Grant Final Report

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Comprehensive Information Technology Solution for Quality and Patient Safety

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Abstract

Purpose: To implement health information technologies (HITs) to deliver better care to children and assess how such HITs contribute to measurable and sustainable improvements in patient safety and quality of care in pediatrics.

Scope: Two hospitals in a pediatric healthcare system implemented key components of an electronic medical record (EMR) using a staged approach. The components were implemented in the following order: pharmacy system, electronic medication administration (eMAR), nursing documentation, physician documentation, and computerized provider order entry (CPOE).

Methods: A mixed method design was employed to evaluate and assess the impact of each stage of the EMR implementation. Methods included workflow evaluation and redesign, HIT usability evaluations, clinician HIT acceptance and safety culture surveys, clinician interviews, and trigger-based chart review of medication related adverse-drug events (ADE's).

Results: Results emphasize the need to focus on change management issues such as communication, clinician involvement, and education and training. They also emphasize the need to address system usability by addressing human-computer interaction and technology fit with complex, dynamic clinical needs and workflows. Addressing these factors is critical to achieving the safety and quality goals for the implementation.

Key Words: electronic medical record, information technology acceptance, usability, implementation facilitators and barriers, medication errors, safety culture

Final Report

Purpose

Under the leadership of Children's Healthcare of Atlanta (Children's), four unique organizations engaged in a partnership to implement health information technologies (HITs) in diverse health care delivery settings for delivering better care to children and assess the extent to which such HITs contribute to measurable and sustainable improvements in patient safety and quality of care in pediatrics. The four organizations engaged in the partnership were:

1. Children's Healthcare of Atlanta (Children's)

2. Georgia Tech Laboratory for Human-Computer Interaction and Health Care Informatics and Georgia Tech Health Systems Research Center (GT)

3. Emory Center on Health Outcomes and Quality (ECHOQ)

4. Epic Systems Corporation (Epic)

In this project, the goals of the partnership were to systematically evaluate, using a mixed-method design, the implementation of several HITs and assess their ability to:

- Improve pediatric patient safety;

- Improve the culture of safety; and

- Improve pediatric quality of care.

The main roles played by each organization in the partnership were as follows:

- Children's, a leading pediatric healthcare system in the country, was implementing a comprehensive series of information technologies to improve safety, quality and efficiency. Children's provided the environment in which the HIT implementation was taking place and led and coordinated all implementation activities.

- Epic was the vendor selected by Children's to provide the HIT, designed tailored modifications of the HIT as well as provided the training required for utilizing the HIT.

- Georgia Tech, through its Health Systems Institute and its Laboratory for Human-Computer Interaction and Healthcare Informatics 1) designed and conducted pre-implementation evaluation studies to provide specific recommendations on the implementation process itself as well as collect baseline evaluation data, 2) collected data about and studied the implementation process itself, and 3) designed and conducted post-implementation evaluation studies.

- Emory, through ECHOQ provided additional evaluation expertise. The research staff advised the medication errors and safety culture studies and conducted a qualitative evaluation of the implementation process and the degree to which it successfully met implementation goals.

Scope

Background

Medical Errors. According to the Institute of Medicine 1999 report (1), it is estimated that there are between 44,000 and 98,000 deaths each year in the United States as a result of medical errors. Medical errors can lead to severe consequences including an increased length of hospitalization, unnecessary treatment, additional costs, and death (2-6). Medication errors can be classified into three groups – adverse drug events (ADEs), medication errors, and rule violations (RV) (7). This grant examined ADEs and medication errors. ADEs are generally defined as an injury resulting from a medical intervention related to a drug and include reactions that are sometimes unpredictable such as unexpected allergic reactions. Medication errors are the result of human mistakes or system flaws and are preventable. They can occur anywhere in the process from ordering to administering regardless of whether it resulted in an injury or just the potential for an injury was present. The error rate is 5 per 100 medication orders for both adults and children, but the reasons for medication errors among children are different and more complex than adults (8).

Children in particular are more susceptible to serious medication errors due to weight-based dosing, off-label drug usage and preparation, limited ability to withstand a dosing error and a limited ability to communicate with healthcare professionals when an error might occur or has occurred (9, 10). In a study in two academic pediatric hospitals, it was found that errors occurred at a rate of 5.7 errors per 100 orders, with 79% of these errors occurring at the ordering stage (9). Moreover, errors with potential to cause harm were three times more likely to occur in pediatric inpatients compared with adults (9, 11). Information technology such as computerized physician order entry (CPOE) and decision support are powerful tools to reduce medication errors. Each intervention will be described in the following sections.

Computerized Provider Order Entry (CPOE). Since the majority of the medical errors occur at the ordering stage (9), CPOE has been identified as one of the most effective tools that may prevent errors that occur during the medication ordering stage (1, 9, 12-15). CPOE ensures that orders are complete, legible, and in a standardized format. The benefits include the elimination of illegible or incomplete orders, and an increased efficiency through instantaneous transmission of orders to the pharmacy. Moreover, when a decision support system is integrated with CPOE systems, CPOE can guide drug dosage, frequency, and choice of route or administration, as well as perform multiple checks and alerts and provide feedback to the physician at the time of ordering. For example, the system can check for age specific dosing regimens and doses above or below the usual range, display alerts to the user if the current laboratory values indicate that the drug would be inappropriate for a certain patient, and check for allergies or drug-drug interactions that could result in adverse drug events. Thus, physicians

are less likely to make a mistake when initially directed to the appropriate medication, dose, or frequency.

A study by Bates et al. (13) demonstrated an initial 64% medical error reduction in an adult hospital using a CPOE system with only basic decision support, and an 83% reduction with more advanced decision support. Moreover, Fortescue et al. (16) also found the 75.8% of medical errors in pediatric inpatients can be prevented when implementing CPOE with clinical decision support system. Potts et al. (7) performed a study in a pediatric critical care unit and found that overall error reduction was 95.9%, which can be classified into 40.9% ADE reduction, 99.4% medication error prescribing reduction, and 97.9% RV reduction. In contrast, a study by Han et al.(17) demonstrated increased mortality for certain high-risk pediatric patients following CPOE implementation.

Unfortunately, designing and implementing a CPOE system in pediatrics is much more complicated than in adult medicine. The system must be able to frequently update the patient's weight because most of the medications are weight-dependent. Also, normal laboratory value ranges vary considerably as the child matures requiring customized checks. However, due to the complicated nature of pediatric medication administration, CPOE would bring greater magnitude of benefits in pediatrics than in adult medicine to prevent the potential errors that can occur.

