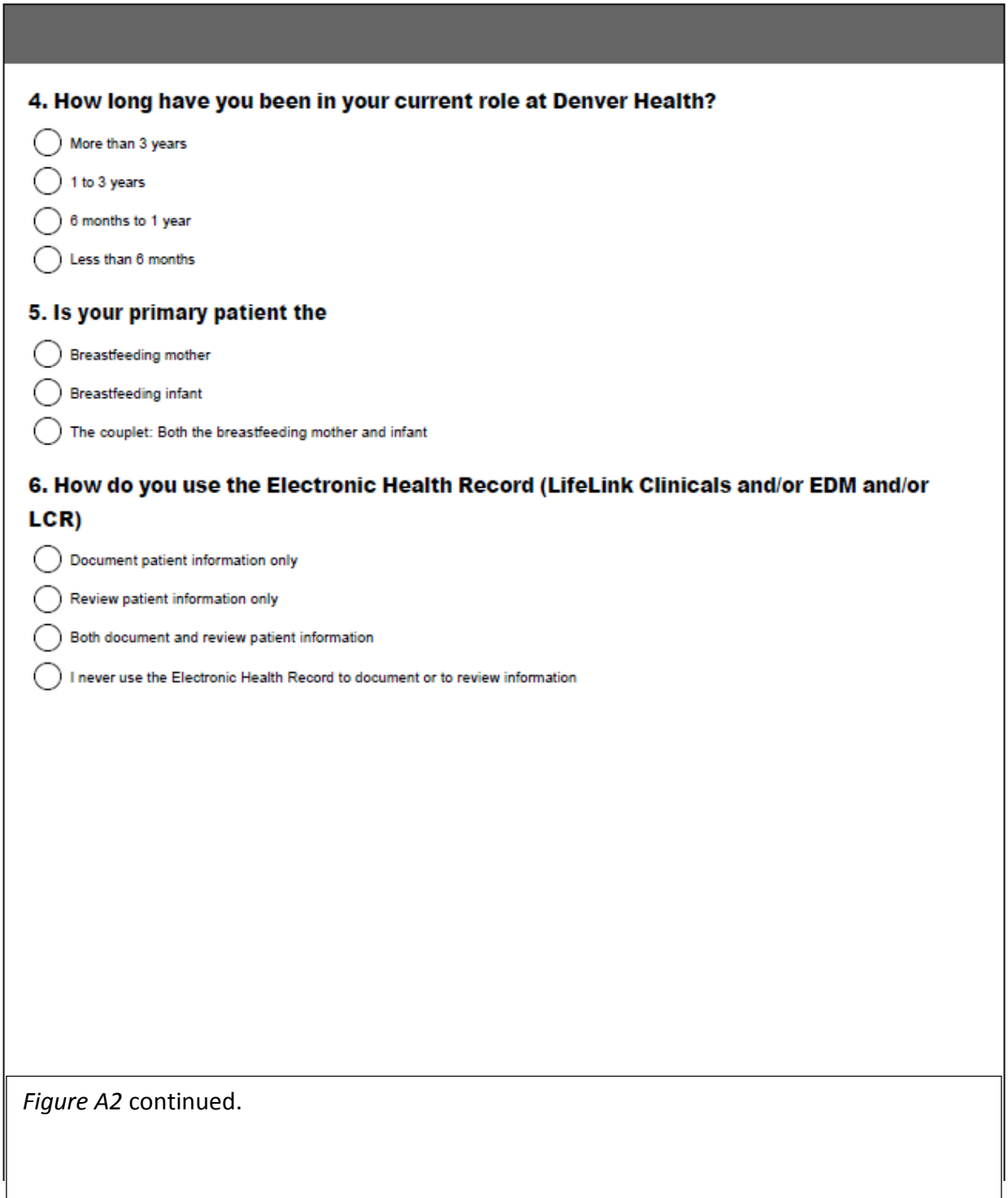


Figure A2 continued.



4. How long have you been in your current role at Denver Health?

- ◯ More than 3 years
- ◯ 1 to 3 years
- ◯ 6 months to 1 year
- ◯ Less than 6 months

5. Is your primary patient the

- ◯ Breastfeeding mother
- ◯ Breastfeeding infant
- ◯ The couplet: Both the breastfeeding mother and infant

6. How do you use the Electronic Health Record (LifeLink Clinicals and/or EDM and/or LCR)

- ◯ Document patient information only
- ◯ Review patient information only
- ◯ Both document and review patient information
- ◯ I never use the Electronic Health Record to document or to review information

Figure A2 continued.

7. Please indicate the frequency which best describes your response to each question below. Often = > 75% Usually = 50-75% Sometimes = 25-50% Rarely = <25%

	Often	Usually	Sometimes	Rarely	Never	Not Sure
When you know that your breastfeeding patient had a lactation consultation, how frequently do you review the consultant's recommendations or information either verbally or in writing?	◯	◯	◯	◯	◯	◯
How frequently do you access this information from a source outside of the EHR? (Examples: discuss verbally with the lactation consultant or another healthcare provider; read a Kardex, email or notes apart from the EHR)	◯	◯	◯	◯	◯	◯
How frequently do you access this information from a source within the EHR? (Examples: LifeLink Clinicals, EDM, a report generated from LifeLink Clinicals)	◯	◯	◯	◯	◯	◯

Figure A2 continued.

