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A Quality Improvement Project to Evaluate Auditor Satisfaction with Different Data
Collection Methods for Auditing Compliance with Catheter Associated Urinary
Tract Infection (CAUTI) Prevention Standards

Andrea S. Balzer

Submitted as partial fulfillment for the Doctor of Nursing Practice Degree

Regis University

March 31, 2015

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Executive Summary

A Quality Improvement Project to Evaluate Auditor Satisfaction with Different Data Collection Methods for Auditing Compliance with (CAUTI) Prevention Standards

Problem

Catheter-associated urinary tract infections (CAUTIs) are among the most common healthcare-associated infection (HAI) in the United States, representing about 40% of all HAIs (Palmer, Lee, Dutta-Linn, Wroe & Hartmann, 2013). Approximately 25% of indwelling urinary catheters are unnecessary and may potentially lead to CAUTIs if not maintained, cleaned, and cared for appropriately (Nazarko, 2012). Literature suggests that preventing CAUTIs is possible by implementing evidence based prevention standards. The PICO research question for CAUTI prevention and prevention standard data collection is: In a sampling of clinical auditors (P) does implementation of an electronic audit tool to collect data on compliance with CAUTI prevention care standards in addition to education on the electronic audit tool (I) differ from paper form auditing for CAUTI prevention care standards (C) and does it impact auditor satisfaction and/or data collected using the new tool (O).

Goal

The goal of this project was to assess if there were differences in paper versus electronic audit collection methods by evaluating pre- and post-implementation auditor satisfaction. In addition, an assessment of the two collection methods was completed to evaluate consistency related to number of audits collected and notable changes in compliance, thereby providing insight into if electronic data capture (EDC) is a reliable and efficient method.

Objectives

Project objectives included determining auditor satisfaction with paper versus electronic data collection methods and evaluation of implications of reliability with data collection methods by maintaining consistency with data.

Plan

Following Institutional Review Board approval from Regis University, the project was implemented and data were collected retro- and prospectively. There was an organizational transition to EDC, a questionnaire was distributed eliciting feedback from auditors on their satisfaction level, and compliance with the prevention standards was assessed for consistency pre- and post-implementation of the EDC tool. Questionnaire data were coded and entered into a spreadsheet and statistical software was used to determine if there were significant changes in auditor satisfaction. Finally, an assessment of differences in processes used to collect CAUTI prevention standard data was completed.

Outcomes and Results

Nine clinical auditors and one data analyst were exposed to both paper and EDC tools and completed the questionnaire. While there was not a statistically significant increase in satisfaction, there was a clinically significant increase in auditor satisfaction. There was a statistically significant difference noted between pre- and post- implementation compliance data, but this does not prove a causal relationship due to other confounding factors. There was also a statistically significant decrease in average time it took for auditors to collect audit data.

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Abstract

Catheter-associated urinary tract infections (CAUTIs) are among the most common healthcare-associated infection (HAI) in the United States, representing about 40 per cent of all HAIs (Palmer, Lee, Dutta-Linn, Wroe & Hartmann, 2013). Literature suggests that preventing CAUTIs is possible by implementing evidence-based prevention standards. In order to understand compliance with completion of CAUTI prevention standards, compliance data is collected by auditors. This capstone project discusses and examines auditor satisfaction with different collection methods (paper versus electronic audit tool), and provides an assessment of how data were collected by two different audit tools and ways in which technology can be leveraged for innovative data dissemination.

Keywords: CAUTI, Pediatric CAUTI, Catheter-associated urinary tract infection, pediatric catheter associated urinary tract infection, Catheter-associated UTI, pediatric catheter associated UTI, CAUTI Prevention, Pediatric CAUTI Prevention, catheter associated urinary tract infection prevention, pediatric catheter associated urinary tract infection prevention, Indwelling urinary catheter, Pediatric indwelling urinary catheter, Pediatric urinary catheter Electronic data capture, Paper and electronic data capture, REDCap©.

A Quality Improvement Project to Evaluate Auditor Satisfaction with Different
Data Collection Methods for Auditing Compliance with Catheter Associated
Urinary Tract Infection (CAUTI) Prevention Standards

Catheter-associated urinary tract infections (CAUTIs) occur as a result of utilizing indwelling urinary catheters for removal of urine from the bladder in patients. Indwelling catheterization may be clinically indicated, but there are times when an indwelling urinary catheter is placed in a patient outside of clinical indications, which is unacceptable practice. Approximately 25 per cent of indwelling urinary catheters are unnecessary and may potentially lead to CAUTIs if not maintained, cleaned, and cared for appropriately (Nazarko, 2012). This capstone project evaluates the processes used to collect compliance data as a means to evaluate adherence with completion of CAUTI prevention standards. CAUTI prevention standards should be strictly adhered to and implemented together in a consistent and reliable way as part of the maintenance care of indwelling urinary catheters. These data were collected via paper and electronic audit tool. This capstone project compared data collected by both the paper and electronic tools and evaluated auditor satisfaction.

Problem Recognition and Definition

The most common definition for preventable harm is “presence of an identifiable, modifiable cause of harm” (Nabhan et al., 2012, p. 8). Preventable harm is currently at the forefront for healthcare and rightfully so because as the term itself indicates, certain types of harm or infections imposed on patients are preventable. CAUTIs are one such type of preventable infection that are not only prevalent in the United States, but also the most common healthcare associated infection (HAI) worldwide (Palmer, et al., 2013; Hooton, et al., 2010).

CAUTIs may be the most preventable HAI with the number of avoidable infections ranging from 95,483 to 387,550 per year (Umscheid et al., 2011).

Furthermore, the risk of a patient acquiring a CAUTI increases by approximately 5-10 per cent each day the indwelling urinary catheter remains in place (Bruminhent, et al., 2010). Removing indwelling urinary catheters along with providing CAUTI prevention standards as part of catheter maintenance care can help prevent and reduce the risk of acquiring a CAUTI. In order to understand a clinician's ability to impact CAUTI reduction, it is important to measure adherence to completing CAUTI prevention standards.

Problem Statement

There is an institutional knowledge and performance gap in articulating and successfully completing CAUTI prevention standards. A multidisciplinary CAUTI work group was formed to focus on CAUTI prevention. This group is considered the organization's subject matter expert (SME) group to advise on products, education needs, and care standards related to urinary issues and initiatives, including CAUTI prevention. CAUTI prevention standards were determined by the CAUTI work group using literature and expert opinion to guide standard, evidence-based practices and used as the standard of practice for the organization (Appendix A). The organization's clinical staff were educated on how to appropriately care for patients with indwelling urinary catheters and implement CAUTI prevention standards in a methodical and consistent way.

There were four identified CAUTI prevention standards and a measurement system was created to evaluate staff compliance with performing these prevention standards. Gillam and Siriwardena (2013) discuss that the clinical audit cycle involves measuring performance against one or more predefined criteria and consistent assessment of performance in criteria against a

standard until that standard is achieved or until a new standard is set. The standard existed for all bedside staff to complete four CAUTI prevention standards for every patient with an indwelling urinary catheter. The four prevention standards include:

1. Urinary catheter care once every 12 hours
2. Urine collection bag below level of bladder
3. Urine collection bag less than half full
4. Daily assessment of indwelling catheter need

In order to determine the extent to which a patient is at risk, the CAUTI prevention standards are audited for completion for any patient with an indwelling urinary catheter. The resulting information is referred to as compliance or reliability to the CAUTI prevention standards. In order to be compliant, all four CAUTI prevention standards must be completed together to provide maximum efficacy in CAUTI prevention (all-or-none compliance) (Appendix B). These data provided valuable information into potential key drivers to achieving CAUTI prevention standard compliance, but also as potential key drivers for preventing CAUTIs. For example, if catheter care is consistently the non-compliant element in the overall bundle compliance, efforts to mitigate for this may result in an increase in compliance by reliably performing catheter care every shift and theoretically, lead to a decreased number of CAUTI events.

Nahm, Pieper, and Cunningham (2008) discuss that in addition to providing objective information about processes, auditing for compliance with prevention standards can prevent future errors by identifying problematic work patterns or behaviors. Auditing is also used in the organization to uncover barriers that prevent staff from completing prevention standards consistently and reliably. Compliance data were historically collected via paper audit tool

(Appendix C), entered into database, and manually analyzed for percent compliance for both the individual prevention standards as well as the all-or-none compliance coefficient. This information was then distributed to inpatient unit-based representatives and leaders for subsequent dissemination to staff.

This capstone project evaluates the implementation of an electronic audit tool called REDCap© (Research Electronic Data Capture) as a replacement for the paper audit form (Appendix D). REDCap© is an electronic data repository that has dynamic functionality that allows the user to build audit tools, safely store protected health information (PHI), as well as de-identify information (REDCap©, 2014). It is a free, web-based and user-friendly electronic data capture (EDC) tool. REDCap© is useful in collecting and tracking information and data and can be quickly developed and customized for users' needs (Harvard Catalyst, 2014). The registered nurse (RN) representatives that sit on the organizational CAUTI work group also function as clinical auditors. REDCap© allows clinical auditors to easily and quickly complete audits via hand held device, laptop, or bedside computer. Collecting audit data via paper audit form was a suboptimal process and the steps of data re-entry and analysis were completely eliminated after implementing the REDCap© EDC process. Data collected via EDC were automatically exported to an organizational data warehouse, then analyzed via code and read by a program that graphically shows CAUTI compliance called the "dynamic dashboard" (Appendix E). This new process has made the data easily accessible, encrypted, and protected by the technological infrastructure of the organization in which this project was implemented.

Furthermore, this technology "talks" to the organization's internal computerized electronic medical record (EMR) which allows for current data (within the last hour) to be pulled into the electronic audit tool. This allows the auditor to answer only the audit questions that are

observed for, therefore eliminating the need for chart review. Changing methodologies from paper to EDC decreased the number of questions the clinical auditor answered on the audit form as well. The paper audit tool was easy to fill out, but there were limitations around data analysis, data graphing, and data distribution. After the paper forms were completed and collected, they were manually entered into a database and analyzed using clinical judgment and cell formulas. The former process increased the potential for error and required more time of the person who entered and analyzed the data, primarily the data analyst. Lastly, this process was not a preferred way to store protected health information (PHI) and the data were aggregated at the end of the month, leading to what was sometimes a month delay in data dissemination.