Computerized Medication Administration Records. Integration of computerized medication administration records with CPOE can eliminate many transcription errors, a common type of medication mistake. This also allows for cumulative dose checking, which is particularly important for medications administered on a per need basis. However, few available data evaluate the effects of computerizing this process (10).

Context

Children's has developed a vision for implementing health information technologies to improve all aspects of Children's operations. Children's embarked on a multiyear process to grow a culture of safety to support safe, consistent, quality care and services. In particular, for this specific project, Children's started the implementation of a series of electronic medical record (EMR) components to improve patient safety and quality as well as increase efficiency of all operations. The wave of implementation focused on the pharmacy aspects of Children's as well as clinical documentation. The implementation stages that were studied in this project, in order of implementation are:

1. Inpatient Pharmacy System (Jan 2005)
2. Electronic Medication Administration Record and Clerk Order Entry (Nov 2005)
3. Nursing & Ancillary Documentation (May 2007)
4. Physician Documentation (Aug 2007)
5. Computerized Provider Order Entry System (June 2008)

Children's partnered with Epic, the EMR technology vendor, and with Georgia Tech and Emory, which together provide the research and evaluation expertise needed to fully document

and evaluate the HIT implementation as well as derive generalizable recommendations for optimal HIT implementation creating maximum benefit in terms of quality, safety, and efficiency.

The first stage implemented the Inpatient Pharmacy System, Epic Rx. The primary users of this stage were pharmacy personnel. This system provides the following features:

- Automates hospital pharmacy communication and workflow
- Coordinates ordering, dispensing, administration (MAR), billing, and patient management activities
- Delivers timely alerts and proactive guidance throughout the treatment process
- Can order any medication quickly from preference lists
- Presents the paperless medication orders to the pharmacist in a configurable workspace for quick review, editing, and approval
- Enables pharmacists to access full clinical information from within the workflow
- Ensures that nurses, physicians, and pharmacists all have access to the most current record of administrations, variances, and notes.

The second stage implemented the Electronic Medication Administration Record (eMAR), clerk order entry and other nursing and ancillary documentation features. The primary users of this stage were nursing staff and ancillary staff (e.g., respiratory therapists). Features and functions included:

- Medication Administration
    - Integration between the eMAR and the EpicRx Pharmacy System
    - Comprehensive list of medications to be administered
    - Documents the dose, route, site, and comments at administration
    - Automatically records discretion-based variances and missed or refused administrations
- Clinical documentation
    - Admissions medical history documentation
- Order entry
    - Electronic entry of clinical ancillary orders by unit clerks and other staff

The third stage implemented Clinical Documentation features. The primary users of this stage were nursing and ancillary staff. Features and functions included:

- Creation of clinical notes by nursing and ancillary staff based on pre-defined templates including 'Pick lists' and other predefined content to streamline creating notes.
- Documentation of patient lines and drains to allow visit specific assessment documentation as well as continued documentation across multiple visits.
- Organization of documentation to match clinician workflow by sequencing various documentation tools together.
- Summary reports for physicians to view clinical documentation in multiple formats, including reports designed for over 20 specialty groups
- Documentation of patient and family education using pre-defined templates with weblinks included for additional reference material.

The fourth stage implemented Physician Documentation features. The primary users of this stage were physicians, physician assistants (PA), and nurse practitioners (NP). Features and functions included:

- Creation of clinical notes based on pre-defined templates including
    - 'Pick lists' and other predefined content provided in templates to streamline creating notes
    - Automated short cuts to pull information to the note from other EMR activities
- Organization of documentation to match clinician workflow by sequencing various documentation tools together

The final stage of the inpatient implementation was CPOE. The primary users of this stage were all ordering providers (e.g., physicians, PA's, and NP's). Functions and features included:

- Streamlined order entry workflows with paper orders virtually eliminated
- Configurable preference lists for common medications, procedures, and referrals
- Synonyms for medication configured to simplify and speed order lookup
- Order sets that promote evidence-based medicine and increases order entry efficiency
- Interactive order summaries allowing quick order cancels, reorders, and a detailed review of existing orders

- Supports clinical workflows by routing orders to worklists, adding flowsheet data points, and inserting patient education topics

- Drug interaction checking

- Real-time dose checking and alerts on duplicate medication orders

Each group/system area contributes to the overall medication error rate in unique ways. For example, at the physician levels, errors happen in medication choice, ordering, dosing, writing/eligibility, etc. At the pharmacy level, errors occur in dose checking, order entry, dispensing, labeling, etc. At the nursing level, errors occur in administration (e.g., wrong patient, wrong drug, wrong route, wrong time, wrong amount, wrong rate). The combination of phases attacks the entire medication error problem. It addresses each "driver" individually and focuses on creating systems that reduce the opportunity for error. It provides IT solutions to address each "driver."

The phased implementation approach allows for the introduction and mastery of each EMR component separately, and for the separate analysis and reporting of each component and its contribution to improving patient safety and quality of care. It changes the culture of the organization over time. It whittles away at the medication error and other quality problems through improved tools, systems, practices and culture. Because each phase concentrates on a select set of functionality (e.g., pharmacy) there is time to focus on human-computer interaction (HCI) and systems design to improve system usability. Additionally, from a change management perspective, it gives users time to adapt to one change (e.g., physician documentation) before taking on the next major change (e.g., CPOE). Ensuring that clinicians have time to learn and adopt new clinical tools like EMR is crucial to ensuring patient safety during the transition.

Setting

The settings of this study were Children's two inpatient facilities: one academic (Egleston), the other community-based (Scottish Rite). In 2005, they had 23,000 hospital admissions and more than 128,000 inpatient days, seeing both patients from the Atlanta metropolitan area and providing tertiary care to children from all over the state of Georgia. At the onset of this study they had 235 and 195 beds, respectively. However, facilities expansions in late 2006 and early 2007 added beds at both facilities, resulting in a total of 255 and 250 beds, respectively at each facility. Although the two hospitals are similar in size, they have a number of differences. For example, 85% of the residents working at Children's work in the academic hospital.

