Computerized provider order entry system field research: The impact of contextual factors on study implementation

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Abstract

Attention to contextual factors is essential to the conduct of high quality informatics field research. This is particularly true when the research focus is on complex information technology innovations like computerized provider order entry (CPOE) systems. From a field research perspective, CPOE systems are considered an organizational intervention. They are designed, implemented and used within an organizational context that encompasses cultural, economic, social and physical aspects. It is essential that informatics researchers address contextual factors when assessing the impact of CPOE systems. Inclusion of organizational contextual factors in CPOE system field studies permits a more accurate evaluation of the true impact these systems have on medication practice processes and outcomes. The goals of this paper are to: (1) identify contextual factors that influenced implementation of a federally-funded field study undertaken to examine the impact of a community hospital CPOE system on medication error outcomes; and (2) describe how these contextual factors influenced study methodology and implementation.

In its 1999 report, To Err is Human: Building a Safer Health System, the Institute of Medicine (IOM) stressed the need to build a safer health care system to decrease medical errors [1]. In a follow-up report, Crossing the Quality Chasm: A New Health System for the 21st Century, the IOM emphasized the need for health care organizations to increase their use of information technology (IT) to support development of safer health care environments [2]. In 2000, the Leapfrog Group, a consortium of companies from the Business Roundtable, specifically endorsed the use of computerized provider order entry (CPOE) systems as one of three changes that would most improve patient safety in American hospitals [3]. Others have also recommended CPOE systems as a primary means by which to reduce medication errors and prevent adverse drug events (ADE) [4,5]. In the wake of these recommendations, field-based CPOE system research has steadily increased in an effort to determine best implementation practices and document system impact on medication practice processes and outcomes.

Research undertaken to examine health care IT implementation has identified generic organizational contextual factors that influence implementation processes and outcomes. Key among these factors are organizational IT innovation culture and climate, linkage of the IT innovation with work processes, end-user engagement and commitment, resource availability for all phases of implementation, end-user computer literacy and training, quality of the IT innovation, availability of vendor support for commercial applications and ongoing administrative support [6–14]. When attention to these contextual factors is lacking, the potential for successful IT implementation diminishes [15–21].
CPOE system implementation is influenced by the same organizational contextual factors that influence other types of IT innovations. However, due to the complexity and inherent safety risks associated with CPOE systems, implementation poses additional and unique organizational challenges. Among these challenges are the large up-front financial investment, substantial impact on clinician medication practice processes, and need for integration with pre-existing information systems, such as laboratory and pharmacy systems, to maintain quality patient care processes [22,23]. These challenges are most effectively addressed through active involvement of end-users at all levels of implementation, special attention to organizational implementation readiness, system design and usability, anticipation of long-range impact of the CPOE system on corollary patient care information systems, and an administrative commitment to ongoing formative evaluation of the impact of the CPOE system on clinician and patient care outcomes [24–29].

Despite the well-recognized importance of contextual factors in outcomes research [30], limited attention has been given to the identification and impact that these factors have on CPOE system implementation field research [31,32]. Lack of a context within which to assess the diverse and often conflicting cultural, economic, social, and physical factors surrounding CPOE system implementation can mitigate the validity of field studies and make interpretation of study findings difficult [33,34]. The goals of this paper are to: (1) identify contextual factors that influenced implementation of a federally-funded field study undertaken to examine the impact of a community hospital CPOE system on medication error outcomes; and (2) describe how these contextual factors influenced study methodology and implementation.

1. Field research study overview

In the mid-1990s, the community-based health care delivery system in which the field study is being conducted announced a four-phased effort to transition to a single system patient-centered electronic medical record. Phase II focuses on implementation of a commercial CPOE system. The ongoing three-year federally-funded field study is being conducted to coincide with the Phase II implementation of the CPOE system. The following sections provide an overview of the study setting, CPOE system, CPOE system implementation process, and methodology.

1.1. Setting

The study is being conducted in three non-teaching community hospitals in an integrated health care delivery system in Southern California. The health care delivery system is comprised of 4 acute care hospitals, 3 specialty hospitals, 3 skilled nursing facilities, 24 medical clinics, and 5 urgent care centers. Its workforce numbers more than 11,000 employees, in addition to 2300 physicians on hospital medical staffs and 1300 physicians associated with various medical groups.

