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Medical Device Alarm Systems: a Multi-Hospital Study of Alarm-Related Events, Caregiver Alarm Response, and Their Contributing Factors

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MEDICAL DEVICE ALARM SYSTEMS: A MULTI-HOSPITAL STUDY OF ALARM-RELATED EVENTS, CAREGIVER ALARM RESPONSE, AND THEIR CONTRIBUTING FACTORS

by

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ABSTRACT

MEDICAL DEVICE ALARM SYSTEMS: A MULTI-HOSPITAL STUDY OF ALARM-RELATED EVENTS, CAREGIVER ALARM RESPONSE, AND THEIR CONTRIBUTING FACTORS

by

Colleen Lindell

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Medical device alarm systems are expected to improve patient care by alerting clinicians about conditions that require attention. However, due to a variety of circumstances, including inadequate training, muting alarms, alarm fatigue, and staffing shortages, the effectiveness of alarm systems may be questionable. This research looked at the appropriateness of time- to-respond (TTR) to alarms, the alarm system configuration, policies and procedures regarding alarms, and the extent of alarm-specific training and education alarms. Using concepts from cognitive systems engineering, organization policy, and organizational learning, a research model was assembled to investigate these relationships.

Quantitative data analysis included an online survey conducted in four hospitals, retrospective review of alarm data related to patient harms, review of Nurse Call download data used to compare self-report of alarms to actual numbers of alarms as well as to assist in answering

exploratory questions. Qualitative data analysis included the clinician survey comments, review of alarm-related policy and procedure, and staff interviews.

Alarm survey data were collected from a total of 107 respondents over a three-month timeframe. Data download of alarms totaled 88,307. Using a logistic regression approach, partial support for the hypotheses was found across contexts of high, medium, and low priority alarms. The overall prediction of appropriateness of alarm response was good, except in the case of medium priority alarms. Examination of the alarm data revealed that clinician response to medium priority alarms was considerably slower than anticipated.

The results indicated that alarm configuration, policy, education, and training provided some explanation about alarm response. However, resulting data also indicated that the relationship between the alarm priorities and response times are not fully understood. While high priority and low priority alarms were approached appropriately, medium priority alarms did not elicit the same response. This is of some concern given that they form the bulk of the alarms in some hospitals. While alarm configuration, policy and procedures, education and training provided some explanation about alarm response, other factors may contribute to the disparity in response which were not clarified in this research. As more devices with alarm capabilities are introduced into patient care, it is imperative that the appropriate response is elicited in clinicians.

To

my parents,

my husband,

my daughters,

my grandchildren

and especially fellow nurses, healthcare practitioners, and health informatics professionals who endeavor to improve the lives of patients and caregivers.

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Alarm source:

Medical devices such as Nurse Call systems, Physiologic monitors, Infusion pumps, Ventilators or other devices as noted in Table 1.

Configuration:

The alarms are customized and configurable based on alarm type, priority, staff assignments, and escalation path (based on availability and timers or delays and can be latched or un-latched).

Middleware:

Systems or "engines" that reside between the alarm source and an end-device such as telephones (VoIP), pager, or communication badge. The middleware collects alarms from the source and distributes to the end device(s).

RT:

Response time.

Time-to-respond (TTR):

The time elapsed from when the alarm was triggered at the bedside to when the alarm returned to normal state.

TJC:

The Joint Commission

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INTRODUCTION

This chapter describes the criticality of medical devices and their corresponding alarms, discusses number and type of alarming medical devices, the under-reporting of patient alarm-related events, and the complexities and trepidations of technology advancements which ultimately impact patient outcomes.

In 1994, Dr. Lucian L. Leape opened a medicine Pandora's Box with his 1994 JAMA paper, “Error in Medicine”. He made the bold statement that only 5-20% of medical errors were being reported and that medical mistakes accounted for approximately 180,000 deaths annually (Leape 1994). In his 2009 “Death by Medicine” paper, Null cites “a study conducted in two obstetrical units in the UK which found that only about one-quarter of adverse incidents were ever reported. Reasons for failing to report include: to protect staff, to preserve reputations, or for fear of reprisals, including lawsuits. An analysis found that only 1.5% of all adverse events result in an incident report, and only 6% of adverse drug events are identified properly. If hospitals admitted to the actual number of errors for which they are responsible, which is about 20 times what is reported, they would come under intense scrutiny (Null, 2009).”

The under-reporting of medical errors is no surprise to most caregivers. Caregivers want employment security, fear legal complications and believe that most medical errors do not cause patient injury or death. The number of medical errors that are determined to be the cause of death is underreported (TJC 2013). However, the impact on the patient’s family, can be immense. In addition, there are serious ethical, social, and legal implications.

In 2014, an Ohio woman having elective surgery on her wrist experienced a sentinel event in the Operating Room and filed a malpractice lawsuit blaming the anesthesiologist for being

"distracted" as well as for "alarm fatigue" for an unnoticed premature release of an upper arm tourniquet which resulted in a bolus dose of Lidocaine into her system causing respiratory arrest. While the alarms on the blood pressure monitor, pulse oximeter and EKG were being triggered, they did not sound. Most likely, the alarming devices were silenced by the end user of the device. What was to be outpatient same-day surgery, ended up being a 23-day hospital stay and left her with on-going memory and speech deficits (Burger, 2014).

Medical devices are used for the purposes of diagnosing, monitoring, treating, or alleviating disease to support or sustain life. As medical devices grow increasingly complex, particularly with the addition of software and new "safety" features such as increased notifications and integration of systems, the ability of caregivers to respond promptly and appropriately to the medical device alarms are affected. Research has found medical device alarm issues to be universal, ongoing, and problematic (Lindell, 2014). Alarm anxieties are a patient safety issue requiring greater clarity to optimize the use and value of medical device systems interactions intended to support or sustain life. Clinical alarms warn caregivers of potential hazards and can be instrumental in preventing patient injury or death. Medical device alarm conditions must be quickly and consistently conveyed. A *critical* clinical alarm is any audible or visual indication from a system or device, that when activated, may result in injury or death without immediate clinical intervention. Thus, particularly with critical clinical alarms, if the alarm indications aren't effectively communicated, patients are at risk. Medical device alarms also warn caregivers of hazards and can be instrumental in preventing patient injury or death. However, there are continued issues associated with clinical alarm systems (Block 1999, Korniewicz 2008, Valentin 2006).

Due to the increasing number of alarming devices being placed on patients and the integration of these systems as one means to adapt, it is important that we fully understand the number and type of medical devices, how these devices function (their defaults, limitations, sounds, color, etc.), how they interact and their effects on patients and caregivers (Table 1). A high rate of false alarms can lead to the disabling of notification alerts and alarms as well as detract from patient care. False alarms include both false negative and false positive alarms, and when prevalent, quickly lead to clinician mistrust (TJC 2013; Block 1999; Korniewicz 2008; Valentin, 2006, Cvach 2014). Alarm fatigue occurs when clinicians become overwhelmed by the total number of alarms (Funk 2015).

Table 1. Examples of alarming medical devices

Attached/on the patient	**In patient room**
Ventilator	Nurse call
Blood warmer	Electrosurgical unit
Sequential compression device	Medical gas alarm
Intra-aortic balloon pump	Line isolation monitor
Defibrillator	Chair/bed occupancy alarm
Pulse oximeter (SA02)	Bathroom emergency call button
Infant warmer	Code blue call
Apnea monitor	Bi-pap unit
Bedside physiological monitor	Infusion pump(s)
Non-invasive blood pressure monitor	Tourniquet
Feeding pump	Hypo/Hyperthermia unit
Infant abduction alarm	Injector

Reference: Seibig 2010 and alarm data

The following chapters will further detail and explain the medical device alarm trepidations of an integrated Nurse Call system, exploring the various dimensions of a comprehensive alarm system included in this research proposal. This proposal seeks to explore the premises that clinician perceptions of the integrated medical device system, specifically alarm system

configuration, integrated medical device policies, and alarm system training and education may affect the time-to-respond to alarms and subsequently effect patient outcome.

BACKGROUND

This chapter presents the background, development and evolution of medical alarm systems with a special emphasis on Nurse Call integrated systems. The topics to be presented in this chapter include:

- A review of alarming medical devices and their evolution of the integration system components including hardware, software and middleware. Several vendor products and systems are reviewed.
- Related national and professional standards and guidelines. The influence of multiple national and professional organizations related to the guidelines and recommendations of this advancing technology as well as expectations of the system and clinicians are presented.
- A review of medical device risk assessments and the potential harms to hospitalized patients.
- A discussion of several preliminary research reviews related to the existence of literature specific to Nurse Call integrated medical device systems, clinician perceptions of an integrated alarm system, and post marker medical device surveillance results information. A new medical device interaction model and the research model for this project are presented.
- Hypotheses and sub-hypotheses presentation.
- Exploratory research questions to be explored.
- A brief discussion on culture and consideration of possible applicable theories.

Integrated systems and vendor samples (Nurse Call, End Device, Middleware):

The effectiveness of medical device alarms has been problematic since before 2004. Early developments seeking to improve these issues over the past decade have included:

- Marquee displays
- One-way pagers
- Voice paging (overhead paging)

Bedside integration emerged and included proprietary interfaces with vendor specific data converters that captured the data and alarm messages, sending them to a central station. Monitoring companies then began to interface with the same bedside devices which resulted in many proprietary interfaces. Interoperability was not present, and the result was many caregivers never receiving the intended messages. Later software developers produced a solution to connect diverse systems across the hospital enterprise.

Some Nurse Call systems have offered the ability to assign patients to caregivers via a control panel and staff assignment whereas the patients are assigned to caregivers with the caregivers wearing locator badges with the ability to track the whereabouts of the caregiver via RFID (Figures 1, 2, 3). The person at the control desk can then connect to the caregiver via hard wired bi-directional speaker panels located in hallways or patient rooms.

More recent software integration solutions such as middleware offer the ability to bi-directionally or multi-directionally connect devices to caregivers and the ability to track response times from the medical devices and telephony systems to the caregivers including medical devices and telephone systems such as:

- Nurse Call

- Ventilators
- Infusion Pumps
- Monitoring systems
- Wireless phones

Middleware systems and end-devices software packages offer the communication link from medical devices to caregivers allowing the caregiver to receive, respond, escalate or forward to another caregiver via configuration input to the systems (Figure 4, 5). Further advancements offer an ability to connect all systems via a single, standards-based approach through a web-based open interface, service-orientated architecture (SOAP) structure. This is accomplished via an interface and / or adapter (Figure 6). These systems also offered the opportunity to vary where staff assignment occurs, allowing flexibility in the coordination of third-party systems and the ability for caregivers to automatically escalate when they cannot answer or reply (caregiver can put their end-device into a "busy" mode allowing for automatic escalation). These integrated systems are often specifically customized to a hospital or unit needs or requests and may become unique to that unit or facility.

Figure 1. Hill-Rom Nurse Call System Components

Figure 2. Critical Alert Nurse Call System Components

Figure 3. Nurse Call System Integration

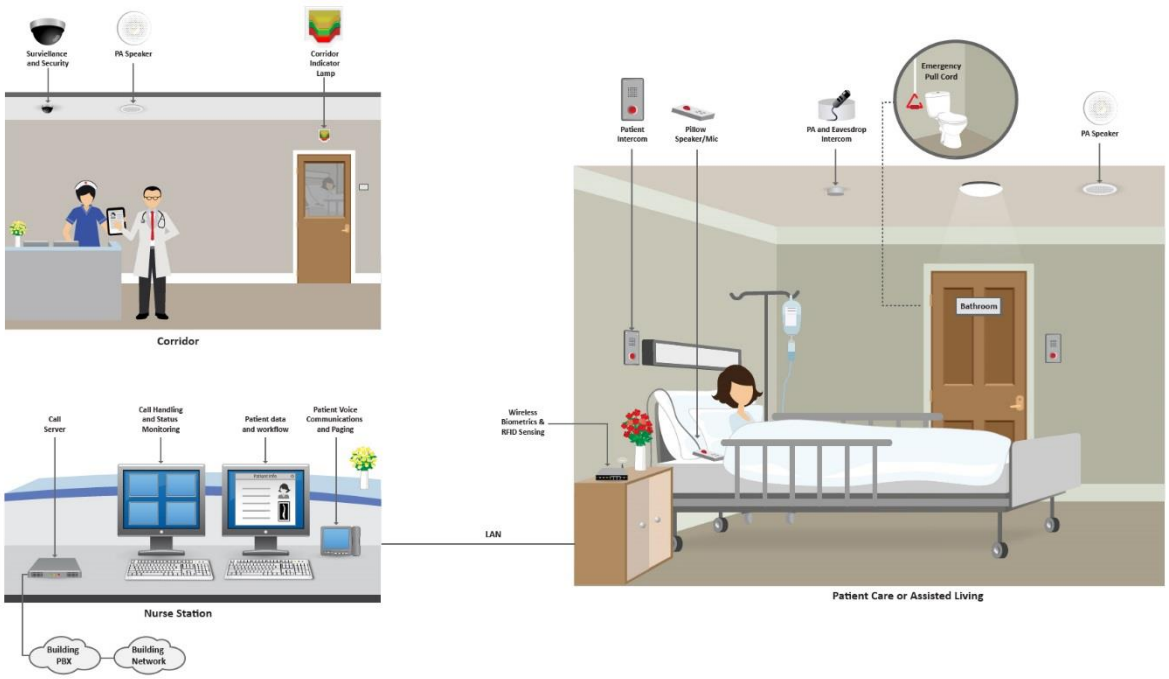


Figure 4. Voalte Communication System

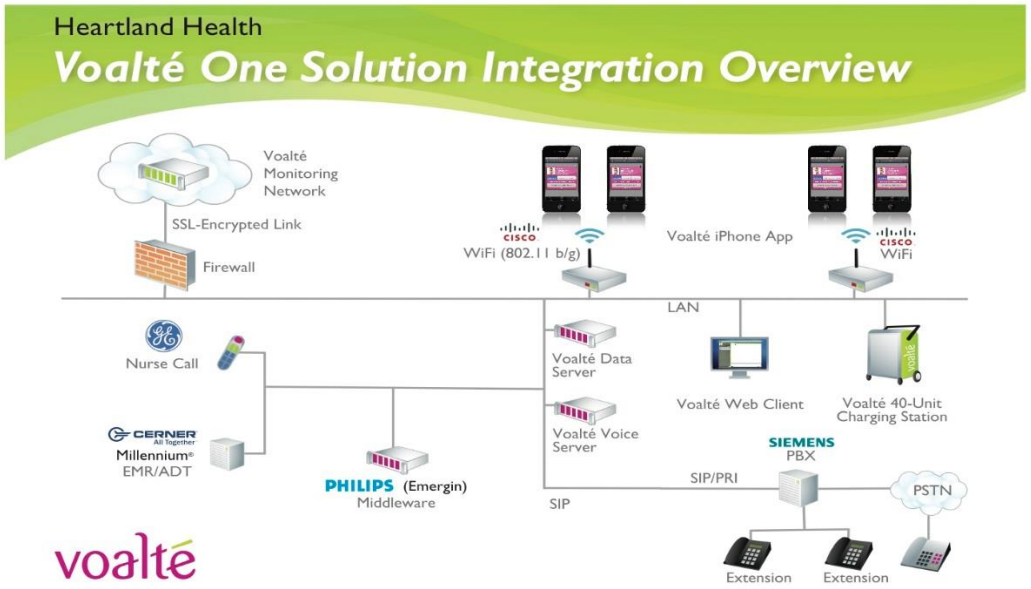


Figure 5. Vocera Communication System

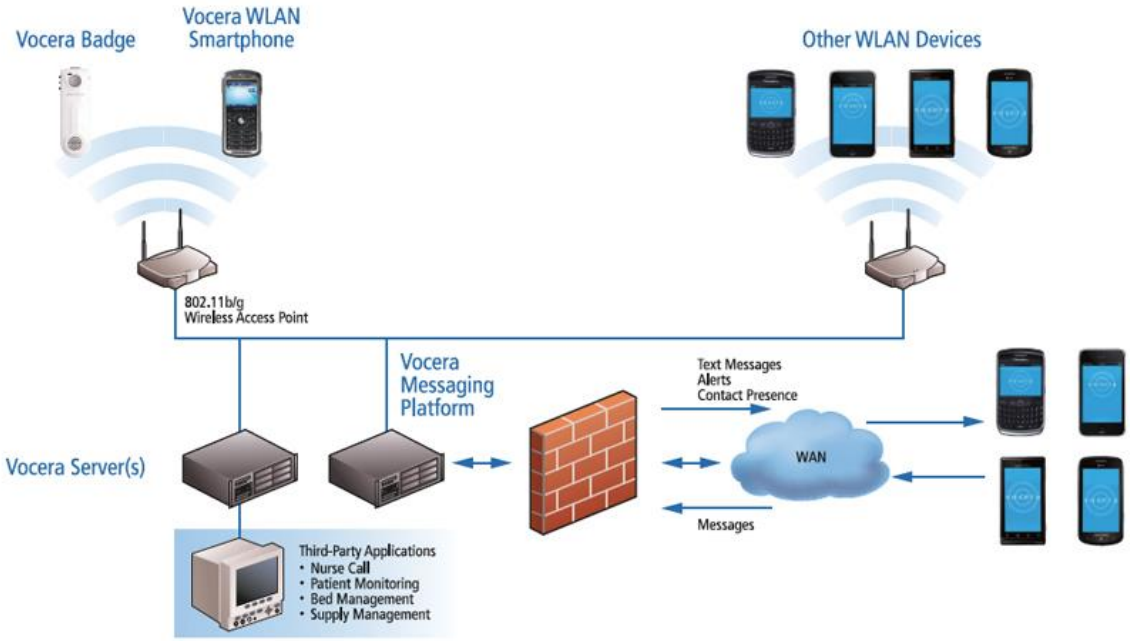
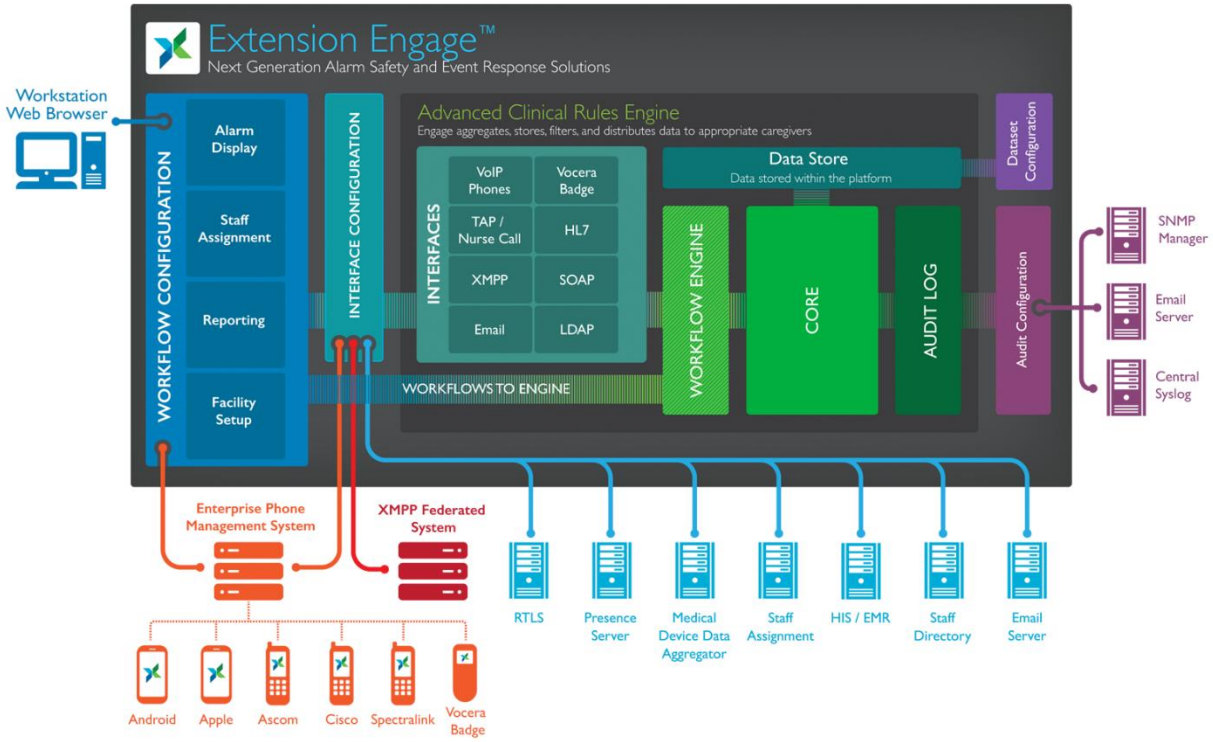


Figure 6. Extension Middleware System



Standards and guidelines

The Joint Commission (TJC)

In 2004 The Joint Commission (TJC) issued a goal for facilities seeking accreditation to **improve the effectiveness of clinical alarm systems** with requirements to 1) implement regular preventive maintenance and 2) testing of alarm systems and to assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. In 2005 because of continued high compliance rates, this goal was retired along with its two requirements.

Fast forward to April 10th, 2013 TJC issued a Sentinel Event Alert related to medical device alarm safety which warned hospitals against alarm fatigue caused by medical devices. TJC stated that 85-99% of the alarms do not require clinical intervention. Consequently, caregivers

became overwhelmed, desensitized, and endure alarm fatigue. If the caregivers turn off the alarm, turns the volume down or changes the default parameters, patient safety is compromised. TJC also reported on 100 alarm-related events occurring between January 2009-June 2012 with 80 of those resulting in death, 13 in permanent loss of function, and 5 requiring unexpected, additional care. Consequently, the TJC re-issued the National Patient Safety Clinical Alarms Standards in 2014 requiring hospitals to identify the most important alarm signals to manage and in 2016 required the establishment of policies and procedures for managing the most important alarms. The year 2015 was a data gathering event for the TJC as they review hospitals against their accreditation standards and assess whether hospitals have identified the most important alarm signals to focus on. This required hospitals to analyze their alarm systems and to identify problem areas to improve on. In 2017, TJC continued to list improving the safety of alarm systems as part of their Hospital National Patient Safety Goals. This includes making improvements to ensure that alarms on medical equipment are heard and responded to on time (TJC 2017). This requires leaders to establish alarm safety as a priority, obtain input from clinical and medical departments, evaluate risk to patients if the alarm is not attended too or equipment or software malfunctions, evaluate whether alarm signals are needed or whether they contribute to alarm fatigue, and evaluate the potential for patient harm. This frequent and persistent alarm problem has multiple contributing factors (TJC 2013; Block 1999; Korniewicz 2008; Valentin 2006):

- Absent or inadequate alarm systems
- Improper alarm settings
- Alarms signals not audible in all areas

- Alarm signals inappropriately turned off
- Alarm fatigue (most common)
- Alarm settings not customized to the patient or the patient population
- Inadequate staff training on the proper use and functioning of the equipment
- Inadequate staffing to support or respond to alarm signals
- Alarm conditions and settings that aren't integrated with other medical devices
- Equipment malfunctions and failures

ECRI

Alarm issues are among the problems most frequently reported to the ECRI. The ECRI Institute (http://www.ecri.org) is a non-profit organization that has been in existence for over forty years. The ECRI has a long history of investigating clinical alarm problems, recommending solutions and is designated as an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research and Quality and is listed as a federal Patient Safety Organization by the U.S. Department of Health and Human Services. Currently, ECRI recommends that medical device alarms be safe, logical and consistent with facility practice, thus encouraging hospitals to conduct an internal assessment and implement actions in response to their findings, with special consideration for personnel, procedures, equipment and local practice. Despite their long-standing recommendations, alarm hazards have continued to be listed on their *Top Ten Technology Hazards"* annual publication since 2008 (ECRI 2008-2017). In 2015 ECRI changed the alarm hazard to be specific to inadequate alarm configuration policies and procedures (ECRI 2015). In 2017, missed alarm for ventilators specifically became part of the Top 10 Health Technology Hazards ECRI list. Ventilators provide life-sustaining therapy and are often

combined with the same patients receiving opioids, whereas a missed alarm could prove deadly for a patient (ECRI 2017).

FDA

The FDA defines "Medical Device Data Systems (MDDS) as hardware or software products that transfer, store, convert formats, and display medical device data. Specifically, a MDDS does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. MDDS are not intended to be used for active patient monitoring" (FDA 2015). This definition by the FDA is a move towards defining the medical hardware and software component of an integrated system(s) and assists in the definition of a "device" which could be the hardware system which "houses" the software.