8. Please indicate your level of agreement or disagreement with each of the following statements regarding lactation information documented in the Electronic Health Record (EHR). The EHR refers to LifeLink Clinicals and/or EDM and/or LCR.

	Strongly Agree	Moderately Agree	Moderately Disagree	Strongly Disagree	Not Sure
Lactation information in the EHR is complete.	◯	◯	◯	◯	◯
I am able to quickly access lactation information in the EHR.	◯	◯	◯	◯	◯
The lactation information in the EHR is accurate.	◯	◯	◯	◯	◯
The lactation information provided in the EHR is relevant.	◯	◯	◯	◯	◯
The lactation information in the EHR is available when I need it.	◯	◯	◯	◯	◯
The format and layout of the lactation information is acceptable.	◯	◯	◯	◯	◯
The lactation assessment is easy to use.	◯	◯	◯	◯	◯
The lactation assessment is integrated with my workflow.	◯	◯	◯	◯	◯
The lactation information found in the EHR improves the quality of care I can provide.	◯	◯	◯	◯	◯
The lactation information found in the EHR makes my job easier.	◯	◯	◯	◯	◯
The lactation information found in the EHR improves our sharing of patient information amongst healthcare providers/clinicians.	◯	◯	◯	◯	◯

Figure A2 continued.

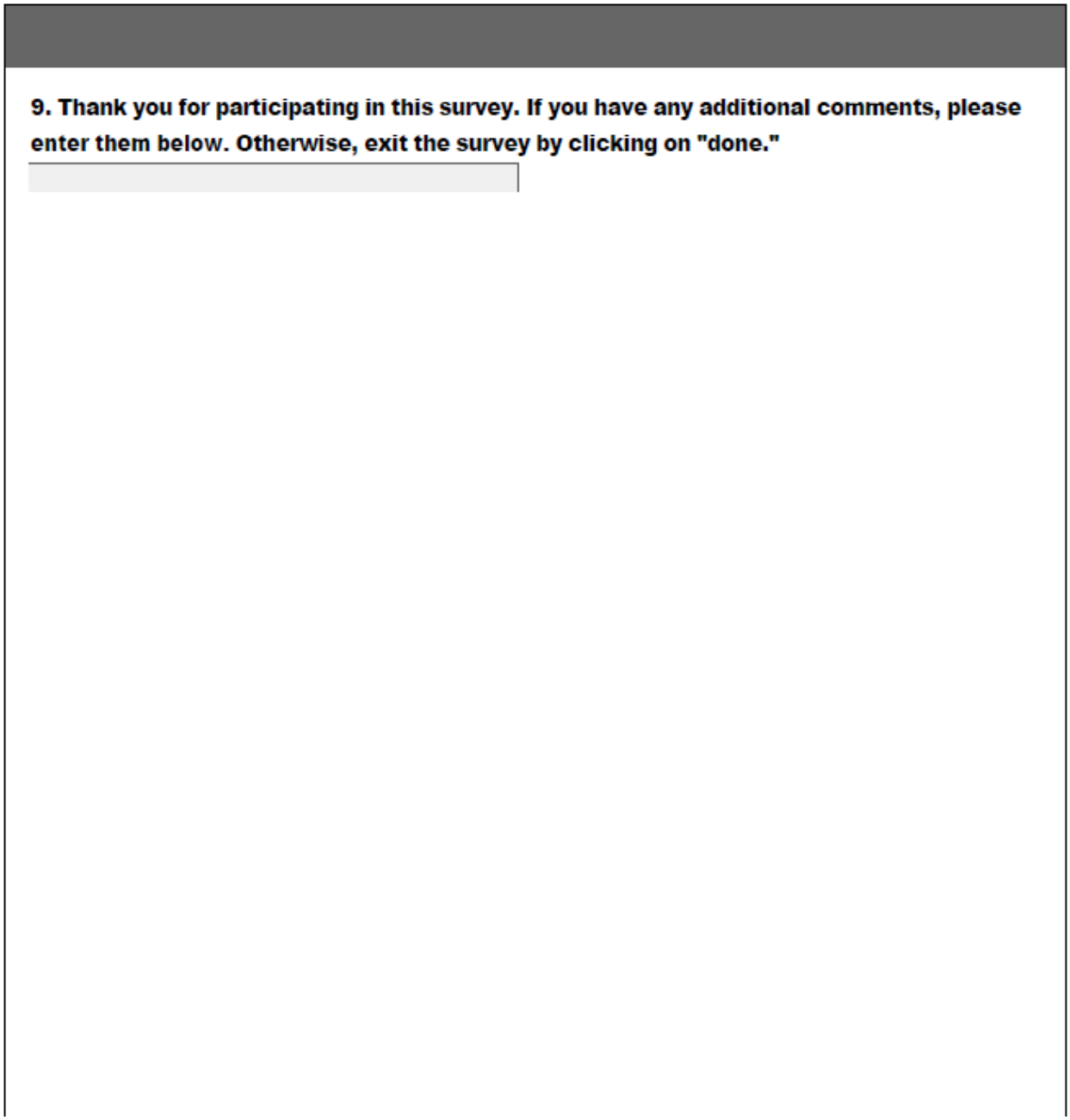


Figure A2 continued.