Methods

Conceptual Framework

In order to determine the impact of the EMR implementation on operations and quality of care, the team developed a conceptual framework of measures to provide a comprehensive picture of quality of care. This framework incorporated Donabedian's (18) recommendation to examine the structure, processes, and outcomes, and the interactions between the three as well as Sainfort, et al.'s (19) Total Quality Management (TQM)/Quality Improvement (QI) framework for transforming healthcare organizations into Healthy Working Organizations (HWO). From this quality improvement perspective, the work undertaken for this grant contributed to improving delivery of care at Children's via the following:

- Structure: provided EMR tools to assist clinicians in care delivery; conducted usability evaluations to improve EMR system usability

- Process: redesigned workflows and policy/procedure to maximize the utility of the new EMR tools; strong focus on user education & go-live support to shorten the learning curve and ensure safety during the transition period; qualitative evaluation of the change process to identify lessons learned to apply to future HIT implementations

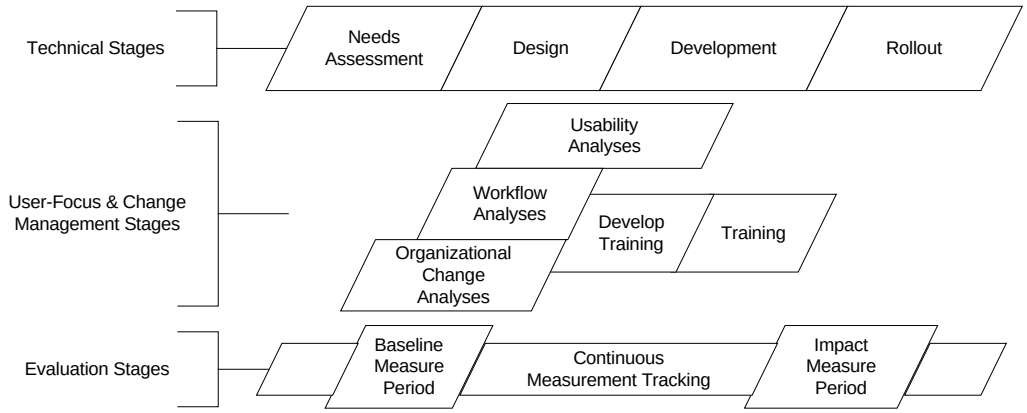
- Outcomes: conducted a trigger-based chart review to measure medication errors and ADE's at key points during the stages implementation; conducted periodic surveys on safety culture and clinician acceptance of the new technologies.

Overview of Evaluation Design and Methods

As discussed earlier, an iterative, phased approach was used to implement the EMR. This phased approach has been used in a variety of industries and has proven to reduce the risk associated with large technology implementations and improve technology adoption by implementing the new technology in smaller phases that are easier for the target users to assimilate. To further reduce the risks of implementing a system of this scale, the technical implementation and training stages were supplemented with several user-focused and change management stages. Additionally, in order to quantify the impact that the Epic implementation and related structure and process changes have on various aspects of delivery of care, evaluation stages were completed as well. Figure 1illustrates how these stages fit in with the technical implementation stages.

Overall, five main studies were conducted and are further described below: 1) clinical staff's safety perception and HIT acceptance over time; 2) preliminary impact on medication errors; 3) system usability; 4) impact on workflows; and 5) facilitators and barriers to HIT implementation.

Figure 1. Stages of implementation for each system phase



Organizational Change Assessment: Safety Perception and Acceptance of HIT. Historically, personnel in many hospitals have been slow to embrace technologies like CPOE. While the reasons for this vary from hospital to hospital, one thing is clear: for the system implementation to be successful, the personnel within the organization must be aware of and prepared for the significant changes that will occur when the system goes live. In order to ensure that the staff is ready to accept, and if possible, embrace this change, we assessed the organizations readiness for and acceptance of this change by administering a series of pre- and post- implementation surveys to evaluate acceptance and safety culture.

Clinical staff perceptions on patient safety and the EMR implementation were assessed through self-administered surveys prior to the beginning of the EMR implementation and then after each implementation stage. Survey participants included physicians, nurses, and other patient care staff. For the safety survey, physicians were not included because the culture survey has not been validated for use by physicians, and an exploratory pilot of the survey with physicians indicated that many of the questions did not apply as written.

All surveys were anonymous. For the baseline surveys, paper surveys were distributed to staff by hand. Responses were returned through interoffice mail to the study investigators using preprinted envelopes. With increased availability of computers in the hospital and growing clinical staff computer expertise, the follow-up surveys were distributed through e-mail and completed on-line through Zoomerang.com, a survey distribution Web site. The format of the questions on-line was comparable to the print format used previously. Paper copies of the survey were provided for participants uncomfortable with completing the survey on-line. Further methodological elements and results are provided in the Results section.

Outcomes Evaluation: Preliminary Impact on Medication Errors. An important goal of this research is measuring the impact of each system phase on medication errors and ADEs. In order to accomplish this, retrospective chart reviews were conducted. Charts were randomly selected for each data collection time period. A trigger chart tool was used to identify possible medication errors and ADEs. The tool used triggers from the IHI trigger tool for measuring ADEs and a list from the Institute of Safe Medication Practice (ISMP). (See Appendix A.) Possible errors or events identified and assigned a severity score based on the system for classifying the medication errors by the National Coordinating Council for Medication Error

Reporting and Prevention. Medication error and ADE rates at each stage of the implementation were analyzed.

System Usability Analyses. For each system phase that introduced new features/functions, an analysis of system usability was performed during design and development. Early in these stages, heuristic walkthroughs were conducted in order to identify significant usability problems. This predictive evaluation technique employs usability experts and requires limited time and cost to identify potential problems. The usability experts' knowledge of human-computer interaction was supplemented with available information collected from the workflow and organizational change analyses to improve their ability to identify potential problems. These expert usability reviews complemented the Design-Build-Validate implementation method, which includes iterative user review and feedback on the design. This combination of usability expert review and frequent user input increases the likelihood that usability problems are identified in advance and either resolved through pre-rollout changes to the system or highlighted in the training to reduce the impact usability problems have on organizational outcomes. Identifying system or training solutions for these problems in advance helps ensure that the system is usable and effective on the first day it is used. Results are provided below.

Workflow Analyses. Analysis of current work processes were conducted during each phase in order to understand the current work practices of the health care professionals who will be using the system and how use of new system will impact these practices. Based on this understanding of current work practices, the team identified potential areas where the technology being implemented may not support the current work practices used by the staff. This information was used to both modify the technology and work practices to optimize workflows. The methods used to collect data regarding workflows and work processes included direct observation methods and interviews and work group discussions with representative users. Current and proposed workflows and processes were documented using workflow diagrams and are further described in the Results section.