Study hospital #1 was opened in 1944 and has 206 licensed acute-care beds, 100 licensed skilled nursing beds, 325 affiliated physicians, 7 operating rooms, and 24 h emergency services with a heliport. Comprehensive specialty services include an outpatient surgical center, a 20-bed Women’s Center, a cardiac care program and facilities, and a certified multi-disciplinary cancer treatment program. Field study patient care units include a total of five critical care, intermediate care and medical surgical units.

Study hospital #2 was opened in 1955 and has 420 licensed acute-care beds, 30 licensed skilled nursing beds, 650 affiliated physicians, 20 operating rooms, and 24 h emergency services with a heliport. Programs and services include comprehensive acute care, cardiac care, physical rehabilitation and therapy, orthopedics, oncology, pediatrics, mental health, hospice, sleep disorder care, and hyperbaric medicine. Field study patient care units include a total of 10 critical care, intermediate care and medical-surgical units.

Study hospital #3 was opened in 1955 and has 464 licensed acute-care beds, including 92 critical care beds, 1131 affiliated physicians, 12 operating rooms, and 24 h emergency services with a heliport. Programs and services include cardiac care, cancer treatment, pulmonary care services, rehabilitation, women’s health and multi-organ transplantation. Field study patient care units include a total of seven critical care, intermediate care and medical-surgical units.

1.2. CPOE system

The commercial CPOE system will provide the following order management support when implemented: (1) access and review of diagnostic reports, lab results, and other documents; (2) tabular or graphical views of trended information; (3) enhanced order legibility; (4) online medication ordering and verification; (5) standing and protocol order sets for specialty services and units; (6) in-box notification of physicians of lab and other diagnostic test results that have not been viewed and orders that require signature; and (7) real-time clinical alerts for drug/drug interactions, drug/allergy interactions, and duplicate orders. Duplicate orders include duplicate drugs (e.g. two antibiotics), duplicate diets, and duplicate labs. It will also be mandatory for allergies to be entered in the system before a medication order will be accepted.

1.3. CPOE system implementation process

A system wide EMR Governance Model has been established to coordinate and guide EMR design and implementation. Project sponsors include top-level executives, and physician champions. Matrix-type interdisciplinary communication structures link the system wide governance structure with individual implementation sites. For example, each study hospital has a “kitchen cabinet” to provide governance and strategic planning, and an “implementation council” to guide tactical activities, such as training and device deployment. Originally, a “big bang” approach was selected as the preferred CPOE system implementation approach for all study hospitals. Implementation was to occur sequentially across the three study hospitals and it was anticipated that, on implementation, all hospital clinical areas and patient care units would immediately switch to the new CPOE system. To ensure medication safety during transition, clinical pharmacy
staff were to receive CPOE system training several months in advance of other user groups.

An interdisciplinary core training team is designated to support all training activities at each study hospital in the month prior to CPOE system implementation and for a limited time post implementation. The team designed and piloted tested a standardized CPOE system user training program. Program content is presented in topical modules, such as CPOE system fundamentals, order communication, and security. Standardized course outlines, training manuals, and corresponding evaluation tools are used to maintain content consistency. While program content remains the same, delivery approaches are tailored to fit the needs and preferences of CPOE system users, i.e. physicians, nurses, and health unit clerks. These approaches include classroom training sessions, one-to-one instructor–user training sessions, and a computerized self-paced instructional program.

1.4. Methodology

The overall purpose of the field study is to describe and compare the impact of a commercial CPOE system on medication error outcomes within the community hospital environment. The specific aims of the study are to longitudinally: (1) test a theoretical model positing relationships between CPOE system implementation and medication error incidence; (2) test the effect of a commercial CPOE system on medication error incidence; and (3) explore the impact of hospital and clinical unit contextual factors on CPOE system implementation and medication error incidence.

The study is comprised of three arms: a survey arm; a medication safety arm; and a contextual arm. Originally, data collection was scheduled for all study arms for 8 weeks prior to CPOE system implementation, and for 8 weeks at 6 and 12 months post implementation for comparison within and across data collection time points.

The purpose of the survey arm is to assess end-user pre-implementation perceptions of hospital readiness for CPOE system implementation and post-implementation perceptions about usefulness of the CPOE system and satisfaction with the system. Clinician end-user perceptions are included in the study as mediating variables that are hypothesized to influence CPOE system adoption and ultimate impact on medication error outcomes.