Appendix C

Permissions

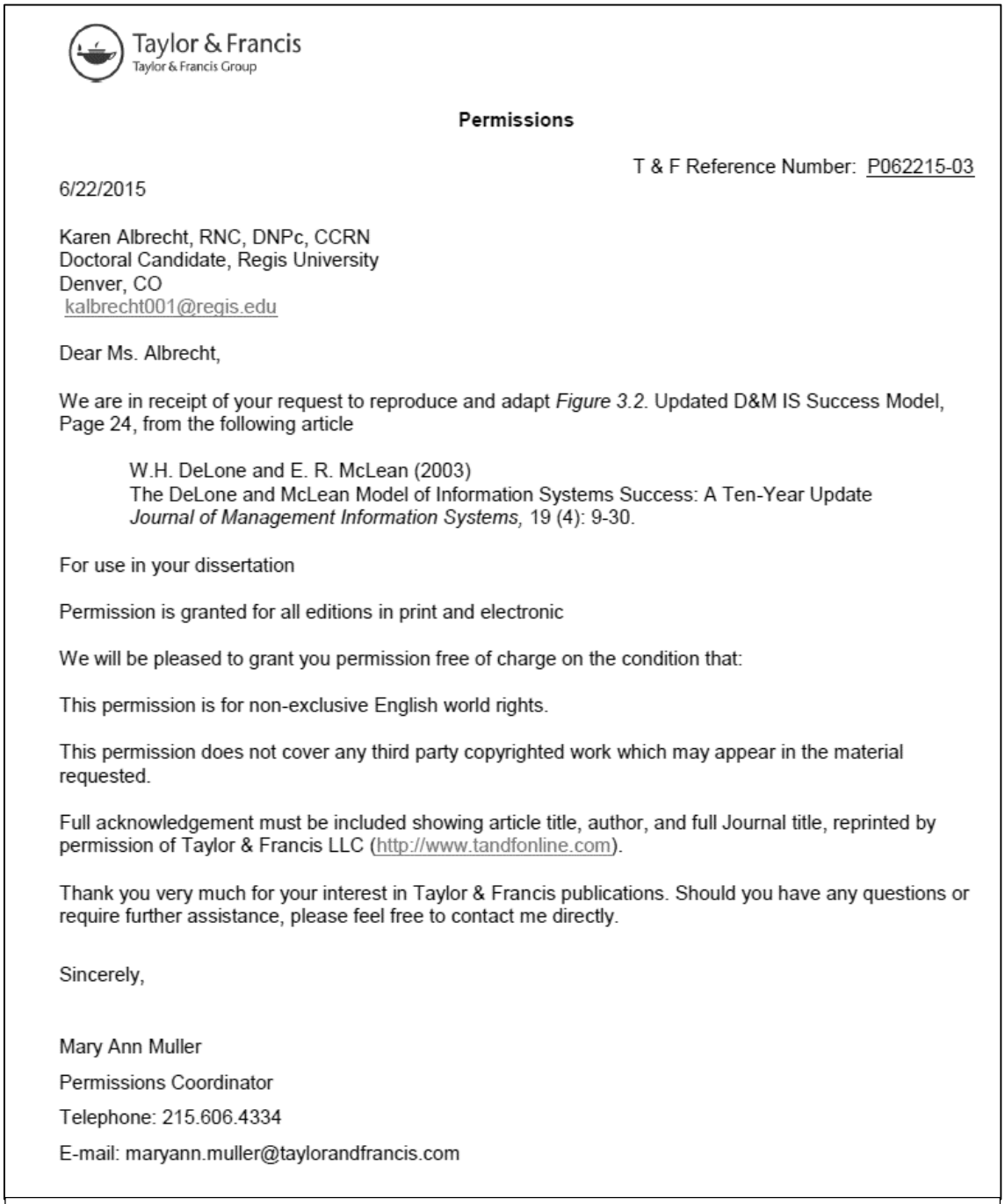
RE: Permission for System and Use Assessment Survey

Hagens, Simon [shagens@infoway-inforoute.ca]
Sent: Wednesday, July 23, 2014 8:51 AM
To: Albrecht, Karen L
Cc: Pereira , Chiara [cpereira@infoway-inforoute.ca]; Tharmalingam , Sukirtha [stharmalingam@infoway-inforoute.ca]

Hi Karen,
You are very welcome to modify and use the tool. The tool has been used extensively across Canada, so if you're interested, we may be able to provide some comparison benchmarks once you have your responses. Please just acknowledge that it was developed by Canada Health Infoway, and if you have feedback or a publication resulting from the survey, we'd love to hear about it.
Best,
Simon

Simon Hagens
Director, Benefits Realization /Directeur, Réalisation des avantages
Canada Health Infoway - Inforoute Santé du Canada
150 King St. W., Ste 1300
Toronto, ON M5H 1J9
☎ Tel: 416.595.3161
Cell: 416.427.4182
e-mail: shagens@infoway-inforoute.ca
Web: www.infoway-inforoute.ca

Figure B1. Permission to Use and Modify *System and Use Assessment Survey*. Permission was received from Canada Health Infoway to use the System and Use Assessment Survey.