Qualitative Investigation: Facilitators and Barriers to Implementation. In addition to the quantitative data collection methods, we also conducted a qualitative implementation case study. Case studies involve exploration of one or more cases (for example, hospitals) through in-depth data collection paying particular attention to context (20, 21). To make our case study evidence stronger, we collected qualitative data using two approaches: open-ended in-depth interviews with key informants and analysis of documentary evidence from the organization. This approach led to a comprehensive assessment of facilitators and barriers to the implementation of HIT. Results are provided below.

Results

Summary results, as well as additional methodological background, are provided for the five major areas described above.

Surveys: Safety Perception and IT Acceptance

Safety and IT acceptance surveys were administered at key points in the study, as outlined in Table 1. Clinical staff perceptions on patient safety in the hospital were measured using the AHRQ Hospital Survey on Patient Safety which measures 9 dimensions of safety culture and 2 overall patient safety outcomes. EMR acceptance was assessed using a survey developed for this research based on previously validated tools from the IT acceptance and HIT literature and measured multiple aspects of HIT acceptance. Questions for each dimension are rated on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree".

Note that following distribution and analysis of the T1 (Staff) post-implementation IT Acceptance survey, minor changes were made to the survey. Additional questions were added to further examine findings from the initial analysis. Also, due to issues raised regarding the length of the combined safety culture and IT acceptance survey, the decision was made to distribute the safety culture and staff IT Acceptance surveys at different time points to prevent survey fatigue. The following sections provide results from the Safety Culture Surveys (4.1.1) and IT Acceptance surveys (4.1.2).

Table 1. Survey distribution timeline and target audience

Timing	Data Set	EMR Users/ Target population	Survey Topics
Jan 2005	T0 Staff	Nurses and other patient care staff	Safety Culture IT Acceptance (Pre)
Nov 2005		**Go-live: eMAR & Clerk Order Entry**	
Apr 2006	T1 Staff	Nurses and other patient care staff	Safety Culture IT Acceptance (Post)
Apr 2006	T1 MDs	Physicians	Adapted Safety Culture Revised IT Acceptance (Pre)
Nov 2006		**Scottish Rite Facility Expansion Opening**	
May 2007		**Go-live: Nursing Documentation**	
July 2007		**Egleston Facility Expansion Opening**	
Sep 2007	T2 Staff	Nurses and other patient care staff	Revised IT Acceptance (Post)
Dec 2007	T2 Staff Safety	Nurses and other patient care staff	Safety Culture
Aug 2007		**Go-live: Physician Documentation**	
Feb 2008	T3 MDs	Physicians	Revised IT Acceptance (Post)
June 2008		**Go-Live: CPOE**	
Oct 2008	T4 Staff	Nurses and other patient care staff	Revised IT Acceptance (Post)
Oct 2008	T4 MDs	Physicians	Revised IT Acceptance (Post)

Safety Culture Survey. Table 2 shows the sample size and response rate for each safety culture survey data set. At all three time periods, responses were approximately evenly distributed between campuses and distribution of respondents across roles was similar to that of the overall population.

Table 2. Safety survey sample size & response rate

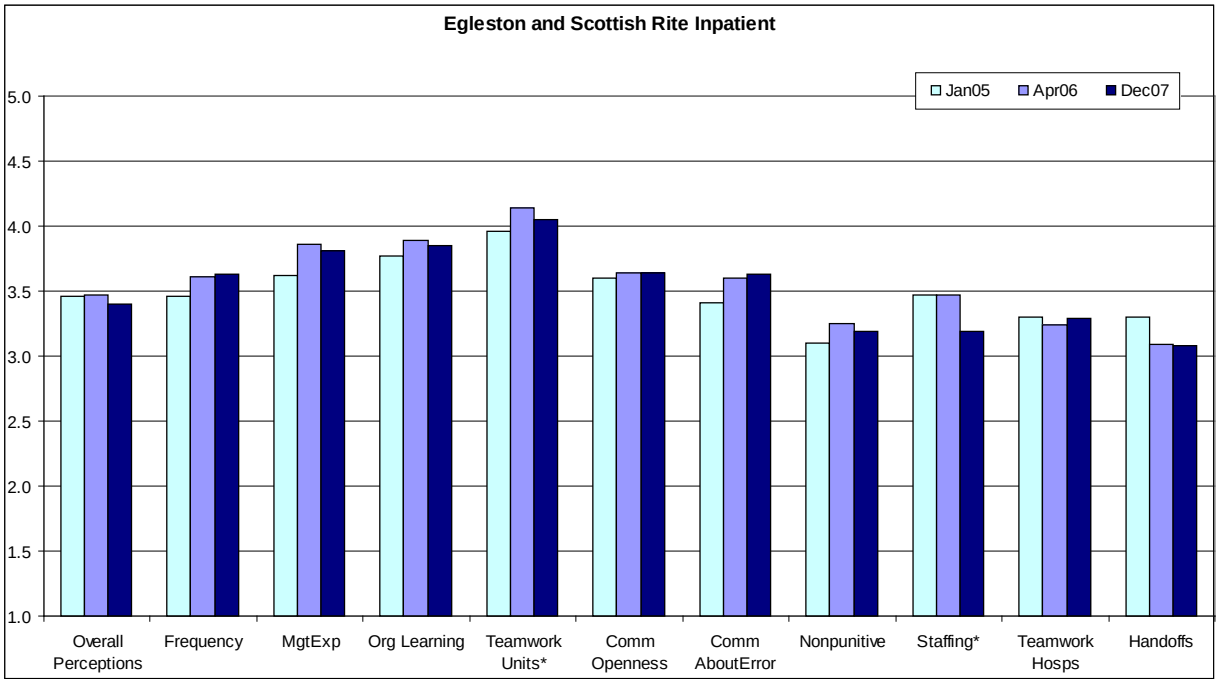
Data Set	Target Sample	# Respondents	Response Rate
T0 Staff	1534	369	24%
T1 Staff	1331	423	32%
T2 Staff Safety	3450	658	19%

Safety Culture Survey: **Analysis.** Scores on each safety culture dimension were calculated for each data set. Differences in dimensions scores were tested using the nonparametric Friedman test with nonparametric post hoc comparisons where appropriate. The Bonferroni correction was used to obtain an experiment-wide > level of 0.05. This analysis was conducted for each survey period. Changes in responses over time were examined for the hospital system as a whole and for each hospital using the MANOVA test. Inter-hospital differences at each survey period were also examined using a 1-way multivariate analysis of variance with Hotelling T2 test ($\alpha<0.05$).