AAMI

The Association for the advancement of Medical Instrumentation (AAMI), a nonprofit organization that develops and publishes standards detailing proper production quality for medical instruments and the procedures in which they are used where these standards are considered one of the benchmarks used in critical health facility inspections. AAMI also serves as the secretariat to ISO/TCs 198 and 210 (International Organization for Standardization/ Technical Committee), as well as the administrator for the U.S. TAGs (United States Technical Advisory Group) and to many ISO/TCs and their subcommittees. Specifically, AAMI IEC 60601-1-8 the standard for Medical electrical equipment general requirements for basic safety and performance tests and guidance for alarm systems is currently in the process of revision (Appendix A). This not-yet approved amendment (AAMI/IEC 60601-1-08, Amd 2, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential

performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems) plans to address:

- Defining alerts vs. alarms
- Differentiation of low priority and low priority with audible.
- Active patient monitoring vs. clinical decision support
- Primary, secondary and tertiary notifications
- Secondary alarm as primary alarm
- Reasonably foreseeable misuse
- Symbols without English text
- Guidance for the creation of evidence to demonstrate reasonable assurance of safety and efficacy of alarm system algorithms.

ANSI/AAMI/IEC 80001-1 Standard speaks to the application of risk management for its networks incorporating medical devices and supports use of a risk assessment in establishing alarm priorities. These risks are related to patients, operators, or third parties (ANSI/AAMI/IEC 21010).

AAMI Healthcare Technology Safety Institute (HTSI) "engages the healthcare community in multidisciplinary safety initiatives that strengthen the development, management, and use of healthcare technology for improved patient outcomes". They have formed a National Coalition for Alarm Management Safety and recently convened a focus group to discuss and respond to questions about the design of alarm reports and to provide recommendations to alarm manufacturers as part of a broader examination of alarm management safety conducted under the auspices of the AAMI Foundation the HTSI group. The participants represented a variety of

medical and surgical units from four US hospitals as well as participants with hands-on experience compiling, analyzing, and reviewing various alarm reports. Regarding alarm reports, there was variability in time of review (weekly, months, as situation warranted), however these reports were noted to promote changes in work procedures such as modifications in nursing practice or configuration changes. Whether these reports contained "meaningful data" was questioned, however there was widespread agreement that this data should be collected, archived and that alarm condition data be integrated into the hospital's electronic health record (EHR) system (AAMI/HTSI 2015). The HTSI alarm reports questionnaire was reviewed in detail and aided with the questionnaire developed for this research project.

Combined efforts of TJC, ECRI, AAMI, and FDA

In 2011 an alarm summit was convened with over 300 representatives from AAMI, FDA, TJC, and ECRI. The goal was to address alarm system safety. When asked for a definition of alarm fatigue, the following answer was noted: "***alarm fatigue is when a nurse or other caregiver is overwhelmed with 350 alarm conditions per patient per day***". Technical alarms are specific to medical devices and have identical prioritization (i.e. Battery without power – high priority, on battery with <15 minutes of power – medium priority, Charging – low priority). One key message was delivered through this collaborative exercise: "When process can drive technology rather than technology driving process, the system is addressing the problem of alarm fatigue" (2011 AAMI Clinical Summit).

Patient and medical device risk

The integration of medical device alarm systems is intended to improve or enhance the communication of medical device alarms. This communication via an integrated medical device

alarm system notifies the caregiver and this system is expected to improve caregiver response times, henceforward improving patient safety and satisfaction. Patient safety is expected to improve as the communication of the need or potential harm is communicated, however these systems don't fully address the problem or decrease the total number of alarms. Patient satisfaction can be improved by allowing caregivers to communicate directly with the patient through in-room speakers or bed speakers. This direct connection to the patient and caregiver provides timely receipt of the patient request. A study reported an improved response time of 62 seconds when calls were communication directly to the clinician's device versus 127 seconds for an indirect connection (Kuruzovich 2008). Patient's knowledge of their medical device alarms communicated directly to their caregiver without a time lapse may also give patient's comfort, however if their alarms go unanswered, patient satisfaction will decline (Purbaugh 2013). If a patient need is not addressed in a timely manner, patient safety may be compromised.

The question as to whether the alarm response times are "improved" with implementation is unclear as often baseline times may not be measured and the decision to implement an integrated system (or portions of) might be due to multiple reasons such as extended response times, unintended patient events, or poor patient satisfaction scores.

Messages sent to end-users generally do not provide clinical information about the alarm or the patient status (Bonafide 2015). This is important as the caregiver have difficulty distinguishing between actionable and non-actionable alarms. Actionable and non-actionable alarms (which require no nursing intervention) still exist with an integrated system as the systems are not intelligent or smart systems (Cvach 2014). They purely connect the alarm from the medical

device to the communication device and often have complex escalation and routing schemes. They are considered secondary notification systems, therefore when systems are not functioning, the primary system still operates as intended.

Further, an integrated system is often viewed as an advanced solution to address the communication of medical device alarms, however coupled with increasing workloads and decreased staffing there can be difficulty in effectively prioritizing and responding to these notifications. Despite these advanced systems, there continues to be a rise in equipment-related errors, patient dissatisfaction and continued concerns regarding patient safety (Frisch 2006). While this alarm integration in theory is an improvement, it may create an additional alarm hazard. Responding to the issue of alarm hazards requires a holistic approach to the patient and caregiver's environment (Tanner 2013).

Much of the alarm fatigue stems from default settings which are individualized to the patient need, however sometimes they stem from other events such as sensitivity and specificity settings or patient or device activity while connected. Medical device alarm configurations in the patient care setting consider the pre-set or "default" values which are manufacturer specific, and which often fail to reflect actual patient clinical needs. For example, a physically fit and active hospitalized patient with a normal resting heart rate of 48 may be experiencing nuisance alarms due to a default low heart rate setting of 50. Alarm fatigue can be overwhelming for clinicians and patients.

The assessment of risk for medical devices is required by ISO 14971:2007, Medical devices – Application of risk management to medical devices, or the regulatory Global Harmonization Task Force (GHTF) states that each system or software application is designated as a medical

device and as such it classified per the level of risk it presents to a patient and organization. These requirements address the identification of hazards and the estimation of risk based on probability and severity harm assessments. One method suggested by ISO is to score a risk rating for each alarm or when the systems are connected such that:

- High – requires immediate attention, device has failed or there is a change in patient condition which poses an immediate serious injury or death risk to the patient.
- Moderate – requires rapid intervention, a device has failed or there is a change in patient condition which poses an injury risk or adverse event to the patient if rapid intervention doesn't occur.
- Low – requires timely intervention, device has failed or there is a change in patient condition which may pose an adverse event risk if timely intervention doesn't occur.

Following a medical device risk assessment, there should be improved understanding of the risk potential and a better understanding of the ability to establish a priority system for the communication of alarms. System improvements and mechanisms can then be put in place to help mitigate hazards. Interface features of medical device alarms should be evaluated for collective risk, making it easier to determine how interoperable a system is as well as plan for future interoperability improvement projects.

High-priority alarms require immediate attention; medium-priority alarms indicate a dangerous situation requiring a quick response; and low priority alarms indicate that attention is needed (Chambrin 2001, IEC60601-1-8). High priority alarms require immediate attention due to the potential for patient injury or death. Alarm risk assessments are encouraged to help assign alarm priority ratings which may be useful when developing alarm policies and procedures and

to help determine proper alarm response times. For purposes of this study, alarm response times (defined as TTR) was measured using these IEC classifications:

- High priority (immediate response required) – less than 1 minute.
    - Timeframe is based on the need to take immediate action to save a life, prevent suffering or to mitigate injury.
- Medium priority (requires a quick response) – less than 2 minutes.
    - Timeframe is based on recommendations of emergency organizations of a response time of <2 minutes can improve the chain of survival (Currents in Emergency Care).
- Low priority (awareness and attention needed) – greater than 2 minutes – less than 5 minutes.
    - Timeframe is based on the expectation that distributed systems are improving those "nuisance alarms" which can lead to alarm fatigue.

Preliminary research

This project began with several preliminary literature reviews. The first was a search of Nurse Call Integrated systems followed by a clinician/nurse perception of integrated alarm systems. Surprisingly, the literature lacked publications addressing these topics. Much of the published alarm literature is specific to physiological monitoring systems in Intensive Care Units. This researcher was interested in the problems addressing the clinician on the ancillary patient care units and the impact of Integrated Nurse Call Systems. The physiological monitoring and the Nurse Call systems capture the majority, but not all medical device alarms, however these two systems aren't often integrated together as one medical device alarm system. Medical device

manufacturers are reluctant to accept the legal risks posed with integration and secondary alarm notification systems.

The research then progressed to evaluating literature addressing global medical device surveillance. The unanswered question of: "How big is the problem of hazards or harms that relate to medical devices?" was outstanding. In seeking to better understand medical device alarm issues from a global perspective, a retrospective literature search was performed to attain medical device regulatory and post-market environment information specific to these questions:

1. What published information exists regarding post-production surveillance data for alarm-related events explicit to medical device alarms globally?
2. Can the reported alarm-related events be categorized into the ECRI's proposed framework of personnel, local procedure, equipment, and policy and procedure as contributing factors to alarm hazards?

The research began with the WHO transnational country database which identifies *Pre-Market Controls, Establishment Controls, Inspections, and Post-Market Surveillance* by country. Overall, the WHO database was found to lack specific information related to recognition of medical alarm system issues and post-market requirements. As concerns are transcultural; improvements in recognition, resolution, and surveillance of medical device alarm system issues carry broad implications.

This was followed with a PubMed literature search to identify reported medical device alarm issues using predetermined broad, then narrowed search criteria further evaluated by countries. Two-hundred, ninety seventy articles were reviewed from the following countries:

France, Germany, Netherlands, United Kingdom, Japan, Canada, New Zealand, Australia, and the United States. Two-hundred seventy-one articles were reviewed, collated, and analyzed by country using the ECRI framework of Medical Device Issues. This global search resulted in the identification of issues which were agreeably categorized using the ECRI's proposed framework for the evaluation of medical device events: personnel, local procedure, equipment, and policy and procedure (Appendix B). These preliminary research findings formed the basis for this research of various hypotheses related to nurse perceptions of alarm system configuration, integrated medical device policies, and alarm system training and education.

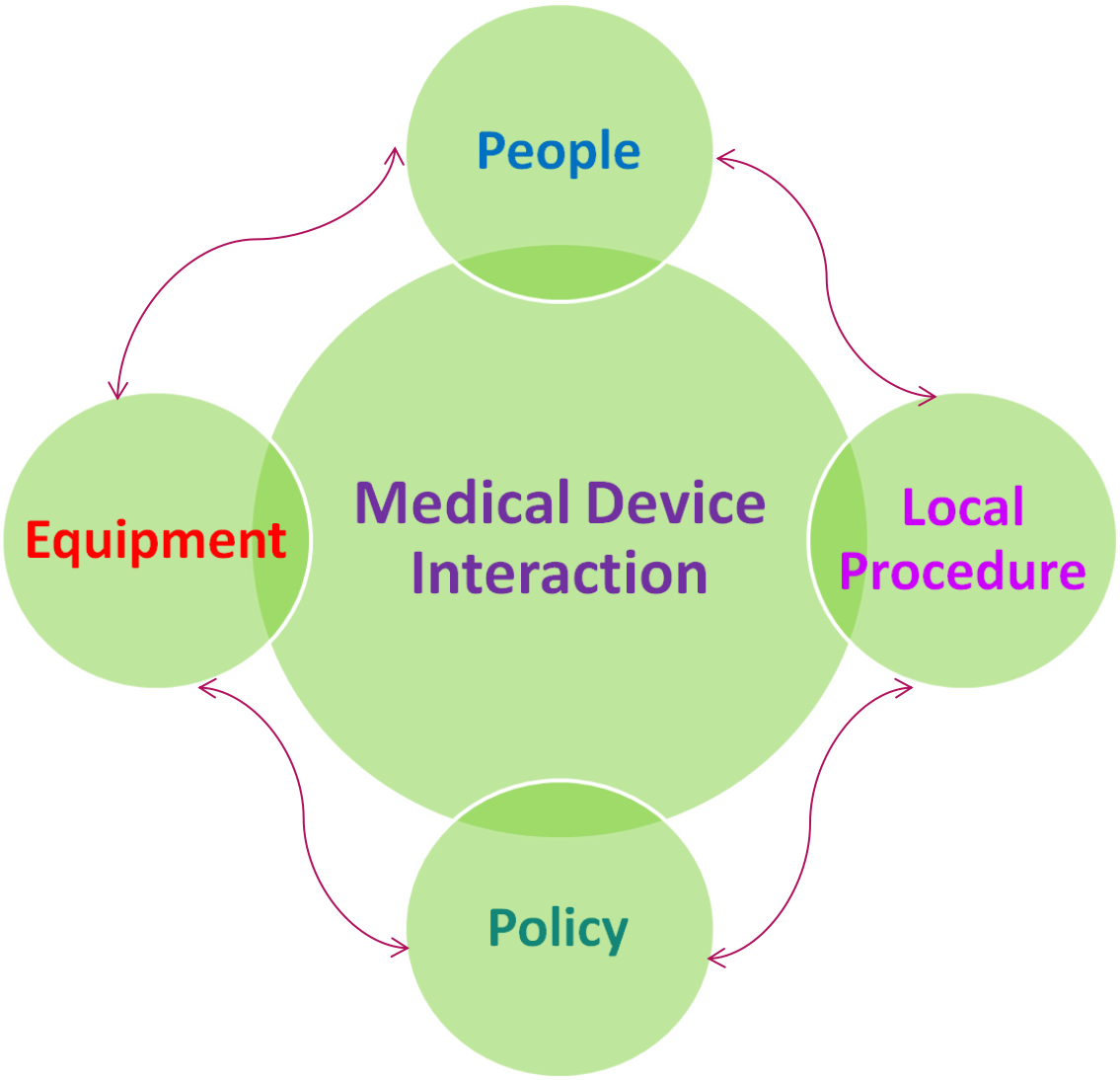
These four areas were further elaborated using a proposed "Medical Device Interaction Model," term which is an extension of Madeline Leinenger's Transcultural Nursing theory (Leininger, 1995). This model takes into consideration Leuning, Swiggum, Wiegert and McCullough-Zander's 2002 proposed standards of transcultural nursing practice and incorporates the ECRI framework of medical device issues. The "Medical Device Interaction Model" (Lindell 2014) considers the many medical device alarms present in a hospital patient setting, referencing them as a ***system*** rather than individual medical devices (Figure 7).

Extrapolations were based on the multi-country publications which demonstrated:

1. ***Medical device*** issues are primarily equipment-related. Equipment was found to be unreliable, confusing, lacking in differentiation, having poor sensitivity and specificity, and inadequate system integration.
2. ***People*** **issues** such as lack of trust, device confusion, staffing, use errors, and misuse of medical devices were found to be universal issues.

3. ***Local procedures*** for device maintenance, monitoring of alarms, training and education programs emerged as inadequate.
4. ***Policies and procedures*** lack specificity related to device use in areas such as setting limits, defaults, adjustment, and lack of standardization. Overall, there was a failure to identify, report, and review medical device related alarm incidents.

Figure 7. Medical Device Interaction Model
Paradigm by Colleen Lindell



This model is intended to demonstrate the many factors that may impact caregiver interactions with a medical device and or medical device system.

Following the preliminary literature research project, the foundation of this research project emerged as an exploratory study to address this fundamental question:

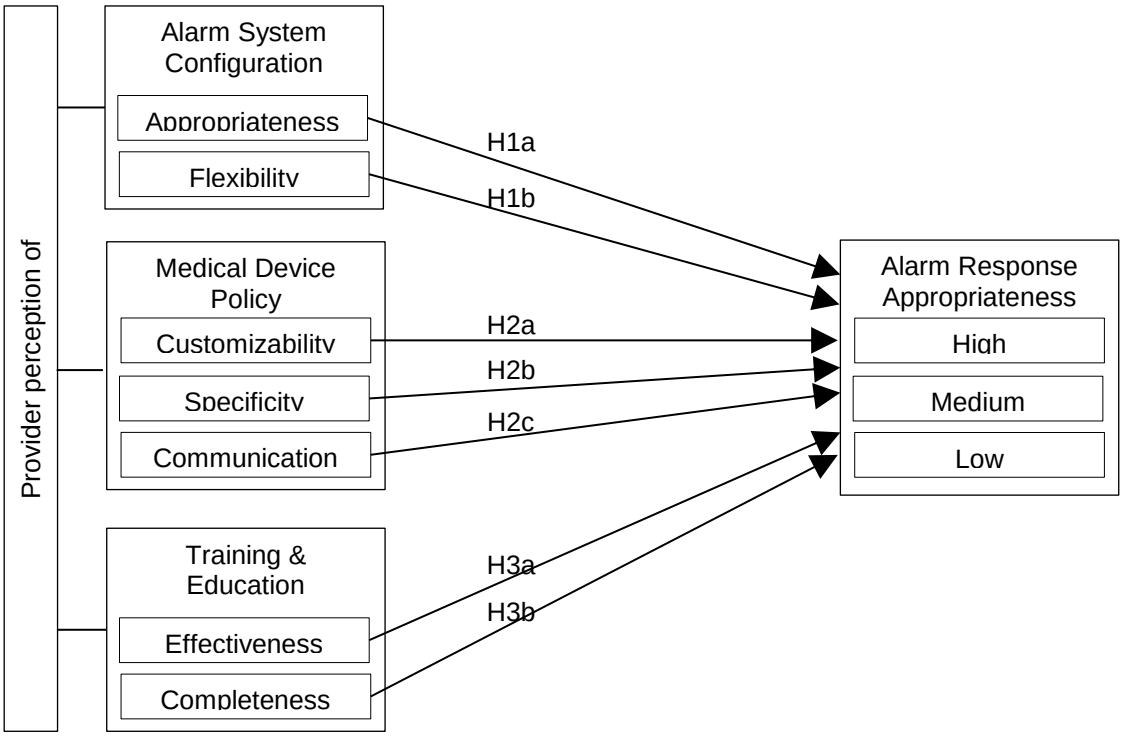
To what extent do the dimensions of alarm system configuration, alarm-related policy and procedure, and alarm system education and training impact caregiver response time and effect patient outcome?

Considering the integrated alarm system, three constructs emerged and became the primary focus of this research (Figure 8):

1. **Alarm system configuration** – addressing alarm system configuration appropriateness and flexibility. Specifically, customization specific to intervention, unit population, individual patient needs, the ability to adapt to changing personnel assignments, general configuration, priority settings, the potential for desensitization, routing of alarms, nuisance alarms and the ability to communicate exactly where care is needed.
2. **Integrated medical device policy and procedure** – addressing the integrated medical device policy customizability, policy specificity, and policy awareness. Specifically, the management of the alarm system (written policy and procedure), access to policy and procedure, overriding alarm priority, changing alarm priority, alarm assignments, recommending changes to alarm assignments or other alarm-related changes, pausing and silencing of alarms, routing of alarms, responding to alarms, back up procedures when the alarm system is down, responsibilities for monitoring, responding to, changing, and testing of the devices/system.
3. **Alarm system education and training** – addressing training and education effectiveness and comprehensiveness. Specifically, education addressing alarm monitoring, response,

override, various alarming devices, consequences of not responding to alarms, use of multiple formats, customization to caregiver needs, refresher training, specificity to devices used, how to manage and care for the alarming medical devices, access to educational material, additional training for updates to the system, vendor provided material, and material provided in-house.

Figure 8. Research Model



Following analysis of the preliminary research and development of the research model, the following three hypotheses were proposed:

Hypotheses 1: Clinician perception of alarm system configuration

Medical device integration is defined as medical devices which are linked together via a network or communication system for improving the communication of medical device alarms and alarm response times. How medical devices are configured and managed directly impact the workflow of the unit. There can be a great deal of variation between caregivers, patient environments, local, individual and hospital system practice. Current alarm systems demonstrate usability concerns primarily related to clinician's reduced trust, low efficiency, and lack of auditory and visual differentiation of the indication, priority level confusion, and ineffective notifications (Korniewicz 2008). Barton (2011) in her review of clinical decision support (CDS) systems comments on information alerts such as interaction alerts and patient reminders stating that they "contribute to alert fatigue" and recommends that more "pertinent" alerts be provided to staff if an action is required (Sendelbach, 2012). With so many false alarms being present in the healthcare setting, it is predicted that those healthcare providers who experience a high number of false alarms become distrusting of medical device alarms and will extend their response time based on an assumption that the alarm is either insignificant or without validity. To date, there have been no published nurse call alarm configuration "best practices".

Alarm sensitivity contributes to the great number of "false alarms" in the healthcare setting, however in majority of instances they are not true alarms. Likewise, if medical devices are known to have a high specificity rate, they will be responded to more rapidly. It is unknown whether having an integrated medical device alarm system will result in decreased false alarms or improved response times. Most medical devices do not reject artifact and do not analyze

another device comparative settings (for example: oximetry of a pulse oximeter, oximetry of a physiologic monitor) to determine specific alarm conditions before alarming (Block 2012). Machine learning algorithms for signal quality and physiological data research is being performed, however the path to acceptable zero true alarm has yet to be attained (Li 2012). Consequently, there are concerns related to medical device configurations such as reliability, differentiation, sensitivity, specificity, and with increasing medical devices (and number of alarms) per patient, the integrated system is uniquely configured to meet the unit and patient clinical needs.

There are also caregiver impacts to alarms which have recently been studied and include: increased occupational stress, decreased work performance, delayed recognition of alarms and increased errors (Choiniere 2010, Hsu 2012). Recent advancements in medical devices and the integration of medical device systems in recent years has created systems intended to improve patient safety, however these "improvements" have failed to demonstrate improvements in caregiver response or to patient safety.

H1: *Clinician perception of alarm system configuration is positively associated with clinician alarm response.*

H1a: *Clinician perception of the **appropriateness** of alarm system configuration is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **appropriateness** measures clinician perception of alarm having the appropriate priority, configured appropriately, desensitization of alarms, alarms sent to the correct provider, ability of the system to pinpoint where care is needed,

generation of few or no false alarms, and alarm conflict with other systems measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

H1b: *Clinician perception of the **flexibility** of alarm system configuration is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **flexibility** is a measurement of clinician perception of system customization specific to the type of intervention, unit or for individual patient need, and the ability of the system to reset quickly when caregivers are assigned measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

Hypotheses 2: Clinician perception of integrated medical device policy and procedure

Healthcare providers in hospital settings function with a great deal of protocols, policies, guidelines or procedures and therefore we expect less ambiguity with roles and responsibilities defined and documented.

These policy and procedure dimension is applicable to the healthcare environmental organization as healthcare providers are responsible for the health and welfare of patients 24 hours a day/365 day a year. Decisions are often made, sometimes independently and sometimes in collaboration with the patients' physician. Sometimes, these decisions are life and death type decisions. Further, a Clinician's licensure is provided for by the states which have written nurse practice acts intended to help to guide and outline clear responsibilities. Their organizations of employment (generally hospitals) further establish policies and procedures by which the profession is expected to abide by. Ultimately, as a patient advocate, the Clinician must establish a trusting relationship with his/her patient by listening, understanding, and allowing patient participation in their healthcare.

How systems function can be a contributing factor to situations leading to workplace conflict, including adverse alarm events (Funk 2015). How work is accomplished, codes of conduct, organizational values, communication patterns, orientation, making assignments, practice guidelines, meeting attendance, policy and procedures, and relational leadership can create conflict for caregivers (ECRI, Gerardi 2015, Joseph 2015). At the unit level, there may be a culture of non-inquiry, blame, or mistrust which can create conflict for the caregiver who is often overwhelmed with medical device alarms. Caregivers rely on medical devices to assist them in monitoring their patient's physiological parameters and while they should be familiar with the medical device settings the parameters between devices often conflict. Alarm options such as synchronization, adjustment, standardization and incident reporting are set by the unit or organizations policies and procedures (Armbruster 2010).

H2: *Clinician perception of integrated medical device policies is positively associated with clinician alarm response.*

H2a: *Clinician perception of the **customizability** of integrated medical device policies is positively associated with clinician alarm response appropriateness.*

The operational definition for the **customizability** of clinician perceptions include the pausing of an alarm, silencing of an alarm, changing alarm priority, override of priority, changing staff assignment, and a back-up system during down time as measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

H2b: *Clinician perception of the targeted **specificity** of integrated medical device policies is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **specificity** measures clinician perception of alarm having the appropriate priority, configured appropriately, desensitization of alarms, alarms sent to the correct provider, ability of the system to pinpoint where care is needed, generation of few or no false alarms, and alarm conflict with other systems measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

H2c: *Clinician perception of institutional **communication** of integrated medical device policies is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **communication** measures clinician perception of alarm management procedures, access to policies, incorporation of staff input, responsibility for response of alarms received, responsibilities for changing alarm priorities, and monitoring and testing of devices as measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

Hypotheses 3: Clinician perception of alarm system education & training

Not only are medical device systems complex, the unique alarm devices that form the system are multifaceted. Often, the operating manuals for patient monitors are extensive and hospitals receive minimal hard or DVD copies. Electronic copies may not be available or may be difficult to find. Caregivers are expected to use these devices according to the instructions provided in the manual. Consequently, clinicians are not always knowledgeable or aware of the purposes, functions, and adjustments of the alarm device. This results in the alarm system not being adapted to the individual patient, which may result in an increased number of false alarms if the alarm thresholds are too narrow, and the potent for missed alarms, if the thresholds are too wide (Borowski 2011). Further, this lack of knowledge puts patients at risk.