Taylor & Francis
Taylor & Francis Group

Permissions

T & F Reference Number: P062215-03

6/22/2015

Karen Albrecht, RNC, DNPc, CCRN
Doctoral Candidate, Regis University
Denver, CO
kalbrecht001@regis.edu

Dear Ms. Albrecht,

We are in receipt of your request to reproduce and adapt *Figure 3.2.* Updated D&M IS Success Model, Page 24, from the following article

W.H. DeLone and E. R. McLean (2003)
The DeLone and McLean Model of Information Systems Success: A Ten-Year Update
Journal of Management Information Systems, 19 (4): 9-30.

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Sincerely,

Mary Ann Muller

Permissions Coordinator

Telephone: 215.606.4334

E-mail: maryann.muller@taylorandfrancis.com

Figure B2. Permission to Use DeLone and McLean D&M IS Success Model.

Appendix D

Systematic Review of the Literature: Exemplar

Table C1

Systematic Literature Review: Exemplar

Search Term	All Results	Included
HIT Success	215	10
Electronic Health Record & Nursing	116	10
Electronic Health Record & Evaluation	416	6
Nursing Documentation Systems AND:	1002	10
• Nursing Attitudes	117	13
• Nursing Satisfaction	76	10
• Quality	347	3
• Usability	8	28
Databases:	CINAHL, MEDLINE, Academic Search Premier, PsycINFO	
Limits	Full text, academic journals, 2003 or later, English language	

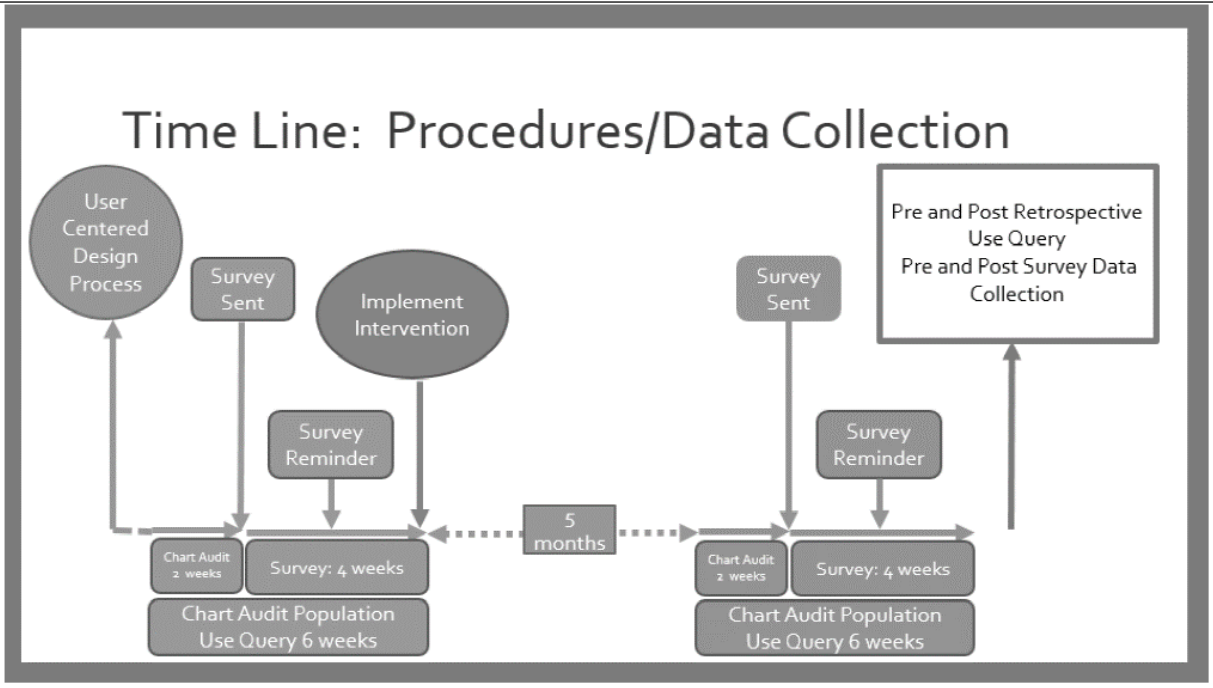
Citation	Key Findings	Level of Evidence
Ammenwerth, E., Gräber, S., Herrmann, G., Bürkle, T., & König, J. (2003). Evaluation of health information systems—problems and challenges. International Journal of Medical Informatics, 71(2/3), 125. doi:10.1016/S1386-5056(03)00131-X	• HIT evaluation is complex: • Evaluation of the OBJECT • Evaluation of the PROCESS	III
Van der Meijden, M., Tange, H., Troost, J., & Hasman, A. (2003). Determinants of success of inpatient clinical information systems: a literature review. Journal of the American Medical Informatics Association, 10(3), 235-243.	• Determinants of success for inpatient clinical information systems • Based on DeLone and McLean framework • Literature Review; 33 articles	IV