Safety Culture Survey: Results. At baseline (T0), several areas in need of improvement were identified [M] and initiatives targeted at improving these areas were initiated. The impact of these initiatives and the EMR implementation were examined at T1 [A,K] and T2. The scores on each dimension at each time period are presented in Figure 2. The notable findings from these analyses include:

- Overall safety perceptions were generally positive at all three time periods.
- At baseline, the areas most needing improvement were: non-punitive response to error, handoffs and transitions, and teamwork across hospital units.
- Scores on most dimensions were fairly consistent across all three time periods.
- From T0 to T1, the following dimensions *significantly improved*: non-punitive response to error, frequency of event reporting, communication about error, organizational learning, and teamwork within units.[A]
- From T0 to T1 ratings on handoffs & transitions *declined significantly*. Anecdotal evidence indicated that workflow changes related to the eMAR implementation may have contributed to this decline. Specifically, the EMR implementation highlighted issues and workarounds previously used, which no longer worked.[A]
- From T1 to T2, ratings of staffing declined. While a number of factors contributed to this change, the major facilities expansion at both hospitals that occurred between T1 and T2 likely played a substantial role in this change.

Figure 2. Safety culture scores across time periods



IT Acceptance Surveys. The IT Acceptance surveys were designed to measure aspects of user acceptance of the HIT and factors anticipated to influence user acceptance. The aspects of user acceptance examined, based on previous studies, were perceptions of the HIT's individual work impact (i.e. based on the perceived usefulness construct in the IT literature) and quality of care impact. Prior research indicates that these aspects are related to both user satisfaction and system adoption.

Table 3 shows the sample size and response rate for each IT acceptance survey data set before and after exclusions. In each data set, the following exclusions were made:

- Missing Data: responses with > 80% of questions left blank or campus missing or invalid
- Outside target population: respondent reports a work area or role not targeted for this study (e.g., the system was not rolled out in the Emergency Department, so any responses from this area were excluded).

Table 3. IT Acceptance survey sample size & response rate

Table 3a. Staff acceptance surveys

	Distributed	Received	Response rate	Response After Exclusions	Final Response Rate
T0 Staff (Pre)	1534	369	24.1%	341	22.2%
T1 Staff (Post eMAR)	1331	423	31.8%	353	26.5%
T2 Staff (Post RN Doc)	2549	469	18.4%	387	15.2%
T3 Staff (Post CPOE)	1321	349	26.4%	340	25.7%

Table 3b. Physician acceptance surveys

Physician Acceptance Surveys	Distributed	Received	Response rate	Response After Exclusions	Final Response Rate
T1 MDs (Pre)	261	113	43.3%	103	39.5%
T2 MDs (Post MD Doc)	707	169	23.9%	155	21.9%
T3 MDs (Post CPOE)	635	208	32.8%	190	29.9%

IT Acceptance Surveys: Analysis. For each data set, a confirmatory factor analysis using Varimax rotation was completed and Cronbach's α's were examined to confirm the validity of the IT acceptance components and the ease of use scale. Each scale was calculated by averaging the survey item scores for that scale. Ratings on each scale within each population (staff and physicians) were compared across all time periods using the ANOVA test with Dunnett post hoc comparisons. In addition, regression models on each of the IT acceptance components were analyzed to identify factors that have a significant impact on individual work and quality of care.

IT Acceptance Surveys: Results. The results of the factor analysis confirmed that the Impact on Individual Work component (Work) consisted of items related to efficiency and effectiveness while the Impact on Quality of Care (Quality) consisted of items related to patient safety and quality of care. Cronbach's α for the Work scale ranged from 0.79 to 0.92. The Quality scale α's ranged from 0.78 to 0.83. The Ease of Use scale α's ranged from 0.84 to 0.93.

Figures 3 & 4 present the Work and Quality ratings, respectively, for both the staff and physician populations at each time period. Overall, both Work and Quality ratings were neutral for both populations at all time periods. However, Quality ratings were slightly more positive. The results of the ANOVA analysis indicate:

- The decline from T0 (pre-EMR) to T1 (post-eMAR) in staff ratings on Work ($p=0.004$) and Quality ($p<0.001$) were significant. Changes in subsequent periods were not significant. This indicates that expectations before implementation were higher than perceptions after the system went live. [F]

- For physicians, the decline in Quality ratings from T1 to T2 were significant ($p<0.001$). Similar to the staff results, this indicates that pre-implementation expectations on Quality were higher the post-live perceptions. Recall that the first physician go-live (physician documentation) went live between T1 and T2.

- For physicians the significant decline ($p=0.011$) in Work came between T2 (physician documentation) and T3 (CPOE). This is consistent with prior studies that have demonstrated that physicians suffered an efficiency decline after CPOE was implemented.

Figure 3. Impact on individual work ratings

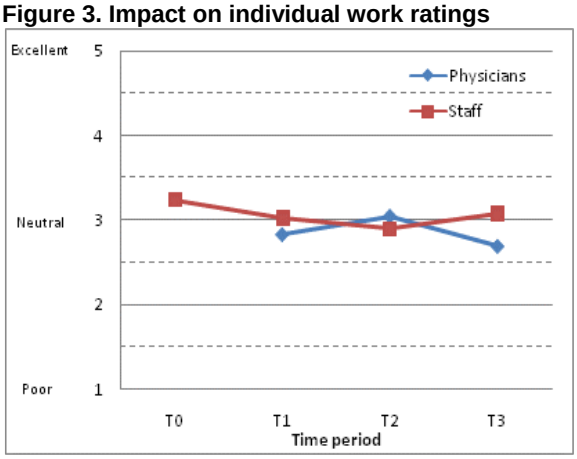
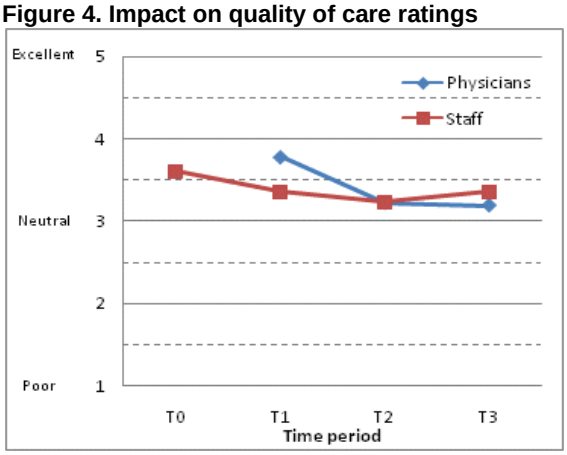


Figure 4. Impact on quality of care ratings



The regression models [L] on Work and Quality ratings identified factors that influence perceptions on Work and Quality. Most models had good predictive ability. r^2-adj values ranged from 0.594 to 0.834 for Work and 0.562 to 0.718 for Quality with the exception of the Physician T1 (pre-implementation) Quality model which had an r^2-adj of 0.304. Due to space constraints, the full models are not presented here. However, notable findings from the models are summarized below:

- For both outcomes and populations, the pre-implementation models had lower predictive ability as indicated by r^2-adj. This indicates higher variability in factors that affect pre-implementation expectations.