A review of the literature, advocates clinician medical education regarding (Konecny 2003, Dumais 2003, Haghnbeck 2005, McConnell 1994, 1995):

- Intended use of the medical device
- Manufacturer instructions for use, labeling, warnings, contraindications, and known complications
- Proper use of the medical device
- Hospital clinical practice's and education department recommendations or guidelines
- Recommended maintenance of medical device
- Knowledge of differences between similar medical devices

Clinicians are exposed to numerous devices, various software versions, multiple manufacturers, different or similar tones, messaging, colors, and use interactions. Particularly, when clinicians move and work at different units or hospitals and care for patient's different circumstances and conditions. Clinicians need to become aware and stay updated with their patient's diagnosis, pre-existing conditions, allergies, treatments, medications, and effects of multiple device use to better understand and anticipate events that may occur (Swayze 2011). Without proper instruction, caregivers may be prone to use errors. When clinicians lack use knowledge, use errors may occur. These errors can include user actions such as extra key presses, inability to ascertain, resolve or acknowledge alarms, which will likely result in a delay in response time. Misuse of medical devices includes actions outside of the intended uses or not abiding by the manufacturer's instructions for use. This would include actions such as silencing latching alarms or not plugging in a medical device exhibiting low battery signals (Murphy, 2006).

H3: *Clinician perception of alarm system training and education is positively associated with clinician alarm response.*

H3a: *Clinician perception of the **effectiveness** of alarm system training and education is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **effectiveness** measures clinician perception of education or training provided specific to alarm monitoring, response and override, specific to various devices on the unit, education specific to alarms they are expected to receive, consequences of non-response, multiple educational formats, customized to the clinician's needs, and the provision of periodic refresher education as measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

H3b: *Clinician perception of the **completeness** of alarm system training and education is positively associated with clinician alarm response appropriateness.*

The operational definition for the assessment of **completeness** measures clinician perception of education on devices used, how to respond, override to alarms, how to manage and care for the devices, additional material availability, additional education when the system is updated, and the provision of vendor-specific and in-house educational materials as measured on a 5-point scale where 1 = Strongly Disagree and 5 = Strongly Agree.

These are the central and sub-hypotheses relating to clinician perceptions of the alarm configurations, policy and procedure and education and training.

This study also included additional exploration and comparison of similarities or differences between hospitals and clinicians' response to high, medium and low priority alarms, overall

response rates, differences between alarm system configurations, and an evaluation of patient adverse event rates.

Exploratory research questions

In addition to acquiring insight into the nurse perceptions specific to the three proposed constructs, additional questions remain unanswered:

1. Do caregivers with similar integration systems respond similarly to high, medium and low priority alarms?
2. Do organizations with a lower number of alarms experience faster response rates?
3. To what extent to alarm configurations vary between organizations?
4. Do organizations with speedier alarm response times have less adverse event rates?

Organizational Culture

Understanding that organizational culture is a shared pattern of beliefs, attitudes, norms, role perceptions and values (Triandis, 2002), we find a lack of this type of study specific to the healthcare environment, nursing and medical device alarm systems.

Organizational culture can have a strong effect on individual's beliefs, attitudes, and behavior within the workplace (Martin 1992, Schein 1985, Schein 1990). Sub-cultures often emerge (Schein 1990; Triandis 1972; Guzman, 2008). Research by Straub et. al in 2002 propose a layering effect of culture whereas an individual's behavior is influenced by national, professional or sub-cultural layers (virtual onion metaphor or nesting effect) and they propose that the influence is dependent on situational circumstances as well as their own personal values. Personal values may translate to personal perceptions. Nursing's professional principles center on patient care as they act as patient advocate; within the boundaries of their

licensure, with knowledge of national, local and organizational standards (policies and procedures) utilizing the tools provided (medical device systems). It is with interest that we propose evaluating the clinician perceptions comparatively utilizing the constructs of alarm system configuration, integrated medical device policies, and alarm system education and training traditionally evaluated as separate constructs within the healthcare or information technology environment.

In seeking to better understand the healthcare work environment and to better appreciate various alarm configurations, policy, and educational effects, this research seeks to examine these dimensions and their effect on clinician response to alarming medical devices, specifically evaluating clinician alarm response (dependent variable) and the impact of nurse call configured system, policy and procedure, and education and training (independent variables).

Theory considerations

When considering theories relating to this research, two were identified. Organizational identity theory which stems from the Social Identity Theory (SIT). Per social identity theory, individuals are influenced by an overabundance of cultures and sub-cultures, some ethnic, some national and some organizational (Straub, 2002). As suggested by Straub, the individual's social identity crosses all cultural boundaries (national, organizational, professional) and fuses together to create one's overall culture and this combination is unique to individuals. We postulate that nurses in the healthcare profession while following the limitations of their licensure and practicing within the organizational expectations (culture of safety), act under their own accord, based on a multitude of inputs and belong to a group of Registered nurses who are universally known and regarded as patient advocates. As noted by Gallivan and Srite

(2005), there are complex and rich implications based on social identity theory (SIT) and the virtual onion metaphor which shapes an individuals' social identity. We believe these implications may contribute to nurse beliefs and actions when the constructs of policy and procedure, medical device, and people intervene, having the potential to affect their response to medical device alarms, specifically their "time-to-respond". While this research initially conducted and measured the culture related aspects which may impact the individual response times, it was determined that the study would be too over-whelming for clinicians to include culture and the culture portion of the clinician survey was eliminated. It is however, important to recognize that organizational culture and social identity have the potential to impact those constructs (people, policy, equipment, and local procedure) which may affect the unique and individual medical device interactions.

The following chapter will discuss the methodology of this multi-hospital, comparative, exploratory research study.

METHODOLOGY

This chapter details the research procedure and process used to evaluate the central hypotheses and exploratory research questions that guide this study. The study is divided into five parts. This chapter outlines the procedures used to address the research questions, and details the site selection process, and provides rationales for inclusion and exclusion criteria. Finally, a review of statistical methods is presented.

Site Selection

The University of Wisconsin Milwaukee's IRB package was submitted for review and approval in the Spring of 2016. Identification of potential hospitals with similar Nurse Call systems and patient care units was facilitated by direct inquiry to Major Nurse Call System Provider's Clinical Department Managers (Hill-Rom, Rauland-Borg, Critical Alert) who provided site names and contact information. The hospital patient care unit managers were contacted and invited to participate in the study via an electronic inquiry or direct telephone contact. Upon agreeing to participate, hospital IRB packages were submitted and approved prior to study initiation. A clinical representative/manager for each hospital was engaged to assist with the data collection. Inclusion/exclusion criteria were then reviewed. The clinical representative/manager then sent invitations to participate and a hyperlink to their staff via the hospital's internal email system. Informed consent was included at the beginning of each online Qualtrics survey with participant acknowledgment requirement of consent prior to participation.

The study comprised five activities:

1. Clinician perception survey.

2. Alarm data download capture for 3-months' time.
3. Staff interviews.
4. Review of alarm-related policy & procedure.
5. Review of alarm-related events (patient outcomes).

Clinician inclusion criteria

- At least 3-month experience within the participating unit.
- Willingness to complete a self-administered online questionnaire.

Clinician exclusion criteria

- Less than 3 months working within the participating unit.
- Inability or unwillingness to complete a self-administered online questionnaire.

Hospital inclusion criteria

- Must have an *alarm distribution system*, minimally consisting of a Nurse Call system and an End-Device (secondary communication methods: telephone, communication "badge").

Hospital exclusion criteria

- Lack of an integrated nurse call alarm systems
- Inability to acquire and provide retrospective and current alarm data for a 3-month period.

Clinician perception survey

The survey was developed as a modification and enhancement of the HTSI alarm reports questionnaire which was completed primarily by Medical Surgical staff. Additional resources

reviewed included integrated alarm system findings published by the ECRI and AAMI (AAMI, HTSI 2015).

The survey was designed to measure clinician perception of:

1. Alarm system configuration
2. Integrated medical device policy and procedure
3. Alarm system education and training
4. Response to alarms of different priority.

The clinician provider survey measured staff perceptions and was therefore considered human subjects research requiring IRB approval prior to distribution.

The survey went through several iterations and was pilot-tested with a group of 10 nursing staff in September 2015. Statistical analysis was conducted to evaluate question validity. Following these results, the survey was modified and re-tested with a group of clinicians from the hospital setting that actively use devices for alarm notifications. These modifications were statistically analyzed, and the final survey was developed in April 2016 (Appendix C). The final survey included the following:

- Informed consent
- 5 descriptive questions: age, job title, time worked as a clinician in the USA/outside the USA, and age
- 43 questions to evaluate 7 constructs using a 5 level, ordinal Likert scale specific to clinician perception of alarm configuration, flexibility of the alarm system configuration, customizability of integrated medical device policy, specificity of integrated medical

device policy, awareness of integrated medical device policy, effectiveness of alarm system training, and completeness of alarm system training.

- 4 questions to estimate the number of alarms per shift, number of high, medium, and low priority alarms.
- 3 questions to estimate the clinician's response time to high, medium, and low priority alarms.
- 4 open-ended comment responses specific to alarm system configuration, alarm response time, alarm system training, and integrated medical device policy and procedure.

The final survey was implemented in 2016 – 2017 and as the survey was not considered a validated-for-use instrument, item-to-total correlations and factor analysis was planned to assess whether the items effectively measured the constructs used in this research.

The study was designed as a systematic, exploratory, and generalizable investigation utilizing a healthcare provider self-administered online questionnaire to assess medical device alarm system perceptions, and the impact of configurations, protocol, policy and education. The questionnaires (Appendix C) were distributed to each patient care unit's staff member who was be sent an email link to the online questionnaire (via QUALTRICS). The email was sent by the clinical nurse manager and included a request for staff members to complete it within two (2) weeks' time. The survey could be completed via desktop computer, laptop, or mobile device. All data were reported in the aggregate. We expected an 80% (+/- 10%) response rate and a minimum of 30 responses per unit.

Staff interviews

Interviews with hospital staff having information specific to the medical device alarm system were conducted to provide insight into the alarming medical device presence, alarm system configurations, staff, unit and alarm workflows, policy and procedure knowledge, use of Nurse Call reports, and alarm-related events. The interview tool (Appendix F) assisted the interview with questions related to medical device historical use, current hardware and software, use of middleware, staff assignment, central station, policy and procedure, alarm workflows, use of Nurse Call system reports, alarm log historical review, and a discussion of alarm-related events as well as contact information for items needing to be requested, such as the data download, alarm events, and policy and procedures (Appendix F). These interviews were conducted after IRB approval and prior to or during the clinician perception survey distribution.

Alarm download data

Alarm response data were obtained via the IT, Biomedical or Clinical Engineering department responsible for electronic, equipment and alarm-related system downloads and the Nurse Call System vendors provided 24-hour nurse call alarm type and response-time logs for a 3-month period, which included the survey period.

Time-to-respond was categorized for all types of alarms and was further classified using the AAMI into terminology choices: low, medium, and high-priority. As there were subtle differences in naming conventions a standard naming nomenclature was used (ie. Water = drink, normal =beep) to provide for consistent data comparison.

A telephone interview with nursing, IT, clinical or biomedical engineering to ensure data completeness and address any gaps was conducted by the author (Appendix F). The hospital

organizations did not have a written definition of expected clinician provider response time. Therefore, response times were classified using the IEC/AAMI characterization of high (< 1 minute), medium (1-2 minutes), and low (2-5 minutes) model for different alarm priority types.

Alarm-related events review

This study included a review of actual or potential adverse patient events or outcomes linked to the alarm system notification. The risk manager or quality reviewer was contacted via telephone and a discussion of alarm-related events occurred, followed by the provision of a detailed description of the patient outcome and an assessment of the potential and actual harms.

Alarm-related policy and procedure review

The study included a review of existing documents related to alarm conditions noted in Appendix F (policies, procedures, log review, adverse or sentinel event reporting, staffing models, scheduling, and reported alarm-related events). The request for this documentation was directed at the Unit Nurse Managers. All data in this segment were de-identified prior to review.

Statistical analysis

Sample Size

A power analysis was conducted using G*Power 3.1.9.2 (Faul, Erdfelder, Buchner, & Lang, 2014) to determine the minimum number of survey responses needed to obtain statistically valid results. This power analysis was based on a multiple linear regression analysis with seven predictors and assumed a medium effect size, a power level of .80, and a significance level of .05. The analysis showed that the minimum sample size for this study is 103 respondents.

Preliminary Data Cleaning

Prior to analysis, the data were checked for accuracy, missing cases, and the presence of outliers Surveys with large numbers of missing items (i.e., greater than 50%) were excluded from the analysis. Data accuracy was checked using frequency distributions to ensure that all data points fall within the possible range of values. The presence of outliers was checked using standardized values. Standardized values were calculated for each subscale score (i.e., the subscales pertaining to alarm system configuration, integrated medical device policies, and alarm system training and education). Standardized values greater than 3.29 or less than -3.29 were considered outliers and removed from the data. (Tabachnick & Fidell, 2012).

Reliability

Cronbach's alpha tests of inter-item reliability was conducted on each of the subscales pertaining to alarm system configuration, integrated medical device policies, and alarm system training and education. Cronbach's alpha provided the mean correlation between each pair of items and the number of items in a scale (Brace, Kemp & Snelgar, 2006). Reliability coefficients greater than .7 indicate acceptable inter-item reliability (George & Mallery, 2010).

Factor Analysis

As the survey instrument had not been previously validated, it was considered important to perform factor analysis to evaluate whether the constructs were distinct, and the items measured the construct correctly. Factor analysis was performed, and the factor structure was examined to evaluate individual construct measures.

Logistic Regression analysis

To test the hypotheses of this study, three binary logistic regression analyses were conducted after the factor analysis. Binary logistic regression is an appropriate statistical analysis when the aim of the research is to examine the relationship between multiple independent continuous variables and a dichotomous dependent variable. For these analyses, the independent variables were the subscales pertaining to alarm system configuration, integrated medical device policies, and alarm system training and education. Each of these variables are continuous measures. The dependent variables were the participants' self-reported low, medium, and high priority alarm response times, categorized as appropriate or inappropriate.

Prior to the analyses, the data was checked for multicollinearity. The absence of multicollinearity indicates that the independent variables are not too highly correlated with each other. This assumption was tested using Variance Inflation Factors (VIF). Per Stevens (2009), VIF values over 10 suggest the presence of multicollinearity.

A separate regression analysis was conducted for each alarm priority. Additionally, the odds ratio and predictive modeling were performed to assess the appropriateness of clinician response to low, medium, and high alarms.

Descriptive Statistics

Descriptive statistics were compiled and reported for each variable in the study. Means and standard deviations were reported for continuous variables, including the alarm response times, subscales for alarm system configuration, integrated medical device policies, and alarm system training and education. Frequencies and percentages were reported for categorical

variables, including job title, gender, country of origin, length of time living in the U.S., and self-reported alarm response times.

The following chapter will present findings of the alarm system perception survey, the staff interviews, the alarm data download capture, the alarm-related events review, and the alarm-related policy and procedure review of four midwestern hospital systems. Quantitative analysis results are presented first, followed by qualitative analysis of the interviews and reviews of the alarm related events and procedures.

RESULTS

The purpose of this study was to investigate Nurse Call alarm management systems which have Nurse Call integrated into an end device (mobile phone, etc.). This examination utilized both quantitative and qualitative methods to evaluate the integrated Nurse Call system.

The hypotheses related to clinician perceptions of alarm configuration, integrated medical device policy, and training and education were assessed by completion of the online clinician survey. Nurse call alarm data download capture and alarm-related patient outcome data were evaluated as quantitative data. The clinician survey comments, staff interviews, and policy review were assessed as qualitative data.

This section begins with a review of the data analyzed. Response rates and demographic summaries of hospital and clinician data is then presented. This is followed by a review of the statistical methods used to evaluate the clinician survey and hypotheses. The results pertaining to the research hypotheses are then presented in detail. This is followed by an analysis of the hospital alarm data, which yielded some insightful observations. Alarm-related events are then discussed. A collation of clinician survey comments is presented, along with some interpretive analysis thereof. The exploratory research questions are then tackled, followed by a review of the policy and procedures at each hospital

Quantitative analysis:

Clinician survey and hypotheses evaluation: The seven independent variables were clinician perceptions of the medical device alarm system configurations, policy and procedure, and education / training questions obtained via clinician survey. The dependent variable was also

obtained via the survey using self-reported response times for high, medium, and low priority alarms.

Alarm data download capture: A review of actual time-to-respond to specific integrated nurse call alarms obtained from was the Nurse Call vendor system for a 3-months' time. This data was used to evaluate and compare actual response times to self-reported response times for the low, medium and high priority nurse call alarms. Review of actual system alarm data such as alarm types and their specific alarm response times were analyzed.

Alarm-related event data: A review of all hospital reported alarm-related patient outcome events for a 3-month consecutive period. Alarm events data results were discussed with the clinician responsible for obtaining and providing the data.

Exploratory research questions: These questions address hospitals having similar integration systems, the number of alarms in relation to response times, the extent of variation in alarm configuration between organizations, and an evaluation of response times in relation to adverse event rates.

Qualitative analysis:

Clinician Survey comments: The self-administered, online, Qualtrics-based survey was administered and collated using the University of Wisconsin's Qualtrics system. Clinicians were asked to provide feedback specific to alarm system configurations, alarm-related policy and procedure, and alarm system education and training. These comments were collated, reviewed and presented as suggested feedback for improvement considerations (Appendix C).

Staff interviews: Interviews with staff having information specific to the medical device alarm system were completed and provided insight into the alarming medical device presence, alarm

system configurations, staff, unit and alarm workflows, policy and procedure knowledge, use of Nurse Call reports, and alarm-related events (Appendix F).

Review of Policy & Procedure: Review of policies related to the medical device alarm system including Nurse Call specific policy to evaluate organizational expectations and evaluate specificities related to alarm system configurations, and system education and training was performed. Further evaluation of the policy and procedure conformance to The Joint Commission 2017 recommendations for making improvements to ensure that alarms are responded to on time was conducted was assessed.

Clinician survey and hypotheses evaluation

The online survey assessment is a multi-dimensional instrument exploring various aspects of clinician responses to the constructs of alarm system configurations, integrated medical device policy and procedure, related education and training, and their self-reported response times for the high, medium, and low alarm priority types. The number of completed respondent surveys was 107, the number accepted for analysis (excluding those with missing or incomplete data) was 105. This number meets the minimum sample size of 103 required for analysis.

Four hospitals in the Midwest participated in the study with survey responses (Appendix C) from clinicians in 3 hospital systems and 1 large hospital unit. The response rate was between 5 - 78% (Table 2). A total of 107 individuals responded to the clinician survey. Prior to any analyses, the survey responses were checked for missing data and the presence of outliers. Two respondents were missing data for 50% or more of the survey questions, and therefore were excluded from the analyses. Outliers were checked by computing standardized values for each

subscale score. Standardized values greater than 3.29 or less than -3.29 are considered outliers (Tabachnick & Fidell, 2012). No outliers were identified.

Table 2. Hospital descriptors and survey response

	Hospital A	Hospital B	Hospital (Unit) C	Hospital D
Description	22 beds Critical access	13 beds Full-service	36 beds Med/Surg/Tele	150 beds Full-service
Survey Invitations	30	198	121	63
Survey response	6	10	42	49
Response %	20%	5%	33%	78%

Table 3 displays descriptive statistics of the survey respondents. Most of the participants were from either Hospital C (*n* = 40, 38.1%) or (Hospital D *n* = 49, 46.7%). Many participants were women (*n* = 91, 86.7%), approximately half of the participants were in the 30 – 50-year age range (*n* = 53, 50.5%), and most participants held a job title of registered nurse (*n* = 95, 90.5%). Most participants indicated that they had not worked as a registered nurse outside the USA (*n* = 89, 84.8%), and many participants had worked as a registered nurse in the USA for more than 10 years (*n* = 58, 55.2%).

Table 3. Descriptive Statistics for Survey Respondents

Variable	Frequency	Percent
Hospital		
A	6	5.7
B	10	9.5
C	40	38.1
D	49	46.7
Gender		
Female	91	86.7
Male	14	13.3
Job title		
Registered nurse	95	90.5
Other	10	9.5
Time worked as RN outside of USA		
I haven't worked as an RN outside of the USA	89	84.8
Less than 2 years	1	1.0
2 – 10 years	7	6.7
Greater than 10 years	8	7.6
Time worked as RN in USA		
Less than 2 years	10	9.5
2 – 10 years	37	35.2
Greater than 10 years	58	55.2
Age		
Less than 30 years	18	17.1
30 – 50 years	53	50.5
Greater than 50 years	34	32.4
Dependent variable		
Self-reported response time (high priority)		
Less than 1 minute	88	83.8
1 – 2 minutes	14	13.3
2 – 5 minutes	3	2.9
Dependent variable		
Self-reported response time (medium priority)		
Less than 1 minute	30	28.6
1 – 2 minutes	58	55.2
2 – 5 minutes	14	13.3
5 – 10 minutes	3	2.9

Dependent variable		
Self-reported response time (low priority)		
Less than 1 minute	18	17.1
1 – 2 minutes	55	52.4
2 – 5 minutes	25	23.8
5 – 10 minutes	6	5.7
10+ minutes	1	1.0

Many participants reported responding to high priority alarms in less than 1 minute (*n* = 88, 83.8%), while most participants reported responding to medium (*n* = 58, 55.2%) and low priority (*n* = 55, 52.4%) alarms in 1 – 2 minutes. When asked about the percentage of alarms addressed during a shift, on average participants indicated that 32.43% (*SD* = 29.61) of the alarms they addressed were high priority, 33.80% (*SD* = 22.97) were medium priority, and 37.61% (*SD* = 29.21) were low priority. However, the accuracy of these figures may be questionable, as many participants reported cumulative percentages across the three alarm types that exceeded 100%. When comparing the self-reported alarm response time (Table 3) to the average actual response times (Table 43) for high, medium, and low priority they matched over 70% of the time.

Hypotheses

The following hypotheses were developed to evaluate the clinician perception of three dimensions of the alarm system: alarm system configuration, alarm-related policy and procedure, and alarm system education and training.

H1: Clinician perception of alarm system configuration is positively associated with clinician alarm response.

H1a: Clinician perception of the appropriateness of alarm system configuration is positively associated with clinician alarm response appropriateness.

- p=0.085 for the medium alarm priority response time

H1b: Clinician perception of the flexibility of alarm system configuration is positively associated with clinician alarm response appropriateness.

- p=0.063 for the medium alarm priority response time

H2: Clinician perception of integrated medical device policies is positively associated with clinician alarm response.

H2a: Clinician perception of the customizability of integrated medical device policies is positively associated with clinician alarm response appropriateness.

- p=0.064 for the low alarm priority response time

H2b: Clinician perception of the targeted specificity of integrated medical device policies is positively associated with clinician alarm response appropriateness.

H2c: Clinician perception of institutional communication of integrated medical device policies is positively associated with clinician alarm response appropriateness.

H3: Clinician perception of alarm system training and education is positively associated with clinician alarm response.

H3a: Clinician perception of the effectiveness of alarm system training and education is positively associated with clinician alarm response appropriateness.

- p=0.041 for the high alarm priority response time

H3b: Clinician perception of the completeness of alarm system training and education is positively associated with clinician alarm response appropriateness.

Hypotheses results

A multi-step statistical approach was used to assess the survey instrument.

three binary regression tests assessing high, medium, and low response self-report of response times, and examination of the predictive model. These approaches are detailed below.

The original statistical analysis with the full set of results are presented in Table 4 and Appendix D. The inter-item reliability of the study subscales pertaining to the seven constructs was assessed using Cronbach's alpha. Three of the seven constructs demonstrated borderline acceptability (<.70 Cronbach's alpha):

1. Flexibility of the alarm system configuration
2. Customizability of integrated medical device policy
3. Specificity of integrated medical device policy

The four constructs demonstrating acceptable reliability (>.70 Cronbach's alpha) included:

1. Appropriateness of the alarm system configuration
2. Awareness of integrated medical device policy
3. Effectiveness of alarm system training
4. Completeness of alarm system training

The items pertaining to each subscale were averaged to create composite scores. The inter-item reliability of the study subscales pertaining to the seven constructs was assessed using Cronbach's alpha (Table 4).

Table 4. Original Reliability Coefficients for Study Subscales

Variable	Number of Items	Cronbach's Alpha
Appropriateness of alarm system ***configuration***	7	.77
Flexibility of alarm system ***configuration***	4	.65

Customizability of integrated medical device ***policies***	7	.68
Specificity of integrated medical device ***policies***	5	.65
Awareness of integrated medical device ***policies***	7	.90
Effectiveness of alarm system ***training***	7	.92
Completeness of alarm system ***training***	8	.81

In efforts to improve reliability scores, based on the inter-item correlation scores, one item each was dropped from flexibility of the alarm system configuration customizability of integrated medical device policy. Correlations were performed with item discarded based on SPSS software recommendations. The inter-item reliability of the study subscales with two items dropped pertaining to the seven constructs were assessed using Cronbach's alpha (Table 5) and resulted in enhanced reliability (Cronbach's alpha scores >.70) for flexibility of alarm configuration and customizability of medical device policy. The subscales for specificity of integrated medical device policies did not demonstrate acceptable reliability; no items could be removed to improve the reliability of this factor (Appendix E).