	• No explicit definition of success • DeLone and Mclean applicable	
Booth, R. (2012). Examining the Functionality of the DeLone and McLean Information System Success Model as a Framework for Synthesis in Nursing Information and Communication Technology Research. CIN: Computers, Informatics, Nursing, 30(6), 330-345.	• Evaluation of nursing research • What are the relevant studies? • Is DeLone and McLean appropriate? • Literature Review; 39 studies • Weak understanding • Over emphasis on user satisfaction	IV
Huryk, L. A. (2010). Factors influencing nurses' attitudes towards healthcare information technology. Journal of Nursing Management, 18(5), 606-612. doi:10.1111/j.1365-2834.2010.01084.x	• • Literature Review; 13 studies • Inclusion: RN attitude towards IT • Demographic data: experience • Enhancing patient care, safety • Poor system design or system quality	IV
Kimiafar, K., Sadoughi, F., Sheikhtaheri, A., & Sarbaz, M. (2014). Prioritizing factors influencing nurses' satisfaction with hospital information systems: a fuzzy analytic hierarchy process approach. Computers, Informatics, Nursing: CIN, 32(4), 174-181. doi:10.1097/CIN.0000000000000031	• Fuzzy analytic hierarchy • Prioritize factors that influence satisfaction • Findings: Information Quality • High quality • Secure • Available when and where needed	III
Hripcsak, G., Vawdrey, D., Fred, M., & Bostwick, S. (2011). Use of electronic clinical documentation: time spent and team interactions. Journal of the American Medical Informatics Association, 18(2), 112-117. doi:10.1136/jamia.2010.008441	• Documentation time and use of information • Academic medical center; inpatient • How long to input; who viewed • Limitation: only clinical notes • 16% attending; 8% resident; 38% RN	III
Keenan, G., Yakel, E., Dunn Lopez, K., Tschannen, D., & Ford, Y. (2013). Challenges	• Flow of information	IV

to nurses' efforts of retrieving, documenting, and communicating patient care information. Journal of the American Medical Informatics Association, 20(2), 245-251. doi:10.1136/amiajnl-2012-0008947	• Qualitative study; 8 units; 4 hospitals • Observation • Three themes: • Variation • No overview • Rare interprofessional communication	
Rojas, C., & Seckman, C. (2014). The Informatics Nurse Specialist Role in Electronic Health Record Usability Evaluation. Computers, Informatics, Nursing: CIN, 32(5), 214-220. doi:10.1097/CIN.0000000000000042	• Framework for evaluation of usability • Rules/ Heuristics • Consistency, Effective Presentation; Real World Match • Evaluate usability through all stages	VII
Kennedy Page, C., & Schadler, A. (2014). A Nursing Focus on EMR Usability Enhancing Documentation of Patient Outcomes. Nursing Clinics of North America, 49(1), 81-90. doi:10.1016/j.cnur.2013.11.010	• Usability evaluation of nursing assessments • Purpose: Increase efficiency, effectiveness, and satisfaction • User Centered Design • Usability Checklist • Instruments: • Survey • Keystroke counter • Quality measures • Pre and Post Test • Significant improvements	III

Appendix E

Project Milestones



Project Milestones:

Spring 2014: Start 3 month UCD process

October 1: Pre Chart Audit Start

October 15, 2014: Pre Survey Sent

November 11, 2014: Implementation

April 14, 2015: Post Chart Audit Start

April 28, 2015: Post Survey Sent

Figure E1: Project Milestones and Timeline with Key Dates Listed.

Appendix F

IRB Approvals and CITI Training

University of Colorado
Anschutz Medical Campus

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
COMIRB Home Page [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

18-Sep-2014

Investigator:	Karen Albrecht
Sponsor(s):	
Subject:	COMIRB Protocol 14-1605 Initial Application
Effective Date:	18-Sep-2014
Expiration Date:	17-Sep-2015
Expedited Category:	5,7
Title:	Evaluation of Information Quality, User Satisfaction and Use of an Electronic Lactation Assessment Pre and Post Optimization with User Centered Design

Submission ID: pp001-2
Description:

APP01-2
Response to minor modifications

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed. Consent and/or assent forms must include the name and telephone number of the investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

Figure F1: Colorado Multiple Institutional Review Board (COMIRB) IRB Approval Letter.

REGIS UNIVERSITY

Academic Grants

3333 Regis Boulevard, H-4
Denver, CO 80221-1099

303-458-4206
303-964-5528 fax
www.regis.edu

IRB – REGIS UNIVERSITY

October 31, 2014

RE: IRB #: 14-289

Dear Ms. Albrecht:

Your application to the Regis IRB for your project, "Evaluation of Information Quality, User Satisfaction, and Use of an Electronic Lactation Assessment Pre- and Post-Optimization with User Centered Design", was approved as an expedited study on October 11, 2014. It is approved per OHRP Category of Research #5 and #7.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval. Projects which continue beyond one year from their starting date require IRB continuation review. The continuation should be requested 30 days prior to the one year anniversary date of the approved project's start date. A completion report of the findings of this study should be sent to the IRB.

In addition, it is the responsibility of the principal investigator to promptly report to the IRB any injuries to human subjects and/or any unanticipated problems within the scope of the approved research which may pose risks to human subjects. Lastly, a final report should be submitted at completion of the project and it is the responsibility of the investigator to maintain signed consent documents for a period of three years after the conclusion of the research.