- Fit with clinical workflows was the strongest predictor of both Work and Quality perceptions, as indicated by the standardized β's. It had the highest |β| in six of seven of the Work models (range: 0.323 – 0.675) and was the second highest in the remaining work model (physician T2). In the Quality models, it had the highest |β| in two models (Staff T3, Physician T3) and second highest |β| in the remaining three staff models (T0, T1, & T3). The only models in which it was not a significant predictor were the physician Quality T1 & T2 models. This

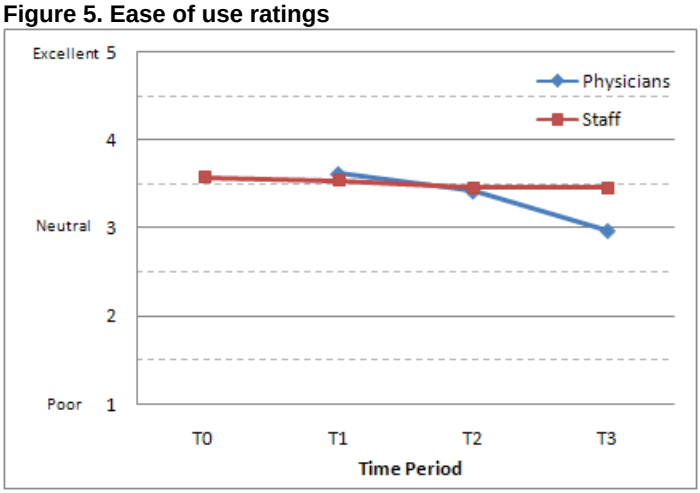
emphasizes the importance of designing EMR technologies to fit with clinical workflows that are often complex and dynamic.

- The importance of change management activities was highlighted by the presence of two variables in the models: feeling their needs were accommodated in design (needs accommodated) and being informed/updated throughout the implementation process (informed). Needs accommodated was a predictor in three Quality models (Staff T0, and physician T1 & T3) and Informed was a predictor in the remaining four Quality models. Needs Accommodated was the strongest predictor (β=0.461) of Quality for physicians at T1 (pre-implementation). It was also a significant predictor in four of the seven Work models (Staff T0 & T3, Physician T1 & T2)

- Ease of Use of the EMR was a significant predictor (β range: 0.161 – 0.335) in all of the post-implementation Work models for both staff and physicians. Ease of Use was also a significant predictor in the staff Quality models at T1 & T2. This emphasizes the importance of addressing usability and human-computer interaction during system design and implementation. (See Figure 5 for average Ease of Use ratings at each time period.)

- In the post-implementation surveys, the degree to which users felt the system provided more information or faster access to information for clinical decision making were significant predictors of both Work and Quality ratings. More information was significant in all five post-implementation Quality models (β: 0.208-0.664) and was the strongest predictor in three of the five. Faster access was significant in all three staff post-implementation models, but none of the physician models. Both were significant predictors in the staff Work models (T1, T2 & T3). In the physician Work models, faster access and more information were predictors at T2 & T3, respectively. This highlights the importance of designing EMR systems to get the right information to the right person at the right time.

Figure 5. Ease of use ratings



Preliminary Impact on Medication Errors

A total of 959 patients were randomized and evaluated for possible ADEs and medication errors using the trigger tool. Note that ADE's include expected side effects associated with a prescribed drug (e.g., nausea). Approximately 160 patient charts were examined for each time period: forty patients each from general care and ICU from both campuses were reviewed. During the implementation of the EMR, Children's initiated other projects in addition to EMR to reduce ADEs and medication errors. During August 2005 smart pump technology for syringes was implemented to prevent medication errors at the bedside by catching any miskeys and/or pump programming errors. Also, in summer 2006 the pharmacy completed a Six Sigma project targeting a reduction in medication errors in preparation and dispensing medications. The phased EMR implementation and these other initiatives have contributed to the changes in medication error rates and ADEs observed in this study.

Table 4. Medication error study data collection time periods

Time Period	Phase
T0 (Dec 2004)	Prior to EMR implementation
T1 (Mar 2005)	Post-Pharmacy system implementation
T2 (May 2006)	Post-eMAR system implementation
T3 (Feb 2007)	Baseline measure pre-CPOE
T4 (Oct 2007)	Post Physician Documentation implementation
T5 (Sept 2008)	Post CPOE implementation

Average length of stay was fairly consistent among each area and time period except for the general peds area of the academic hospital (Hospital A) during T1 (post-pharmacy system) and the community-based hospital's (Hospital C) general peds area during T5 (post-CPOE). The length of stay was longer in those two units at those time periods. For each time period the ADE and medication error rates per 1000 doses were calculated and trends across time periods examined. For each, a sub-group analysis focusing on the highest severity events (D and higher) was also conducted.

The D and Above error rate was quite low to start and remained low throughout the study period. Overall error rates (including low severity) dropped to almost zero at T4 and T5. ADE rates, since they include known, expected medication side effects, were more variable across the study period. However, they varied basically in the same range throughout the study period. There was a spike in the overall ADE rates during T3 & T4 in the general care unit of the community-based hospital. However, this was primarily due to an increase in low-severity ADE's that did not reach the patient (severities A-C). A statistical analysis of these trends is underway. Results will be disseminated via conference papers or journal publications, as appropriate.

System Usability Studies

Usability evaluations were conducted during development in order to identify and address potential usability problems in the design of the EMR functionality. Usability errors can lead to the commission of errors by users while using the system to perform their clinical tasks. These

usability evaluations complimented the Design-Build-Validate (DBV) design methodology employed. Core principles of the DBV methodology are user involvement and iterative design review and feedback, both of which facilitate improving the usability of the IT system.