The purpose of the medication safety arm is to assess medication error incidence pre- and post-CPOE system implementation. Data consist of medication safety event (MSE) cases that are documented on Event Tracking, Event Identification and Event Classification Forms. MSE cases are detected using voluntary and non-voluntary methods. Voluntary methods consist of written incident reports, pharmacist clinical surveillance and intervention reports, and anonymous verbal hotline reports. Non-voluntary methods include: (1) computerized triggers and alerts of critical lab values, e.g. glucose levels; (2) daily computerized antidote reports, e.g. 50% dextrose and Vitamin K; and (3) 5% random chart reviews. A two-fold process is used to detect and classify MSE cases. First, Registered Nurse research associates use voluntary and non-voluntary detection methods to identify MSE cases. Subsequently, detected MSE cases are classified in two ways: (1) through research associate application of pre-established decision rules; and (2) referral to an MSE Case Review Panel comprised of the study pharmacist co-investigator and three physicians. Referral to the Review Panel is done when decision rules are not appropriate and/or not available. Using these two classification approaches, MSE cases are classified as to: (1) the presence of a medication error; (2) the type of medication error, e.g. adverse drug event (causes patient harm) and potential adverse drug event (potential for causing patient harm); (3) severity of the actual or potential adverse drug event; and (4) preventability of the actual or potential adverse drug event.

The purpose of the contextual arm is to assess the impact of contextual events on study processes and outcomes. It is anticipated that contextual factors will influence the field study and that they should be identified, monitored and measured whenever possible over the course of the study. Both quantitative and qualitative contextual factors were identified as important. Quantitative contextual factors include: (1) CPOE system user demographic characteristics documented with a User Profile Form administered during surveys; (2) hospital and study clinical unit characteristics, e.g. average patient acuity, census and nursing care delivery method, documented with an Organizational Profile Form completed at each data collection point; and (3) pre-implementation medication error incidence documented with medication safety arm data collection methods described above.

Based on review of previously cited CPOE system implementation literature, five preliminary qualitative contextual categories were identified at the beginning of the study as most likely to influence CPOE system implementation and field study validity: (1) CPOE system training program variations; (2) CPOE system implementation process variations; (3) CPOE system functionality changes; and (4) new hospital medication safety initiatives. Since the field study was initiated, these five categories have been representative of emerging contextual factors. However, additional unanticipated contextual factors have also been identified leading to a need to more comprehensively identify emerging contextual factors and assess their impact on field study methodology.

2. Interview methodology

An interview methodology was employed to identify contextual factors that were perceived by core research team members to have influenced the conduct of the field study and to document their perceptions of the impact of these factors on study methodology. The following sections describe interview subjects and the process used to collect and analyze interview data.

2.1. Interview subjects

The sample consisted of the five members of the core research team: (1) principal investigator; (2) two co-investigators; (3) project director; and (4) lead field-based research associate. All individuals had been involved with the study since its inception.
### 2.2. Interview process

Phone and face-to-face interviews were conducted by a registered nurse doctoral student (interviewer) who was not a member of the core research team and who was new to the study. The interviewer used a pre-established list of questions (Table 1) to conduct interviews of approximately 1 h in length with each member of the core research team. Interviews were audio tape recorded and transcribed verbatim by the interviewer.

### 2.3. Interview data analysis

Interview data were analyzed by the interviewer with the assistance of two faculty qualitative research experts who had no involvement in the field study. Preliminary content analysis was undertaken with written interview transcripts to code and then categorize words and phrases according to their meaning. Content analysis results were shared with interviewees to elicit their feedback and enhance accuracy and credibility of findings. Subsequently, a constant comparative analysis of coded words and phrases was undertaken to determine conceptual linkages, theme identification and theme reduction.

### 3. Findings and discussion

Five categories of contextual factors were viewed by core research team members as having the greatest impact on field study methodology: (1) Uncontrolled CPOE System Intervention; (2) Evolving Medication Practices; (3) Study Hospital and Clinical Unit Variations; (4) Internal Environmental Factors; and (5) External Environmental Factors. These categories and their associated factors are summarized in Table 2. An in-depth discussion of each of the five categories, their associated contextual factors, and the impact of these factors on field study methodology is presented in the following sections.