Sincerely,

Patsy Cullen

Patsy McGuire Cullen, PhD, PNP-BC
Chair, Institutional Review Board
Professor & Director
Doctor of Nursing Practice & Nurse Practitioner Programs
Loretto Heights School of Nursing
Regis University

cc: Dr. Lynn Wimett

Figure F2: Regis University IRB Approval Letter.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Albrecht (ID: 3214269)
- **Email:** kalbrecht001@regis.edu
- **Institution Affiliation:** Regis University (ID: 745)
- **Institution Unit:** nursing
- **Phone:** 303-395-1294

- **Curriculum Group:** Human Research
- **Course Learner Group:** Biomedical Research Investigators and Key Personnel
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 9208998
- **Completion Date:** 11/20/2012
- **Expiration Date:** 11/20/2015
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Avoiding Group Harms - U.S. Research Perspectives (ID:14080)	11/20/12
Introduction (ID:757)	11/20/12
History and Ethics of Human Subjects Research (ID:498)	11/20/12
Basic Institutional Review Board (IRB) Regulations and Review Process (ID:2)	11/20/12
Informed Consent (ID:3)	11/20/12
Social and Behavioral Research (SBR) for Biomedical Researchers (ID:4)	11/20/12
Records-Based Research (ID:5)	11/20/12
Genetic Research in Human Populations (ID:6)	11/20/12
Research With Protected Populations - Vulnerable Subjects: An Overview (ID:7)	11/20/12
Vulnerable Subjects - Research Involving Prisoners (ID:8)	11/20/12
Vulnerable Subjects - Research Involving Children (ID:9)	11/20/12
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID:10)	11/20/12
International Studies (ID:971)	11/20/12
FDA-Regulated Research (ID:12)	11/20/12
Research and HIPAA Privacy Protections (ID:14)	11/20/12
Vulnerable Subjects - Research Involving Workers/Employees (ID:483)	11/20/12
Conflicts of Interest in Research Involving Human Subjects (ID:488)	11/20/12
Regis University (ID:1164)	11/20/12

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Figure F3: CITI Training Certificates: Human Research Biomedical Research Investigators and Key Personnel.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Albrecht (ID: 3214269)
- **Email:** kalbrecht001@regis.edu
- **Institution Affiliation:** Regis University (ID: 745)
- **Institution Unit:** nursing
- **Phone:** 303-395-1294

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social Behavioral Research Investigators and Key Personnel
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 9207286
- **Completion Date:** 11/20/2012
- **Expiration Date:** 11/20/2015
- **Minimum Passing:** 80
- **Reported Score*:** 96

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Introduction (ID:757)	11/20/12
History and Ethical Principles - SBE (ID:490)	11/20/12
The Federal Regulations - SBE (ID:502)	11/20/12
Assessing Risk - SBE (ID:503)	11/20/12
Informed Consent - SBE (ID:504)	11/20/12
Privacy and Confidentiality - SBE (ID:505)	11/20/12
Regis University (ID:1164)	11/20/12

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Figure F4: CITI Training Certificates: Human Research Social Behavioral Research Investigators and Key Personal.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Albrecht (ID: 3214269)
- **Email:** karen.albrecht@dhha.org
- **Institution Affiliation:** University of Colorado Denver (ID: 610)
- **Institution Unit:** nursing
- **Phone:** 303-602-4217

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 1 Biomedical Investigators
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 13118033
- **Completion Date:** 06/01/2014
- **Expiration Date:** 05/31/2017
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Introduction (ID:757)	11/20/12	No Quiz
History and Ethics of Human Subjects Research (ID:498)	11/20/12	6/6 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID:2)	11/20/12	5/5 (100%)
Informed Consent (ID:3)	11/20/12	4/4 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID:4)	11/20/12	4/4 (100%)
Records-Based Research (ID:5)	11/20/12	2/2 (100%)
Genetic Research in Human Populations (ID:6)	11/20/12	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview (ID:7)	11/20/12	4/4 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID:8)	11/20/12	4/4 (100%)
FDA-Regulated Research (ID:12)	11/20/12	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID:488)	11/20/12	4/5 (80%)
UCD (ID:918)	06/01/14	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Figure F5: CITI Training Certificates: Human Research Biomedical Investigators.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Albrecht (ID: 3214269)
- **Email:** karen.albrecht@dhha.org
- **Institution Affiliation:** University of Colorado Denver (ID: 610)
- **Institution Unit:** nursing
- **Phone:** 303-602-4217

- **Curriculum Group:** CITI Health Information Privacy and Security (HIPS)
- **Course Learner Group:** CITI Health Information Privacy and Security (HIPS) for Students and Instructors
- **Stage:** Stage 1 - Basic Course
- **Description:** This course for **Students and Instructors** will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

- **Report ID:** 13118034
- **Completion Date:** 06/01/2014
- **Expiration Date:** 06/01/2017
- **Minimum Passing:** 80
- **Reported Score*:** 95

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Introduction (ID:12786)	06/01/14	No Quiz
About the Course (ID:1416)	06/01/14	1/1 (100%)
Basics of Health Privacy (ID:1417)	06/01/14	16/16 (100%)
Health Privacy Issues for Students and Instructors (ID:1420)	06/01/14	4/4 (100%)
Basics of Information Security, Part 1 (ID:1423)	06/01/14	No Quiz
Basics of Information Security, Part 2 (ID:1424)	06/01/14	5/5 (100%)
Completing the Privacy and Security Course (ID:1434)	06/01/14	No Quiz
UCD (ID:918)	06/01/14	No Quiz
Protecting Your Portable Devices (ID:1427)	06/01/14	6/6 (100%)
Protecting Your Identity (ID:1428)	06/01/14	5/7 (71%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Figure F6: CITI Training Certificates: Health Information Privacy and Security.