Web-based data collection appears to be a promising data collection tool and have the potential to offer improvements over paper data collection methods (Chizawsky, Estabrooks, & Sales, 2009). Due to the risk associated with manual data entry and analysis, the organization implemented REDCap© as the chosen tool for data collection. REDCap© was initially developed to provide scientific research teams with intuitive and reusable tools for collecting, storing, and disseminating project-specific clinical and translational research data. This capstone project evaluation looks at efficiency and satisfaction after implementation of REDCap© as the replacement for the paper audit form.

Literature Review

Searches for CAUTI, CAUTI prevention, and electronic data capture (EDC) were completed using CINAHL, Medline, Ovid, and Cochrane. Searches were completed using subject headings related to CAUTI, Pediatric CAUTI, CAUTI prevention, Pediatric CAUTI prevention, electronic data capture (EDC), REDCap©, paper versus electronic auditing, and paper versus electronic data capture (Appendix F). Literature between the years 2003-2014 were

utilized related to CAUTI, CAUTI prevention, and EDC. Research evidence gaps of this project relate to there being limited research on the pediatric population, limited research on clinical auditing for quality improvement, and difficulty finding literature related to the specific type of EDC used in the clinical, inpatient setting.

CAUTI/pediatric CAUTI. In general there is limited information related to the pediatric population. A literature search was initiated using the key words “pediatric CAUTI” (spelling out catheter associated urinary tract infection) and “CAUTI” in CINAHL, Cochrane, MEDLINE and PubMed. The searches resulted two, zero, five, and six articles, respectively, for “pediatric CAUTI” and 103, nine, 187, and 188 for “CAUTI”. The key words “catheter-associated urinary tract infection” resulted 424, three, 531, and 672 articles and a search on “pediatric catheter associated urinary tract infection” resulted 14, one, 17, and 23 articles.

An article by Elvy and Colville (2009) discusses that CAUTIs are one of the most frequently encountered HAIs due to their susceptibility to be colonized with microorganisms in long-term catheterized patients. They further discuss that a majority of the cases go undetected with more than 90 per cent being asymptomatic and thereby fall into the category of asymptomatic bacteriuria (ABU). CAUTI and ABU require different treatment measures and understanding there is a distinction between the two is important. Consequently, catheter biofilm and bacteria are difficult to eradicate (Slater, 2011).

In order to identify CAUTI events, there are specific criteria and an algorithm provided by the National Healthcare Safety Network (NHSN) as part of Centers for Disease Control and Prevention (CDC). The CDC identifies core CAUTI prevention strategies such as only inserting indwelling catheters when appropriately indicated, leaving indwelling catheters in place only as long as needed, and maintaining a closed system, for example (CDC, 2010). Healthcare

Infection Control Practices Advisory Committee (HICPAC) (2009) is a branch of the CDC that provides a user-friendly website and PDF version of “Guideline(s) for Prevention of Catheter-Associated Urinary Tract Infections, 2009.”

Implications of acquiring a CAUTI potentially relate to length of stay (LOS) as well as mortality. Chant, Smith, Marshall, and Friedrich (2011) completed a systematic review to determine whether CAUTIs are associated with increased morbidity and mortality in critically ill patients and found while there is increased mortality and LOS in ICU patients in their unadjusted analysis, the mortality increase does not exist when the analysis is adjusted for other prognostic factors. LOS, in contrast, does relate to CAUTI acquisition, however it is unclear which causal relationship exists (CAUTI causes increased LOS versus longer ICU stays cause CAUTIs). “Incurred costs derive from increased LOS, urinalysis, and urine culture and sensitivity tests as well as the use of antibiotics” further contribute to the negative impact of acquiring a CAUTI (Palmer et al., 2013).

CAUTI prevention/pediatric CAUTI prevention. If there is no indwelling urinary catheter in place, there is no subsequent risk, therefore making removal of an indwelling urinary catheter the primary goal of CAUTI prevention. Additionally, the most effective way to prevent urinary tract infections is to reduce the incidence of urinary catheterization (Nazarko, 2012). Wald, Ma, Bratzler, & Kramer (2008) propose that “the longer a urinary catheter remains in place, the greater the risk of infection” (p. 580). Moreover, Nazarko also notes that approximately 25 per cent of indwelling urinary catheters are unnecessary and there are certain populations (such as the elderly) that are more likely to be catheterized.

Established clinical guidelines exist to prevent CAUTIs according to Hooton, et al. (2010) and, as noted previously, HICPAC as part of the CDC outlines core CAUTI prevention

strategies that highlight best practices and evidence for indication of indwelling urinary catheter need, catheter insertion, and catheter maintenance (HICPAC, 2009). Furthermore, the need for CAUTI prevention is further substantiated by Flores-Gonzalez, et al. (2011) who found that a patient suffering from a CAUTI had significantly more relevant medical antecedents and an increased LOS. They also found, while statistically non-significant, a tendency towards increased CAUTIs in younger patients and those who required indwelling urinary catheters for longer duration.

The United States Department of Health and Human Services (DHHS) established the goal of decreasing the incidence of CAUTI by 25 percent from the 2009 baseline to achieve a reduction in preventable HAIs by 2013 (DHHS, 2014). Currently, they are not on track to meet this goal and 2014 goals have not been released yet. Incentives related to lack of prevention are tied to CMS non-repayment and reimbursement related to hospital-acquired CAUTIs is at stake. Meddings et al. (2012) and Fakih et al. (2012) discuss that the Center for Medicare and Medicaid Services (CMS) consider CAUTI a HAI that is “reasonably preventable.” CMS’ decision to incentivize prevention of CAUTIs, and more broadly “reasonably preventable” HAIs, is part of a value-based purchasing plan to encourage hospitals to improve patient safety and reduce Medicare spending (Meddings et al); thereby linking payment with quality (Palmer et al., 2013).

While proper maintenance has been shown to be fundamental in preventing CAUTIs, there are known barriers to reliably and properly completing maintenance elements. Krein, Kowalski, Harrod, Forman, and Saint (2013) find that there are three common barriers to bundle implementation:

1. Difficulty with nurse and physician engagement
2. Patient and family request for indwelling urinary catheters

3. Catheter insertion practices and customs

Krein et al. couple their knowledge of barriers with strategies to mitigate said barriers by:

1. Incorporating urinary management (e.g. planned toileting) as part of other patient safety programs, such as fall reduction
2. Explicitly discussing the risks of indwelling urinary catheters with patients and families
3. Engaging with emergency department nurses and physicians to implement a process that ensures that appropriate indications for catheter use are followed (2013).

Electronic data capture. Welker (2007) discusses that while conversion to electronic data capture (EDC) has been a slow progression, the use of EDC should bring with it improved data integrity, cost savings, among other benefits. Another important benefit of EDC allows for increased database access to the analyst, therefore the potential to accommodate more timely feedback to the end-user (2007).

Additionally, Welker discusses respondent results from an international survey as they relate to identified barriers and pertinent solutions to enabling use of EDC technology. Welker provides information on 12 highlighted barriers and solutions, but only the potential barriers and solutions related to this capstone proposal will be highlighted. Applicable barriers include:

1. User input is not always captured from the appropriate end-users. Instead, focus on gathering input from a process-oriented group rather than technology-oriented group to better-understand their needs and suggested solutions.
2. Technical support can sometimes be a source of delays, therefore keeping in close and constant contact with the Information Technology (IT) department is pivotal to minimizing delays and receiving appropriate support.

3. User motivation is often referred to as WIIMS (plural for “what’s in it for me?”) and considering users that are disinterested or disengaged prior to implementation may potentially garner motivation during the implementation phase.
4. Regulatory requirements “set challenging expectations of EDC systems” (p.332). Prior to implementing an EDC system, the organization should ensure compliance with these regulatory requirements.
5. Lack of communication with users can be improved by having a convenient feedback loop to the end-users as well as keeping the end-user informed of implementation progress.
6. Timing of implementation can be perceived as a barrier if not done with cognizance by utilizing time when staff are “less busy than average and engaged in learning a new project or techniques” (p. 332).
7. Due to the time constraints software updates can bring, it is very important to heavily partner with IT so as to understand requirements from both perspectives. This may allow adequate time for IT to build enough server space to allow for EDC use for the purposes warranted.
8. Welker discusses identification of “bridgers,” “early adopters who become the support person for other members of the team,” also known as super users (p. 333). Bridgers can give early visibility and encourage users throughout the implementation process.
9. Welker poses that “a truly comprehensive EDC system would include direct data entry for both investigators and patients” whereby patients have their own login and perform direct data entry (p. 333).

While patient participation was out of scope for this capstone proposal, it is a goal of future studies and potential optimization opportunities. The other two barriers relate to availability of technology such as internet and computer availability and costs. These two barriers are discussed by Welker in the scope of research and are not seen as barriers to future project implications because existing technology is established and widely available in the organization.

Shah, et al. (2010) discuss that spreadsheets and offline databases, while common, are not dynamic, secure, workflow friendly, do not support the generation of standardized data, and are not interoperable in nature. Interoperable is defined as the ability to share data between different computer systems (The Free Dictionary, 2014). “EDC systems, in addition to addressing these limitations, reduce a substantial amount of workload, time, and cost as well as enhance the quality of data collected” (Shah, 2010, p. 2665).

In light of quality improvement and nursing research, Colfer, Brodecki, Hutchins, Stellar, and Davis (2011) express that:

As increasing numbers of nursing research studies and QI (quality improvement) projects are being conducted to improve practice, it is clear that nurses need to embrace the technological advances in data collection, as well as managing, accessing, and interpreting data so that meaningful analysis can occur. (p. 595)

Colfer et al. (2011) collected user survey results that showed 95 per cent satisfaction as well as time saved in the data collection process. Some issues, such as internet disconnection, laptop charge, and the new process being outside of the auditor’s previous auditing process were uncovered.

Wahi, Parks, Skeate, and Goldin (2008) offer that paper audit processes are often preferred for researchers and auditors due to their comfort with this process and related discomfort with electronic data capture processes. However, paper forms tend to pile up quickly requiring time spent retrospectively entering data whereas EDC removes the subsequent data entry component. Wahi et al. did not find a statistically significant difference in the data quality captured via electronic method versus entry via a staff member. They do note, however, that their data entry staff member's error rate was acceptable, implying the ability to validate and test data entry personnel error rate is an important factor in data quality. An additional study by Pavlovic, Kern, and Miklavcic (2009) found that an advantage of EDC is that data managers have continuous insight into the data and the data collection processes and thus can manage the data collection process more effectively (p. 300).

Finally, Shervin, et al. (2011) completed a prospective repeated-measures analysis of variance looking at three different data collection modes: paper, touch screen, and web-based. While all no significant difference between data collection modes were identified, they did find that the computer-based questionnaires showed high validity and reliability.