#### 3.1. Category 1. Uncontrolled CPOE System Intervention

The CPOE system implementation was not under the control of the research team and was studied as a naturally occurring intervention within the field sites. This resulted in four contextual factors that influenced study design and processes: (1) unpredictable changes in CPOE system implementation time line; (2) unpredictable changes in CPOE system implementation period; (3) CPOE system evolution; and (4) user training variation. These factors are discussed in the following sections.

##### 3.1.1. Unpredictable changes in CPOE system implementation time line

The CPOE system implementation time line was controlled by the health care network and not the research team. Time line decisions were influenced by patient safety needs, CPOE system upgrades and competing priorities and resource issues. These considerations were dynamic and resulted in an ongoing need to monitor and revise the implementation time line. For example, the health care network originally planned to implement the CPOE system simultaneously across all study clinical units within each of the three study hospitals, and mandate its use by all clinicians and health unit clerks. When physicians expressed concern about the approach and evidence of negative consequences of using the approach emerged from other hospitals engaged in CPOE system implementation, the governance structure decided to use a voluntary phased approach.

The change to a voluntary phased implementation approach resulted in dramatic changes to the field study time line. The original implementation time line was conducive to fixed data collection points. When implementation dates became fluid, coordination of data collection timing became more challenging to ensure equivalent and comparable data over time. For example, baseline data collection was done prior to anticipated CPOE system implementation. With a fixed implementation date across all study clinical units, it was easy to anticipate when baseline data collection should be undertaken and to deploy research associates accordingly. However, when implementation dates were customized by study clinical unit, it became necessary to also customize baseline data collection by individual study clinical unit, resulting in occasional overlapping data collection activities across units and hospitals. This required careful planning to avoid undue strain on study personnel and resources.

Another important time line consideration was delayed or prolonged CPOE system implementation on study clinical units. Delays are frequent when implementing complex computerized health care information systems. However, each delay required a complete reconfiguration of data collection periods to keep the study time line synchronized with the CPOE system implementation time line. Consideration of equivalent and comparable data over time was a crucial component of reconfiguration decisions, as well as the funding
period within which the study was to be conducted. For example, the study was originally designed to include 6 and 12 month post implementation data collection periods. As implementation dates were delayed, investigators decided to collect post implementation data at 3 and 6 months to ensure that adequate data analysis time would be available in the final phase of the study.

### 3.1.2. Unpredictable changes in CPOE system implementation processes
The same forces that drove implementation time line changes also drove process changes. For example, an unanticipated need to upgrade an early version of the CPOE system medication order entry software led to a decision to split CPOE system implementation into two phases. Phase one was designated the “Order Entry (OE) Phase” and focused on non-medication order entry. Nurse and health unit clerk users were the focus of this phase. Phase two was the “Provider Order Entry (POE) Phase” and addressed both non-medication and medication order entry. Physician users were the primary focus of this phase.

The change to phased implementations had a dramatic impact on study data collection processes. The study design originally incorporated an 8-week baseline pre-implementation data collection period to support evaluation of CPOE system impact on all users. The phased implementations led to a decision point for investigators: (option 1) collect 8 weeks of baseline data for each phase so all users were included; (option 2) delete baseline data collection for the OE Phase since medication orders were not included; or (option 3) redefine baseline data collection periods to 4 weeks rather than 8 weeks pre-implementation. Option 1 essentially doubled data collection and was immediately rejected as fiscally prohibitive. Option 2 was also rejected as baseline pre-OE implementation data collection had already been completed in the first study hospital. After consulting with a study methodology consultant, investigators selected option 3. This option reduced pre-implementation baseline data collection to 4 weeks for both phases, provided baseline data for all users, provided comparison points to assess baseline data equivalence for both phases, and was fiscally neutral.

### 3.1.3. CPOE system evolution
Commercial vendors have marketed computerized health care software and systems since the 1980s. Health care, however, has been slow to embrace these innovations, which has resulted in their delayed maturation. Implementation of immature CPOE systems frequently results in a need for software upgrades during implementation. This influences users’ perceptions of CPOE systems and often results in difficult and delayed implementation.

The evolution of the CPOE system was an important contextual factor in the study. For example, medication order entry software immaturity resulted in the need for a two-phased implementation process while upgrades were completed. This had a significant impact on the study time line and data collection processes. Ongoing CPOE system evolution was documented in two ways during the study. First, users were encouraged to note system usage problems and report them using various feedback mechanisms, e.g. written online feedback reports and verbal reports to unit-based trainers. Second, field-based research team members documented software problems and planned upgrades. Both of these data sources provided valuable contextual information that permitted the research team to assess when user responses to software upgrades influenced the impact of the CPOE system on study outcomes.