Appendix G

Agency Letters of Support

DENVER HEALTH
Level One Care for ALL

NURSING MANAGEMENT

RESEARCH INVOLVING NURSING RESOURCES APPROVAL FORM

Instructions:

Please submit completed approval form to:
Kathy Boyle, RN, Ph.D.
Chief Nursing Officer
Administration, 660 Bannock Street, MC 0278
Kathy.Boyle@dhha.org
(303) 602-4957

Project Title:

Evaluation of Information Quality, User Satisfaction and Use of an Electronic Lactation Assessment Pre and Post Optimization With User Centered Design

Project Period
Start Date: September 1, 2014 End Date: May 30, 2015

Project Team (List only DHHA personnel)

Name	Role	Phone Number	Dept/Div
Karen Albrecht	Principal Investigator	303-602-4217	eHS
Bonnie Adrian	Co-Investiagor	303-602-2965	Nursing

Required Materials for Review:

☐ **Protocol**
☐ **Education Plan** (Describe plan for educating Nursing personnel about study protocol and the activities they are expected to perform (i.e. monitoring for adverse effects of medications). If additional space is needed please attach separate document to this form.

Purpose: The purpose of this study is to evaluate the effect of an optimized electronic lactation assessment on information quality, use and user satisfaction.

Background
Electronic nursing assessments serve as locations for nurses to document observations and care and as communication tools to provide the healthcare team with information for clinical decision making. The design of the assessment can influence the quality of information. When the design of an electronic lactation assessment impedes the collection of complete and accurate data or limits access to information, then users' dissatisfaction may impact the use of information to support the provision of patient care. Assessments should be optimized to increase information quality, use and user satisfaction.

Figure G1: Denver Health Nursing Letter of Approval.

Intervention: Optimized electronic lactation assessment with changes to improve the efficiency and effectiveness of data entry and viewing information.

Dependent Variables: Use, User Satisfaction, Information Quality

Population:

Inpatient and outpatient healthcare providers who provide care to breastfeeding couplets and who document in and/or access information from the EHR.
Postpartum breastfeeding women and newborns that have a lactation consultation documented electronically during their inpatient stay.
Exclusion Criteria: Prisoners, Children < 18 years of age, Pregnant women and fetuses, decisionally challenged

Methodology: Pre and Post Quasi-experimental design. Each study period is 4 weeks in length. Pre study period will be early Fall, 2014 and Post study period will be Spring of 2015.

Instrumentation:
Electronic Survey for user perceptions of Use, User Satisfaction, and Information Quality: time estimate 20 minutes.
Chart Audits for information quality (presence of required Baby Friendly documentation) completed by PI during non-working hours.
Electronic Use Log to measure the number of times users access the completed lactation assessment from LLC or EDM.

Educational Plan:
The lactation consultants have been involved with the optimization of the electronic assessment. Other staff members have been consulted as part of a User Centered Design for optimizing the assessment. Nursing staff will be educated on the study through the email inviting participation in the survey and/or through a Huddle inviting participation in the study.

Clinical Resources Required:

1. Describe the grant/research related activities for which nursing staff will be responsible for (check all that apply):

☐ Survey
Complete an electronic survey on their perception of the information quality of the electronic lactation assessment as well as their use of the information and satisfaction with the assessment. Anticipated time commitment is 10 – 20 minutes during each study period (2 periods total).

2. Type and number of nurses needed: Nurses who provide care to breastfeeding mothers and/or newborns: NICU, M/B, and float pool.
All nurses who fit the inclusion criteria listed above will be invited to participate in the survey.

Nursing shifts needed to complete the study. Any Shift

3. Time Commitment: 10 – 20 minutes to complete survey
Will this study require dedicated nursing time? No
Will this study require the nurses' full attention for their entire shift? No

Time Required of Each Nurse			
Role	**Study Orientation**	**Per Subject Contact**	**Overall Participation (hours per week)**
As study team	N/A		

Figure G1. Continued.

4. Type and number of patients/research participants sought: **20 -40 survey participants for each study period**
5. Time of day when data will be collected: ☐ Day ☐ Evening ☐ Night Shift
6. How will nursing staff time be compensated?
   - ☐ Time and Effort allocation
   - ☐ Unfunded – Part of nursing operational budget
   - ☐ OP/IP Care costs budgeted in grant/contract
   - ☐ Other: _____

Equipment needed for this protocol:

Computer access to complete electronic survey.

Clinical supplies needed for this protocol:

None

Clinical service areas to be used (state specific unit(s)/clinics):

None

Comments:

Additional data collection will be completed by chart audits conducted by the principal investigator during non-working hours.

If at all possible, I as the PI agree to share the results of this study with the nursing units that participated in conducting the research. I understand providing this type of feedback tends to promote active participation in future research studies.