REDCap®. The Research Electronic Data Capture system was developed by Vanderbilt University through support by a large consortium of domestic and international partners (Obeid, et al., 2012). To date, there are upwards of 92,000 projects currently in production or build-status with over 120,000 users spanning the globe (REDCap®, 2014). REDCap® is a technology that provides a workflow process used to support clinical and translational research (Harris, et al., 2008). Additionally, the REDCap® user interface provides an intuitive method to securely and accurately input data, hardware and software requirements are modest, and is an easily maintainable resource for multiple concurrent studies (Harris et al., 2008).

Obeid et al. (2008) further defines data validity as the “degree to which the data measure what they are intended to measure” and standardized data collection implies “the use of standards such as data structures or data models” (p. 260). These elements will be further discussed in the instrument reliability section of this capstone project.

Theoretical Foundation

Rogers’ Diffusion of Innovations theory provides the framework for this capstone project. Diffusion of Innovations is a highly complex, adaptive process in which the organization adapts the innovation and the innovation is adapted to the organization (Greenhalgh, Robert, MacFarlane, Bate & Kyriakidou, 2004).

Rogers (2003) discusses the *innovation-diffusion process* as “the process through which an individual (or other decision-making unit) passes from gaining initial knowledge of an innovation, to forming an attitude toward the innovation, to making a decision to adopt or reject, to implementation of the new idea, and to confirmation of this decision” (p. 168). Furthermore, Rogers elaborates that the innovation-diffusion process consists of five stages:

1. Knowledge of being exposed to the innovation’s existence and understanding of how it works,
2. Persuasion and subsequent forming of a favorable or unfavorable attitude toward innovation,
3. Decision to adopt or reject the innovation,
4. Implementation of the new idea,
5. Confirmation resulting in the need to acquire more information of the innovation-decision or reverse the previous decision (p. 169).

Three types of knowledge about innovation relate to:

1. Awareness knowledge
2. How-to knowledge
3. Principles knowledge (Rogers, 2003, p. 173).

The heart of the diffusion process consists of the modeling and imitating by potential adopters to get future adopters on board (Rogers, 2003). Change agents and early adopters primarily concentrate their efforts in creating awareness-knowledge. These first level adopters could be the “bridgers” or “super users” as discussed previously in the literature review section as important factors in EDC implementation success.

Another enabler of adopting innovation is if the innovation is made via *authority innovation-decision*. Rogers outlines that authority innovation-decisions are “choices to adopt or reject an innovation that are made by relatively few individuals in a system who possess power, status, or technical expertise” (2003, p. 28-29). Additionally, this type of decision usually has the fastest rate of adoption by a group or organization due to its authoritative nature. The use of REDCap© to collect data is an authority innovation-decision originating from a joint agreement between the division and quality and patient safety leaders and the division of information technology leaders.

Key drivers to successful adoption of innovation include characteristics of the innovation (intervention), methods of communication (training), characteristics of the end users (auditors), and characteristics of the organization or system (Rogers, 2003). Rogers outlines an additional four main elements of Diffusion of Innovations as a process by which (1) an innovation (2) is communicated through certain channels (3) over time (4) among members of a social system (p. 11).

Rogers further explains that “the *critical mass* occurs at the point at which enough individuals in a system have adopted an innovation so that the innovation’s further rate of adoption becomes self-sustaining” (p. 363). Critical mass seems to concurrently rely on individuals’ thresholds on which the number of individuals who must be engaged in an activity lead to a given individual joining that activity (p.363). Another point made is that the more persons involved in making an innovation-decision, the slower the rate of adoption, but the point at which opinion leaders adopt is when the greatest response to a change effort occurs and will then spread with little promotional effort (p. 223).

This investigator believes that using Rogers’ Diffusion of Innovation framework was particularly applicable and helpful in completing this capstone project. Berwick (2003) stresses that Diffusion of Innovations is a major challenge in all industries, including healthcare and even when innovations are implemented successfully, spread of that innovation takes time. Berwick outlines several recommendations to aid in accelerating the rate of diffusion of innovations: ensure innovation is easy to adopt and understand, recruit engaged early adopters, showcase and make early adopter activity transparent, trust and enable reinvention, create space for change, and lead by example. Coupling Rogers’ theory along with Berwick’s keys to accelerating diffusion of innovation provided actionable and tangible resources for implementation of the REDCap© EDC tool.

In addition to using Rogers’ Diffusion of Innovation theoretical underpinnings, the project investigator chose to leverage Malcolm Knowles’ adult learning theory (ALT). Knowles’ theory has two distinct pieces, principles and a model. The underlying principles include self-concept, experience, readiness to learn, orientation to learning, and motivation to learn (infed.org). These principles are anchored in the characteristics of adult learners and are

relationship-focused to create what Knowles refers to as the ALT model. The model is a step-wise approach that was utilized in the implementation of the capstone project when REDCap© went live, as well as with the dissemination and teaching of the CAUTI prevention standards to all clinicians. Elements of Knowles' model include:

1. Diagnosing learning needs
2. Formulating learning needs
3. Identifying resources for learning
4. Choosing and implementing appropriate learning strategies
5. Evaluating learning outcomes

Market/Risk Analysis

Strengths, Weaknesses, Opportunities, and Threats

Strengths of the project include being aligned with organizational priorities and having an organizational multi-disciplinary group aligned to this work. As discussed above, the internal CAUTI work group is focused on this effort and has, therefore, brought tremendous value to the organization in terms of creating awareness and driving compliance with CAUTI prevention standards. Additionally, the implementation of REDCap© eliminated manual entry of audit data, as well as helped provide near real-time data to visualize the audit data collected.

There was a learning curve and training involved in order to implement EDC tool which carried the potential to impact user satisfaction and was noted as a weakness. The implemented technology was not as appealing to those who were less “tech-savvy.” The EDC method required limited analysis and clinical judgment when adding branching logic for questions in the electronic tool. The REDCap© build must be done by someone who has training and is proficient in using REDCap© in the healthcare setting.

The development of the EDC tool and this project offered several opportunities to expand the project and apply the methodology to other organizational groups focused on eliminating preventable HAI conditions. Opportunities associated with REDCap© implementation such as streamlining data analysis processes enabled the end-user to have easy access to viewing data in a dynamic way. REDCap© could also lead the way in process data collection and analysis for a similar market.

Auditors did not feel completely comfortable with process at beginning and one clinical auditor considered reverting to the more comfortable paper process. There was a threat that staff perceived the paper process as easier and time-saving based on a familiarity factor. The training schedule was not initially ideal for all auditors and the investigator ultimately tailored the training to meet the needs of the clinical auditors, which took more time. This aspect was not a huge threat, however, and was actually a facilitator in using one-on-one education which was found to be preferred teaching modality (Appendix G).

Needs, Resources, and Sustainability

This project was supported by the investigator's institution of employment and was aligned to the organization's strategic plan and internal safety initiative (Appendix H). The investigator's role at the organization was directly aligned to the house-wide internal safety initiative.

Furthermore, audit data collection had been sustained for over one year for CAUTI as required by the organization. The new method using REDCap© replaced the previous organizational method of using the paper audit form and, to that end, provided the resources and sustainability for this project.

Auditing is recognized as an important process in this organization. The process of auditing is an important part as quality improvement as discussed by Travaglia (2009); auditing is:

...A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the review of change. Aspects of the structure, process and outcome of care are selected and systematically evaluated against explicit criteria. Where indicated changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery (p. 3).

Clinical staff, managers, and organizational leaders rely on audit data to drive improvements in their respective units. It was important to provide them with this information on a consistent and timely basis as these data helped them focus on where improvement opportunities exist. Some of the clinical staff that used CAUTI compliance data are also clinical auditors for CAUTI and are accountable to institution through annual goal and incentive planning.

The organization's clinical auditor group was made up primarily of nurses from various units aligned to various HAI groups. There are CAUTI auditors in every unit where indwelling urinary catheters are present in the patient population. These units included four medical and surgical floors, the Pediatric Intensive Care Unit (PICU), the Neonatal Intensive Care Unit (NICU), and the Cardiac Intensive Care Unit (CICU). PICU, CICU, and one medical and surgical unit had higher incidences of indwelling catheter use than others. At the time of this project, there were approximately nine clinical auditors collecting data for compliance with CAUTI prevention standards using the paper form as the data collection method.

Training for the clinical auditors was provided by the investigator and the data analyst in three forums. Thirty minutes of technical overview was followed by auditing real-time utilizing the “just in time” training method. Lastly, a one hour comprehensive, hands-on training was also required for all the clinical auditors. Links to tutorials and training materials were embedded in the EDC tool that allowed the clinical auditor direct access if further questions arose. The investigator provided their personal phone number and email address in the event questions arose during auditing, during off-hours, and after the initial training period. In order to maintain the momentum and keep information fresh and available, there were “refresher” materials sent out for clinical auditors as available.

Target Market

The project target market included clinical auditors that collected compliance data in their respective units for the organization. There were no age, sex, ethnicity, or cultural exclusions. Clinical auditors self-selected as part of alignment to unit goals or were selected by unit leadership.

The secondary customer was the patient for whom care was being provided and CAUTI prevention standards were audited for completion. There were no sex, ethnicity, or cultural exclusions. By nature of being treated at a pediatric institution, the age range for the secondary customers was age 0 (neonatal population) to 17 years, which is the definition of pediatric (Federal Interagency Forum on Child and Family Statistics, 2013). However, on occasion, there may have been a patient that fell out of the pediatric age range due to medical complications that required them to continue care at a pediatric institution beyond the age of 17 years old. They were included in the audit data if they required indwelling urinary catheterization. However, patient information that was directly imported into the EDC tool was not used for the project,

and was therefore discarded for project analysis. Another secondary customer was the organization in which this capstone project took place. The organization was considered a customer because the information and insights gained from this project directly applied and were used to further the organization's internal patient safety initiative.

Stakeholders and Project Team

There were multiple key stakeholders and members of the project team. Members of the project team and CAUTI work group included: DNP student (project investigator) whose primary role was to advise on quality and process improvement methodologies, the CAUTI house-wide lead who was a PICU registered nurse clinical coordinator, the chief of urology, various nurse unit representatives, some of which were also clinical auditors, a family member, and organizational leaders including the chief quality officer and quality and process improvement manager who attended and provided input on an ad hoc basis. Additionally, patient care staff and unit leaders were direct beneficiaries of the work done in the organizational CAUTI work group. As a result of the work done in this project, inpatient unit staff and leaders were informed of applicable unit-specific data through their CAUTI work group unit nurse representative.