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3.1.4. User training variation
Standardized user training program content was developed prior to the start of the study and remained fairly stable during the study. However, user training delivery approaches and time frame variations occurred secondary to implementation time line and process changes. For example, users were originally to receive training starting 1 month in advance of the implementation date for their clinical unit. This made it easy to schedule training sessions at fixed intervals and control for comparable training effects. However, when implementation was split into two phases, training was modified to support more flexible approaches, e.g. one-to-one computer-based training sessions with a trainer and a computer-assisted instruction module for individual users. This flexibility resulted in users receiving training at different intervals and introduced variability in terms of the time between user training and actual live use of the system as well as the impact of different training approaches.

Training variability introduced contextual factors that potentially had a direct impact on two primary study variables: user perceptions of CPOE system usability and satisfaction with the system. It became important to capture training variations and system usage patterns to assess their impact on these two variables. This was addressed by modifying pre- and post-implementation survey user profile forms to include items about type of training, extent of system usage and perceived level of expertise with the CPOE system.

3.2. Category 2. Evolving Medication Practice Processes

Evolving Medication Practice Processes and practice variations within and across study clinical units and hospitals was another important contextual factor category. Three contextual factors emerged as important considerations when assessing the impact of the CPOE system on medication errors: (1) changing medication practice processes; (2) clinical medication practice innovations; and (3) clinical medication practice variations. These factors are discussed in the following sections.

3.2.1. Changing medication practice processes
One of the more common contextual factors in field research is the interactive nature of the study and setting within which it is conducted. Study hospitals and clinical units had a well-established emphasis on safe medication practice. This emphasis and commitment to medication safety made these settings ideal for the study, but also meant that medication safety process improvement efforts would continue to evolve and influence practice during the course of the study. For example, when the study began, prescribing beta blockers for a patient who had experienced a myocardial infarction was left to the discretion of the physician. However, as the study progressed, increasing evidence supported the use of beta blockers as a standard practice when managing myocardial infarction. What began as a physician preference became a medical practice error when the physician failed to prescribe the drug.

During the study it was important to note changing medication practices to ensure that when new and/or revised decision rules were invoked to classify medication safety events, the impact of these rules on study data could be determined. In some instances, findings from medication safety event case reviews also highlighted medication practice patterns that required process improvement. When these patterns were identified, investigators were ethically obligated to share their findings with the health care organization, and this occasionally resulted in changes in medication practice processes. For example, when a pattern of errors related to a specific drug was identified, the study co-investigator, a clinical pharmacist, moved forward to create and/or revise order set(s) to assist clinicians to more safely manage the medication. This type of clinical intervention could potentially alter study medication error outcomes in that these errors would decrease due to the clinical intervention rather than the CPOE system innovation. Routine medication practice processes also benefited from rigorous study medication safety data collection processes that enhanced the consistency and accuracy with which medication errors were identified. As a result, there was increased evidence to support medication practice improvements. For example, study findings contributed to and supported opioid usage process improvement efforts underway throughout the health care network. Similarly, clinicians involved with the study had a social network within which they shared study insights and preliminary findings. These informal communications, which are very characteristic of the social networking aspect of innovation diffusion processes, potentially influenced medication practice processes and, in turn, provided a contextual influence on study outcomes.

3.2.2. Clinical medication practice innovations
Adoption of new drugs and medication safety devices were also important contextual factors that could influence medication error rates. The impact of medication practice innovations was comparable to changes in practice processes described above in that they can potentially confound the impact of the CPOE system on medication error outcomes. During the study it was important to document when these types of medication safety innovations were introduced to study clinical units to ensure that their impact on medication error outcomes could be examined.

3.2.3. Clinical medication practice variations
Medication practice variations occurred on multiple levels and potentially had a contextual effect on medication errors. For example, medication management of the patient with Type 2 diabetes varied significantly among physicians across study clinical units within the same hospital as well as between study hospitals. Multiple clinical management protocols and heuristics for this patient population were described by reviewers during medication safety event case review panel sessions. These medication practice variations often made medication safety event case classification difficult. To enhance case classification consistency, a series of decision rules were developed to remind reviewers of previous decisions in comparable cases.
3.3. Category 3. Study Hospital and Clinical Unit Variations

The study was conducted across 22 critical care, intermediate care, and medical-surgical clinical units in three community hospitals within the same health care network. It was anticipated that setting characteristics and variations would, potentially, have an effect on CPOE system implementation and study outcomes. Five contextual factors emerged as important considerations: (1) profile variations; (2) competing technology innovation; (3) different cultures; (4) different medication practices; and (5) different medication practice resources. These factors are discussed in the following sections.