Due to time and resource constraints, a predictive evaluation method, the Heuristic Walkthrough (HW), was used to identify potential usability issues and suggest ways to resolve identified issues prior to rollout. To accomplish this, usability experts –trained in human-computer interaction theory and practice – and clinical experts evaluated the system using a two-pass approach. The first pass is task-focused, the second a free form evaluation based on established usability heuristics. Evaluators identify instances in which the design and function of the system may lead to user error, frustration, confusion, and so on. When a possible issue arises, the evaluator documents the instance in detail. The collection of these documented issues are then discussed by the overall group of evaluators and then assigned importance ratings, based on issue severity (how serious the problem is) and frequency (how often or for how many users the problem occurs). This prioritization is used to determine which problems should be addressed prior to go-live. Evaluations were conducted prior the following go-lives: pharmacy system, eMAR & ancillary order entry, and nursing documentation.

Following each evaluation, a prioritized report of identified issues and suggested resolutions was provided to the implementation team. Prior to rollout, the team focused on addressing Critical and High priority issues. Where possible, issues were addressed through configuration changes. However, in cases where a vendor change was required or a technical resolution was not possible, issues were addressed through targeted user training. The leading sources of identified issues included [A]:

- Consistency. While most consistency issues were not severe, when considered in combination they increase the learning curve and cognitive attention required by users. Problems with consistency are frequently observed in complex commercial system because each system component is usually developed independently, resulting in little standardization of terminology and design conventions.

- Flexibility & efficiency. A number of issues were related to limited flexibility and/or efficiency in completing steps or tasks. Several of these issues related to instances in which the system required the users to reenter information. However, on a case-by-case basis the system could be configured to inherit information from previously completed forms. Utilizing this potential functionality more would help alleviate the user's data entry workload and reduce opportunities for data entry errors.

- User knowing there is a control. Some issues were related to users being unable to notice or appropriately use a control to complete a task or perform an action. For example, on some screens the number of controls on the toolbar made it difficult to distinguish between controls and determine their function. In designing and configuring toolbars it is important to judiciously select which items to include and use functional grouping to make identifying the appropriate control easier for the user. In some cases, controls did not have affordances that made it readily apparent that they could be interacted with (e.g., were "clickable").

- User knowing what to do next. Other issues centered on confusion over what next step the user should take. For example, in the admissions documentation the 'expected

discharge date' was configured to be a required field. However, in many cases, the nurse will not know the expected discharge date at the time the patient as admitted. Since this was a required field, it was unclear what the nurse should do if the discharge date was unknown. In this case, changing the field from required or instituting a policy about what to do when the discharge date is not known would resolve the issue.

Workflow Redesign

Redesigning workflows to incorporate the new systems was a critical component to ensuring that the EMR had the desired effects on quality, safety, and efficiency and on user acceptance. The transition from paper to an electronic medical record is difficult, and it is important to address both the technology and workflow changes needed for a successful transition. For Children's, the transition from paper documentation to Epic, the EMR system, began with clinicians. The clinicians involved in the transition included the core Clinical Informatics (CI) team as well as representatives for each user group (e.g., clinical role, specialty, etc.) who worked with the CI team to design workflows for their area. The CI team is a diverse group with experience as nurses, respiratory therapists, pharmacists and a clinical nutritionist. Many members of the team worked clinically at Children's prior to joining the Epic project team.

The clinical documentation and physician order entry (CPOE) teams consisted of a project manager, clinical informatics specialists, application analysts and lead trainers. Each team member was responsible for various workflows to evaluate, build required system components and test the components and workflows in the EMR. The analysis included meeting with subject matter experts, shadowing to observe workflow and review of paper documentation and order entry. The team diagramed 50+ separate workflows to capture the thousands of steps that make up various clinical documentation and order entry processes. These teams documented the current paper workflows and future (electronic) documentation processes in addition to physician order entry.

Bedside clinicians were active participants in the workflow design process. Design groups met approximately every 2 weeks during design phase to review build in Epic and provide feedback. The design groups and EMR champions also received training on change management. This enabled them to help prepare other staff to move from paper to electronic documentation.

The design groups also participated in testing prototypes to ensure they worked as expected and matched the actual workflows. The clinical documentation team tested prototypes of documentation by shadowing staff and documenting on actual patients in a test environment to ensure that the proposed technology and workflow design would work in a real world setting. Design team members also functioned as super users to support their coworkers with the transition to EMR. This included helping users learn the new workflows, in addition to the new technology, during both training and rollout.

Qualitative Study: Facilitators and Barriers to HIT Implementation

For the two earliest implementations, the pharmacy system and eMAR/ancillary orders, a qualitative study of facilitators and barriers to HIT implementation was conducted. Prospective

interviews, pre- and post-implementation, were conducted with a sample of key pharmacy and clinical managers.

We designed a 24-item baseline questionnaire and a 37-item follow up questionnaire. The baseline survey consisted of three parts: 1) questions about the participant's job title, location of work, and role in the implementation; 2) questions about the respondents' concerns about the system implementation, steps taken to ensure a successful implementation, anticipated goals, and the expected impact of the system on staff; 3) open-ended question about any issue the interviewee believed would impact the success or failure of the implementation project. The follow-up questionnaire contained questions about the participant's general impressions of the actual implementation process, factors contributing to success of the implementation, barriers to implementation, strategies to combat implementation problems, and lessons learned. Narrative content from the interviews was analyzed and key themes were identified by consensus.

For the pharmacy system implementation, a total of 9 pharmacy managers and/or team leaders and eight (8) clinical managers and/or directors from comparable departments across the two facilities were invited to participate. 70% of those invited participated at baseline and 65% also participated at post-go-live. Baseline interviews were conducted approximately two months prior to the system implementation and the second interviews were conducted 3 to 4 months post-implementation at each hospital. For the eMAR implementation 24 nurses across the two hospitals were invited to participate in post-go-live interviews and 58% participated. Surveys were conducted six months post-implementation.