Cost-Benefit Analysis

Electronic data capture. The work done for this capstone project was required by the organization and was budget neutral. The organization's finance department did not feel it was necessary to extrapolate and assign costs to the various elements identified in this project including the REDCap© technology, time of clinical auditors, or assistance of the data coordinator as these elements were considered overhead and part of the monies already being allocated as part of clinical and administrative role functions already planned for. Per the

literature, there may be a potential time savings associated with implementation of REDCap© after training and establishing the new process. While the amount of time it took to collect data with the newly implemented process increased initially, the realized time after implementation and training was no different between collection methods. Thriemer et al. (2012) realized a decrease in time and a 25 per cent reduction in cost by using EDC versus a paper method.

There was a large benefit realized by eliminating double entry of data in decreasing the time for data analysis. By implementing REDCap© there was no subsequent data entry and only a quick validation of the data to make sure fields are completed was needed rather than a full data scrub and analysis. Programming logic was built into the tool that allowed for programmed data analysis, rather than manual data analysis.

Preventing CAUTI through prevention standards. While there is less literature that stratifies pediatric and adult populations related to HAIs, the United States Department of Health and Human Services (DHHS) conveys that “at any given time, about one in 20 patients has an infection related to their hospital care” (2010). This adds up to a yearly cost between \$28-\$33 billion dollars in preventable expenditures (2010). However, out of all discharges in the United States annually (39,435,000), 6,393,800 of them are pediatric discharges (Yu, Wier, & Elixhauser, 2009). Whether the focus is a broad national or international population of pediatric patients or at the local microsystem level such as a children’s hospital, nearly 6.4 million children are needlessly put at risk for acquiring preventable harm or infectious conditions every year.

The organization in which this project was completed had six patients acquire CAUTIs in 2013 and seven in 2014. Through implementing REDCap© and achieving reliability with data

collection processes, the goal is to achieve highly reliable completion of CAUTI prevention standards and subsequently decrease the incidence rate of CAUTIs.

Budget and Resources

Auditors fell under unit-specific budget resource and allocations per each unit leaders' discretion. Each auditor's time was commensurate with their hourly rate, but it was difficult to ascertain direct cost incurred as auditing is part of their daily role at the bedside or as part of their duties outside of bedside care used during their allotted administrative time.

The Bureau of Labor Statistics lists the average hourly rate of a registered nurse working in a hospital setting in the state of Colorado as \$32.66 (2012). The estimated cost per auditor was \$32.66 multiplied by 4 hours for one-time EDC tool and auditing training plus \$32.66 multiplied by one hour for every month after that totaling approximately 522.56 for a 12 month time period initially and \$391.92 for every year after that for one clinical auditor.

Although REDCap© is a free software program from Vanderbilt University, the technology requires IT resources and the oversight of a data analyst to integrate the software with an organization's existing technological infrastructure as well as tailor it to the organization's specific auditing and data needs. The average computer systems analyst in the state of Colorado earns, on average, \$40.29 per hour (Bureau of Labor Statistics, 2012). Time spent developing, integrating, building, coding, testing, and maintaining REDCap© is, initially, a large requirement. For this project, the estimated time spent on REDCap© related specifically to CAUTI was approximately 12 hours per week for a period of four months. Maintaining data and functionality tapers to approximately four hours per month after the initial build. The estimated budget requirement for the first year is $\$40.29 \times 12 \text{ hours} \times 16 \text{ weeks} = \$7,735.68 + \$40.29 \times 4 \text{ hours} \times 12 \text{ months} = \$1,933.92 = \$9,669.60$. However, building in extra time on a yearly basis

would serve as a proactive measure to accommodate maintenance needs and innovative optimizations (Appendix I).

Bedside unit computers were the primary tool for using EDC by auditors. The Quality and Patient Safety Department purchased eight hand held tablets for use by all clinical auditors for all HAC groups. Clinical auditors also had the option to use their own personal hand held device as REDCap© is compatible with multiple devices through an application that ensures the protection of PHI via server encryption and password protection. REDCap© could not be accessed through any other server or website that was not supported or approved by the IT department.

Project Objectives

Mission and Vision

Vision and mission statements reflect the values, commitments, service, and outcomes of the organization (Fortenberry, 2010). The organization in which this capstone project was conducted has strong vision and mission statements with which the investigator's mission and vision statements supported.

Mission statements have begun to play an increasingly important role in modern health care organizations (Desmidt, Prinzie, & Heene, 2008). The mission of this project was to maintain the aim and ability of the organization's clinical staff and auditors to improve quality of care provided through the utilization of the REDCap© electronic data collection tool for compliance with CAUTI prevention standards. Additionally, it was important to ensure the EDC audit process was not more arduous than using the paper form and the new technology did not inhibit data collection progress by imposing undue stress on the clinical auditors because of the learning curve.

The vision of a project gives strategic direction to the purpose and also serves as the basis for decision-making in long run keeping the question, “What do we want to become?” at the forefront (Kukkurainen, Suominen, Rankinen, Harkonen, & Kuokkanen, 2012). The vision of this project was to understand the implications of different data collection methods and share knowledge with other internal work groups so that reliable and valid data continue to be collected, analyzed, and utilized appropriately, effectively, and efficiently.

Project Goal

Zaccagnini and White (2010) explain that goals provide the overarching structure and direction toward the expected outcomes of a project. The primary goal of this project was to determine the implications of implementing the REDCap© EDC tool on data collection reliability and to understand the impact of the EDC tool on auditor satisfaction (Appendix J).

Outcomes Objectives One and Two

The first objective of this project was to maintain or increase auditor satisfaction post-implementation of REDCap©. A mixed-method nine item pre- and post-implementation questionnaire was given to nine clinical auditors and one data analyst (Appendix K). The questionnaire remained consistent when administered both prior to REDCap© implementation and after the clinical auditors were trained and began using REDCap© as the only data collection tool. The questionnaire consisted of three items measured on the Likert scale, two items requiring “yes” or “no” responses, and concluded with three open-ended questions. A paired sample t-test (dependent t-test) was completed to determine the significance to which satisfaction scores changed on the first five items.

The second objective of this capstone project was to assess consistency in data collected via both collection methods. Galliber et al. (2008) postulate that “electronic survey forms may

be more accurate and complete than paper forms because limits can be imposed on data fields and respondents can be “forced” to answer each question” (p. 154). However, it was not a project objective to find a notable difference in the data collected through the implementation of REDCap©. There was much attention and rigor given to the process of data collection using the paper method. For the implementation of REDCap©, clinical auditors remained consistent, the training was given by two consistent administrators, and the pre- and post- data collection forms contained the same questions, therefore the same process and rigor persisted into the process using EDC. Ongoing improvement efforts to bring reliability of completion of CAUTI prevention standards to 90 per cent or above continued hampered the investigator’s ability to determine exactly what change impacted data. There were no major increases or decreases in compliance, which was the preferred outcome.

Process Objectives Three and Four

The third and fourth objectives, which were process objectives, included providing training to auditors and implementing the REDCap© EDC tool. The investigator utilized a project timeline to ensure specific deliverables associated with the process objectives were met (Appendix L).

Auditor training. In order to train and support staff on the new electronic tool, there were three elements the investigator and data analyst partnered in offering; technical training, just-in-time training, and one-on-one support.

Technical training on REDCap© was provided so the clinical auditors had knowledge of how to use the computer program, user access, and a basic orientation on where to find the CAUTI EDC audit tool. The same paper audit tool questions were added to the electronic tool to ensure consistency. One difference noted between the paper form and EDC tool was that for the

one question that asked about indwelling urinary catheter care completion, this information was pushed directly into REDCap© from the EMR in near real-time. The other three questions were asked in the same manner by the clinical auditors as was with the paper audit.

The second type of training offered was referred to as “just-in-time” training. In essence, the trainer went with each clinical auditor in their environment as they were using the new EDC tool and proactively assisted the clinical auditors as issues or EDC tool-related questions arose. The investigator and data analyst chose these methods for two reasons; so the clinical auditors were afforded real-time feedback and so the tools and information needed to understand the EDC were provided at the point of use.

The third type of support that was provided consisted of one-on-one assistance outside of the REDCap© implementation phase. Questions arose after the implementation phase and it was a priority of the investigator to support clinical auditors during the post-implementation time period. Rogers’ Diffusion of Innovations theory discusses that the rate of awareness-knowledge is more rapid than its rate of adoption (Rogers, 2003). Consequently, providing consistent support after training until the adoption of REDCap© was achieved and was pivotal to the project’s success initially, but also to maintaining REDCap©’s success within the organization through replication efforts. The organization’s decision to implement REDCap© was an *authority innovation-decision* according to Rogers, so supporting staff and providing them with tools were essential steps in giving them a voice in how the EDC tool was implemented and built which cultivated auditor buy-in (2003).

REDCap© Implementation. While REDCap© was seen as an innovative workflow and software solution designed for rapid development and deployment, there was still a technical learning curve (Harris, et al., 2008). Clinical auditors were required to complete and pass an

online learning course on REDCap© created internally. Clinical auditors were then granted access to the REDCap© system and could navigate to the EDC CAUTI tool and begin auditing. By requiring the auditor to provide their user ID and password, PHI remained protected and a tracking log of all data collected by every clinical auditor was created when logged in to REDCap©. An additional facilitator of auditors being able to quickly learn the REDCap© technology was, as discussed in the literature review section, the user interface provided an intuitive method to accurately input data (Harris, et al., 2008).

At the point in which the clinical auditors gained access to REDCap© the investigator and data analyst provided technical training on how to navigate REDCap©, where to find important web links, an overview of the actual audit tool, and how to submit the completed audit. The monthly CAUTI work group meeting time was utilized for training on REDCap© for clinical auditors able to attend. For clinical auditors that were unable to attend, one-on-one training with the investigator or data analyst was set up at a mutually agreeable date and time. In the case that one-on-one technical training was necessary, the investigator or data analyst included the additional just-in-time training for the clinical auditor as an efficiency measure.

Objective Five

The fifth objective in this project was to determine impact of the REDCap© EDC tool on clinical auditor time spent auditing. The goal for after the implementation phase and completion of training was to decrease or keep steady the amount of time clinical auditors spent from the pre-implementation mean (average) baseline audit time of 16 minutes. The baseline time was calculated via time studies by the investigator observing auditors performing audits in real-time.