3.3.1. Profile variations
Study hospitals and clinical units varied in terms of their profiles. These different profiles interacted with study variables in different ways. For example, census, patient acuity, and nursing care delivery method could all influence medication safety practice and outcomes. To ensure that contextual variations were adequately identified, a baseline profile was developed for each study hospital and clinical unit and re-evaluated at each subsequent data collection point for changes. The hospital profile included contextual factors for structure, technology, services, utilization, and innovation environment, while the clinical unit profile included contextual factors for structure, technology, services, utilization, personnel, innovation environment, and degree of CPOE system implementation. Variations in these factors, both within the same data collection period and across these periods, were viewed as having an important and potentially confounding impact on study outcomes.

3.3.2. Competing technology innovation
Simultaneous implementation of competing technology on a clinical unit was an important contextual factor. This can place a serious burden on clinicians who may be required to concurrently learn and adopt multiple technology innovations while providing patient care. The increased “learning workload” of clinicians confronted by new information technology can potentially affect user response to the CPOE system and confound survey responses. This situation may also increase the potential for practice variation and medication errors as clinicians adjust routine established work processes to incorporate technology innovations.

3.3.3. Different cultures
Cultural variations within and across study hospitals and clinical units were also viewed as an important contextual factor. For example, some clinical units used electronic medication administration documentation, while other units used paper documentation. This introduced variability in user experience with computerized documentation systems and also required study research associates to learn each documentation system, which had an impact on data collection processes across study sites. For example, dictionary-driven electronic documentation provided an efficient source for detecting medication safety events but also placed constraints upon the amount of narrative data that could be entered in these records. This same constraint did not exist for narrative documentation in paper records. This variation was important to study outcomes as narrative information is the primary source for detecting adverse drug events that are manifested by signs and symptoms. Random retrospective reviews of paper patient records were required to ensure that these types of adverse drug events were detected in the study.

Other sources for detecting medication safety events also varied among study hospitals. For example, Phytonadione (Vitamin K), an antidote for Warfarin-induced excessive anti-coagulation, was an important study trigger medication for detection of adverse drug events associated with the use of Warfarin. At one hospital, daily reports from an automated medication dispensing system, Pyxis, did not include Phytonadione as they did at the other two study hospitals. Upon further investigation, research associates learned that, for safety reasons, Phytonadione was no longer stocked in the hospital’s Pyxis units for subcutaneous and intravenous administration, and was dispensed directly from pharmacy for intravenous piggyback administration. As a result, the planned method for detecting the use of Phytonadione at this hospital, i.e. running daily Pyxis reports, was insufficient for detection of the use of this antidote. As the medication was only dispensed from the pharmacy, a special report had to be prepared with the assistance of pharmacy staff to identify patients for whom Phytonadione had been dispensed.

3.3.4. Different medication practice resources
Differences in resources allocated for safe medication practice support across study hospitals also introduced potentially confounding variation in the study. These different levels and types of support influenced clinical medication practice processes and outcomes as well as study data collection processes. For example, each hospital had established a position for a full-time safe medication practice pharmacist. Due to site-specific administration philosophy, one study hospital had filled the position with a half-time, i.e. 50% full-time equivalent (FTE), pharmacist. In this hospital, it was much more difficult for research associates to detect medication safety events since the sources for these data were not routinely compiled or analyzed by pharmacy staff in a timely manner. In another study hospital, where there was only an 80–85% FTE safe medication practice pharmacist, medication safety data were compiled, but, due to time constraints, the pharmacist often was unable to review these data concurrently. This resulted in a time-consuming retrospective analysis to support research associates in their data collection activities.
Varying levels and types of support resources also potentially influenced medication safety event incidence. For example, the availability of a unit-based clinical pharmacist for some study clinical units increased attention to medication safety practices. This attention led to enhanced medication safety process improvement efforts. Study units that were not supported by this resource potentially had less effective medication safety practices and processes leading to more medication safety events.