Table 5. Revision #1 - Reliability Coefficients for Study Subscales – 2 items drop

Variable	Number of Items	Cronbach's Alpha
Appropriateness of alarm system ***configuration***	7	.77
Flexibility of alarm system ***configuration***	3	.74
Customizability of integrated medical device ***policies***	6	.71
Specificity of integrated medical device ***policies***	5	.65
Awareness of integrated medical device ***policies***	7	.90
Effectiveness of alarm system ***training***	7	.92
Completeness of alarm system ***training***	8	.81

Continued efforts to improve the reliability scores included correlation review on resulting items followed by item drops for those with correlations <0.3 dropped. Correlations were performed with item discarded based on SPSS software recommendations. The revised

statistical analysis with the discarded set of results are presented in Appendix E. The inter-item reliability of the study subscales with 6 items dropped (final set) pertaining to the seven constructs were assessed using Cronbach's alpha (Table 6). The final set of items for each construct is presented in Tables 7-13.

Table 6. Revision #2 - Reliability Coefficients for Study Subscales – 6 items drop

Variable	Number of Items	Cronbach's Alpha
Appropriateness of alarm system ***configuration***	6	.74
Flexibility of alarm system ***configuration***	3	.74
Customizability of integrated medical device ***policies***	5	.74
Specificity of integrated medical device ***policies***	4	.65
Awareness of integrated medical device ***policies***	7	.90
Effectiveness of alarm system ***training***	7	.92
Completeness of alarm system ***training***	7	.81

Table 7. Appropriateness of Alarm System Configuration (H1a)

Survey questions (#6)	**Item Code**
The clinical alarm system is configured appropriately.	ASCA1
The clinical alarm system generates alarms that have the appropriate priority.	ASCA2
The clinical alarm system has not led to desensitization to alarms.	ASCA3
The clinical alarm system routes alarms to the correct providers.	ASCA6
The clinical alarm system generates alarms that conflict with other systems.	ASCA7
The clinical alarm system generates few or no false alarms.	ASCA5

Table 8. Flexibility of Alarm System Configuration (H1b)

Survey questions (#3)	**Item Code**
The clinical alarm system can be customized for the type of intervention.	ASCF1
The clinical alarm system can be customized for my unit.	ASCF2
The clinical alarm system can be customized to match individual patient needs.	ASCF3

Table 9. Customizability of Integrated Medical Device Policy (H2a)

Survey questions (#5)	**Item Code**
At my organization any provider can override an alarm priority on an exception basis.	MDPC3

At my organization any provider can recommend a change to an alarm priority.	MDPC2
At my organization any provider can recommend a change to an alarm assignment (role).	MDPC6
At my organization any provider can pause an alarm.	MDPC4
At my organization any provider can silence an alarm.	MDPC7

Table 10. Specificity of Integrated Medical Device Policy (H2b)

Survey questions (#4)	**Item Code**
At my organization most, alarms are sent to a limited set of providers, instead of a broadcast to all providers.	MDPS1
At my organization alarms are set to the correct set of providers.	MDPS2
I do not have to respond to alarms if I am not directly involved in care for that specific patient.	MDPS3
I receive alarms only on patients that I am currently caring for.	MDPS4

Table 11. Awareness of Integrated Medical Device Policy (H2c)

Survey questions (#7)	**Item Code**
My organization has policies and procedures for alarm management.	MDPA1
I am aware of the policies and procedures for alarm management at my organization, or I know where to access them.	MDPA2
At my organization policies and procedures for alarm management incorporate staff input.	MDPA3
At my organization policies and procedures for alarm management address who is responsible for monitoring and responding to alarms.	MDPA4
At my organization policies and procedures for alarm management address who is responsible for changing alarm priorities.	MDPA5
At my organization policies and procedures for alarm management address the monitoring and testing of medical devices that generate alarms.	MDPA6
At my organization policies and procedures for alarm management address the monitoring and testing of devices that relay and receive alarms.	MDPA7

Table 12. Effectiveness of Training and Education (H3a)

Survey questions (#7)	**Item Code**
My organization provides training and education for alarm monitoring, response, and override.	TEE1
My organization provides training and education on the various alarm devices I use (on my unit).	TEE2

My organization educates providers on the alarms they are expected to receive.	TEE3
At my organization providers are informed about the consequences of not responding appropriately to alarms, for patient and provider.	TEE4
At my organization education and training material is provided in multiple formats.	TEE5
The training I received was customized to my needs.	TEE6
My organization provides periodic refresher training sessions.	TEE7

Table 13. Completeness of Training and Education (H3b)

Survey questions (#7)	**Item Code**
My organization provides training on how to respond to alarms.	TEC8
My organization provides training on how to override alarms.	TEC2
My organization provides training on how to manage and care for the alarm devices I use.	TEC3
I can access additional material at my organization on the alarm devices I use.	TEC4
I receive additional training whenever the alarm system or its components are updated.	TEC5
The training I received included vendor supplied material.	TEC6
The training I received included material developed in-house.	TEC7

Factor analysis

Considering this study used an unproven instrument (survey) which had not been psychometrically validated, the construct correlations were examined and those less than 0.3 were discarded. Factor analysis using an oblique rotation was used to confirm the item discard (Table 14).

The following six items were discarded:

1. The clinical alarm system resets quickly when caregivers are reassigned. (ASCF4)
2. The clinical alarm system pinpoints where patient care is needed. (ASCA8)
3. My organization has an alarm management committee that can change the priority of alarms. (MDPC1)
4. My organization has a backup plan when the alarm system is down. (MDPC5)
5. The number of alarms that I must respond to in a shift is manageable. (MDPS5)
6. I am fully trained on all the alarm devices that I use. (TEC1)

Table 14. Rotated component matrix

Item	1	2	3	4	5	6	7
ASCF1	0.14	-0.04	-0.02	-0.01	0.3	-0.05	0.5
ASCF2	0.14	0.1	0.05	0.46	0.37	-0.18	0.48
ASCF3	0.14	0.14	0.04	0.03	0.07	-0.15	0.57
ASCA1	0.25	-0.02	0.07	0.66	0.25	-0.13	0.08
ASCA2	0.31	-0.04	-0.06	0.67	0.27	-0.09	0.05
ASCA3	0.34	-0.06	0.02	0.49	-0.11	-0.04	0.1
ASCA5	0.18	-0.15	-0.15	0.66	-0.16	0.05	-0.02
ASCA6	0.07	-0.06	-0.18	0.57	0.28	0.13	0.37
ASCA7	-0.13	0	0.14	0.74	-0.36	0.03	-0.19
MDPC2	0.37	0.11	0.4	0.12	-0.34	0.01	0.41
MDPC3	0.05	-0.05	0.71	0.03	0.05	-0.05	0.1
MDPC4	-0.06	-0.06	0.97	0	0.08	-0.06	-0.01
MDPC6	0.35	0.08	0.29	0.07	-0.28	0.1	0.36
MDPC7	-0.15	-0.02	0.97	-0.12	0.05	0.03	-0.03
MDPS1	0.23	0.02	-0.04	0.07	0.72	0.07	0
MDPS2	0.32	-0.05	0.12	0.52	0.39	0.02	0.17
MDPS3	0	0.04	0.09	-0.01	0.31	-0.06	0.02
MDPS4	0.14	0.02	0.02	0.14	0.86	0.18	0.11
MDPA1	0.48	0.11	-0.02	0.02	0.01	-0.11	0.08
MDPA2	0.61	0.19	0.06	-0.04	0	0	0.03
MDPA3	0.58	0	0.12	0.39	0.14	0.12	0.05
MDPA4	0.61	-0.06	-0.01	0.12	0	-0.03	0.11
MDPA5	0.63	0.02	-0.11	0.16	0.05	-0.07	0.06
MDPA6	0.53	0.12	0.08	0.04	0.06	-0.13	0.12
MDPA7	0.47	0.13	0	0.19	0.06	-0.1	0.14
TEE1	***0.78***	-0.06	0.02	0.18	0.14	0.03	0.02
TEE2	***0.77***	-0.22	-0.04	0.15	0.02	0.09	0.06
TEE3	***0.82***	-0.11	-0.04	0.07	0.07	-0.03	0.15
TEE4	***0.62***	-0.2	-0.03	0.01	-0.1	0.17	-0.08
TEE5	***0.74***	-0.21	0.05	0.04	0.29	0.06	0
TEE6	***0.68***	-0.2	-0.11	0.42	0.16	0.17	0
TEE7	***0.66***	-0.27	-0.08	0.19	0.32	0.08	0.06
TEC2	-0.13	1.04	-0.51	0	0.07	-0.2	***-0.82***
TEC3	0.01	0.72	0.01	-0.24	0.35	0.04	***-0.93***
TEC4	-0.12	1.27	0.02	-0.22	0.05	0	0.18
TEC5	0.01	0.58	-0.13	-0.07	0.34	***1.21***	-0.3
TEC6	0.02	0.88	-0.01	-0.04	-0.22	***0.98***	-0.2
TEC7	-0.09	1.11	0.15	-0.09	0.07	***0.37***	-0.03
TEC8	-0.16	0.69	-0.35	0.02	-0.08	0.32	0.26
% of variance	24.92	9.22	7.07	6.64	5.34	5.00	4.12
Eigenvalue	9.72	3.60	2.76	2.59	2.08	1.95	1.61

Factor structure analysis submits that the factors are not flawless. Two of the constructs loaded on the same factor:

1. Awareness of integrated medical device policy (MDPA)
2. Effectiveness of alarm system training (TEE)

Factor analysis demonstrated that the constructs measured had a mostly clean factor structure, however further examinations reveal that these constructs (MDPA, TEE) are loading on the same factor demonstrating a correlation and this is concerning. Undeniably these constructs of policy and training are different constructs. There is no clear explanation as to why this occurred. Other discrepancies include another factor (completeness of alarm system training – TEC) has some of the items loading on other factors. Given these constructs are not clearly separating, it is possible that they are measuring a larger construct. There is support for some of the construct measures showing independence as some of them show a clear separation, however we acknowledge that the *awareness of integrated medical device policy* and *completeness and effectiveness of the alarm system training and education* constructs lack factor independence in this study.

Binary Logistic Regression

To address the research hypotheses, three binary logistic regressions were conducted using the combined construct scores, not the individual item scores. Binary logistic regression is an appropriate statistical technique when the aim of the research is to determine the relationship between multiple continuous independent variables and an ordinal dependent variable. For these analyses, the independent variables were the composite scores of the subscales pertaining to alarm system configuration, integrated medical device policies, and alarm system

training and education. The dependent variables were participants self-reported the low, medium, and high priority alarm response times. A separate regression analysis was conducted for each dependent variable. The response times were categorized for the binary regression analysis as either appropriate or inappropriate using the clinician self-report time responses (Table 15).

Table 15. Response time classification

Level of Priority	Appropriate [0]	Inappropriate [1]
High	<1 minute	1-2 minutes 2-5 minutes 5-10 minutes 10+ minutes
Medium	<1 minute 1-2 minutes	2-5 minutes 5-10 minutes 10+ minutes
Low	<1 minute 1-2 minutes 2-5 minutes	5-10 minutes 10+ minutes

Multicollinearity

Prior to the analysis, the presence of multicollinearity was tested using Variance Inflation Factors (VIFs). Per Stevens (2009), VIF values over 10 suggest the presence of multicollinearity. Table 16 displays the VIF values for the independent variables used in the analysis. All values were less than 10, indicating that multicollinearity was not a problem (Table 16).

Table 16. Variance Inflation Factors for Independent Variables

Variable	VIF
Appropriateness of alarm system configuration	1.35
Flexibility of alarm system configuration	1.25
Customizability of integrated medical device policies	1.06
Specificity of integrated medical device policies	1.25
Awareness of integrated medical device policies	2.15
Effectiveness of alarm system training	2.26
Completeness of alarm system training	1.14

Low Priority Alarm Response Time

The results of the overall binary logistic regression model predicting low priority alarm response time appropriateness were not significant, -2 Log Likelihood = 34.9, Cox + Snell R^2 = 0.1, Nagelkerke R^2 = 0.28. The Nagelkerke R^2 value indicates that the model accounted for approximately 28% of the variability in self-reported low priority alarm response time appropriateness. The full results of the regression are presented in Table 17.

Table 17. Binary Logistic Regression Predicting Self-Reported Low Priority Response Time

Independent Variable	B	Std. Error	Wald	*df*	Sig.*	Exp(B)
Flexibility of alarm system configuration	0.09	0.25	0.13	1	0.721	1.09
Appropriateness of alarm system configuration	0.11	0.13	0.69	1	0.407	1.11
Customizability of medical device policies	***-0.31***	***0.17***	***3.44***	***1***	***0.064***	***0.73***
Specificity of integrated medical device policies	0.21	0.18	1.27	1	0.259	1.23
Awareness of integrated medical device policies	-0.07	0.2	0.12	1	0.733	0.93
Effectiveness of alarm system training	0.12	0.13	0.92	1	0.337	1.13
Completeness of alarm system training	-0.19	0.14	1.89	1	0.169	0.83
Constant	-0.65	4.26	0.02	1	0.878	0.52

*Note: 0.1 alpha used to determine significance.

These results indicate that the subscales except for customizability of medical device policies were not significantly associated with self-reported low priority alarm response time appropriateness. The implications of this construct being significant may indicate that the customizability of the medical device policy has influence on the clinician's response times to low priority alarms. There were associations between perception of the customizability of integrated medical device policies and self-reported response times, so H2 sub hypotheses H2a, was supported for the low priority response.

The equation generated from this logistic regress analysis was used to predict clinician response to a low priority alarm. This prediction equation = log(p/(1-p)) =-0.65 + 0.09 Flex + 0.11 Appropriateness + -0.31 Customizability = 0.21 Specificity + -0.07 Awareness + 0.012

Effectiveness + -0.19 Completeness. Here's how we interpret the prediction results for the clinician response to a low priority alarm. For example, an Exp(B) of 0.73 as noted in the customizability construct can be interpreted as a 1-unit change in the response results in a 27% increase of not responding correctly.

To classify whether this logistic regression model could be used to adequately predict clinician response time for low priority alarms, the classification table predicts the percent correct which for the low priority model which has an overall accuracy of 94.2% (Table 18).

Table 18. Classification Table – Low

		Predicted response		% correct
		0	1	
Observed response	0	97	0	100
	1	6	0	0
Overall accuracy				94.2%

From a model prediction perspective, the classification accuracy of 94.2% for foreseeing clinicians' response to a low priority alarm in an appropriate time frame provides a sense of satisfaction in the model and demonstrates that the model is good at predicting appropriate responses for the seven constructs. Of the 103 cases, 97 responses were appropriate and 6 were not.

Medium Priority Response Time

The results of the overall binary logistic regression model predicting medium priority alarm response time appropriateness were not significant, -2 Log Likelihood = 131.42, Cox + Snell R^2= 0.09, Nagelkerke R^2 = 0.13. The Nagelkerke R^2 value indicates that the model accounted for

approximately 13% of the variability in self-reported medium priority alarm response time appropriateness. The full results of the regression are presented in Table 19.

Table 19. Binary logistic Regression Predicting Self-Reported Medium Priority Response Time

Independent Variable	B	Std. Error	Wald	*df*	Sig.*	Exp(B)
Flexibility of alarm system configuration	***-0.19***	***0.1***	***3.46***	***1***	***0.063***	***0.82***
Appropriateness of alarm system configuration	***0.1***	***0.06***	***2.97***	***1***	***0.085***	***1.1***
Customizability of medical device policies	-0.01	0.05	0.04	1	0.85	0.99
Specificity of integrated medical device policies	-0.11	0.07	2.3	1	0.129	0.89
Awareness of integrated medical device policies	-0.06	0.07	0.65	1	0.421	0.95
Effectiveness of alarm system training	0.05	0.06	0.7	1	0.403	1.05
Completeness of alarm system training	0	0.03	0	1	0.998	1
Constant	1.66	1.86	0.8	1	0.372	5.26

*Note: 0.1 alpha used to determine significance.

These results indicate that all subscales except for those pertaining to the flexibility and appropriateness of the alarm system configuration were not significantly associated with self-reported medium priority alarm response time appropriateness. The implications of these two constructs being significant may indicate that the flexibility and the appropriateness of alarm system configuration has influence on the clinician's response times to medium priority alarms. There were associations between perception of alarm system flexibility and appropriateness of alarm system configuration and self-reported response times, so H1 and sub hypotheses H1a and H1b were supported for the medium priority alarm response.

The equation generated from this logistic regress analysis was used to predict clinician response to a medium priority alarm. This prediction equation = log(p/(1-p)) =-1.66 + -0.19 Flex + 0.1 Appropriateness + -0.01 Customizability = -0.11 Specificity + -0.06 Awareness + 0.05 Effectiveness + 0 Completeness.

From a model prediction perspective, the overall classification accuracy of 66.02% (Table 20) for foreseeing clinicians' response to a medium priority alarm in an appropriate time frame does not provide a sense of satisfaction in the model's accuracy in predicting the correct response.

Table 20. Classification Table – Medium

		Predicted response		% correct
		0	1	
Observed response	0	43	14	75.44
	1	21	25	54.35
Overall accuracy				66.02%

Of the 103 cases, 43 responses were predicted to be appropriate and 25 predicted to be inappropriate. Incorrect responses of 14 and 21 demonstrates that the model doesn't classify very well and has poor predictive abilities. For the medium alarm priority, there is a wide range of responses and clinician's may respond sooner or later as opposed to high priority alarms where an increased response time is not expected and low priority alarms whereas a longer response time is considered appropriate.

High Priority Response Time

The results of the overall binary logistic regression model predicting high priority alarm response time appropriateness were not significant, -2 Log Likelihood = 83.28, Cox + Snell R^2 = 0.05, Nagelkerke R^2 = 0.09. These results indicate that the subscales pertaining to alarm system configuration, integrated medical device policies, and alarm system training and education were not significantly associated with self-reported high priority alarm response time appropriateness. The Nagelkerke R^2 value indicates that the model accounted for

approximately 9% of the variability in self-reported high priority alarm response time appropriateness. The full results of the regression are presented in Table 21.

Table 21. Binary logistic Regression Predicting Self-Reported High Priority Response Time

Independent Variable	B	Std. Error	Wald	*df*	Sig.*	Exp(B)
Flexibility of alarm system configuration	0.06	0.14	0.2	1	0.651	1.06
Appropriateness of alarm system configuration	-0.01	0.07	0.02	1	0.881	0.99
Customizability of medical device policies	-0.02	0.07	0.04	1	0.841	0.99
Specificity of integrated medical device policies	-0.05	0.1	0.3	1	0.585	0.95
Awareness of integrated medical device policies	-0.09	0.1	0.88	1	0.349	0.91
Effectiveness of alarm system training	***0.18***	***0.09***	***4.16***	***1***	***0.041***	***1.2***
Completeness of alarm system training	0.02	0.05	0.16	1	0.687	1.02
Constant	-3.79	2.75	1.91	1	0.167	0.02

*Note: 0.1 alpha used to determine significance.

The results for each binary logistic regression were not significant except for the effectiveness of alarm system training and education. The implications of the effectiveness of alarm system training and education's significance may indicate that this construct has influence on the clinician's response times to high priority alarms. There were associations between perception of effectiveness of alarm system training and education and self-reported response times, so sub hypotheses H3a was supported for high priority response.

The equation generated from this logistic regress analysis was used to predict clinician response to a high priority alarm. This prediction equation= log(p/(1-p)) =--3.79 + 0.06 Flex + -0.01 Appropriateness + -0.02 Customizability = -0.05 Specificity + -0.09 Awareness + 0.18 Effectiveness + -0.02 Completeness.

From a model prediction perspective, the overall classification accuracy of 84.47% (Table 22) for foreseeing clinicians' response to a high priority alarm in an appropriate time frame provides a sense of satisfaction in the model,

Table 22. Classification Table – High

		Predicted response		% correct
		0	1	
Observed response	0	87	0	100
	1	16	0	0
Overall accuracy				84.47%

When considering the constructs demonstrating significance for the various priority types, the frequency of the type of alarm is an important consideration as the number and type of alarms may indicate a pattern of precedence. Data extracted from Table 23 establishes that most alarms are of medium priority (n=58757, 66.5%), followed by high priority (n=28992, 32.8%, and low priority (n=558, 0.6%) with the mean time-to-response being quickest for the high priority alarm (n=35.95, SD 192.97), low (n=41.37, SD 67.77), and medium (n=51.67, SD 193.04). With low variance in the average clinician response between the three types of alarms and a total average time to respond of less than one minute for all alarms, the interpretation of the three dependent variables within these confines of limited difference is imperfect.

Hypotheses analysis summary

There were associations between perception of alarm system flexibility and appropriateness of alarm system configuration and self-reported response times, so H1 and sub hypotheses H1a and H1b were supported for the medium priority alarm response. There were associations

between perception of the customizability of integrated medical device policies and self-reported response times, so H2 sub hypotheses H2a, was supported for the low priority response. Finally, there were associations between perception of effectiveness of alarm system training and education and self-reported response times, so sub hypotheses H3a was supported for high priority response.

While the hypotheses of clinician perceptions were not supported for ***all*** priority alarm types, there were associations related to the main constructs of alarm configurations, integrated medical device policy, and training and education.

Alarm data download capture

The frequencies and percentages for the hospital-provided alarm data is presented in Table 23. There was a total of 88,307 alarm events across all hospitals included in the final dataset. Most of alarm events came from Hospital D (*n* = 61471, 69.6%). The most frequent alert type was beep (*n* = 47927, 54.3%) and the most frequent priority type was medium (*n* = 58757, 66.5%). Hospital D exceed the AAMI, FDA, TJC, ACCE and ECRI guidelines, as more than 350 per patient alarm conditions per day contribute to alarm fatigue (2011 AAMI Clinical Summit).

Table 23. Frequencies and Percentages for Hospital Alarm Data

Variable	Frequency	#Alarms/day	Percent
Hospital			
A, 22 beds, critical access	1110	12	1.3
D, 13 beds, full-service	7229	80	8.2
R, 36 beds, med/surg/tele	18497	205	20.9
S, 150 beds, full-service	61471	683	69.6
Alert Type			
Accident-Linen change	1		0.0
Assist-Chair	2		0.0
Aux Jack	586		0.7

Bath	5880	6.7
Bath Emergency	120	0.1
Bed	396	0.4
Bed Exit	17017	19.3
Bed Out	35	0.0
Beep	47927	54.3
Code	140	0.2
Code 2	3	0.0
Cord Out	179	0.2
Drink	557	0.6
Emerg	377	0.4
Equip	2732	3.1
iBed Brake	3495	4.0
iBed Height	52	0.1
Monitor Alarm/Check	2	0.0
O2 Sat	4944	5.6
Pain	532	0.6
Potty/Toilet	2271	2.6
Shower	499	0.6
Siderails	406	0.5
Staff Assist	140	0.2
Staff emerg	14	0.0
Priority Type		
High	28992	32.8
Medium	58757	66.5
Low	558	0.6

One hospital (Hospital C) had the physiological monitoring system integrated into the Nurse Call communication system as a tertiary alarm notification system ("monitor alarm/check") with most of the units or hospitals keeping the integration of the full alarm systems separate.

The average alarm response times are further broken down by average alarm response times per hospital for each alarm type including the priority type. Table 24 displays means and standard deviations for alarm response times (measured in seconds) by hospital, alert type, and priority type. On average, Hospital A had the lowest response times (M = 31.20, SD = 150.72), while Hospital D had the highest (M = 48.28, SD = 211.25). Among alert types, code had the

lowest average response time (*M* = 7.56, *SD* = 42.58), while monitor alarm/check had the highest (*M* = 1839.50, *SD* = 622.96). Among priority types, high priority alarms had the lowest average response times (*M* = 35.95, *SD* = 192.97), while medium priority alarms had the highest (*M* = 51.67, *SD* = 193.04).