Objective Six

The sixth and final objective related to evaluating the use of a “dynamic dashboard” as a data visualization tool. In concurrence with REDCap© implementation, the organization decided to provide data in a much different way to the end-user. The manner in which CAUTI compliance data were displayed was transitioned to a new technology called a “dynamic dashboard.” Essentially, data collected by REDCap© were available for real-time analysis through computer software programmed to display data in pre-determined graphs. The goal of using the “dynamic dashboard” was to offer data end-users faster turn-around time for utilization of unit-based and house-wide CAUTI compliance data. Additionally, this was another innovation that no longer required the investigator or data analyst to analyze data, create graphs, or distribute data on a monthly basis. A table representing the proposed objectives of this project can be found in Appendix J.

Evaluation Plan

Logic Model

In an effort to conceptualize and plan out the capstone project, a logic model was created (Appendix M). Zaccagnini and White (2011) describe a logic model as being “a picture of how the project developer believes the program will work” (p. 478). The project’s logic model takes a step-wise approach starting with the first step of identifying resource needs and project inputs. The second step lists activities for what facilitated project progress which then flow into outputs of the project. The fourth step consists of project outcomes and precedes the fifth and final step of achieving the goal.

Population and Sampling Parameters

There were a total of nine clinical auditors and one data analyst included in the satisfaction survey sample. The investigator was excluded to deter potential bias based on the vested interest in the capstone project.

The average number of patients per day with an indwelling urinary catheter was 15. Random sampling and auditing of catheterized patients was used to guide the auditing process. The clinical auditors collected data during their work shift as time allowed and when they had administrative time. Only one clinical auditor per 12 hour shift (0700-1900 or 1900-0700) completed an audit to prevent against double auditing.

Auditors used a real-time EMR report detailing patients who not only currently had indwelling urinary catheters, but also the patient's location and other pieces of information to guide auditing in real-time (Appendix N). The data in the real-time EMR report refreshed automatically every 15 seconds and provided every auditor with up to date and accurate information that pulled directly from the patient EMR.

There were approximately 40 urinary catheter days per month in the organization during the project time period. The number (N) of audits expected per auditor per month was decided upon by the organization's CAUTI Work group. The auditors collected data in their representative unit two times per week which usually achieved a total N of 20-25 audits per auditor per month. This number did not change after implementation of the REDCap© EDC tool. The N for each unit varied and auditors collected a proportionately random number of audits related to the number of patients with indwelling urinary catheters. PICU, CICU, and one medical/surgical unit held the highest number of patients with indwelling urinary catheters. Conversely, the other three medical/surgical units rarely had patients with indwelling urinary

catheters, therefore the opportunities for auditing was decreased and the associated N was smaller.

Setting

The capstone project took place in a large, urban, not-for-profit pediatric hospital. Children of all ages and stages of growth utilize more than 1,000 pediatric specialists and more than 3,000 full-time employees and volunteer hours that support the organization. Clinical auditors were employed by the organization at part time (0.5 full time equivalents (FTE)) up to full time (1 FTE). There was no compensation for clinical auditor participation and recruitment was completed prior to this capstone project with the initiation of paper form auditing.

Methodology and Measurement

This project is an evidence-based practice (EBP) project in which a quality improvement plan, program evaluation, or simple educational or standard of care intervention will be completed. In most cases, a simple pre-test/post-test evaluation will assess the effect of the intervention. The project will be internal to an agency and will inform the agency of issues regarding health care quality, cost, and patient satisfaction. The results of this project are not meant to generate new knowledge or be generalizable across settings but rather seek to address a specific population, at a specific time, in a specific agency. These projects translate and apply the science of nursing to the greater health care field.

Projects utilize the acronym “PICO”, rather than stating a formal research hypothesis. The acronym stands for: Population or Disease (P), Intervention or Issue of Interest (I), Comparison group or Current Practice (C), and Outcome (O) and is usually framed as a question (Melnik and Fineout-Overholt, 2011, p. 31).

The question this study seeks to address is: In a sampling of clinical auditors, does implementation of an electronic audit tool to collect data on compliance with CAUTI prevention care standards in addition to education on the electronic audit tool differ from paper form auditing for CAUTI prevention care standards and does it impact auditor satisfaction and/or data collected using the new tool?

The capstone project utilized a time-series, mixed methods embedded design where the data collected were a combination of both qualitative and quantitative. Utilizing a mixed-methods study design combined the strengths of both qualitative and quantitative research and allowed the investigator to achieve a broader perspective than what was possible with a single research method (Terry, 2012). Furthermore, this type of approach best reflected the real-life situation within the CAUTI work group, organization, and auditors' workflows by utilizing anecdotal data.

The pre- and post- implementation survey measuring staff satisfaction yielded a mix of both qualitative and quantitative data (Appendix K). The first six questions were asked based on a Likert scale or "yes" or "no" questions and were therefore considered quantitative data. The last three questions were open ended questions seeking to capture anecdotal feedback about the process and were considered qualitative data. Satisfaction data were gathered to determine if the REDCap© EDC tool was successfully implemented. The satisfaction questionnaire was distributed via email to all clinical auditors. In addition, input from the clinical auditors about the process were observed for and collated while the investigator and data analyst provided just-in-time teaching. Understanding and collecting anecdotal feedback in real-time enabled the investigator to make real-time modifications to training tactics and tailor the experience to meet each clinical auditor's learning needs. This was another way in which Knowles' ALT was

successfully applied the capstone project. There was no missing data and all respondents completed the questionnaire in its entirety.

Human Subjects Protection

The population of focus for the capstone project was clinical auditors. There was no research conducted on the patients being audited. Allen, Parillo, Will, and Mohr (2013) discuss vulnerable populations as including children or pediatric patients and having distinct attributes much different than an adult. Therefore, the target population of clinical auditors was not considered vulnerable.

PHI was collected as part of the REDCap© EDC process as a result of EMR information automatically transferring into the EDC tool, but was not utilized, reported, or exported as part of the capstone project and the data were therefore de-identified. Protected health information was secured as part of the organization's intranet server. The additional measure of requiring a personal REDCap© username and password to log in created a subsequent record of all clinical auditor activity for added protection. This project was submitted and approved through the study site's Organization Research Risk and Quality Improvement Review Panel (ORRQIRP) and was deemed exempt by the Regis University Institutional Review Board on March 25, 2014 (Appendices O and P). See Appendix Q for Collaborative Institutional Training Initiative (CITI) certification completed by the investigator.

Clinical auditor participation was voluntary and there was minimal risk associated with completing the pre- and post-implementation satisfaction questionnaire. The investigator realized the importance of creating and sustaining an ethical and supportive relationship with each clinical auditor. Shenton talks about what trustworthiness of data means related to four criteria: credibility of the investigator, transferability, dependability, and confirmability.

Credibility of investigator focuses on having and building trusting relationships with the clinical auditors and was fostered through the investigator's clinical background and credibility in the organization. Transferability relates to the ability of project findings' applicability to other situations. For example, clinical auditors felt a greater inclination to follow the process and provide valuable feedback based on the fact that the process would be used for other groups in the organization and potentially impact some of their colleagues. Clinical auditors wanted this process to succeed and be user-friendly. The investigator needed to ensure dependability of the process and that if the work were repeated, in the same context, with the same methods and with the same participants, similar results would be obtained. Dependability and transferability were closely related and even mutually exclusive attributes in the project. Confirmability ensured the investigator's concern about objectivity and keeping an unbiased approach were priorities.

While the investigator served multiple roles in this project as a clinical auditor as well as another data analyst, the questionnaire and anecdotal feedback were collected only from other clinical auditors and data analyst and excluded the investigator's opinions or feedback.

Instrument Reliability

A paper audit form and the EDC tool were the two instruments compared in the capstone project. The paper audit form was printed out by clinical auditors and used to collect CAUTI compliance data (Appendix C). The CAUTI work group leader or data analyst collected the completed paper forms each month and entered them into a database. The data analyst completed the analysis piece to yield compliance at the individual element level (bag level, catheter care, urine bag emptied, daily need assessed) and an aggregated compliance rate (all four elements completed for the patient). A combination bar and line chart was manually created

showing monthly compliance data which was then distributed back out to the CAUTI work group, units, and leaders to be used for action planning (Appendix E).

The newly implemented REDCap© EDC tool replaced the paper audit form and removed the subsequent manual data entry and data analysis components previously required for the paper process. The most recent catheter care completion time automatically transferred from the EMR to the EDC tool which eliminated the need to ask the question and shortened the EDC tool. The clinical auditor continued to answer the bag level, urine bag emptied, and daily assessment questions. Patient identification and unit information flowed automatically from the EMR to the EDC tool so the only additional information that required entry was the date and time of the audit.

The final optimization employed with the new instrument was the ability to use the dynamic dashboard. The CAUTI compliance analysis was calculated automatically on the “back end” by the organization’s data warehouse through coding and data logic which then allowed this information to be imported to a data visualization tool, the dynamic dashboard. Analyzed data were imported and refreshed at hourly intervals to the dynamic dashboard allowing organizational end-users to leverage data in more real-time for action planning. Leventhal (2013) discusses that in order to effectively deliver practice-based population health management, it is important to have the right data at the right fingertips at the right time (p. 34).

Inter-rater reliability was completed for all clinical auditors previously and was not repeated after implementation of the REDCap© EDC tool as the questions did not change from paper form to EDC tool. Initially, a Gage R&R (reproducibility and repeatability) analysis, which is a Lean Six Sigma methodology tool, was performed to measure reproducibility and repeatability between auditors and the “standard”. The “standard” was the investigator and was

used as the standard practice to which others were compared. The purpose of the Gage R&R is to achieve greater than 90 per cent instrument reliability with data collection methods among auditors, which was accomplished as evidenced by achieving 100 per cent reliability (Appendix R). The process by which the Gage R&R was completed involved investigator auditing with each clinical auditor independently and answering the two questions collected via observation: urine collection bag below level of bladder and urine collection bag less than half full. The completed audits were compared for consistency and agreement against the standard and the results of the Gage R&R were documented.

The other two elements, catheter care and daily need assessment, were not tested for inter-rater reliability via the Gage R&R. Catheter care data was found in the EMR and daily need assessment was a nurse self-report question that was answered as either “yes” or “no” (“yes”, the need of the catheter was discussed, or “no” it was not discussed). However, if, at the time of the audit, the need assessment had not occurred clinical auditors were to reinforce with the bedside nurse that having a conversation about the need of the indwelling urinary catheter is an important question regardless of if they personally feel it is or is not needed. Additionally, the CAUTI work group decided that the conversation of the indwelling urinary catheter need should happen as a multi-disciplinary group during patient rounds.