3.4. Category 4. Internal Environmental Factors

Internal environmental events unique to study hospitals and clinical units also influenced study processes and outcomes. Four contextual factors emerged as important considerations: (1) unexpected environmental events; (2) competing research-service demands; (3) competing medication safety initiatives; and (4) CPOE system impact on clinician medication practice processes. These factors are described in the following sections.

3.4.1. Unexpected environmental events

Two unexpected internal environmental events occurred that disrupted routine practice processes. The first event was a murder–suicide that occurred between a family member and a terminally ill patient on a study clinical unit during the baseline data collection period. While this tragic event did not directly influence data collection processes, it potentially disrupted routine medication practice processes and, potentially, could have contributed to medication errors. The second event was a broken water main that delayed a planned move by one study hospital into a new building. This delay resulted in a revision of the OE Phase implementation time line. However, the delayed move and corresponding implementation delay had a positive effect on users as it provided them with additional time to complete the move and become accustomed to new practice surroundings before being required to learn the new computer system.

3.4.2. Competing research-service demands

An important contextual factor in any field study is the competing research-service challenges that ultimately develop. Study aims, design and data collection plans were explicit and focused. However, CPOE system implementation was responsive to project management needs and dynamic events occurring within the patient care environment. These priorities frequently altered the CPOE system implementation time line. When this occurred it resulted in an immediate impact on the study time line and data collection processes. The overarching goal of the service provider is successful CPOE system implementation, while research priorities are driven by a need to accomplish study aims and maintain design integrity within a constrained time frame. Resolution of competing demands required frequent and careful communication to meet both research and provider goals.

3.4.3. Competing medication safety initiatives

During the course of the study, new software was installed on study clinical units to support CPOE system implementation. Some clinical units experienced problems with the software, which delayed CPOE system implementation. These problems had the potential to influence user responses to the CPOE system and confound user survey data. For example, the upgrade of an existing Windows-based nursing documentation system was problematic. As a result, OE Phase One implementation was delayed until software issues were resolved and an adequate time of stability had occurred within the user community to support another major information system change. As one research team member stated, “[To a clinician] when a computer system doesn’t work a computer system doesn’t work. Users don’t really differentiate that much across [different] applications. They just know that IS [information systems] did something to them that made their life worse”.

3.4.4. CPOE system impact on clinician medication practice processes

The introduction of the CPOE system had a definitive impact on routine clinician medication practice processes. As clinicians learned how to use the new system and incorporate it into their work processes, it sometimes had a negative impact on customary medication safety practices. For example, time constraints resulted in a decrease in voluntary reporting of medication safety events. This is an important contextual factor in that a decrease in reported medication safety events could be attributed to a positive impact of the CPOE system when the decrease is actually due to altered reporting practices.

Another important contextual factor is efficiency loss secondary to introduction of the CPOE system. For example, decreases in work efficiency secondary to the introduction of the CPOE system created time constraints for pharmacists that resulted in a significant decline in routine pharmacist medication safety interventions. This potentially increased the number of medication safety events and could be interpreted as a negative impact of the CPOE system, when the increase is actually due to the decline in pharmacist interventions.

It is important to note that the assessment of contextual factors associated with CPOE system impact on clinician medication practice processes is time-related. Once clinicians successfully master the CPOE system and resume routine medication safety practices, the true impact of the CPOE system on medication safety events can be assessed. If the CPOE system continues to have a negative impact on clinician medication safety practices after sufficient learning time has occurred, this may be indicative of CPOE system functionality problems.

3.5. Category 5. External Environmental Factors

External environmental events surrounding study hospitals and clinical units may also influence study processes and outcomes. Two contextual factors emerged as important when examining the impact of these events: (1) catastrophic natural events; and (2) competing research initiatives. These factors are described in the following sections.

3.5.1. Catastrophic natural events

During the study’s baseline data collection period a catastrophic fire occurred in the geographical area surrounding study hospitals. This resulted in home loss for information
system and study clinical unit staff. This community disaster became the focus of study hospitals as they addressed the needs of their employees and patients. The OE Phase implementation was delayed by 1 week resulting in a study timeline adjustment. The additional potential impact of this disaster on clinician performance and medication error incidence was noted as an important contextual consideration.