Table 24. Average Alarm Response Times (seconds) by Hospital, Alert Type, and Priority Type

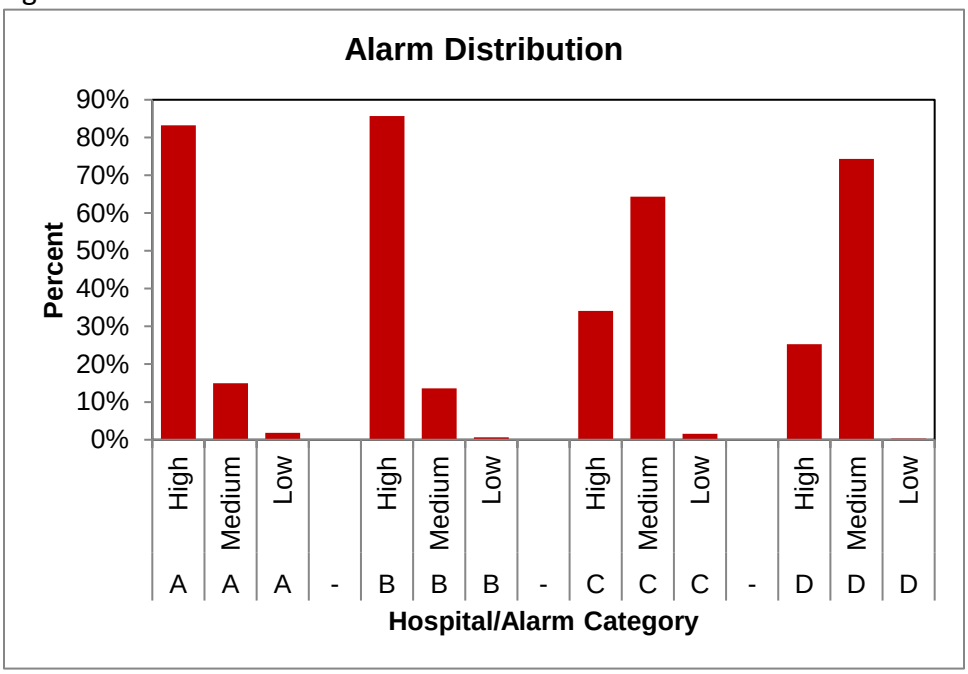
Variable		*M*	*SD*
Hospital			
A, 22 beds, critical access		31.20	150.72
B, 13 beds, full service		45.85	244.58
C, 36 beds, med/surg/tele		41.49	63.57
D, 150 beds, full service		48.28	211.25
Alert Type	***Priority type***		
Accident-Linen change	Medium	1399.00	*
Assist-Chair	Medium	364.50	430.63
Aux Jack	Medium	35.06	55.28
Bath	High	38.64	60.41
Bath Emergency	High	52.34	58.12
Bed	Medium	155.94	420.35
Bed Exit	High	10.32	24.52
Bed Out	Medium	59.69	62.05
Beep	Medium	39.47	71.07
Code	High	7.56	42.58
Code 2	High	56.33	95.85
Cord Out	Medium	25.92	36.98
Drink	Low	39.51	51.70
Emerg	High	12.44	24.47
Equip	Medium	32.08	35.44
iBed Brake	Medium	211.78	664.52
iBed Height	Medium	345.38	664.21
Monitor Alarm/Check	Medium	1839.50	622.96
O2 Sat	High	16.69	23.06
Pain	Medium	59.68	160.30
Potty/Toilet	Medium	43.36	47.79
Shower	High	1083.86	977.75
Siderails	Medium	186.02	651.95
Staff Assist	Medium	18.64	21.80
Staff emerg	High	19.36	28.86

Priority Type		
High	35.95	192.97
Medium	51.67	193.04
Low	41.37	67.77

Note. *Standard deviation could not be calculated due to having only one observation.

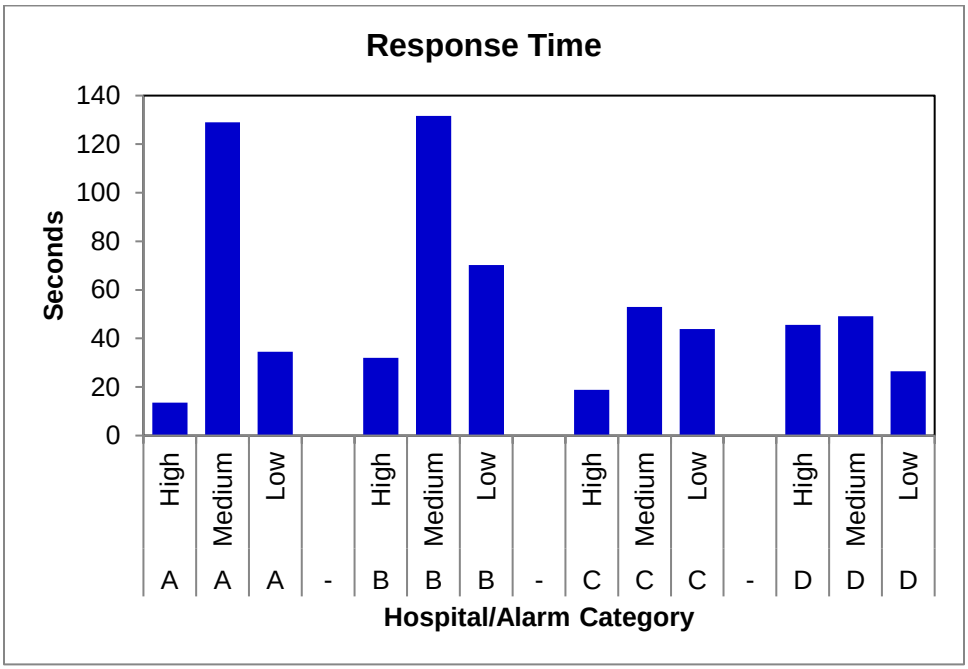
The analysis of response times for high, medium, and low priority alarms was performed using the average response time. Consequently, comparisons made between response and the per call type data are limited to the average response times (Table 24). It was not possible in this study to review individual response times due to IRB limitations. The distribution of alarms across the four hospitals is depicted in Figure 9. It demonstrates that for this study, the smaller hospital sizes (Hospital A, B), had comparatively higher number of high priority alarm types. Based on staff interview, this was due to a higher number of equipment testing (bed, shower). Interestingly, the larger hospitals (Hospitals C, D) had a higher number of medium priority alarms over the 3 month review period.

Figure 9. Alarm Distribution



The time to respond to different alarms is depicted in Figure 10. It is interesting to note that medium priority alarms experienced the longest times to respond. It is difficult to report exact reasons for this however, considerations can be given to alarm overload causing staff to ignore alarms, staffing models, patient population, or equipment testing. A quicker response time was expected. It was outside of the scope of this study to review individual response times because of IRB limitations. These responses correlate with the poor model prediction accuracy (66%) for the medium response time appropriateness (Table 20). Whereas correlations to the high (Table 21) and low (Table 19) models had higher prediction accuracy and as shown in Table 10, response times were appropriate at less than one minute correspondingly.

Table 10. Response Time



Alarm data download capture summary

There are wide variations in alarm frequency between the four hospitals (1110-61,471), this is probably best explained by varied types of hospitals (Table 2) some being critical access (rural), full-service (sub-urban) and Med/Surg/Tele (urban) as well as variations in patient diagnosis and needs (data not collected). The hospital (S) having the most alarms (61,471) had the longest response time (48.28 seconds). The hospital (A) having the least number of alarms (1110) had the quickest response rate (31.20 seconds). Not surprisingly, the most frequent Nurse call alarm was the patient assist or "beep" alarm (54.3%), followed by bed exit (19.3%), bath (6.7%), O2 sat (5.6%). Most alarms were of medium priority (66.5%), followed by high (32.8%), low (0.6%). The longest mean response times were for Monitor alarm/check (1829 seconds), accident-linen change (1399 seconds), assist-chair (364 seconds), iBed height (345 seconds), iBed brake (211 seconds), siderails (186 seconds), and bed (155 seconds). The quickest response was for a Code at 7.56 seconds, followed by bed exit (10.32 seconds), emergency (12.44 seconds), O2 sat (16.69 seconds), staff assist (18.54 seconds), and staff emergency (19.36 seconds).

Exploratory research questions

1. **Do caregivers with similar integration systems respond similarly to high, medium and low priority alarms?**

Review of the hospital alarm systems reveals varied integration systems (Table 30), therefore the answer to this question would be considered speculation. The average response to high, medium, and low priority alarms were similar with *all* responses under 50 seconds (Table 24).

2. **Do organizations with a lower number of alarms experience faster response rates?**

Hospital A had the lowest number of alarms (Table 23) for a total of 1,1110 in the 3-month period, averaging 12 alarms per day. This number of alarms is specific to the Nurse Call system only and does not include other medical device alarms. The response rate for Hospital A averaged the quickest response of all 4 hospitals (Table 24) having an average response time of 31.20 seconds. There is support for this investigative question whereas the hospital with the lowest number of alarms indeed had a faster response.

Hospital D has the highest number of alarms (Table 23) for a total of 61,471 in the 3-month period, averaging 683 alarms per day. This number of alarms is specific to the Nurse Call system only and does not include other medical device alarms. The response rate for Hospital D averaged the longest response time of all 4 hospitals (Table 24) having an average response time of 48.2 seconds. Comparatively, the hospital with the highest number of alarms had the longest response time.

3. To what extent to alarm configurations vary between organizations?

Staff interviews revealed the configurations vary greatly between hospitals (Table 30) and there were no two hospital configurations the same. This confounds the ability to define and accurately compare *similar* systems.

4. Do organizations with speedier alarm response times have less alarm-related adverse event rates?

Hospital A had the quickest average response time of 31.20 seconds (Table 24) with a corresponding lowest number (3) of alarm-related events (Table 25).

This research supports a faster clinician response associated to lower adverse alarm-related patient outcomes, and those with the lowest number of alarms per day having the quickest response time.

Alarm-related events (patient outcomes)

In the process of requesting and acquiring data specific to alarm-related events, it was clear throughout all participating hospitals that the assigned review of a link or a potential link to the alarm system was not assessed per se' and explicitly recorded in the patient event log. This evaluation of an actual of potential link required the hospital's agent to collect all patient outcome data for the 3-month period and individually assess as to whether an alarm-relation would or could be present. The collected data did not include if an alarm was initiated or what the delay was in terms of specified time (Table 25). All events were related to "delays" in the provision of clinician identification and care, also known as time-to-respond. Specific patient outcomes were identified as:

- Potential for physiological harm with potential to affect cardiac, respiratory, or the delivery of an intravenous medication = 10
- Minimal intervention required for physiological harm (cardiac or respiratory) = 2
- Physiological harm requiring intervention and/or additional procedure (delay in bathroom resulting in catheter pulling out when transitioning) = 1
- Fall with no or minimal harm such as bruising or aching = 8
- Fall with harm requiring intervention such as x-rays, pain medication, or additional procedure = 2

Data review of patient harms were related to notifications involving equipment, falls, and physiological changes. Examples of equipment notification included dysfunction with an auxiliary jack, displaced cord, absence of bed brake, and other aspects of the bed placing the patient at risk. Included in fall notifications were risks relating to the bath, toilet, shower and safety rails. Physiological notifications included code, emergency, monitor alarm check, oxygen saturation, pain, and other signs of pending harm to the patient's acute life status.

Table 25. Alarm-related events per hospital (patient outcomes)

	Hospital A 22 beds Critical access	Hospital B 13 beds Full-service	Hospital (Unit) C 36 beds Med/Surg/Tele	Hospital D 150 beds Full-service	Total
Alarm events	3	6	7	7	23
No Harm	3	4	2	3	12
Minimal Harm	0	1	1	2	4
No detectable Harm	0	1	2	2	5
Harm	0	0	2	0	2

Alarm-related event summary

The primary risk prevention benefit of Nurse Call alarm systems is falls prevention. Primary reasons for patient-initiated calls were not uncovered, however "beeps" which are patient-initiated calls were the highest in number, at 47,927 (54.3%). Notification of the need for assistance is critical to preventing patient fall and subsequent injury. This is accomplished primarily through use of the beep, bed, bed exit, bath, bathroom, shower, potty/toilet, side rails and assist alarms. Systems which are integrated into communication devices function as a secondary notification system allowing for nearly instant notification to the primary or secondary assigned caregivers. Nurse Calls system's also helps to address risk related to patient physiological changes by communicating equipment malfunctions (brakes not set, bed height,

cords not connected) and out-of-range equipment parameters (SA02, monitor alarm check). The configuration of an integrated alarm system addressed "who" responds with the option to have multiple staff assignments using "escalation" when then primary assigned fails to respond after a certain pre-determined timeframe as well as the ability to re-send alarms when critical alarms are not cancelled within the patient's room.

It is important to note that the average responses for the dependent variables were used for analysis with minimal variation in response times across ***all*** priority types. The alarm-related events regardless of the degree of harm/no harm were all attributed to delays in response. As the research was analyzed at the unit or hospital level it was impossible to identify the precise caregiver, alarm type, and exact response time which is critical to the analysis of patient events.

Survey comments

Exploratory analysis of clinician free-text comments relating to alarm response time, alarm system configuration, integrated medical device policy, and education and training were examined. Patient adverse events, actual time-to-respond data, and an evaluation of system and policy and procedure similarities and differences were conducted to further explore the medical device system (Table 26, 27, 28, 29). The following survey comments relate to the last four questions of the survey, were open-ended, free-text fields, asking for clinician feedback specific to:

- Alarm system configurations
- Alarm response time
- Integrated medical device and alarm training and education
- Integrated medical device alarm policy and procedure

These comments are noted individually below. Comments specific to the alarm system configuration = 26 comments, alarm response time = 21 comments, hospital unit policies and procedures = 12 comments, and medical device education and training = 27 comments.

Table 26. Alarm system configuration comments (Q18)

Hospital A:
• As an end-user I don't know about the system configuration • Clinical alarms do not apply to my position • Bathroom alarms and bed/chair alarms should not sound the same. • The new alarm system is hard to determine bathroom lights and fall risk • New call light system, no training provided. • Alarms are not set to individual providers. • We are a critical access hospital with limited monitoring capabilities. We do not have an ICU or critical care area other than the emergency department. • Alarms are not set to individual providers.
Hospital B:
• IBEDs are a pain, we need education on the different "zones". • We have some new alarms, specifically patient nurse call alarms. Training was weak, and we are still trying to figure the system out. • Currently the only configuration with the nurse call system is the bed settings including bed exit, and chair exit. No other alarms are yet associated with the call system. other independent alarms are IV, telemetry, temperature controls. • Non-essential alarms are routed to areas off unit, where pt. is roomed. • Not connected to unit that patient is located on. Everything rings in the ED. • Configuration poor.
Hospital C:
• Can manipulate some alarms to specific needs, but not all. • The only alarm training I was given was my Nurse manager called me one day and said I needed to manage my alarms better. yet there was no training in how to accomplish that. I research this area and observed the alarms on our floor and have learned how to manage some of the alarms on my own. I do not have any cooperation from any of the RNs in setting their alarms to coincide with what the Pt. is doing. If they come in w/ HR in 140s the alarm is left at 120 regardless of the Pt. • One problem is that Vocera call light, bed exit, is at times over ridden by tele alarms. During this time a PCA / RN cannot override the alarm if they need help. • ECG alarms are by far the most difficult to manage especially in the case or low voltage QRS waves mixed with elevated t waves resulting in continuously interruptive alarms. • The remote tele techs self-train on alarm management. The only hospital guidelines we receive regard how we contact RN's about specific alarms and how much time we must make the contact.

• There are times when nurses down one wing receive all the alarms rather than their specific patients, so the configurations can vary. I would like to see quicker responses to alarms
Hospital D:
• We are currently undergoing an upgrade - it does not sound beneficial for our department. • Alarm parameters often reset, causing the need to frequently readjust even when orders are present to justify parameter change. • Some of the alarms sound the same so is hard to tell what the alarm is for. • Bed alarms too sensitive creating more havoc than necessary. • We get a lot of false alarms.

Overwhelming, the four hospitals clinician comments reveal that while clinicians can change some alarms, there is an in-ability or lack of knowledge of the clinician to manipulate alarms specific to patient needs which could contribute to alarm fatigue. With the inability to manage all alarms, the concept of management of alarms becomes vague and could create increases concern as well create liability distress for the clinician. Clinicians may be unaware, lack the education and training, or are uninformed of the configuration variations such as alarm priority communication settings whereas the system is configured to manage multiple alarm types and prioritize their distribution to the clinician. Several references are made to alarm sound confusion, and the inability, lack of ability, or permission of the clinician to override alarms. Statements related to what a clinician can and can't do relate to the hospital or unit specific policy and procedures for the integrated system. Staff assignment of their individual patient alarms is an area of misperception whereas clinicians may be removed from assigning or re-assigning staff-to-patients and have the inability or lack authorization to participate in this task.

Table 27. Alarm response time comments (Q19)

Hospital A:
• We have a policy that says we must be in the patient's room within 5 minutes of the alarm notification. • All staff work to answer all alarms.

• As an end-user, I am unaware of the response time, but usually within 2-3 minutes (managers know this information. • Dependent upon area from which they come. • Alarms are responded to in less than a minute involving all staff available. • Mundane; so many alarms going off that you finish what you are doing before responding....no urgency anymore. • Very quick alarm response times. We try to minimize alarm fatigue by minimizing alarm sounds in our department.
Hospital B:
• I work in a small department. • Many nurses are desensitized to alarms especially because most are false
Hospital C:
• High priority alarms call Vocera which is helpful. I feel low priority alarms are more constant and increase alarm fatigue. • 90% of the time I respond quickly to all alarms just to make them stop. • The floor responds to their alarms when they feel they have time to do so. • We have tried assigning just the RN and PCA to call light, bed alarms but if the nurse and PCA are tied up, the call light is not being answered for a long time. Now we have the RN's on a wing helping answer the alarms. • Alarm response time seems to most effected by other nurses establishing custom settings alarms to the patient need or status, or their response times to alarms. • Alarm response time depends on the day and patient workload. • Some alarms that are high priority will broadcast to more people hence there is a heightened response for a good reason. • Quicker responses as this is a cardiac unit.
Hospital D:
• I'm in a very small unit, so we do not use the call system at the desk - we just always respond in the room. • Response time is good. • In a unit of this size and layout very difficult to manage. • We get a lot of false telemetry alarms.

Overwhelmingly, all four hospitals clinician responses discuss the high number of alarms, desensitization and alarm fatigue; citing the number of alarms is overwhelming including Hospital C unit which had the lowest frequency of alarms post implementation of an alarm – reduction project. Most clinicians answer alarms quickly to make them stop and there isn't a differentiation as to who is responsible for what type of alarms. All staff responds to alarms.

There is an appreciation of the alarm system configuration noted by Hospital C unit whereas the high priority alarms are being distributed to an increased number of staff.

Table 28. Integrated medical device education and training comments (Q20)

Hospital A:
• New call light system, and no training provided. • Most education is done by using the device. • We had medical device education a long time ago. • Adequate training. • Received education and training on older Mindray system several years back, there may be newer nursing staff that haven't had any training. • The staff are updated with all new or changing information on all medical devices prior to implementing the device system. • One training session prior to installation.
Hospital B:
• I didn't receive other than what I learned on the job. • Little or no refreshers. I have worked here a very long time and I feel initial training is adequate but follow up on knowledge retention is weak. • Training given on Nurse Call and Vocera. • We need more
Hospital C:
• Easy to ask charge nurse for help - they are the best resource. • Training is sporadic and can lag updates. • We have no training for alarms • Maybe twice per year training or refresher, included in skills day would be nice. improvement in refresher would allow for more compliance and better efficient use of alarms. • My observation is that RNs are not provided any training on how to tailor alarms to the individual patient. Consequently, the nurses are fearful of making changes to the default parameters. • Training is done with the initiation of new equipment. • More training is always appreciated.
Hospital D:
• As an end-user I am unaware of the response time but usually within 2-3 minutes (managers will know this information). • Training prior to installing new system. • I have not been trained in MANY years on our alarms. • This will be overkill, especially in our unit. • Good training. • Refresher training is always good. • We had education on the medical device a long time ago.

• Most education is done by using the device. • The Vocera trainer was not a good presenter.

Overwhelmingly across the hospital systems, clinician's response indicates that training and education occurs prior to the installation or use of a new system, however this may not be complete as it doesn't always include the entire staff or incorporate staff working after the new system is in use. Education and training is noted to be sporadic, not occurring or occurring with use of the medical device system. A lack of ongoing or refresher training is desired.

Table 29. Hospital or unit integrated policies and procedures comments (Q21)

Hospital A:
• Policies and procedures are easily accessible and adequately cover everything. No way to know if floor RN is responding until you get to that area (ER nurse). • I don't think there are policies and procedure for this. • All staff are educated on how to find policies and procedures on the computer and follow policies per facility protocol.
Hospital B:
• Alarm policy is in place, but not specific to each piece of integrated equipment such as Nurse Call and Vocera. • There is a clinical alarm policy and procedure that addresses clinical alarms (continuous cardiac monitoring), the administration of intra-muscular medications and intracapsular medications and therapies by infusion pumps. They are adequate.
Hospital C:
• 100% sure we have policies and procedures - not always easy to find and can be written in jargon • I am not aware of any policies and or procedures that are about managing alarms • Procedures vary between different units. • On our cardiac telemetry unit, we have a tele tech who alerts us with high priority alarms or alarms that have been "off the range" for a certain period. E.g. 02 sat at 85 for more than 3 minutes or so.
Hospital D:
• I am unaware of any policies and procedures on integrated medical devices. • Different units use different medical monitoring alarms systems throughout the hospital and are monitored by different personnel depending on the unit type. • I am not aware of any specific medical device policies and procedures for alarm management other than the continuous cardiac monitoring guideline.

Almost all hospitals respondents indicate knowing there are policies and procedures in place, however some are unaware of their existence and how to access them. The impact, effect of, or importance of integrated medical device policies and procedures is not evident in the clinician responses.

Comments Summary

Several comments (Q19 – Hospital C, Hospital B, Q19 – Hospital D, Q21 – Hospital C) relate to the physiological monitoring and distribution of physiological alarms and the remote monitoring of telemetry alarms which increase concern related to the continuous or "false" ECG telemetry alarms and the ability of the remote monitor to contact the caregiver. These comments, in addition to the comments specific to the Nurse Call system (bed, bathroom, etc.) point to the complexity of the integrated medical device alarm system and support the need for clinician contribution to system architecture.

While this study didn't address the priority of alarm distribution, it is clear by the comments that clinicians question how the system prioritizes the distribution of multiple alarms occurring at the same time. The distribution of alarms via configuration also vary, whereas in certain instances or when caregivers aren't available the alarms distribute to other clinicians unassigned to the patient or to the unit caregivers. Further, this study did not evaluate the variations in the distribution and communication of alarms.

Staff interviews

Interviews were conducted with Nurse Managers, IT, Clinical and Biomedical engineers, and Quality/Risk managers to assist with understanding of alarm systems, configurations, policy and procedure implementation, and adverse events related to alarm systems. These responses are

captured in Table 30. Not one hospital had the components, even those within the same hospital system (Hospital A, S, and D). Interview responses relay that each hospital was in a different state of updates for both hardware and software. These same hospitals had varied staffing models with no consistent model or means of assigning staff to patients within the integrated system. Patient acuities were no longer measured. The hospital goal is technology standardization, however there was frustration with this process as well as obstacles such as logistical unit layout with poor audio systems, varied expected response times, varied unit-by-unit workflow, no standards for responding, some personnel setting reminders for unanswered calls, while others would not set reminders. Further, there was stated overall staff discomfort with a lack of confidence and competence to change the default medical device parameters. This hospital did not have their system integrated to the physiological monitoring system, ventilators, infusion pumps, or other alarming devices. Alarm fatigue was specified as having effect on staff motivation and workflow efficiency. While they have an alarm committee, there mission was stated as more of having a big picture role, than addressing needs at the unit level. Ultimately, the perfect system was viewed as having the alarms go to the right person, the right device, and at the right time. Hospital C had the same system on the unit studied, however verbalized different versions of hardware and software throughout the hospital units and verbalized issues and concerns similar Hospitals A, B, and D. Hospital C revealed a recent alarm improvement project which measured 12,000 alarms per day on a cardiac unit with up to 99% not requiring immediate attention. This prompted them to allow for change in the oxygen saturation threshold (decreased to 87%) and the addition of a 15 second delay in communication to the caregiver via the Vocera badge. They also made a change to the Bed Exit

whereas the alarm notification goes to the primary ***RN and PCA*** with escalation to unit staff after 60 seconds. This change decreased alarms by 300 per hour with a 90% response by the primary caregiver.

Table 30. Nurse Call configuration per hospital

Components	Hospital A	Hospital B	Hospital (Unit) C	Hospital D
Nurse Call System	Hill Rom Critical Alert	Hill Rom Critical Alert	IdeaComm(Rauland)	Critical Alert
Nurse Call Reports	Cerner Alert	Cerner Alert	IdeaComm(Rauland)	Cerner Alert
Middleware System	Cerner iBus	Cerner iBus	Emergin	Cerner iBus
RTLS System	Aeroscout	Mission Critical	None	Aeroscout
Communication System	Overhead page Phones Vocera	Overhead page Phones Vocera	Overhead page Vocera	Overhead page Phones Vocera
Integrated into Nurse Call system?	No	No	Yes – Vocera, Nurse Call, telemetry, SA02	No
RTLS?	Yes	No	No	Yes
Central station?	Yes	Yes	Yes	Yes
Alarm committee?	No	No	Yes	No

Interview summary

Interviews conducted with the hospital representatives and the information obtained demonstrate alarm systems that are in flux, with various degrees of integration, use of real-time locating, continual upgrades of the hardware systems, possible implementation of or elimination of a middleware system, and software differences with upgrades or changes that may differ between units of a hospital system. Most Nurse Call reports were only referenced for instances of patient adverse events directly related to call response time. Use of a central station varied between units and hospitals and most had no alarm committee established to

identify a plan to address identification of the most important alarm signals, evaluate alarm fatigue and conduct a risk assessment review of alarms.