Project Findings and Results

Description of the Sample

The 22.0 Statistical Package for the Social Sciences (SPSS) was used to analyze project data. Project findings describe the sample of nine clinical auditors and one data analyst who completed both the pre- and post-implementation satisfaction questionnaire. The N for both the pre- and post- questionnaire respondents was 10. There were six outcome objectives of the

capstone project. Each outcome objective provides supporting data for the capstone project's success.

Objective One

Using a paired sample t-test for the dependent clinical auditor satisfaction data determined that there was not a statistically significant increase in satisfaction pre- and post-implementation of the REDCap© EDC tool ($p = 0.074$). However, these findings are clinically significant as clinical auditor satisfaction increased from 3.7 pre-implementation out of 5 on the Likert scale to 4.1 post-implementation. The objective outcome was to maintain or increase clinical auditor satisfaction and that objective was met as evidenced above.

Qualitative data collected via the satisfaction questionnaire was aggregated and categorized thematically (Appendix S). While feedback was mixed, the key takeaway from the majority of the clinical auditors was that while the paper form may have been quicker initially, all of the clinical auditors appreciated the optimizations to the process of auditing that REDCap© brought and were therefore satisfied with the REDCap© EDC tool and data collection process.

Objective Two

A one-sample t-test was completed to show the change of CAUTI compliance data pre- to post-implementation of EDC. While the investigator did hope to see compliance maintain or increase, the change was not anticipated solely because of the implementation of the EDC tool. Ongoing improvement efforts to increase the reliability of completion of CAUTI prevention standards happened concurrently with the capstone project. However, there was a statistically significant increase in CAUTI prevention standard compliance from 65.6% pre-EDC to 74% post-EDC implementation ($p = 0.000$).

Objective Five

Observations and time studies were completed by the investigator to determine average length of time spent on one full unit audit. An average of 16 minutes was spent by clinical auditors to complete a paper form audit for their respective units. After the implementation of the EDC tool the average time for a clinical auditor to complete a full unit audit decreased to 14 minutes. A paired t-test was completed and there was a statistically significant decrease in time spent auditing post-implementation ($p = 0.0150$).

Additional Objectives

Objectives three, four, and six were measured based on being successfully completed or implemented. The three training elements that comprised objective three, technical REDCap© training, just-in-time training, and one-on-one training and support was provided to all nine clinical auditors and the data analyst, therefore the objective was met. The fourth objective was implementation of REDCap© which was successfully implemented on time and made the capstone project possible. The sixth objective was to provide the organization with CAUTI compliance data through the use of the “dynamic dashboard” which was implemented in June, 2014; slightly off-track of the May, 2014 projected implementation date. There was no negative impact because of the delay of the dynamic dashboard implementation.

Limitations, Implications and Recommendations

While there were limitations in the project, the degree to which these limitations affected the project outcome objectives is unknown. The number of clinical auditors (nine) with the additional data analyst provided a small sample size of 10. Even with a smaller sample size, statistical significance was shown between the pre- and post- implementation paired samples for time spent auditing. Additionally, a driving factor in keeping the number of clinical auditors

limited was to ensure rigor in the key data collection principles of reproducibility and repeatability.

As noted previously, there are limitations with understanding the per cent change in CAUTI prevention standard compliance. There were ongoing organization and unit-based initiatives to increase compliance but the implementation of the REDCap© EDC tool also provided the auditor with more real-time data pulled directly from the EMR. Initial perceived limitations related to use of the new technology existed, but after the three training modalities were offered, this limitation was not realized and all clinical auditors were able to appropriately use the REDCap© EDC tool.

The implication for change and recommendation are two-fold and were predetermined by the organization to adopt REDCap©. However, how REDCap© was implemented and utilized was determined, in part, by the key successes gleaned from this project. Auditing through the use of EDC was found to be more efficient and provided more reliable data. As the tasks of data entry, analysis, and graph creation turned obsolete additional implications surfaced around the ability to divert the data analyst resource to other departmental priorities, which is a recommended practice.

Summary

While CAUTIs are the most prevalent HAI, hope remains they become the most preventable one. Through EDC, data collection is more efficient and optimizations with technology are possible. While paper audit tools may seem like a fast and efficient way to collect data for the auditors, there are negative downstream effects such as double entry of data, rework, a time-lag for data distribution, additional unnecessary data analysis, and manual data graphing. The project demonstrated that while learning a new technology may take time and

require adaptation to change early in the implementation phase, the benefits of automating the data collection process allow for increased process efficiency and, eventually, user satisfaction. By automating data collection, data are readily available for other software programs to utilize, thereby making the “dynamic dashboard” a feasible and accessible way for end-users across the organization to have easy and timely access to their data, allowing for meaningful action planning in more real-time. Furthermore, the project garnered support by the clinical auditors outside of the discomfort of learning a new system, because there were minimal risks associated with switching from paper audit tool to REDCap®. Finally, the gains related to automating data analysis and graphing as well as pulling key pieces of audit data directly from the EMR to supplement the EDC tool were evident to the clinical auditors as valuable and therefore outweighed any discomfort associated with the new technology.

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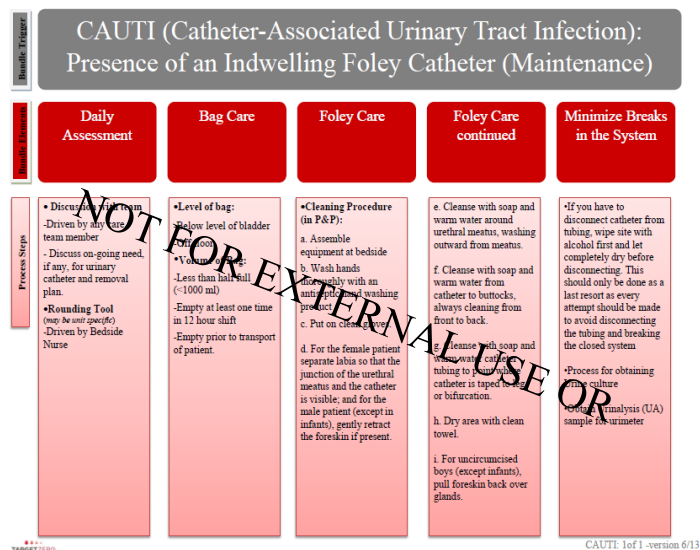
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Appendix A Organization's Internal Indwelling Urinary Catheter Care Bundle

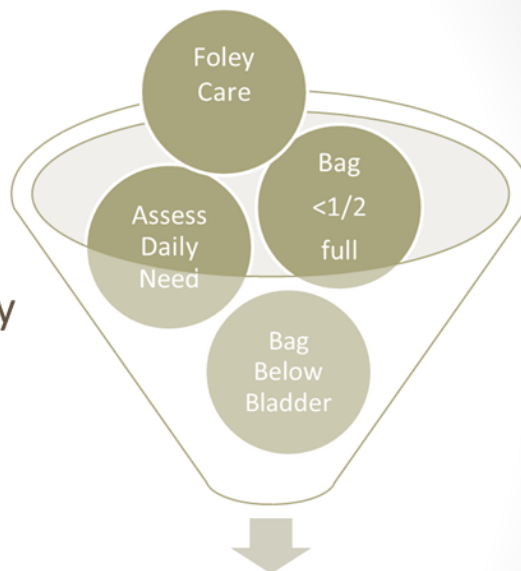


Appendix B Data Definition for CAUTI Prevention Standards Compliance

CAUTI Prevention Care Standards

Compliance Data

1. Daily indwelling catheter need assessment (*self-report data*)
 2. Urinary catheter care every 12 hours (*documentation*)
 3. Urinary collection bag below level of patient's bladder (*observation*)
 4. Urine in collection bag less than $\frac{1}{2}$ full (*observation*)
- Aggregated to **All or None compliance**



Care Element Compliance

("All or None" - all elements must be completed together to be compliant)

Appendix C Paper Data Collection Form

Unit: _____

Auditor: _____

Date/Time: _____

Patient	*Foley care done? (once in 12 hour shift) (Y/N/NA)	Collection bag less than 1/2 full? (once in 12 hour shift) (Y/N)	Collection bag below level of bladder? (once in 12 hour shift) (Y/N)	*Did RN and Provider Discuss Foley Need? (once in last 24 hours via rounds or other discussion) (Y/N/NA)	Compliant?	Comments/Unable to meet criteria reason
Compliant =	Y	Y	Y	Y	Y (All must be answered as "Y" to be considered compliant)	
	Please Circle "Y", "N" or "NA" Under Each Question					
1	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
2	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
3	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
4	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
5	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
6	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
7	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
8	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
9	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
10	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
11	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
12	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
13	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
14	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
15	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
16	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
17	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
18	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
19	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
20	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	
21	Y / N / NA	Y / N	Y / N	Y / N / NA	Y / N	

Number Compliant: _____

Total Number of Audits: _____ = _____ %

* "Foley Care Done" - auditor to review charting in EPIC to determine if foley care documented in previous 12 hour shift if not documented, ask RN if done. If documented once in previous 12 hr shift, it is compliant and mark as Yes

* "Foley Need Discussed" - auditor to ask RN or provider if Foley need has been discussed in last 24 hours

Appendix D REDCap® Electronic Data Capture (EDC) Tool

Confidential

NAC - CAUTI Bundle Compliance
Page 1 of 2

CAUTI Bundle Audit

Study ID	_____
Date/Time of Observation	_____
Auditor Initials	_____
Medical Record Number	_____ (EPIC Field)
Patient Name	_____ (EPIC Field)
Room Number	_____ (EPIC Field)
Patient Date of Birth	_____ (EPIC Field)
Unit	<input type="checkbox"/> NICU <input type="checkbox"/> PICU <input type="checkbox"/> CICU <input type="checkbox"/> 6th Floor Surgical <input type="checkbox"/> 7th Floor CCBD <input type="checkbox"/> 8th Floor Medical <input type="checkbox"/> 9th Floor Medical <input type="checkbox"/> 9th Floor CPCU <input type="checkbox"/> Other
EPIC Unit	_____ (EPIC Field)
Service	_____ (EPIC Field)

CAUTI Bundle Compliance Audit

Was indwelling Urinary Catheter need discussed in rounds?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - Rounds have not occurred, nurse/provider informed to have this discussion when rounds occur
Indwelling Urinary Catheter Care Date/Time	_____ (EPIC Field)
Indwelling Urinary Catheter care done in the last 12 hours?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - Catheter inserted within the last 12 hours (EPIC Field)
Is collection bag less than 1/2 full?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is collection bag below the level of the bladder?	<input type="checkbox"/> Yes <input type="checkbox"/> No
CAUTI Compliant?	_____
Audit Comments	_____