CERTIFICATION

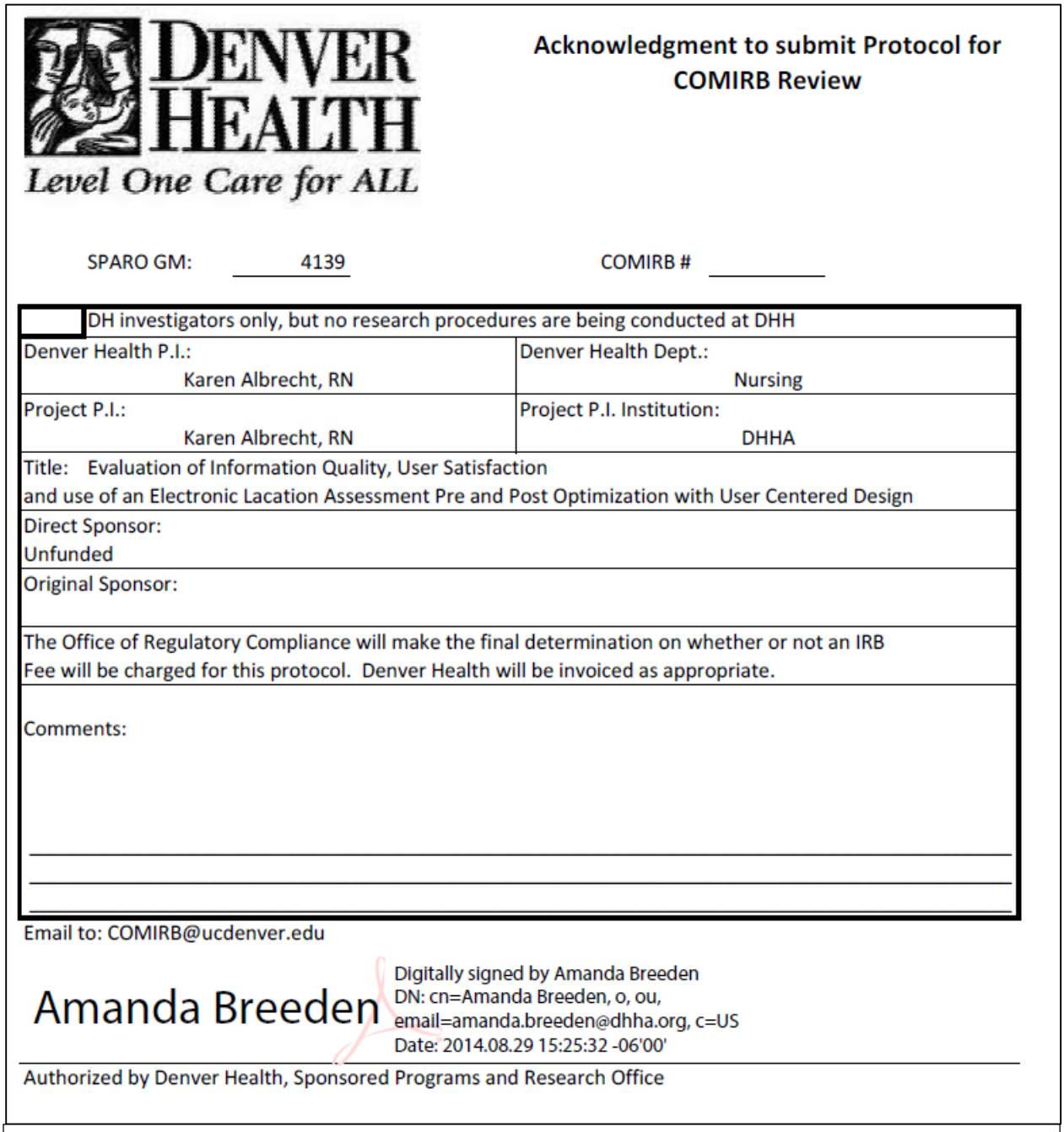
I certify that the above information is correct:

Karen Albrecht (Principal Investigator) — August 6, 2014 (Date)

APPROVAL SIGNATURES

☐ Approved ☐ Denied — 8/11/14 (Date) — Kathy Bayke, Chief Nursing Officer

Figure G1. Continued.



DENVER HEALTH
Level One Care for ALL

Acknowledgment to submit Protocol for COMIRB Review

SPARO GM: 4139 COMIRB # _____

☐ DH investigators only, but no research procedures are being conducted at DHH	
Denver Health P.I.: Karen Albrecht, RN	Denver Health Dept.: Nursing
Project P.I.: Karen Albrecht, RN	Project P.I. Institution: DHHA
Title: Evaluation of Information Quality, User Satisfaction and use of an Electronic Lacation Assessment Pre and Post Optimization with User Centered Design	
Direct Sponsor: Unfunded	
Original Sponsor:	
The Office of Regulatory Compliance will make the final determination on whether or not an IRB Fee will be charged for this protocol. Denver Health will be invoiced as appropriate.	
Comments:	

Email to: COMIRB@ucdenver.edu

Amanda Breeden

Digitally signed by Amanda Breeden
DN: cn=Amanda Breeden, o, ou, email=amanda.breeden@dhha.org, c=US
Date: 2014.08.29 15:25:32 -06'00'

Authorized by Denver Health, Sponsored Programs and Research Office

Figure G2: Denver Health Sponsored Programs and Research Office