Policy and procedure review

All facilities had periodically reviewed policy and procedures specific to clinical alarm systems, however these policies and procedures were primarily limited to the physiological and physical patient monitoring alarms which have alarms activated via default, set parameters or self-activated by the patient.

The policy and procedure purpose are to ensure that the clinical alarm systems are managed and monitored properly so that the systems alert caregivers to potential patient safety concerns.

The Clinical alarm management Policy covered the topics of:

- Alarm coverage or detectability.
- Appropriate alarm uses before, during and after patient use.
- Guidance on safe operation.

The policy and procedures did not define specific expected clinician response times for Nurse Call alarms, however three of the hospitals defined a response time for lethal cardiac arrhythmias as noted below. The alarm "system" was not defined in any of the reviewed policy and procedures, however definitions were given for "clinical alarm" and "critical alarm".

Clinical alarm = alarm intended to protect the patient receiving care or to alert staff that the patient is at increased risk. These alarms are considered to indicate non-life-threatening situations. None of the sites defined an expected staff time-to-respond.

Critical alarm = an audible or visual indication from a system or device, that when activated, may result in injury or death of a patient unless immediate clinical intervention results. "Immediate" staff response is expected. A thirty second staff response is expected for lethal arrhythmias. Three sites, specify that if no response within 30 seconds, a code blue will be initiated. Examples of critical alarms included: Physiologic monitors, Life-sustaining equipment, Infusion pumps, and central monitoring systems (tele, fetal monitoring).

Training and Competence of the alarm system, included:

- Knowledge of how the alarms are activated.
- Knowledge of alarm limits based on the type and condition of the patient and environmental testing.
- Knowledge of the operation of the device including equipment self-check procedures before and during equipment use.
- Verification of alarms during transport and at the time of "hand-off".

Alarm response is a broad "all staff responsibility".

- Staff are responsible to set and activate "appropriate" visual and audible clinical alarms. Considerations include patient's baseline, current physiological assessment, assessment of the disease state, active medical treatment of the condition producing the alarm, practitioner prescribed parameters.
- When alarms are activated, staff must check the patient and evaluate the alarm condition before resetting the alarm.
- Staff are responsible to remove from service and mal-functioning or non-functioning medical alarm device.

- Alarms are not to be disabled or inactivated, except: may be muted or suspended for a brief period when a staff member is monitoring, evaluating, or treating the patient. Non-critical alarms (known, stable patient condition) may be in-activated.
- Alarm parameter changes are to be documented on a "report" sheet.
- No facility specified expected response times specific to alarm types except for devices such as physiologic monitors, life-sustaining equipment, infusion pumps and central monitoring systems.

Responsibility for alarm systems is directed to the patient care areas (e.g. "units) who are responsible for:

- Effective alarm coverage.
- Appropriate alarm use (defaults set at actionable levels).
- Alarms are annunciated adequately.

Policy and Procedure review summary

The policies reviewed were noted to be broadly based as well as Nurse Call agnostic. Configuration of the alarm system and the process of alarm review was not discussed. The high priority alarms intended to help prevent patient harms such as Code, Bath, Shower, Bed exit, Emergency, and Oxygen saturation (SA02) were not discussed. Perhaps, this is because the knowledge of an immediate response need is a known and expected response of the staff.

This chapter concludes the results of the alarm system perception survey, the staff interviews, the alarm data download capture, the alarm-related events review, and the alarm-related policy and procedure review of four midwestern hospital systems. In the final discussion

chapter, interpretations, limitations, differences between different hospitals, and a future vision will be discussed.

DISCUSSION

Results of hypothesis testing did not support a significant relationship between the Time-To-Respond and the alarm system configurations, policy and procedure and education and training. Hence the research model validity cannot be fully confirmed based on results from this sample of participants. Relationship support was found; however, each relationship was significant for only one of the dependent variables:

- There were associations between perception of the customizability of integrated medical device policies and self-reported response times, so H2 sub hypotheses H2a, was supported for the low priority response.
- There were associations between perception of alarm system flexibility and appropriateness of alarm system configuration and self-reported response times, so H1 and sub hypotheses H1a and H1b were supported for the medium priority alarm response.
- There were associations between perception of effectiveness of alarm system training and education and self-reported response times, so sub hypotheses H3a was supported for high priority response.

Alternative explanations for lack of statistical significance for the complete model include:

1. **Use of an unvalidated survey instrument.** While factor analysis was used to confirm the underlying constructs, the results are not as clean as desirable. That can be seen in the factor loadings. Items from 2 constructs loaded on one factor (perception of communication of integrated medical device policy and perception of effectiveness of the alarm system training and education), and another factor had no construct load on it

(perception of training and education effectiveness). This underlying factor structure is not as clean as expected and may be indicative of a greater or different construct.

2. **Clinician differentiation between high, medium, and low priority**. The survey did not explain or provide examples of "high", "medium", and "low" priority alarms, yet asked for self-report specific to these alarm types with accompanying expected response times for high, medium, and low priority. Perhaps, by providing alarm type examples versus time response expectations the respondent's answer might be different. The self-report response based on alarm type vs. high, medium, low was similar in response times, with the comments reflecting potential confusion when answering questions specifically related to high, medium, and low alarms. Clinicians answer call types without direct consideration of priority types and this may have created confusion when responding to questions specific to "high", "medium", and "low" priority.
3. **Little or no variance between the dependent variables (high, medium, low priority) actual self-reported response times.** Consequently, there is little room for the independent variables (configuration, policy and procedure, education and training) to provide adequate explanation. Perhaps, if the survey questions were specific to response to the high, medium, and low priority alarms were re-written to specific types of alarms such as "toilet", the self-reported responses may differ.
4. **Self-report bias**. The evaluation of the self-report response time for high, medium, and low priority against the self-reported perceptions of alarm system configuration, alarm-related policy and procedure and alarm system education and training is inherently

biased as a response is required of all types of alarms and clinicians don't necessarily track their response times or aim to complete the alarm within a set time-frame.

5. **Low response rate overall**. With 3 hospitals and 1 hospital unit participating, and a corresponding mean survey response rate of 23.75%, this is low and may not accurately reflect generalizable nurse perceptions of the alarm system.
6. **Clinician medical device differentiation confusion.** Clinician comments support medical device alarm differentiation confusion. While this research didn't specifically study clinician perception of medical device issues, nor did it match the individual response time to the individual's actual response time, it is evident from the actual data reports that the Nurse Call system experienced medical device issues such that both the frequency of medical device alarms is high in number (iBed brake alarms #3,495) and the response time has variance (Table 24) which could mean the clinician determined there were nuisance alarms and ignored many of them.
7. **Differences between different hospitals.** Hospital C had an active alarm improvement committee working on unit or patient specific problems such as addressing a high number of alarms of one type, whereas Hospitals A, B, and D have an alarm committee working at a broader level (system purchases and implementations). Staffing models, staffing roles, responsibilities, as well as patient population types and diagnoses play an important role in the differentiation and configuration of alarms. No two systems were alike in their configuration set-up and their hardware and software had variances.
8. **Varied degrees of system integration**. Three of the four hospitals were not "fully integrated" whereas they are using the Vocera communication device for clinician-to-

clinician communication vs. direct relay of the Nurse Call alarm messages. The hospital with "full" integration (Nurse Calls configured direct to the caregiver or unit via the communication device) demonstrated a quicker response time. This hospital also has an alarm committee which reviews alarms of highest risk as well as a review of alarms contributing to alarm fatigue. These variations may have caused clinician confusion when answering questions related to the configuration of the alarm system.

Implications for research

As this is the first study measuring clinician perception of alarm configurations, policy and procedure, and education and training specific to an integrated Nurse Call system and is anticipated that these findings will help to shape future research projects specific to integrated Nurse Call systems.

There is limited generalizability to medical device integrated systems overall. While the study is the first hospital comparative integrated Nurse Call study, it included only four Midwest hospitals systems and the degrees of integration and standardization may be more advanced in other healthcare organizations. This may impact the survey findings as clinician perceptions may differ based on the degrees of integration and system standardization. This study did not include all alarming medical devices. The focus was on Nurse Call systems which may or may not have all other alarming devices integrated into the alarm system.

Based on the findings of this study, it may be beneficial to compare whether an integrated system versus a non-integrated system makes a difference in response times as well as patient outcomes. One benefit of this study is the use of actual alarm-related event data versus the use of a proxy (i.e. patient safety culture or perception of patient safety). Use of a proxy are

known to have inverse relationships (Farup 2015), therefore this research supports a true measure of patient safety. Notwithstanding, a system to more accurately identify alarm-related events and a process to review these sentinel events is needed to better understand the true existence and extent of alarm-related patient events.

There is a need for further research specific to identifying clinical best practices for education, configuration, implementation, and maintenance of a distributed alarm system. This knowledge not only will assist to improve efficiencies but will assist in the attainment of no alarm-related patient events. Delays related to response times continue to affect patient outcomes. Improvement of integrated systems conceptually lead to enhanced human caregiver response, improved patient care, and a more meaningful flow between technology and people.

While this research did not focus on the Information Technology aspect of configurations, future research specific to configuration relevance, understanding of priorities, algorithms, and impact to patients and clinicians is critical to identify areas of improvement.

Future research should assist with the eventual implementation of an intelligent, distributed alarm system which will have the greatest impact for clinicians and patients world-wide.

There is however, insight value provided through the data download, clinician comments, policy and procedure review, staff interviews, and alarm-related events review which provides an improved understanding warranting further research of the integrated systems particularly in the areas of: alarm configuration, alarm differentiation, training and education, policy and procedure, and the prevention of patient harm.

Implications for practice

Alarm configuration:

In this study, one hospital (Hospital A) had the lowest number of alarms (~12 per day), the quickest response times (31.20 seconds), and the lowest number of patient alarm-related events (3). This connection supports the importance of low alarm burden, quick response times, and prevention of patient harm. Conversely, Hospital D had the highest number of alarms per day (683) with the longest response time (48.2 seconds) and was tied with Hospital C for the number of alarm-related patient events (7). This connection supports the high alarm burden, response time, and patient harm. The number of alarms in this study is under-reported as the research did not include all alarms, however if hospitals accept and adopt the concept that >350 alarms per day is overwhelming to clinicians and contributes to alarm fatigue (2011 AAMI Clinical Summit), the importance of alarm configuration cannot be under-estimated. Further with average numbers of alarms between 12 – 683 per day for the Nurse Call system only, nurses cannot possibly respond to all alarm devices (Graham 2010, Purbaugh 2013). Owners of the "alarm system" is an area of ambiguity. An integrated system involves not only hardware and software, it may involve multiple medical devices (multiple vendors) and a middleware system to configure alarm notifications. It is often unclear whether there is potential conflict between systems. This could affect the priority settings affecting when and how the clinician received a high, medium or low priority alarm.

Medical devices themselves are considered the primary alarming system, however when they become part of an integrated alarm system, the secondary alarm notifications help to quickly get the alarm notifications to caregivers. These notifications however, can cause interruptions

in the clinician workflow and can contribute to alarm fatigue. This research did not review all alarming systems present in the hospital or unit, nor did it review the number of alarms in totality. In a 2015 article, Funk compared the Healthcare Technology Foundations 2005-2006 online alarm surveys to their 2011 survey and found limited change to the clinical alarm hazards, noting only a small percentage of hospitals reporting alarm improvement initiatives and 20% relating adverse alarm events (Funk 2015). To fully address alarm fatigue, the total number of alarms and all alarming medical devices should be considered. Hospital or unit alarm initiatives continue to be weak and reasons for this should be fully explored.

Alarm differentiation:

An assessment of risk for each type of alarm helps to define the priority and determine the expected alarm response. Clinician response in this study did not vary significantly based on the type of alarm and the clinician's voiced an inability to manipulate some alarms, a reluctance to change alarm settings, priority confusion, over-alarming (sensitivity) of certain types of alarms (ECG), difficulty differentiating the type of alarm due to over-alarming, audible similarities in types of alarms with different priorities, location, and communication prioritization.

There may be similarities in the audible and alarm type notifications which may contribute to similar response times for high, medium, and low alarms. This problem points to a continued issue with alarm specificity and over-sensitivity. Many clinician comments reference the high number of alarms occurring. In general, clinicians are expected to respond to all alarms in a timely manner.

Training and Education:

Clinicians tend to "learn on the job" as the systems are complex and being upgraded, adjusted or software changes occur. Some calls are integrated into the phone or badge, creating a primary and secondary notification system, while some notifications just use the primary (hardware) system. Training may be lacking or not available "when needed", whereas clinicians utilize their colleagues as a resource.

Policy and Procedure:

Policy and procedures reviewed were ambiguous and non-specific. It is postulated that having policies and procedures specific to the alarm system process will assist clinicians to better understand the system as well as increase their involvement in improving the clinical alarm system. Policy and procedure help to define the process and explain systems or processes. Discussing configuration settings (including disabling, silencing, volume) as well as the process for determining risk assessment of nurse call alarms considering both number and types of alarms may help to improve clinician alarm fatigue and improve the alarm differentiation confusion that clinician's experience currently.

While policy and procedure often abdicate responsibility of parameter changes to the clinician, the clinician may experience a lack of confidence, competence, comfort as well as a heightened sense of liability to change these parameters. The lack of alarm initiatives within these facilities may contribute to the vague and ambiguous nature of the alarm-related policies and procedures.

It is interesting considering The Joint Commission's scrutiny in recent years that the participating hospitals' policy and procedure did not specifically address alarm system

configuration, the process for determining alarm system configurations, appropriateness, customizability, specificity, and the communication between systems. Further, it was surprising to discover the lack of mention of an alarm committee to address specifics such as: alarm fatigue, identification of the most important alarm signals, and the risk assessment review of those signals. Hospital C demonstrated that having a multi-disciplinary alarm committee review and recommend changes to the alarm system settings and communication of the medical device alarms resulted in changes both to the number of alarms as well as helped to reduce alarm fatigue. Further study of hospitals with established alarm committees would provide helpful insight into their ability to impact alarm fatigue and improve patient risk of harm related to the alarm system.

This study reports that while nurse perceptions are not all associated with statistical significance to the time-to-respond, actual response times still varied, and alarm events still occurred with two events resulting in patient harm requiring intervention and additional care. These harms as well as all potential harms with a related and associated Nurse Call were evaluated as "delays" in clinician response, therefore a continued review of Nurse Call system is warranted. Hospital policy and procedure ought to detail processes such as:

- Evaluation of system "pieces and parts". As many of these systems are purchased from multiple manufacturers with various types and versions of hardware and software, it is essential that compatibility exists, and that the system is user-friendly and regularly evaluated. Back-up systems for failures in connectivity or networks require further investigation as evidenced by the lack of reference in related policies and procedures in this study.

- A team approach to identify nuisance alarms and alarms of highest risk. The involvement of staff, information technology, biomedical, medicine, and quality or risk management in a formalized manner helps to decrease nuisance alarms, decreased the total number of alarms, and identify high risk alarms to address as a team (Hospital C).
- Alarm analytics. Nurse call systems provide alarm data which can be used to better understand the system, configurations, and identify alarms to review further. Alarm data can also provide benefit at the patient, caregiver, unit and hospital level.

Prevention of patient harm:

While this research didn't address the number of false alarms, the total number of alarms was high at 981 per day (not including all alarming systems or devices), clinician comments support an environment of continued false alarms, and alarm-related events persist. False alarms not only contribute to the noise on the unit, but they also contribute to the persisting sentinel events linking to alarm fatigue and are a distraction that interrupts patient care and potentially increases the risk for error (Brammer 2012, Funk 2015, AORN 2014). An exploratory Nurse Call research project evaluating the reasons for patient-initiated calls in a cross-sectional, multi-hospital survey which uncovered the primary reasons to be: toileting assistance, pain medication, intravenous problems, personal assistance, repositioning, or accidental. Interestingly, this study also found that only 49% of the clinicians perceived that these patient-initiated calls mattered to patient safety (Tzeng 2010).

Patient falls occurred ten times in a three-month period within the four hospitals with root causes identified as delays in the provision of care. The Joint Commission reviewed patient falls for a 9-year period (1995-2004) and found that the primary root causes of falls ending in death

to be: inadequate staff communication, incomplete orientation and training, incomplete patient assessments and reassessments, environmental issues, incomplete care planning, delayed or unavailable care provision, and inadequate organizational culture of safety (TJC 2005). A 2009 study reviewed Nurse Call light data and response times of 3 units in a Midwestern hospital and found that the average beeps were 4.37 per day with a mean response time of 197.68 seconds. Using the same formula for calculating call light use per patient day, this study averaged 4.4 per day with a mean response of 39.4 seconds. It is interesting that most hospitals regard the "beep" patient call as a medium priority alarm, yet the risk for a fall harm is high. Comparatively, this hospital had a higher fall rate of approximately 22.6 in a 3-month period. Interestingly, they also found that increased patient calls for assistance may lead to less fall-related patient harm (Tzeng 2008). More research is needs to examine call light use, patient requests, clinician response, the "beep" workflow, the effect of alarms on workflows, patient falls, and falls requiring treatment.

This research may provide additional value to stakeholders such as clinicians, clinical nurse managers, hospital administrators, quality and risk prevention personnel, bio-medical or clinical engineers, human factors experts, and researchers interested in improving alarm systems. Hospitals can use this data to assist with their analysis of data they collect on alarms.

Public Health

Implications relative to public health are based on the premise that patient safety is non-negotiable. Therefore, the quicker response time to alarms, the better for preservation of patient safety. Given the resulting number of events, desired response time was not demonstrated in this study. Based on these data, there is a need for further

examination of the relationship of the three variables of technology, process and procedure, and training and education to improve appropriateness of alarm response time to optimize patient care. Additional constructs to be explored that may impact the appropriateness of alarm response include: culture, staffing models, patient population, alarm committee activity, and staff workflows that are not only hospital-specific, but department-specific as well.

Limitations

1. **Survey validation.** While the survey utilized in this study was based on framework established by ECRI, it is not considered a validated survey and is therefore subject to further analysis and validation.
2. **Low N, Low response rate.** While the study met the minimum statistical requirement for analysis, the total N was expected to be higher. Data from the Bureau of Labor Statistics on the number of Registered Nurses (RNs) in the USA is reported to be 3.1 million, with 85% being employed in nursing. This equates to approximately 10 nurses per 1,000 persons (BLS 2016). To establish confidence in the results, a larger clinician sample size would be required to increase confidence and to establish that the results are truly representative of the population. An estimation of an 80% response rate for each hospital was predicted, however actual response rates were low at 5%, 20%, 33%, and 78%
3. **Clinician interpretation.** While the intent of this research was Nurse Call integrated systems, the survey questions were not specific to the Nurse Call system, therefore clinician interpretation and answers may relate to other systems such as the

physiological systems known for continuous or false alarms (TJC 2013; Block 1999; Korniewicz 2008; Valentin, 2006).

4. **Use of high, medium, and low alarm terminology.** Clinicians do not necessarily view alarms from this perspective, rather they seem to view from an immediate vs. non-immediate need. The difficulty for a clinician evaluating a Nurse Call alarm is that unlike a physiological monitor which provides visual and audio cues, the Nurse Call alarms are varied and do not provide visual or audio cues that correlate with patient condition. They are strictly a means of communicating a condition or need. Future research should make distinctions between alarm types by providing definitions of the types of alarms being evaluated and consider the baseline assumption of clinicians that most alarm do not represent life-threatening (high priority) conditions (Bonafide 2017).
5. **Clinician self-report bias.** Questions related to response times were overwhelming fast with 83.8% asserting a less than 1-minute response for high priority, 55.2% asserting a 1-2-minute response for medium priority, and 52.4% asserting a 1-2-minute response for low priority. The actual average response rates ranged from 35.95 (high) with a standard deviation of 192.97, 51.67 (medium) with a standard deviation of 193.04, and 41.37 (low) with a standard deviation of 67.77. Taking into consideration the standard deviations, the actual response times data points are in fact spread out over a wide range of values.
6. **Perception vs. Real-world.** This study of perceptions impact on response time may not accurately reflect the real-world clinical scenario of patient alarms. In actual patient care settings there are many factors that are in constant flux such as staff numbers,

nurse-to-patient ratios, location and design of the unit, acoustics and sound, light, and competing notifications, patient diagnosis, patient acuity, and most impactful would be other competing systems or alarms as well as individual trends or patterns of response. This study focused on integrated Nurse call systems at the unit or hospital level and did not collect or compare data specific to the unit logistics, individual assigned caregiver nor any competing or additional alarm notification systems.

7. **Average alarm response time.** In the real-world, average response times are not clinically relevant. Ideally, the actual response time correlated to the individual clinician would provide the most accurate and clinically relevant evidence.
8. **Generalizability.** The findings are applicable to North America, Midwest hospitals only. They may generalize to hospitals of similar size; however they are not generalizable to all hospitals. The variations in software and hardware as well as the patient care unit types and hospital size do not allow these results to be generalizable to all hospitals. No two hospital configurations were similar. This confounds the ability to define and accurately compare *similar* systems. The ability to truly look at the complete medical device system is also limited due to the difficulties in obtaining a complete data set of all medical-device alarming data and all integrated software systems. The unit hospitals in this study had integrated medical device alarm systems, however all were incomplete systems. They are termed incompletely integrated because following the interviews, they all acknowledged a state of fluidity with their systems (varied and different types of systems were integrated at the time of this research).

9. **Alarm correlation.** The alarm data was not correlated to the patient record and therefore the ability to identify nuisance alarms associated with medical device sensitivity could not be performed.
10. **Clinician correlation to response time.** Due to IRB limitations specific to human subject research, it was not possible to correlate the individual self-report response times to the actual response times. This limits the ability to adequately measure response times as the variable became the unit response time versus the individual response time and this confounds the results.
11. **Medical device logs of alarm download data.** The device logs provided were specific to the Nurse Call system and cannot be considered as a complete data set for all medical device alarms. There is no universal system for logging all alarm data into one system. Data specific to medical device calibration, cleaning and maintenance records, fault codes and intrusion activities per device were not reviewed.
12. **Reporting of patient alarm-related events.** The capture of alarm-related events at all hospitals in this study was incidental to this project. This data was not readily available nor do these hospitals have a system of review for assessing the alarm-related component of evaluating adverse patient outcomes, therefore the true number of alarm-related events is not truly known. Likely, it is much higher than reported. As each outcome was reviewed by the requestor for this project, it is possible that interpretation bias may also ensue.
13. **Failure to report alarm-related incidents.** Alarm-related events were not reported as primary events in any of the four (4) hospitals, rather they become part of a secondary

review of a patient reported event. Therefore, the accurate number of alarm-related adverse events is truly unknow and likely, under-reported (Leape 1994, TJC 2013).

14. **The "sound or hearing" of the alarm was not reviewed.** Critical alarms must be communicated via an audible indication from the system. While the clinician perception survey did assess alarm configuration, it did not specifically measure the effectivity of alarm communication and whether the sound was transferred appropriately.
15. **Lacked review of all alarm conditions and setting with all alarm medical devices.** This research focused primarily on the Nurse Call alarm system and its integration to a communication device and did not incorporate other systems such as physiological monitors, infusion pumps, security systems, ventilator, and other medical devices which may or may not be integrated within the system. These results are limited as a sub-population of the entire alarm system.
16. **Cost differences.** This study did not address nor compare the cost of various systems for the different types of system integrations.

Future vision

The current alarm system is a complex and confusing system with a need for improvement. Clinician comments and patient adverse events support the need for a change in the system. An integrated system is considered an advanced system; however, it is not an intelligent alarm system. The answer to whether these systems "improve" alarm notifications, response, and patient outcomes is still outstanding.

The ideal configuration system would be one of inputs from subject matter experts, real-world knowledge, and with the ability to be easily or automatically adjusted in an environment of

changing patient care and staff needs. This authors' perception of a "perfect" clinical alarm system would be such that the primary caregiver would have one master control panel for each patient integrated into the electronic patient record, with malleable defaults, automatic notifications, automatic determination of priorities based on call types, and auto-escalations based on the physical condition of the patient, availability of caregivers, and the clinician's plan of care. Perhaps, the ability of the system to automatically assess and configure alarm routing so that clinicians are not overwhelmed would help clinicians to respect each alarm as meaningful, and important. This requires an open system and an infrastructure whereas manufacturers would need to open their platforms, allowing for true hardware and software system integration, input of actual patient condition based on real-time data, and primary clinician involvement. In conjunction, a machine learning approach with true device interoperability and validated algorithms for the entire system with an ability to suppress false alarms may help to reduce false alarms and better predict ongoing patient deterioration (Li 2012, Hatcliff 2012, Hu 2012).