This pharmacy system study identified major facilitators and barriers to the implementation of an inpatient pharmacy system at two pediatric hospitals [A]. Overall, 73% of participants rated the success of their hospital's implementation as "very good" or "good" and the lessons learned can help future adopters of similar technology. Training and education was considered one of the most significant facilitators to the adoption of this technology. The training instructors were highly regarded and respected by their peers. Along with the formal training sessions, the availability of pharmacy "super users" was identified by a majority of study participants as a key implementation strategy. Super users were available in the clinical work setting for several weeks post implementation. There was also a 24-7 phone number to call for assistance. Clinical staff, including physicians, pharmacists and nurses, played a significant role in the selection of the system which was important in fostering ownership by future users. Finally, while there was some staff resistance and apprehension, the majority of study participants enthusiastically supported the introduction of the new system. Our findings confirm that when the impetus for change comes from the clinical staff, adoption will occur sooner as readiness will be at a higher level.

The case also offers some general lessons concerning barriers that were experienced during the implementation of this pharmacy system, especially in a pediatric hospital setting. Most notable were customization and display issues with the system's drug files that persisted post-deployment. Based on the number of informal requests to revise the drug file and in recognition of a need to better respond to pharmacist's requests, the project team developed a formalized modification plan 5-months after system deployment. With this process in place, the project team was better able to document the issues, provide updates to the pharmacy staff, and improve pharmacy satisfaction. Second, the timing of the staged implementation may have produced a negative perception of the system by pharmacy users. Following the initial rollout stage, project staff shifted priorities and moved onto other stages of the roll out process. The ability to respond to users concerns and obtain prompt feedback is a high priority strategy for successful IT

implementation. This case study finds, as others, that care must be taken not to divert attention and resources to the next phase too soon as this may ultimately threaten system usability. Avoiding such circumstances requires organizations to closely examine the allocation of resources necessary to optimize the effectiveness of the system. Although this is often difficult to accomplish with competing demands for organizational resources, it is a critical step toward maximizing benefits and preventing loss of trust.

In the eMAR interviews, 14 (100%) participants rated the success of their hospitals implementation plan as "good", "very good" or "excellent" and 12 participants (85.7%) believed that at least 75% of the implementation plan met their expectations. Participant ratings of 10 key technical features of the eMAR system were very positive with the exception of the slow log in times, overly sensitive and/or nonfunctioning proximity badges, and the timing of the automatic log out feature. However, while half of the respondents believed eMAR enhanced their ability to perform day to day tasks, the remaining reported ongoing problems which negatively impacted their job performance. In addition, 55% of non-ICU participants reported that charting medications at or near the bedside was being done "sometime" or "seldom".

The most significant facilitator to successful implementation was increasing patient safety by reducing transcription errors. Other key facilitators were improved access to patient information, improved intra-department communication (e.g., between nursing and pharmacy), and improved ease of locating information within the chart. The most significant barriers to adoption of eMAR were excessive login times, a cumbersome process for co-signing medications, and generation of new kinds of practice related medication errors. The primary new error noted in the interviews was an increased potential to administer medication at the wrong time. A number of examples were cited by participants in which a standard medication time would appear in eMAR but the time did not take into account when the medication was last administered. This issue was especially problematic with new admissions and with those patients receiving medical care in departments that were not linked to the eMAR system such as the emergency room or operating room.

Summary

This HIT Implementation grant supported the implementation and evaluation of key components of an EMR system at two inpatient facilities of a large pediatric hospital system. The following EMR components were implemented using a phased approach over four years: pharmacy system, eMAR, clinical documentation (nursing & ancillary), physician documentation, and CPOE. During the implementation, clinical workflows were examined and redesigned, IT usability was evaluated and improved, and implementation lessons learned were identified. Outcomes were examined over the course of the implementations: medication error rates, user acceptance of the EMR, and clinical staff safety culture.

While overall medication error rates started low, the trend in overall medication error rates declined over the study period. Staff perceptions regarding safety culture were moderate at the beginning of the study period. While there were several statistically significant changes (both positive and negative) at points during the study, these were small changes, emphasizing that changing safety culture is a long and difficult process, even when a large change like implementing an EMR is undertaken to improve safety.

The efforts examining the implementation process and end user acceptance of the technology provide some valuable lessons learned. First, they highlight that change management activities

like communication, user involvement in design and implementation, and education are critical for user acceptance and for ensuring patient safety during the transition to EMR. This is evidenced by the findings of the qualitative study and the presence of two predictors in the regression models on Impact on Work and Quality of Care: needs represented in design, informed/updated throughout the implementation.

The regression models and usability studies also highlight the importance of usability to EMR success. Issues with usability can lead to errors, declines in efficiency, and, consequently, lower user acceptance of the technology. IT fit with clinical workflows, ease of use and providing faster access to information were significant predictors of users' perceptions of the EMR's Impact on Work and Quality of Care. The usability evaluations highlighted themes in usability problems identified: lack of consistency, problems with flexibility and efficiency, the user not knowing there is a control available, and the user not knowing what to do next. EMR vendors need to ensure that they are actively working to improve usability in their base products. Similarly, organizations implementing EMR's need to ensure that their configuration of the system facilitates ease of use for their population of clinicians and clinical work context.

Children's put significant effort into ensuring that clinicians were engaged at all stages of the EMR implementation and that change management needs were addressed. Despite these efforts, clinician ratings of the system's Impact on Individual Work (efficiency, effectiveness) and Quality of Care were moderate and changed very little over the course of the implementation. This indicates the current generation of EMR's has room for improvement, both in the design of the technology and the methods used to ensure successful implementation and adoption of these systems. If the promise of EMR systems is to be achieved, greater emphasis has to be placed on the human element. How can the technology be designed to work better for the clinicians who use them and in the dynamic environment in which they work? How can the clinical users be better informed and prepared to adopt the dramatic change that accompanies the implementation of EMR? Future research needs to focus in these areas so that the next generation of EMR systems can have a greater positive impact on clinical care delivery.

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Appendix

Appendix A: List of Triggers Used to Identify Possible Medication Errors and ADE's in the Medication Error Outcome Evaluations

- Naloxone
- Antiemetics (ondansetron, promethazine)
- Diphenhydramine/hydroxyzine
- Phytonadione (vitamin K)
- Flumazenil
- Anti-diarrheals
- Sodium polystyrene
- Dextrose 50 in Water
- Glucagon
- Methylprednisolone
- Topical steroids
- Vancomycin oral solution
- Nitazoxonide (Alinia)
- Clotrimazole troches
- Nystatin oral suspension
- Phenytoin/fosphenytoin
- Lorazepam/diazepam
- Phenobarbital
- Protamine

- Physostigmine
- Calcium chloride
- Atropine
- Digoxin immune FAB
- Dextrose + insulin
- Digoxin + amiodarone
- Charcoal