3.5.2. Competing research initiatives

The health care network within which the study was conducted is nationally recognized as one of the most technologically advanced health care networks in the country. As such, it is often asked to participate in research initiatives. During the course of the study, two medication safety research initiatives presented unique challenges to study design integrity. The first challenge occurred when a nationally-recognized consulting firm requested access to study hospitals and clinical units during baseline data collection to conduct physician interviews about readiness for CPOE system implementation. Readiness was a key baseline study variable and these interviews had the potential to confound physician responses to the study’s survey questionnaire on readiness for CPOE system implementation. Ultimately, the decision was made not to conduct these interviews.

The second challenge was the trial evaluation of a new computerized medication safety device in study critical care units during baseline data collection. The use of this new device altered routine medication practices and had the potential to artificially increase or decrease medication safety events thus altering baseline data comparability across study units. Ultimately, the testing process for this device did not conflict with study data collection and its temporary introduction and subsequent removal from study clinical units did not have a contextual impact on the study.

Both of these events raised awareness about the potential impact of other parallel research initiatives on study design integrity. This awareness underscored the need to monitor and document similar events that occurred on study clinical units so that the impact of these contextual events could be assessed.

4. Conclusions

A major tenet of the scientific process is to ensure that study outcomes can be directly attributed to the study intervention and not to contextual factors embedded within the field environment [33]. This tenet drives the need for a contextual component in health care informatics field studies that permits identification and assessment of these factors. When the ongoing study described in this paper was originally planned, four literature-based contextual categories were hypothesized to be important to the interpretation of study findings. However, as the study was implemented, it became clear to investigators that other contextual events in addition to the four hypothesized categories were influencing study implementation. Use of a formative interview methodology assisted investigators to identify these contextual factors and assess their impact on study methodology.

As depicted in Table 2, when original literature-based contextual categories are compared to the interview-derived five contextual categories and their associated 18 factors, it becomes clear that original categories were too narrow to capture the full array of contextual factors influencing the study. For example, three of the four original literature-based contextual categories were consistent with three factors identified for the interview-derived Uncontrolled CPOE System Intervention contextual category (Table 2). The remaining original literature-based contextual category was consistent with one factor for the interview-derived Evolving Medication Practices contextual category (Table 2). An examination of these comparative differences suggests that the original contextual emphasis of the study was too narrowly focused on CPOE system intervention to the exclusion of other key contextual factors. Greater attention was needed to those contextual factors associated with the medication error outcome variable, i.e. evolving medication practices, and factors influencing the general organizational innovation environment surrounding CPOE system implementation, i.e. Study Hospital and Clinical Unit Variations; and Internal and External Environmental Factors. The use of an interview methodology provided a formal approach that increased investigator contextual awareness early in the study and supported a broader and more effective identification of contextual factors influencing study methodology.

5. Health care informatics field research recommendations

Five recommendations for health care informatics field research emerged from the insights gained from the interview outcomes described in this paper.

1. Field researchers need to incorporate a contextual component into their studies. This component is essential to effective assessment of the true impact of health care information technology innovations on organizational, clinician and patient outcomes.
2. The inclination to focus narrowly on the information technology intervention when identifying contextual factors should be avoided. Information technology innovation occurs within a larger organizational environment and contextual factors occurring internally and externally to this environment must be examined for their impact on study methodology. In addition, information technology innovation is purposeful. It is undertaken as a means of influencing specific organizational, clinician and/or patient outcomes. Contextual events surrounding these outcomes must be considered when evaluating the true impact of the technology innovation.
3. A formative qualitative validation of originally hypothesized contextual factors should be formally incorporated into field study designs. Interviews were conducted early in the described study to validate hypothesized contextual factors. Findings from these interviews enlightened investigators about contextual events influencing the study and gave them important information regarding the need to modify original categories. This information supported
expansion of contextual documentation processes for better and more comprehensive capture of contextual data.

4. Contextual categories and their associated factors described in this paper should be assessed in other CPOE system implementation field studies to determine their generalizability. The ongoing assessment of these contextual factors, coupled with new and/or additional factors associated with different implementation settings, will build a broader array of contextual factors for consideration by informatics field researchers and individuals engaged in evaluation of the impact of CPOE systems within their organizations.

5. It is also recommended that research grant application scientific reviewers and funding sponsors recognize the importance of incorporating contextual factors into CPOE system field study designs and processes. Explicit identification, observation and documentation of these factors will ensure a more rigorous assessment of the true impact of CPOE systems on medication safety outcomes.

REFERENCES