A future where alarm reports are not referenced only when an alarm incident occurs but become a meaningful and suitable part of nursing analytics with the ability to model the effect of subtle changes such as clinician staffing or roles, and patient individual circumstances. Finally, the constructs of alarm system configuration, policy and procedure and education / training ought to be further studied and research undertaken to develop specific measures for these constructs such that this information can be applied towards improvements to practice, research, and education. Further study should aid in the development of conclusive statements toward optimizing response time and improving patient outcome.

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APPENDICES

APPENDIX A: IEC 60601-1-8 alarm priority recommendations

5.1 Requiring an ALARM CONDITION and its priority

5.1.1 Recommendation

ME EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate the [describe the ALARM CONDITION here]. The [describe the ALARM CONDITION here] ALARM CONDITION shall be at least {choose a priority from the choices below}, unless an INTELLIGENT ALARM SYSTEM is utilized that uses additional physiological information to determine [describe the ALARM CONDITION here] is not true, but that a different ALARM CONDITION is present.

Choices:

- HIGH PRIORITY
- MEDIUM PRIORITY
- LOW PRIORITY with auditory ALARM SIGNAL
- LOW PRIORITY

Table 1 — Recommendations for collateral standard IEC 60601-1-8:2006 and AMD:2012 CSV references

Subclause of the collateral standard	Recommendation number	Topic	Page
201.7.9.2.8.101	5.5	Requiring disclosure of a means of testing ALARM SIGNALS	9
201.7.9.3.101	5.6	Requiring disclosure of a means of testing ALARM SYSTEM	10
208.6.6.2.101	5.4	Requiring a restriction for the adjustment range of an ALARM LIMIT	8
208.6.8.2	5.7	Requiring REMINDER SIGNALS, option 1	10
208.6.8.2	5.8	Requiring REMINDER SIGNALS, option 2	11
208.6.8.5	5.2	Requiring a maximum pause duration, option 1	7
208.6.8.5	5.3	Requiring a maximum pause duration, option 2	7
	5.9	Requiring Logging?	11
—[a]	0	Requiring a maximum ALARM SIGNAL GENERATION DELAY	12
—[a]	5.1	Requiring an ALARM CONDITION and its priority	6
—[b]	5.10	Requiring capability for a connection to a DISTRIBUTED ALARM SYSTEM	12

[a] Generally placed in a particular standard subclause calling out the ALARM CONDITION.

[b] Generally placed in a particular standard in subclause 201.10x.

APPENDIX B: PubMed results of reported issues by country

PubMed Categorization of Reported Issues	USA	FR	GER	IRAN	NETH	UK	JP	CA	NZ	AU
Equipment (121)	77	8	11	1	2	9	1	7	2	3
Personnel (109)	80	4	7	1	3	7	1	5	0	1
Local Procedure (50)	37	2	3	0	3	3	0	2	0	0
Policy/Procedure (17)	14	1	1	0	0	1	0	0	0	0

FR=France, GER=Germany, NETH=Netherlands, UK=United Kingdom, JP=Japan, CA=Canada, NZ=New Zealand, AU=Australia

Equipment (n=121) - Reliability, lack of differentiation between devices, priority confusion, effective exchange of information, sensitivity and specificity, and integrated systems issues (software, network, wireless, etc.).

Personnel (n=109) – clinician trust, confusion, staff assignment, staffing model, shift change, role clarity, back up procedures. Lack of intelligent and predictive medical device alarm systems has led to nurse distrust, silencing, disabling or turning off medical device alarming system(s), and expectations vs. actual may differ. Misuse of medical device equipment by the end-user (e.g. disabling the safety features) is clinician specific.

Local Procedure (n=50) – such as device maintenance, alarm sitters, remote alarm monitoring, reporting systems, education or training programs, and real-time temporary changes to alarm settings.

Policy and Procedure (n=17) – specific to medical device and their alarms may or may not address alarm limits, alarm priorities, default settings, adjusting alarm settings, silencing, notification, response (primary, secondary, and tertiary), disabling, standardization, downtime, and assignment, accountability for alarm response, adverse event documentation and review.

APPENDIX C: Survey

Q1

Consent to Participate in Online Survey Research

Study Title: Medical device alarm systems: A multi-hospital study of alarm-related events, caregiver alarm response, and their contributing factors.

Person Responsible for Research: Colleen Lindell, Derek Nazareth, PhD

Study Description: The purpose of this research study is to investigate alarm management systems which have Nurse Call integrated into an end device. Approximately 160 subjects will participate in this study. If you agree to participate, you will be asked to complete an online survey that will take approximately 10-20 minutes to complete. The questions will ask about your perceptions of alarm configurations, policy and procedures related to alarms and education and training that you've received.

Risks / Benefits: Risks to participants are considered minimal. Collection of data and survey responses using the internet involves the same risks that a person would encounter in everyday use of the internet, such as breach of confidentiality. While the researchers have taken every reasonable step to protect your confidentiality, there is always the possibility of interception or hacking of the data by third parties that is not under the control of the research team.

There will be no costs for participating. There are no benefits to you other than to further research in this field of study.

Limits to Confidentiality Identifying information such as the Internet Protocol (IP) address of this computer will be collected for research purposes (linking data collection time points). Data will be retained on the Qualtrics website server for three months and will be deleted after this time. However, data may exist on backups or server logs beyond the timeframe of this research project. Data transferred from the survey site will be saved in an encrypted format for three months. Only Colleen Lindell and Derek Nazareth will have access to the data collected by this study. However, Derek Nazareth PhD, the Institutional Review Board at HealthPartners or appropriate federal agencies like the Office for Human Research Protections may review this study's records. The research team will remove your identifying information before downloading and all study results will be reported without identifying information so that no one viewing the results will ever be able to match you with your responses.

Voluntary Participation: Your participation in this study is voluntary. You may choose to not answer any of the questions or withdraw from this study at any time without penalty. Your decision will not change any present or future relationship with the Regions Hospital or HealthPartners.

Who do I contact for questions about the study: For more information about the study or study procedures, contact Colleen Lindell at clindell@uwm.edu or 715-254-9173.

Research Subject's Consent to Participate in Research: By entering this survey, you are indicating that you have read the consent form, you are age 18 or older and that you voluntarily agree to participate in

this research study. Thank you!

Q2 Please select your gender:

- Female (1)
- Male (2)

Q3 Please select your job title

- Registered Nurse (1)
- Other: Enter Job title below (2)

Q4 Select the length of time you've worked as an RN outside of the United States of America

- I haven't worked as an RN outside of the USA (1)
- Less than 2 years (2)
- 2 - 10 years (3)
- Greater than 10 years (4)

Q5 Select the length of time you've worked as an RN in the United States of America

- Less than 2 years (1)
- 2 - 10 years (2)
- Greater than 10 years (3)

Q6 Select your age range:

- Less than 30 years (1)
- 30 - 50 years (2)
- Greater than 50 years (3)

Q7 Please respond to the following items about the way the alarm system is currently configured at your organization.	Strongly disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
The clinical alarm system can be customized for the type of intervention. (ASCF1)	❍	❍	❍	❍	❍
The clinical alarm system can be cust-omized for my unit (ASCF2)	❍	❍	❍	❍	❍
The clinical alarm system can be customized to match individual patient needs. (ASCF3)	❍	❍	❍	❍	❍
The clinical alarm system resets quickly when caregivers are reassigned. (ASCF4)	❍	❍	❍	❍	❍
The clinical alarm system is configured appropriately. (ASCA1)	❍	❍	❍	❍	❍
The clinical alarm system generates alarms that have the appropriate priority. (ASCA2)	❍	❍	❍	❍	❍

The clinical alarm system has not led to desensitization of alarms. (ASCA3)	❍	❍	❍	❍	❍
The clinical alarm system routes alarms to the correct providers. (ASCA6)	❍	❍	❍	❍	❍
The clinical alarm system generates alarms that conflict with other systems. (ASCA7)	❍	❍	❍	❍	❍
The clinical alarm system pinpoints where patient care is needed. (ASCA8)	❍	❍	❍	❍	❍
The clinical alarm system generates few or no false alarms. (ASCA5)	❍	❍	❍	❍	❍

Q8 **Approximately how many alarms do you respond to during a shift? (please enter a numeric)**

Q9 **What percentage of the alarms you address during a shift fall into the following categories? (please have them total to 100%)**

High Priority (urgent) (4)	
Medium priority (normal) (5)	
Low priority (6)	

Q10 **Please respond to the following statement about alarm response.**
I usually respond to a "high" priority (urgent) alarms within:

- ❍ Less than 1 minute (1)
- ❍ 1-2 minutes (2)
- ❍ 2-5 minutes (3)
- ❍ 5-10 minutes (4)
- ❍ 10+ minutes (5)

Q11 **Please respond to the following statement about alarm response.**
I usually respond to a "medium" priority (normal) alarms within:

- ❍ Less than 1 minute (1)
- ❍ 1-2 minutes (2)
- ❍ 2-5 minutes (3)
- ❍ 5-10 minutes (4)
- ❍ 10+ minutes (5)

Q12 **Please respond to the following statement about alarm response.**
I usually respond to a "low" priority alarms within:

- ❍ Less than 1 minute (1)
- ❍ 1-2 minutes (2)
- ❍ 2-5 minutes (3)
- ❍ 5-10 minutes (4)
- ❍ 10+ minutes (5)

Q13 **Please respond to the following items that describe how the alarm system is managed at your organization.**	Strongly disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
My organization has an alarm management committee that can change the priority of alarms. (MDPC1)	❍	❍	❍	❍	❍
At my organization any provider can override alarm priority on an exception basis. (MDPC3)	❍	❍	❍	❍	❍
At my organization any provider can recommend a change to an alarm priority. (MDPC2)	❍	❍	❍	❍	❍
At my organization any provider can recommend a change to an alarm assignment (role). (MDPC6)	❍	❍	❍	❍	❍
At my organization any provider can pause an alarm. (MDPC4)	❍	❍	❍	❍	❍

At my organization any provider can silence an alarm. (MDPC7)	❍	❍	❍	❍	❍
My organization has a backup plan when the alarm system is down. (MDPC5)	❍	❍	❍	❍	❍

Q14 **Please respond to the following items about the alarm system at your organization.**	Strongly disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
At my organization most alarms are sent to a limited set of providers, instead of a broadcast to all providers. (MDPS1)	❍	❍	❍	❍	❍
At my organization alarms are set to the correct set of providers. (MDPS2)	❍	❍	❍	❍	❍
I do not have to respond to alarms if I am not directly involved in care for that specific patient (MDPS 3)	❍	❍	❍	❍	❍
I receive alarms only on patients that I am currently caring for. (MDPS4)	❍	❍	❍	❍	❍
The number of alarms that I have to respond to in a shift is manageable. (MDPS5)	❍	❍	❍	❍	❍

Q15 **Please respond to the following items about policies for the alarm system at your organization.**	Strongly disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
My organization has policies and procedures for alarm management. (MDPA1)	❍	❍	❍	❍	❍
I am aware of the policies and procedures for alarm management at my organization, or I know where to access them. (MDPA2)	❍	❍	❍	❍	❍
At my organization policies and procedures for alarm management incorporate staff input. (MDPA3)	❍	❍	❍	❍	❍
At my organization policies and procedures for alarm management address who is responsible for monitoring and responding to alarms. (MDPA 4)	❍	❍	❍	❍	❍

At my organization policies and procedures for alarm management address who is responsible for changing alarm priorities. (MDPA5)	❍	❍	❍	❍	❍
At my organization policies and procedures for alarm management address the monitoring and testing of medical devices that generate alarms. (MDPA 6)	❍	❍	❍	❍	❍
At my organization policies and procedures for alarm management address the monitoring and testing of devices that relay and receive alarms. (MDPA7)	❍	❍	❍	❍	❍

Q16 **Please respond to the following items about training and education for alarm management at your organization.**	Strongly disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
My organization provides training and education for alarm monitoring, response, and override. (TEE1)	❍	❍	❍	❍	❍
My organization provides training and education on the various alarm devices on my unit. (TEE2)	❍	❍	❍	❍	❍
My organization educates providers on the alarms they are expected to receive. (TEE3)	❍	❍	❍	❍	❍
At my organization providers are informed about the consequences of not responding appropriately to alarms, for patient and provider. (TEE 4)	❍	❍	❍	❍	❍

At my organization education and training material is provided in multiple formats. (TEE5)	❍	❍	❍	❍	❍
The training I received was customized to meet my needs. (TEE6)	❍	❍	❍	❍	❍
My organization provides periodic refresher training sessions. (TEE7)	❍	❍	❍	❍	❍

Q17 **Please respond to the following items about the training that you received on the alarm system at your organization.**	Strongly Disagree (1)	Disagree (6)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)
I am fully trained on all the alarm devices that I use. (TEC1)	❍	❍	❍	❍	❍
My organization provides training on how to respond to alarms. (TEC8)	❍	❍	❍	❍	❍
My organization provides training on how to override alarms. (TEC2)	❍	❍	❍	❍	❍
My organization provides training on how to manage and care for the alarm devices that I use. (TEC3)	❍	❍	❍	❍	❍
I can access additional material at my organization on the alarm devices I use. (TEC4)	❍	❍	❍	❍	❍

I receive additional training whenever the alarm system or its components are updated. (TEC5)	❍	❍	❍	❍	❍
The training I received included vendor supplied material. (TEC6)	❍	❍	❍	❍	❍
The training I received included material developed in-house. (TEC7)	❍	❍	❍	❍	❍

Q18 Comments specific to alarm system configuration:

Q19 Comments specific to alarm response time:

Q20 Comments specific to integrated medical device education and training:

Q21 Comments specific to hospital or unit integrated medical device policies and procedures:

APPENDIX D: Statistical analysis – with full set

Scale: H1a

VARIABLES=Q7_6 Q7_7 Q7_8 Q7_9 Q7_10 Q7_11 Q7_12

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.772	.776	7

Item Statistics

	Mean	Std. Deviation	N
ASCA1	3.3429	.96903	105
ASCA2	3.3714	1.00247	105
ASCA3	2.6286	1.07647	105
ASCA6	3.3143	1.03138	105
ASCA7	2.8857	1.06802	105
ASCA8	3.6000	1.00575	105
ASCA5	2.5905	1.08038	105

	ASCA1	ASCA2	ASCA3	ASCA6	ASCA7	ASCA8	ASCA5

ASCA1	1.000	.669	.381	.420	.289	.507	.292
ASCA2	.669	1.000	.138	.584	.265	.502	.284
ASCA3	.381	.138	1.000	.253	.163	.314	.488
ASCA6	.420	.584	.253	1.000	.103	.465	.263
ASCA7	.289	.265	.163	.103	1.000	.100	.276
ASCA8	.507	.502	.314	.465	.100	1.000	.184
ASCA5	.292	.284	.488	.263	.276	.184	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
ASCA1	18.3905	16.029	.662	.559	.710
ASCA2	18.3619	16.099	.621	.619	.717
ASCA3	19.1048	17.095	.432	.388	.756
ASCA6	18.4190	16.650	.521	.404	.737
ASCA7	18.8476	18.342	.286	.142	.785
ASCA8	18.1333	16.828	.516	.372	.738
ASCA5	19.1429	16.951	.448	.319	.753

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
21.7333	22.101	4.70120	7

Scale: H1b

VARIABLES=Q7_1 Q7_2 Q7_3 Q7_4

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.647	.636	4

Item Statistics

	Mean	Std. Deviation	N
ASCF1	3.4762	.91036	105
ASCF2	3.5524	1.02826	105

ASCF3	3.4762	.97167	105
ASCF4	3.1810	.85238	105

Inter-Item Correlation Matrix

	ASCF1	ASCF2	ASCF3	ASCF4
ASCF1	1.000	.466	.567	.099
ASCF2	.466	1.000	.456	.203
ASCF3	.567	.456	1.000	.034
ASCF4	.099	.203	.034	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
ASCF1	10.2095	4.052	.554	.377	.490
ASCF2	10.1333	3.713	.540	.298	.490
ASCF3	10.2095	3.994	.508	.372	.519
ASCF4	10.5048	5.618	.140	.047	.744

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
13.6857	6.910	2.62867	4

Scale: H2a

VARIABLES=Q13_1 Q13_2 Q13_3 Q13_4 Q13_5 Q13_6 Q13_7

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.675	.674	7

Item Statistics

	Mean	Std. Deviation	N
MDPC1	3.0381	1.00884	105
MDPC3	2.8476	.98821	105
MDPC2	3.3048	1.03890	105
MDPC6	3.2762	.99513	105
MDPC4	3.1905	1.12741	105
MDPC7	3.1714	1.13897	105
MDPC5	3.0571	1.03616	105

Inter-Item Correlation Matrix

	MDPC1	MDPC3	MDPC2	MDOPC6	MDPC4	MDPC7	MDPC5
MDPC1	1.000	.237	.191	.124	.095	.070	.292
MDPC3	.237	1.000	.355	.200	.441	.562	.121

MDPC2	.191	.355	1.000	.680	.204	.150	.144
MDPC6	.124	.200	.680	1.000	.141	.144	.068
MDPC4	.095	.441	.204	.141	1.000	.716	-.116
MDPC7	.070	.562	.150	.144	.716	1.000	-.025
MDPC5	.292	.121	.144	.068	-.116	-.025	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPC1	18.8476	15.150	.268	.143	.670
MDPC3	19.0381	13.210	.569	.423	.589
MDPC2	18.5810	13.515	.482	.535	.612
MDPC6	18.6095	14.452	.374	.474	.642
MDPC4	18.6952	13.445	.431	.541	.626
MDPC7	18.7143	13.091	.472	.604	.613
MDPC5	18.8286	16.220	.118	.134	.709

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
21.8857	18.275	4.27496	7

Scale: H2b VARIABLES=Q14_1 Q14_2 Q14_3 Q14_4 Q14_5

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0

Total	105	00.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.650	.642	5

Item Statistics

	Mean	Std. Deviation	N
MDPS1	2.9423	1.09568	104
MDPS2	3.1442	1.01845	104
MDPS3	1.7115	.82053	104
MDPS4	2.1635	1.17507	104
MDPS5	3.2404	.99995	104

Inter-Item Correlation Matrix

	MDPS1	MDPS2	MDPS3	MDPS4	MDPS5
MDPS1	1.000	.408	.197	.437	.163
MDPS2	.408	1.000	.097	.345	.452
MDPS3	.197	.097	1.000	.372	.062
MDPS4	.437	.345	.372	1.000	.107
MDPS5	.163	.452	.062	.107	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPS1	10.2596	7.068	.472	.268	.562
MDPS2	10.0577	7.162	.517	.350	.541
MDPS3	11.4904	9.010	.271	.144	.650
MDPS4	11.0385	6.717	.479	.310	.557
MDPS5	9.9615	8.387	.281	.209	.651

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
13.2019	11.017	3.31920	5

Scale: H2c VARIABLES=Q15_1 Q15_2 Q15_3 Q15_4 Q15_5 Q15_6 Q15_7

Case Processing Summary

		N	%
Cases	Valid	103	98.1
	Excluded[a]	2	1.9
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.902	.904	7

Item Statistics

	Mean	Std. Deviation	N
MDPA1	3.7379	.71347	103
MDPA2	3.6990	.79007	103
MDPA3	3.2621	.93893	103
MDPA4	3.5631	.82450	103
MDPA5	3.3592	.87284	103
MDPA6	3.4466	.80108	103
MDPA7	3.3981	.78390	103

Inter-Item Correlation Matrix

	MDPA1	MDPA2	MDPA3	MDPA4	MDPA5	MDPA6	MDPA7
MDPA1	1.000	.659	.499	.637	.656	.516	.469
MDPA2	.659	1.000	.477	.594	.571	.571	.512
MDPA3	.499	.477	1.000	.643	.662	.442	.510
MDPA4	.637	.594	.643	1.000	.738	.506	.408
MDPA5	.656	.571	.662	.738	1.000	.596	.591
MDPA6	.516	.571	.442	.506	.596	1.000	.776
MDPA7	.469	.512	.510	.408	.591	.776	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPA1	20.7282	16.200	.712	.567	.889
MDPA2	20.7670	15.808	.695	.537	.890

MDPA3	21.2039	15.046	.669	.526	.894
MDPA4	20.9029	15.343	.740	.657	.885
MDPA5	21.1068	14.645	.807	.689	.876
MDPA6	21.0194	15.706	.701	.667	.889
MDPA7	21.0680	15.966	.674	.666	.892

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
24.4660	20.800	4.56074	7

Scale: H3a VARIABLES=Q16_1, Q16_2, Q16_3, Q16_4, Q16_5, Q16_6, Q16_7

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.915	.916	7

Item Statistics

	Mean	Std. Deviation	N

TEE1	3.3654	.97600	104
TEE2	3.4808	.93457	104
TEE3	3.4615	.96465	104
TEE4	3.5096	.91371	104
TEE6	3.2212	1.06084	104
TEE6	3.1058	1.06048	104
TEE7	3.0000	1.07937	104

Inter-Item Correlation Matrix

	TEE1	TEE2	TEE3	TEE4	TEE5	TEE6	TEE7
TEE1	1.000	.742	.747	.497	.587	.619	.608
TEE2	.742	1.000	.807	.586	.675	.663	.654
TEE3	.747	.807	1.000	.601	.649	.607	.504
TEE4	.497	.586	.601	1.000	.454	.495	.473
TEE5	.587	.675	.649	.454	1.000	.549	.678
TEE6	.619	.663	.607	.495	.549	1.000	.585
TEE7	.608	.654	.504	.473	.678	.585	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
TEE1	19.7788	24.057	.776	.654	.898
TEE2	19.6635	23.779	.854	.758	.890

TEE3	19.6827	23.966	.798	.752	.896
TEE4	19.6346	25.885	.615	.416	.914
TEE5	19.9231	23.761	.730	.593	.903
TEE6	20.0385	23.940	.710	.513	.905
TEE7	20.1442	23.795	.710	.605	.905

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
23.1442	32.435	5.69520	7

Scale: H3b VARIABLES=Q17_1, Q17_2, Q17_3, Q17_4, Q17_5, Q17_6, Q17_7, Q17_8

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.812	.811	8

Item Statistics

	Mean	Std. Deviation	N

TEC1	3.1923	1.34437	104
TEC8	3.1635	1.22364	104
TEC2	3.3462	1.59957	104
TEC3	3.4615	1.51320	104
TEC4	3.2308	1.55314	104
TEC5	3.3750	1.60211	104
TEC6	3.1346	1.53318	104
TEC7	3.1827	1.50575	104

Inter-Item Correlation Matrix

	TEC1	TEC8	TEC2	TEC3	TEC4	TEC5	TEC6	TEC7
TEC1	1.000	.111	.452	.428	.239	.034	.228	.237
TEC8	.111	1.000	.353	.163	.440	.350	.387	.352
TEC2	.452	.353	1.000	.531	.401	.301	.353	.385
TEC3	.428	.163	.531	1.000	.301	.388	.341	.282
TEC4	.239	.440	.401	.301	1.000	.308	.435	.492
TEC5	.034	.350	.301	.388	.308	1.000	.537	.358
TEC6	.228	.387	.353	.341	.435	.537	1.000	.570
TEC7	.237	.352	.385	.282	.492	.358	.570	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
TEC1	22.8942	52.484	.364	.305	.812
TEC8	22.9231	51.742	.463	.296	.800
TEC2	22.7404	45.806	.601	.438	.780

TEC3	22.6250	48.004	.529	.409	.791
TEC4	22.8558	46.979	.563	.366	.786
TEC5	22.7115	47.974	.488	.396	.797
TEC6	22.9519	45.988	.627	.483	.776
TEC7	22.9038	47.059	.584	.416	.783

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
26.0865	61.381	7.83459	8

APPENDIX E - Statistical analysis – with discarded items

Scale: H1a

VARIABLES=Q7_6 Q7_7 Q7_8 Q7_9 Q7_10 Q7_12

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.738	.742	6

Item Statistics

	Mean	Std. Deviation	N
ASCA1	3.3429	.96903	105
ASCA2.	3.3714	1.00247	105
ASCA3	2.6286	1.07647	105
ASCA6	3.3143	1.03138	105
ASCA7	2.8857	1.06802	105
ASCA5	2.5905	1.08038	105

Inter-Item Correlation Matrix

	ASCA1	ASCA2	ASCA3	ASCA6	ASCA7	ASCA5
ASCA1	1.000	.669	.381	.420	.289	.292
ASCA2.	.669	1.000	.138	.584	.265	.284
ASCA3	.381	.138	1.000	.253	.163	.488
ASCA6	.420	.584	.253	1.000	.103	.263
ASCA7	.289	.265	.163	.103	1.000	.276
ASCA5	.292	.284	.488	.263	.276	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
ASCA1	14.7905	11.744	.624	.542	.661
ASCA2	14.7619	11.837	.578	.605	.672
ASCA3	15.5048	12.502	.416	.365	.719
ASCA6	14.8190	12.342	.472	.379	.702
ASCA7	15.2476	13.284	.309	.138	.748
ASCA5	15.5429	12.077	.477	.313	.701