Confidential

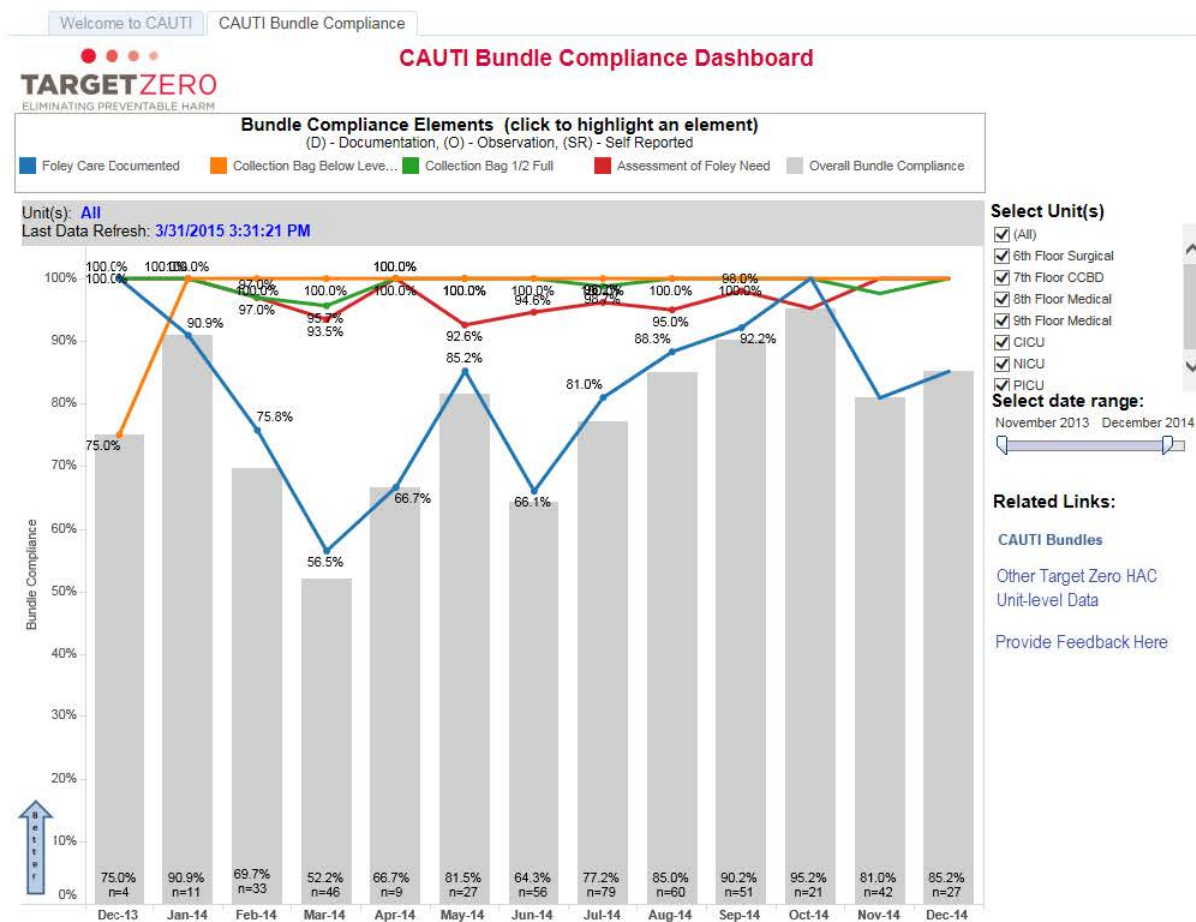
Page 2 of 2

Your audit is complete.

Do not change answers below this section. Please proceed to bottom of page, mark audit complete, and then save record.

Patient ID	_____ (EPIC Field)
CSN	_____ (EPIC Field)
Hospital Account Number	_____ (EPIC Field)
Indwelling Urinary Catheter	_____ (EPIC Field)
Indwelling Urinary Catheter Insertion Date	_____ (EPIC Field)
Indwelling Urinary Catheter Line Insertion Time	_____ (EPIC Field)
Indwelling Urinary Catheter Days	_____ (EPIC Field)

Appendix E Dynamic Dashboard



Appendix F Literature Review of Key Words and Associated Number of Articles

	Databases		
Key Terms:	CINAHL	Cochrane	MEDLINE
CAUTI	103	9	187
Pediatric CAUTI	2	0	5
Catheter-associated urinary tract infection	424	3	531
pediatric catheter associated urinary tract infection	14	1	17
Catheter-associated UTI	37	2	123
pediatric catheter associated UTI	1	0	3
CAUTI Prevention	85	5	114
Pediatric CAUTI Prevention	2	0	3

Appendix G Strengths, Weaknesses, Opportunities, and Threats (SWOT) Matrix

<p>× Strengths</p> <ul style="list-style-type: none"> + Aligned with organization + Internal CAUTI Group buy-in + Eliminates manual entry of audit data + Quality and Process Improvement skill set of investigator to run project 	<p>× Weaknesses</p> <ul style="list-style-type: none"> + Learning curve/training involved to use new tool + May not appeal to those who are not “tech-savvy”
<p>× Opportunities</p> <ul style="list-style-type: none"> + Stream-lines/automates data analysis process + Identifies potential impact of different data collection methods + External: Leading the way in process data collection and analysis in market 	<p>× Threats</p> <ul style="list-style-type: none"> + Auditors may not feel comfortable with process at beginning and revert to comfortable paper process + May see paper process as easier + Training schedule may not work for all auditors + External: intellectual property compromise

Appendix H Facility Letter of Support



11/4/13

Andrea Balzer has my permission to perform her Regis University Loretto Heights School of Nursing Doctor of Nursing Practice (DNP) Capstone quality improvement project at Children's Hospital Colorado. Andrea's DNP Capstone QI project is analyzing different process data collection methods for catheter-associated urinary tract infection (CAUTI) prevention. She is employed by Children's Hospital Colorado and works under my leadership in the Division of Quality and Patient Safety.

Sincerely,

Daniel Hyman MD, MMIM, Chief Quality Officer
Children's Hospital Colorado
13123 East 16th Avenue, Box 400
Aurora, CO 80045
Phone: (720) 777-8019
daniel.hyman@childrenscolorado.org

Appendix I Estimated Budget

Item	Estimated Cost	Estimated Time	Total Cost
REDCap™	Free from Vanderbilt University	n/a	\$0
*Information Technology Support & Data Analyst	\$40.29/hour	<u>Implementation:</u> 12 hours, 4 months = 192 hours <u>Maintenance:</u> 4 hours every month after (projected for 12 months) = 48 hours	\$9,669.60
*Clinical Auditor	\$32.66/hour	<u>Implementation:</u> 4 hours total <u>Maintenance:</u> 1 hour every month after (projected for 12 months) = 12 hours	\$522.56
*Computer/ iPad/Laptop	Varies	Needed throughout implementation and maintenance	\$500 - \$2000
Handouts/Training Materials	\$40.00	Only for first session	\$40.00
*In-kind donations provided by Children's Hospital Colorado			\$10,732.16 - \$12,232.16

*Children's Hospital Colorado did not approve or deem the financial estimations above as accurate. This information is an estimate based on current Bureau of Labor Statistics Data

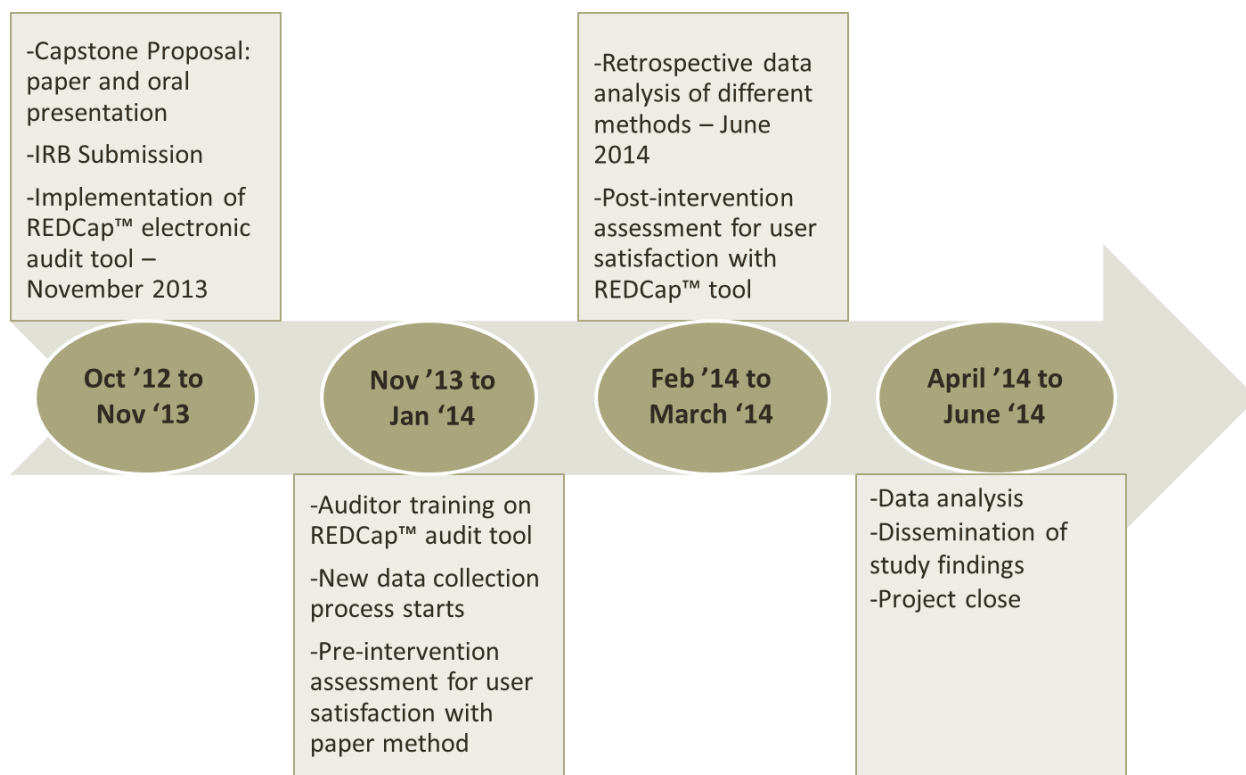
Appendix J Capstone Project Objectives

Objectives for DNP Capstone Project			
Outcome	<u>(Auditor Satisfaction – Objective 1)</u> Maintain or increase auditor satisfaction post-EDC implementation	Goal	Project Close
		Low p-Value indicating there is a statistical significance	pValue = .074 *clinical significance of increased auditor satisfaction
	<u>(Data – Objective 2)</u> Maintain or increase CAUTI prevention standard compliance post-EDC implementation	Increase or static compliance number	Pre-EDC = 65.6% Post-EDC = 74% (pValue = .000) *note other contributing factors
Process	<u>Objective 3</u> - Provide technical , just -in-time, and one-on-one training & support for 9 clinical auditors and one Data Analyst (N=10)	10	10
	<u>Objective 4</u> - Implement REDCap™ electronic audit tool by November 2014	Implemented	Implemented
Balancing	<u>Objective 5</u> - Maintain or decrease average time spent auditing	Pre-Implementation = 16 minutes	Post-Implementation = 14 minutes
	<u>Objective 6</u> - Dissemination of data through a “dynamic dashboard”	Implement by May 2014	Implemented