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
18.1333	16.828	4.10222	6

Scale: H1b

VARIABLES=Q7_1 Q7_2 Q7_3

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.744	.747	3

Item Statistics

	Mean	Std. Deviation	N
ASCF1	3.4762	.91036	105
ASCF2	3.5524	1.02826	105
ASCF3	3.4762	.97167	105

Inter-Item Correlation Matrix

	ASCF1	ASCF2	ASCF3
ASCF1	1.000	.466	.567
ASCF2	.466	1.000	.456
ASCF3	.567	.456	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
ASCF1	7.0286	2.913	.604	.376	.626
ASCF2	6.9524	2.777	.521	.271	.723
ASCF3	7.0286	2.759	.593	.369	.633

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
10.5048	5.618	2.37018	3

Scale: H2a

VARIABLES=Q13_2 Q13_3 Q13_4 Q13_5 Q13_6

Case Processing Summary

		N	%
Cases	Valid	105	100.0
	Excluded[a]	0	.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.738	.737	5

Item Statistics

	Mean	Std. Deviation	N

MDPC3	2.8476	.98821	105
MDPC2	3.3048	1.03890	105
MDPC6	3.2762	.99513	105
MDPC4	3.1905	1.12741	105
MDPC7	3.1714	1.13897	105

Inter-Item Correlation Matrix

	MDPC3	MDPC2	MDPC6	MDPC4	MDPC7
MDPC3	1.000	.355	.200	.441	.562
MDPC2	.355	1.000	.680	.204	.150
MDPC6	.200	.680	1.000	.141	.144
MDPC4	.441	.204	.141	1.000	.716
MDPC7	.562	.150	.144	.716	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPC3	12.9429	9.362	.557	.398	.673
MDPC2	12.4857	9.656	.460	.528	.707
MDPC6	12.5143	10.271	.383	.473	.733
MDPC4	12.6000	8.819	.540	.523	.677
MDPC7	12.6190	8.623	.566	.600	.666

Scale Statistics

Mean	Variance	Std. Deviation	N of Items

15.7905	13.706	3.70212	5

Scale: H2b

VARIABLES=Q14_1 Q14_2 Q14_3 Q14_4

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.651	.642	4

Item Statistics

	Mean	Std. Deviation	N
MDPS1	2.9423	1.09568	104
MDPS2	3.1442	1.01845	104
MDPS3	1.7115	.82053	104
MDPS4	2.1635	1.17507	104

Inter-Item Correlation Matrix

	MDPS1	MDPS2	MDPS3	MDPS4

MDPS1	1.000	.408	.197	.437
MDPS2	.408	1.000	.097	.345
MDPS3	.197	.097	1.000	.372
MDPS4	.437	.345	.372	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPS1	7.0192	4.796	.498	.268	.533
MDPS2	6.8173	5.452	.399	.203	.605
MDPS3	8.2500	6.481	.295	.142	.662
MDPS4	7.7981	4.337	.545	.307	.493

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
9.9615	8.387	2.89601	4

Scale: H2c

VARIABLES=Q15_1 Q15_2 Q15_3 Q15_4 Q15_5 Q15_6 Q15_7

Case Processing Summary

	N	%

Cases	Valid	103	98.1
	Excluded[a]	2	1.9
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.902	.904	7

Item Statistics

	Mean	Std. Deviation	N
MDPA1	3.7379	.71347	103
MDPA2	3.6990	.79007	103
MDPA3	3.2621	.93893	103
MDPA4	3.5631	.82450	103
MDPA5	3.3592	.87284	103
MDPA6	3.4466	.80108	103
MDPA7	3.3981	.78390	103

Inter-Item Correlation Matrix

	MDPA1	MDPA2	MDPA3	MDPA4	MDPA5	MDPA6	MDPA7

MDPA1	1.000	.659	.499	.637	.656	.516	.469
MDPA2	.659	1.000	.477	.594	.571	.571	.512
MDPA3	.499	.477	1.000	.643	.662	.442	.510
MDPA4	.637	.594	.643	1.000	.738	.506	.408
MDPA5.	.656	.571	.662	.738	1.000	.596	.591
MDPA6	.516	.571	.442	.506	.596	1.000	.776
MDPA7	.469	.512	.510	.408	.591	.776	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
MDPA1	20.7282	16.200	.712	.567	.889
MDPA2	20.7670	15.808	.695	.537	.890
MDPA3	21.2039	15.046	.669	.526	.894
MDPA4	20.9029	15.343	.740	.657	.885
MDPA5	21.1068	14.645	.807	.689	.876
MDPA6	21.0194	15.706	.701	.667	.889
MDPA7	21.0680	15.966	.674	.666	.892

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
24.4660	20.800	4.56074	7

Scale: H3a

VARIABLES=Q16_1, Q16_2, Q16_3, Q16_4, Q16_5, Q16_6, Q16_7

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.915	.916	7

Item Statistics

	Mean	Std. Deviation	N
TEE1	3.3654	.97600	104
TEE2	3.4808	.93457	104
TEE3	3.4615	.96465	104
TEE4	3.5096	.91371	104
TEE5	3.2212	1.06084	104
TEE6	3.1058	1.06048	104
TEE7	3.0000	1.07937	104

Inter-Item Correlation Matrix

	TEE1	TEE2	TEE3	TEE4	TEE5	TEE6	TEE7

TEE1	1.000	.742	.747	.497	.587	.619	.608
TEE2	.742	1.000	.807	.586	.675	.663	.654
TEE3	.747	.807	1.000	.601	.649	.607	.504
TEE4	.497	.586	.601	1.000	.454	.495	.473
TEE5	.587	.675	.649	.454	1.000	.549	.678
TEE6	.619	.663	.607	.495	.549	1.000	.585
TEE7	.608	.654	.504	.473	.678	.585	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
TEE1	19.7788	24.057	.776	.654	.898
TEE2	19.6635	23.779	.854	.758	.890
TEE3	19.6827	23.966	.798	.752	.896
TEE4	19.6346	25.885	.615	.416	.914
TEE5	19.9231	23.761	.730	.593	.903
TEE6	20.0385	23.940	.710	.513	.905
TEE7	20.1442	23.795	.710	.605	.905

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
23.1442	32.435	5.69520	7

Scale: H3b

VARIABLES=Q17_2,Q17_3,Q17_4,Q17_5,Q17_6,Q17_7,Q17_8

Case Processing Summary

		N	%
Cases	Valid	104	99.0
	Excluded[a]	1	1.0
	Total	105	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.812	.812	7

Item Statistics

	Mean	Std. Deviation	N
TEC8	3.1635	1.22364	104
TEC2	3.3462	1.59957	104
TEC3	3.4615	1.51320	104
TEC4	3.2308	1.55314	104
TEC5	3.3750	1.60211	104
TEC6	3.1346	1.53318	104
TEC7	3.1827	1.50575	104

Inter-Item Correlation Matrix

	TEC8	TEC8	TEC8	TEC8	TEC8	TEC8	TEC8

TEC8	1.000	.353	.163	.440	.350	.387	.352
TEC2	.353	1.000	.531	.401	.301	.353	.385
TEC3	.163	.531	1.000	.301	.388	.341	.282
TEC4	.440	.401	.301	1.000	.308	.435	.492
TEC5	.350	.301	.388	.308	1.000	.537	.358
TEC6	.387	.353	.341	.435	.537	1.000	.570
TEC7	.352	.385	.282	.492	.358	.570	1.000

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
TEC8	19.7308	43.208	.484	.295	.799
TEC2	19.5481	38.852	.555	.393	.787
TEC3	19.4327	40.850	.483	.358	.799
TEC4	19.6635	39.080	.566	.365	.785
TEC5	19.5192	39.223	.533	.358	.791
TEC6	19.7596	38.029	.640	.477	.771
TEC7	19.7115	39.120	.589	.415	.781

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
22.8942	52.484	7.24457	7

APPENDIX F: Interview Tool

Alarm Analysis Assessment Tool© ***Facility Name/Address***	
Unit #1 name / # beds	
Unit #2 name / # beds	
Unit #3 name / # beds	
Clinical Unit Manager Name / email / Telephone Alarm Committee member?	Unit #1: Unit #2: Unit #3:
Safety / Regulatory Name / email / Telephone Alarm Committee member?	Unit #1: Unit #2: Unit #3:
Vendor Contact – Nurse Call Name / email / Telephone Alarm Committee member?	Unit #1: Unit #2: Unit #3:
Bio Med or Clinical Engineering (CE) Name / email / Telephone Alarm Committee member?	Unit #1: Unit #2: Unit #3:
IT Applications / Database Name / email / Telephone Alarm Committee member?	Unit #1: Unit #2: Unit #3:
Other contacts:	Unit #1: Unit #2: Unit #3:
Patient Population	Unit #1: Unit #2: Unit #3:

Q1. Medical Devices Intake Form: Medical devices alarming equipment and any known or historical malfunctions or noted problems

Nurse Call:
Vendor(s):
Bed Model #:
Software Version:
Location of central station(s):

Alarm Parameters:
Volume settings:
Components / Accessories:
Configuration of unit alarms for room calls (i.e. By wing, north/south, etc.):
Types of alerting or alarming calls (by bed, by room):
Bathroom emergency call:
Bed status monitoring: exit alert, bedrails, bed position, brakes, HOB, weight:
Code Blue:
Real-time status board?
Staff locating enabled?
Auto-disabling of safety alerts on caregiver presence?
Patient safety reporting? If "yes", provide a 3-month historical report per unit, per patient, per staff assignment, per location:
Is Nurse call system integrated into the EMR?
Any known problems, historical malfunctions or noted issues?

Middleware (if applicable):
Vendor:
Software Version:
Location:
Configuration: Date/Time, Room #, Patient Alarm, Latched/Unlatched Alarms, Silence, Pause, Modified, Disabled, Assigned Caregivers/Roles/Teams.
Sample Algorithm(s):
Any known problems, historical malfunctions or noted issues?

End device:
Phone (model number):
Vocera:
Pager(s):
Vendor:
Model #:
Software Version:
Location:
Alarm Parameters:
Volume settings:
Any known problems, historical malfunctions or noted issues?
Staff Assignment:
Entered which system?
Any known problems, historical malfunctions or noted issues?

Central stations:
Location:
Staffing model:

Q2. Alert/Alarm related policies and procedures Intake Form: Provide all alarm-related policies and procedures.

- Alert / alarm settings (patient or default?):
- Alert / alarm silencing:
- Alert / alarm limits:
- Alert / alarm modification:
- Alert / alarm disabling:
- Downtime procedure:
- Staff assignment:
- Other:

Q3. Review of alert/alarm workflow processes:

- Is there a written workflow document specific to medical device alarms?
- Who assigns patients? Who delivers the information?
- How is the information delivered?
- Who is responsible for addressing the condition?
- What is current back up when assigned staff are unavailable?
- What happens when there are competing tasks?
- Are the alerts / alarms audible?
- What is the noise level of the unit?
- Are there similar or competing alarms?
- Is staff able to clearly identify the cause of most alarms?
- Does alert / alarm silencing occur?
- Are there barriers to audible or visual Alerts / Alarms

Nurse call reports questions:

- How often are the call reports reviewed?
- Who reviews the nurse call reports?
- Do the call reports affect nurse call assignment workflows?
- Are the call reports ever viewed in “real-time”? If yes, for what purpose?

Comments:

Q4. Alarm Log and Reporting 3-month historical review:

- What is the average number of alarms per patient/per shift/per caregiver for the 3-month time period?
- Per alarm type (priority)
- Per Patient / Unit
- Response time

Q5. Alarm-related events Intake Form

- Specific to the 3-month time of analysis, has there been any adverse, near misses or sentinel events related to clinical alarms?

Additional comments:

CURRICULUM VITAE

COLLEEN LINDELL, RN-BC, MHSA, CNOR, PHD(C)

SUMMARY

Versatile, healthcare professional with administrative, medical product (biologics, pharmaceuticals, medical device/combination devices/pharmaceuticals), informatics, medical research, trial, rural and urban clinical experience. Experience in various medical therapeutic areas: Pain, Hematology, Gastro-enterology, GYN, Oncology, Surgery, Interventional Radiology, and Diabetes/Endocrinology. Enthusiastic, highly motivated, adaptable team player respected for resourcefulness, knowledge and collaborative style.

EXPERIENCE

3/17 - Present **Medical Science Liaison – Oncology** *Tardis/Publicis/Novartis – Midwest USA*

- Serves as a clinical/scientific resource for Breast cancer related products and therapeutic area.
- Successfully identifies appropriate clinical investigators and facilitates placement into Novartis-sponsored clinical trials.
- Responds to healthcare professional medical information requests.

3/16 – 3/17 **Medical Science Liaison – Pain, Specialty Therapeutics, InventivHealth***/Endo – Central USA*

- Serve as a clinical/scientific resource for products and therapeutic areas (internal and external customers).
- Identify and build long-term relationships with thought leaders in 20 Midwest states.
- Share knowledge and participate in scientific exchanges with thought leaders.
- Present clinical, scientific and economic product data and relevant therapeutic areas to formulary decision-makers.
- Identify and communicate key clinical and research issues to appropriate internal partners to shape company research, development and commercial strategies.
- Develop and implement business plans to support Medical Affairs strategic direction.

3/14 – 3/16 **Professional Technical Services Specialist**, *3M Infection Prevention Division – MN*

- Provide internal/external clinical expertise for IPD devices in market development.

- Develop and present technical bulletins, customer letters, and education tools for internal and external customers.
- Respond to requests for information and analyze quality complaints.
- Collaborate, plan and conduct USA and Global customer clinical studies, including usability simulated evaluations.
- Liaise as a clinical/technical expert with regulatory, legal, quality, marketing and lab personnel on a regular basis.

9/11 - 3/14 **Medical Science Liaison, Oncology** BTG *International – North Central Region*

- Recipient - Most Valuable Person 2013 (Medical affairs team).
- Provided interim management support for Western USA region (9 months).
- Provided scientific support for marketed and development projects in loco-regional therapies (drug eluting microspheres and ^{90}Yttrium-microspheres in the Interventional Radiology space resulting in cross-fertilization of clinical, regulatory, pharmaceutical and scientific information for treatment of primary/secondary liver cancer.
- Medical Science Liaison Lead for Pancreatic/Neuro-endocrine cancer.
- Developed and maintained external expert partnerships at key medical institutions with key opinion leaders (MCW / UW / MN / IA / NE / IL / KUMC / NE / Wash U / SLU).
- Responded to unsolicited requests for medical and scientific information and acted as a scientific resource for physicians leading their own clinical trial activities (IIS) as well as company sponsored trials (act as a CRA, - assist with patient enrollment).

2/07-1/11 **Senior Clinical Affairs Manager, Medical Science Liaison -***Baxter USA*

- Provided and maintained currency with TJC, FDA, GCP, scientific, and evidence-based information specific to Biosurgery's Medication Delivery portfolio (drug/device).
- Conducted risk assessment for new product development/marketed product
- Developed, recruited and conducted internal and external design protocols and Simulation Laboratory studies with Human Factors in preparation for FDA submission.
- Assisted with evaluation and selection of Clinical Research Organizations.
- Identification, recruitment and development of KOLs in 6 Midwest states.
- Acted as primary liaison to investigators who initiate clinical and non-clinical trial studies.
- Project co-lead for Steep Rock (opinion leader electronic management system).
- Reviewed, revised, and updated advertising / promotional product and scientific presentations.
- Developed, presented and validated PowerPoint presentations for customers, colleagues & multi-disciplinary staff.
- Participation in high-level training sessions, medical congress, clinical/scientific symposiums.
- Corresponded with Bioscience team (medical affairs, sales, marketing, R & D) on local, national, and international levels to improve patient care & respond to customer needs.

2/05 – 2/07 **Clinical Applications Specialist, Nurse Consultant**, Hill *Rom – Workflow Solutions – USA*

- Project management for nurse-call system (bed alerts, alarms, locating, reporting); Vocera (wireless communications system); and Navicare (scheduling/communication software system).
- Provided education, implementation of integrated hospital systems.
- On-site consultative services - mid / upper-level nursing and informatics executives.
- Developed and presented recommendation proposals to customers and company.
- Reviewed and provided consultative services regarding new system development.

8/99 - Present **Registered Nurse, Charge Nurse**, Regions *Hospital (HealthPartners) - MN*

- Provide peri-operative nursing care to surgical patients (all specialties) Level 1 Trauma Center.
- Act as Nursing Supervisor for peri-operative services.
- Preceptor for new nursing RN employees.
- Nursing professional recognition program recipient 2003 and 2004.
- Communicate and coordinate patient care within multiple hospital departments.

1/96 – 8/99 **Clinical Coordinator, Nurse Consultant**, Medwave*, Magellan Medical Services - USA*

- Developed and provided national education programs for non-invasive arterial blood pressure monitoring system, IV pumps, and spinal implants.
- Wrote Internal Review Board (IRB) applications and clinical research protocol.
- Investigated, monitored, evaluated and assisted with publication of clinical research projects.
- Ensured compliance with good clinical practice (GCP) guidelines.
- Provided feedback to company regarding new product development.

2/84 – 1/96 **Director of Surgical Services, SDS Manager, Charge Nurse, RN**, St. *Croix Hospital – WI*

- Administrative responsibility for Operating Room, Central Sterile Processing, Post-anesthesia care, same day surgery and Pre-operative education / scheduling units.
- Successfully prepared, educated and passed four JCAHO surveys.
- Fiscal responsibility for $2.5 million-dollar budgets (multiple).
- Founder West-central Wisconsin American association of diabetes educators (WCWAADE).
- Developed, submitted, and achieved American Diabetes Education national program recognition.

- Evaluated equipment, negotiated and purchased O.R. supplies and capital equipment.
- Developed HR through orientation and development program, training, and staffing.
- Led and sponsored multiple quality improvement projects (scheduling, staffing, program).

EDUCATION

2017 PhD(c) Biomedical & Health Informatics, University *of Wisconsin - Milwaukee*

2008 Master's in Health Services Administration, Saint *Joseph's College - ME*

2000 BS in Health Services Administration, Saint *Joseph's College - ME*

1984 Associate Degree, Nursing *Saint Mary's College - MN*

CONTINUING EDUCATION

21 CFR training by CDRH, Simulation in Healthcare 2009 (22 CEU's), Human Factors consideration in Designing Medical Device trials conference, Statistics, Epidemiology and Surveillance Training Modules 1-4 (Baxter Healthcare), Microsoft Project Methods for the PMM (1.5 days training course) and attendance at annual AORN, Pain Management and HIMSS conferences.

CERTIFICATIONS

Current: Operating Room Nursing (CNOR), Advanced Coronary Life Support (ACLS), Pediatric Advanced Life Support (PALS), Pain Management

Past: Nursing Administration, Diabetes Educator

LICENSURE

Registered Nurse Licensure: WI #89477 (multi-state) - Current and unrestricted

PROFESSIONAL ASSOCIATIONS

Association of Operating Room Nurses – Member since 1987, book reviewer, Perioperative Resource Network, Volunteer Consultant. President East Metro MN Chapter, 2006 – 2008, Past President 200-2010, Simulation Task Force member 2014-2015.

American Society for Pain Management Nursing - Member

American Society of PeriAnesthesia Nurses – Member

American Nurses Association – Affiliate member

AMIA – Member (student)

AAMI / Medical Device Alarms – Committee member

AAMI / Multifunction monitor committee – Committee member

HIMSS (Health Informatics) – Member

IEEE – Graduate Student Member

IV Nurses Society (INS) - Member

Minnesota State Council – Peri-Op Nursing – Member

Society for Simulation in Healthcare – Member

WCWAADE - Founder of West-central Wisconsin American association of diabetes educators. 1995

PROFESSIONAL PRESENTATIONS

Medical Device Alarm Trepidations. 3M Healthcare Academy. Live webinar. March 2015.

Perioperative Clinical Simulations Poster Presentation "Difficulty Airway" - Proposal ID: 4591.

AORN Annual Meeting. Denver CO 2015.

Transcultural Analysis of Medical Device Alarm Trepidations Poster Presentation. UW–Milwaukee 2nd Annual Informatics Symposium. Milwaukee, WI. 2015.

24th Summer Institute of Nursing Informatics, University of Maryland - School of Nursing, 2014.

Community of Practice Presentation: Annual Risk File Review for Devices. Baxter Medication Delivery 2010.

Global Infusion Systems Clinical Library: Current Status, Right-sphere, and Future Status. Baxter Healthcare 2010.

Medical Device Alarms. Baxter Healthcare Global Infusion Systems Division. IL 2010.

Understanding the differences: Hemostats, Sealants and Adhesives. MW USA Hospitals 2007.

Online Medical/Nursing Informatics. RNMarket, Tampa, FL. Feb. 2006.

Successful expert testimony. National Nurses in Business. Chicago, IL. June 2005.

OR Mock Trial. East Metro AORN. Minneapolis, MN. May 2005. Abbott NW 2006.

Internet Medical Research Poster Presentation. Professional Nursing Education Group. Atlanta, GA. 2004.

MediPro Seminars. New Orleans, LA. 2004.

Searching the Internet Successfully. National Nurses in Business, Chicago, IL. 2003.

Internet research for the healthcare professional. NursingMatters/WI ed. 2003.

Documentation Issues & Charting for the future in Minnesota. Lorman Ed., 2002.

Independent Legal Nurse Consulting. NNBA Annual Meeting. Las Vegas, NV. 2002.

Win with the Aces – Online research/resources for Standards of Care - NMLCI. Las Vegas, NV. March 2002.

Medical Internet Database Searching: Getting Results! Regions Hospital, St. Paul, MN. 2002.

Searching the Internet for Quality Medical information – Regions Hospital, St. Paul, MN. 2001.

Internet Medical/Health Information Poster Presenter – MLA Annual Meeting – Chicago, IL. 1999.

Non-invasive Arterial Blood Pressure Monitoring – ASAT – Orlando, FL. 1998.

Developing Ambulatory Recovery Pathways – AHA's Society for Ambulatory Professionals – New Orleans, LA. 1993.

Surgery Scheduling - Rural Nurse Managers – New Richmond, WI. 1992. Diabetes: Forming Support Groups.

Managing Diabetes, Updates, Pathophysiology, Hyperglycemia, Hypoglycemia – Ambulance Rescue & Community Groups – WI. 1990-1995.

PUBLICATIONS & ASSIGNMENTS

AAMI TIRR66: 2017 Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms. AAMI alarm committee representative.

Moderator, ASPMN Annual Meeting 2016. Louisville, KY.

Simulation Task Force Member appointment. AORN. 2014-2015.

Adjunct Instructor 2011. Medical Literature Research Module. University of Florida Legal Nurse Consulting Online Pre-Certificate Program.

AMIA-0483-A2011 – Poster, EMR Practicum University of Wisconsin-Milwaukee. Eric Dohman, Colleen Lindell, Natalie Rahmin, Timothy B. Patrick, PhD.

57th Annual AORN Congress Session Assistant. 2010. Denver, CO.

Peri-operative Resource Network member 2004-2009. AORN. Denver, CO.

Annual 2007 HIMSS Conference Presentation Reviewer. 2006.

Competency & Credentialing Institute. CNOR Item/Test Form Review Committee CCI Champion. 2006-2007.

Standards of Care research - author. LNCRESOURCE national newsletter. 2004 - 2006.

Council Peri-operative Board Nursing (CPBN)-Certification exam reviewer. 2004.

Council Peri-operative Board Nursing (CPBN)–Certification exam writer. 2002.

National Council of State Boards of Nursing (NCLEX) – Item writer. 2002.

Expert Panel/Best Practices –panel member. MLCI Journal. 2002–Present.

How to get great search results on the Internet-author. IMPRINT. Vol. 48, No. 3. May 2001.

Legal Tips Weekly- author – Health Resources Unlimited http://www.hru.net, 2000.

Four steps to Better Search Results on the Internet-author NursingSpectrum.com. 2000.

Malpractice: A step-by-step guide to understanding the process- author. Nurses.com. 1999.

Internet Medical & Health, Searching & Sources Guidebook/CD – KC Press 1998 - 2004. Searching the Internet for Medical & Health Information – CEU Module - Pacific West Health Education. 1999.

Book reviewer. AORN Journal 1997 - 2004. Standards reviewer. AORN. 2003 – 2004.

Reviewer, Medical Reference Services Quarterly Haworth Information Press. 1999.

Work Redesign in the Peri-operative setting – AORN Management Specialty Publications, 1996. Ambulatory Recovery Pathways-author – Society for Ambulatory Care Professionals of the AHA journal, 1994.

Volunteer, Camp Nurse, Diabetes Educator & Speaker, CQI Team Leader, Diabetes Advisory

Committee Facilitator, Wellness Committee member, Nursing Executive Committee member, Orthopedic Task Force Committee member, and Surgical Services/Tissue Review Committee Co-Chair, and Founder WI Diabetes Educator Association. Diabetes Ed. 1987 - 1996.

Sunday School Teacher / Assistant.