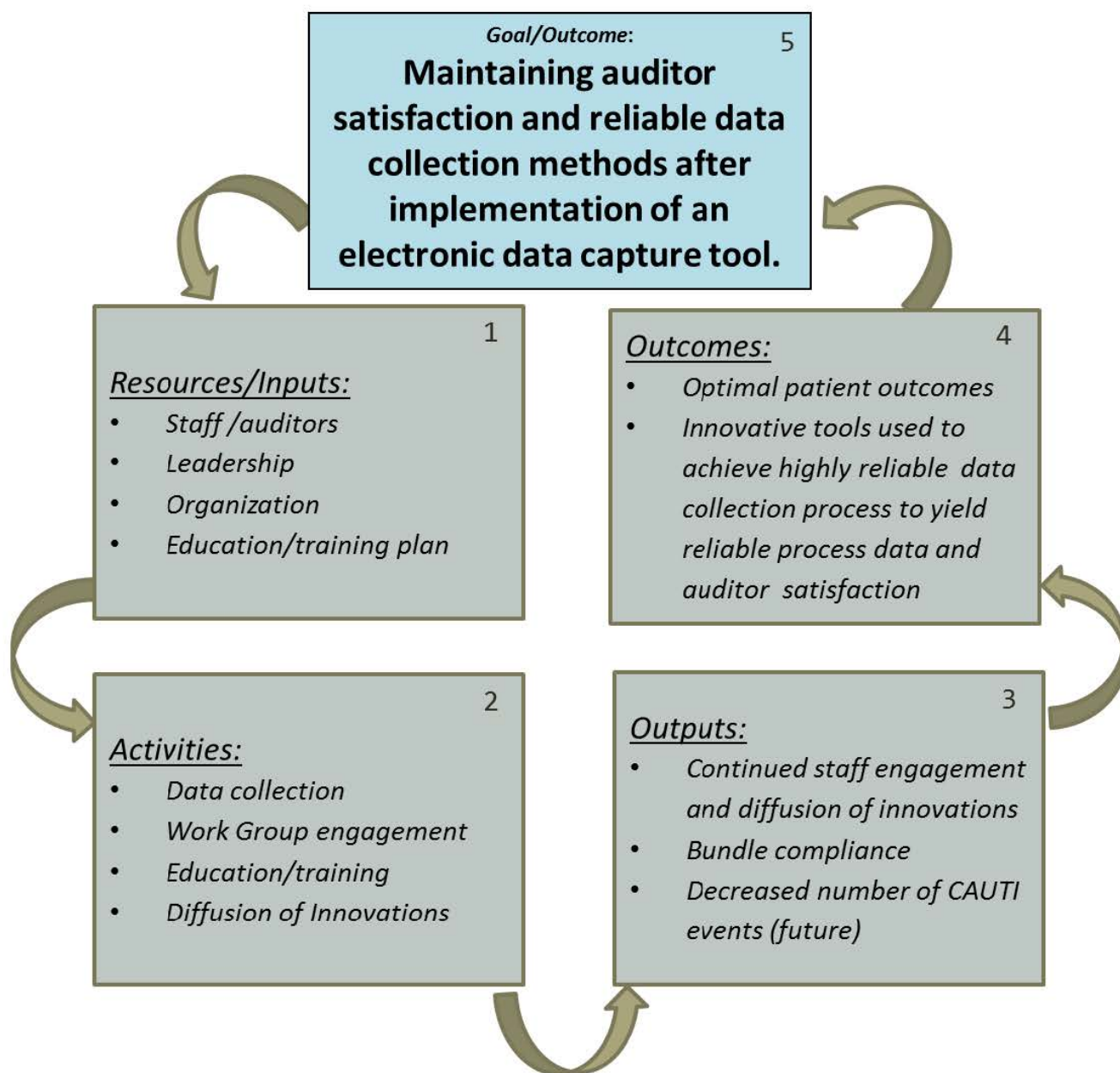
Appendix K Pre- and Post-EDC Implementation Satisfaction Questionnaire

Paper Audit vs. REDCap Clinical Auditor Questionnaire (Please circle response where applicable)						
1.	How satisfied were you on a scale of 1-5 with the paper data collection process?					
	1	2	3	4	5	
2.	How satisfied are you on a scale of 1-5 with the electronic data collection process?					
	1	2	3	4	5	
3.	How satisfied are you on a scale of 1-5 with the data analysis process? (n/a if you do not analyze data)					
	1	2	3	4	5	N/A
4.	Do you feel the new electronic data collection process adds value to your collection processes?					
	Y		N			
5.	Please explain:					
6.	Do you perceive any difference in time spent for auditing?					
	Y		N			
7.	To what do you attribute this difference?					
8.	What is the perceived time difference?					
9.	Any other information you'd like to add?					




Appendix L Capstone Project Timeline



Appendix M Capstone Project Conceptual Logic Model



Appendix N Real-Time EMR Report Used to Guide CAUTI EDC Audits

LDA - FOLEY [979459] as of Thu 10/31/2013 7:32 AM									
 Filters  Options ▾  Hospital Chart									
Dept	Room #	Patient Name	MRN	Line Name	Insertion Date	Insertion Time	Line Days	LDA status	Foley Care
SIXWEST				Urine Drain- 10 fr. Foley	10/30/2013	1255	0	Active	10/31 0100

Appendix O Organizational Research Risk and Quality Improvement Panel (ORRQIRP)

Approval



www.childrenscolorado.org

Organizational Research Risk & Quality Improvement Panel (ORRQIRP)

March 3, 2014

Investigator: Andrea Balzer, RNC, MSN, LSSGB
ORRQIRP #: 1402-2
Project Title: Catheter-Associated UTI (CAUTI): A QI Evaluation Project to Analyze Differences in Data Collection Methods

ORRQIRP reviewed the above-titled project on February 26, 2014. The review panel is of the opinion that this project does not test a research hypothesis but instead wishes to access process judged by established standards. Therefore, ORRQIRP supports the proposed project being conducted under the auspices of quality improvement .

Should you have any questions or concerns, please feel free to contact me at 720-777-4781.

Sincerely,

A handwritten signature in blue ink, appearing to read "D. Staley".

David Staley, MA
ORRQIRP Chair

Appendix P Regis University Institutional Review Board Approval

Institutional Review Board

To: Balzer, Andrea S; McCallum, Colleen A
Cc: Institutional Review Board

Inbox

Tuesday, March 25, 2014 4:26 PM

- This message was sent with High importance.
- You forwarded this message on 3/26/2014 12:39 PM.

Dear Ms. Balzer...

The Institutional Review Board has completed a thorough evaluation of your submitted proposal, *Catheter-Associated Urinary Tract Infections (CAUTI): A Quality Improvement Project to Analyze Differences in Data Collection Methods*. You may begin study implementation and data collection upon receipt of this email. Please forward the approval letter you received from the Organizational Research Risk and Quality Improvement Review Panel (ORRQIRP) at Children's Hospital Colorado for our files prior to beginning data collection. An official letter for your study files will be forthcoming. We certainly wish you success with your investigation!

Patsy McGuire Cullen, PhD, PNP-BC
Chair, Institutional Review Board
irb@regis.edu

Appendix Q Collaborative Institutional Training Initiative (CITI)

Main Menu

- This is the email address we have for you: asbalzer@gmail.com. If this is not correct, click [here](#) to edit your email address and other account information security question and answer.
- You are affiliated with 1 participating institution(s) on the CITI website. You will have at least one **grade book** per institution to track your progress in institution's coursework requirements (see below).

[Affiliate with another institution](#) | [Change login information](#) | [Change CITI Account Information](#)

Regis University

[View Regis University](#)

You have enrolled for the following courses:

My Courses

Social Behavioral Research Investigators and Key Personnel, Basic Course

Status

Passed - 11/27/12

Completion Reports

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report

Printed on 11/27/2012

Learner: Andrea Balzer (username: abalzer)

Institution: Regis University

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Social Behavioral Research Investigators and Key Personnel:

Stage 1. Basic Course Passed on 11/27/12 (Ref # 9233764)

Required Modules	Date Completed	
Introduction	11/26/12	no quiz
History and Ethical Principles - SBR	11/27/12	4/5 (80%)
The Regulations and The Social and Behavioral Sciences - SBR	11/27/12	4/5 (80%)
Assessing Risk in Social and Behavioral Sciences - SBR	11/27/12	4/5 (80%)
Informed Consent - SBR	11/27/12	5/5 (100%)
Privacy and Confidentiality - SBR	11/27/12	4/5 (80%)
Regis University	11/27/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Appendix R Gage R&R Auditor Sampling of Inter-rater Reliability

[illegible]

Appendix S Anecdotal Feedback Themes from Satisfaction Survey

Comment	Deduction/Induction
<i>Availability of data</i> “Paper is definitely quicker, but will lag in getting the summary of monthly data”	This is only possible with REDCap™ method, therefore this is a value-added aspect from the user-perspective
<i>Paper vs. Electronic</i> “Once the audits are entered in Redcap, I don't have to do anything else”	While paper may be quicker, the end result is increased time savings due to elimination of secondary data entry and analysis
<i>Laptop or iPad unavailable</i>	There are various technologies to use to complete audits – iPads, laptops, bedside computers. There is never a time when one of the 3 is unavailable
<i>Real-time data imported to audit tool</i> “You don't have to read through pages of EHR info to find your unit's data”	Availability of data from EHR eliminates chart review aspect and is value-added from end-user perspective
**KEY TAKEAWAY: While paper may have been faster initially, all clinical auditors appreciate the optimizations to the process that REDCap™ brought, therefore are satisfied with REDCap™	

