

Reducing the Harm Associated with Clinical Alarm Systems: Meeting the Joint Commission

National Patient Safety Goal.06.01.01 Performance Elements

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This practice inquiry project has been approved for meeting partial requirements for the
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Abstract

Problem: Clinicians and patients are vulnerable to alarm fatigue (AF). AF is a patient safety hazard and the leading cause of alarm-related sentinel events. The Joint Commission proclaimed reducing the harm associated with clinical alarm systems as a 2014 National Patient Safety Goal (NPSG.06.01.01). **Aims/Objectives:** Develop and implement a survey to assess AF amongst Intensive Care Unit (ICU) clinicians; Complete STEP 2 of NPSG.06.01.01 for an ICU which includes to “identify the most important alarm signals to manage...”. **Design:** Project design/methods were derived from an AF Conceptual Framework and the Iowa Model.

Participants: Convenience sample of 28 ICU clinicians. **Setting:** An 11-bed medical-surgical ICU located in a 276 bed community hospital in Hawaii. **Data Collection:** NPSG.06.01.01 Clinical Alarm Management Questionnaire. Participants completed the survey electronically/anonymously via “Survey Monkey”. Electronic databases used for a literature review included Cochrane Reviews, National Guideline Clearinghouse, Agency for Healthcare Research and Quality, Dynamed, PubMed, CINAHL, MEDLINE. **Data Analysis:** “Survey Monkey” was used for descriptive/quantitative analysis of demographic and likert-scale survey measures. There was one qualitative survey response. **Results:** The majority of participants appear to be affected by AF on 78% of the AF survey measures. Thus, AF is likely a problem in this ICU. Additionally, results indicate that physiologic monitor alarms are most important to manage followed by ventilator, IV infusion pump, and bed exit alarms. **Recommendations:** Management can use these results when proceeding to NPSG.06.01.01 STEP 3 and STEP 4, which include establishing policies for managing alarms identified in STEP 2 and educating staff.

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Chapter 1: Statement of the Problem

Introduction

Alarm signals in hospitals today are essential to providing safe patient care, however, alarm signals can also create numerous challenges due to multiple similar sounds, mismanaged settings and equipment, and failure to respond, which can lead to patient harm rather than safety (American College of Clinical Engineering Healthcare Technology Foundation [ACCE], 2007; American Association of Critical-Care Nurses [AACN], 2013; Association for the Advancement of Medical Instrumentation [AAMI], 2011; Association for the Advancement of Medical Instrumentation Foundation & Healthcare Technology Safety Institute [AAMI & HTSI], 2012, 2013; Aztema & Schull, 2006; Chambrin et al., 1999; Cvach, 2012; Drew, Musters, Markham, & Samore, 2007; Emergency Care Research Institute [ECRI], 2007, 2011, 2012; Kowalsk, 2010a, 2010b; Lawless, 1994; Schmid et al., 2011; Siebig et al., 2010; The Joint Commission [TJC], 2013a; Tsien & Fackler, 1997). According to the AAMI (2011) and TJC (2013a), alarm signals can easily number in the thousands within one hospital unit and in the tens of thousands throughout the hospital every day. Alarm sources can include cardiac rhythm, vital signs, end-tidal carbon dioxide (CO₂), dialysis machine, ventilator, intravenous (IV) and feeding pumps, wound vacuum devices, call lights, sequential compression devices (SCDs), and bed settings amongst others (ACCE, 2007; AAMI & HTSI, 2012; ECRI, 2011, 2012, 2013; Phillips & Barnsteiner, 2005; Siebig et al., 2010; TJC, 2013a). Studies have shown that 80 to 99% of clinical alarms do not require intervention and can easily lead to desensitization, or alarm fatigue (AF) amongst clinicians (ACCE, 2007; AACN, 2013; AAMI & HTSI, 2012, 2013; Atzema &

Schull, 2006; Chambrin et al., 1999; Cvach, 2012; Drews et al., 2007; ECRI, 2012; Lawless, 1994; TJC, 2013a; Schmid et al., 2011; Siebig et al., 2010; Tsien & Fackler, 1997).

AF is a phenomenon that occurs when healthcare providers become overwhelmed and desensitized by a multitude of alarm noises from various clinical devices which can result in patient harm when *important* (i.e. actionable) alarm signals are inadvertently ignored or inappropriately adjusted (see Appendix A) (ACCE, 2007; AACN, 2013; AAMI, 2011; AAMI & HSTI, 2013; Atzema & Schull, 2006; Chambrin et al., 1999; Cvach, 2012; Drews et al., 2007; ECRI, 2007, 2011, 2012; Graham & Cvach, 2010; Kowalcsk, 2010a, 2010b; Lawless, 1994; Schmid et al., 2011; Siebig et al., 2010; TJC, 2013a, 2013b; Tsien & Fackler, 1997).

According to the AAMI (2011), there are a variety of AF interpretations which may include: 1) when a nurse or other caregiver is overwhelmed with 350 alarm conditions per patient per day; 2) when a patient can't rest with the multitude of alarm signals going off in the room; 3) when a true life-threatening event is lost in a cacophony of noise because of the multitude of devices with competing alarm signals, all trying to capture someone's attention, without clarity around *what* the someone is supposed to do; 4) when there are inconsistent alarm system functions (alerting, providing information, suggesting action, directing action, or taking action) or inconsistent alarm system characteristics (information provided, integration, degree of processing, prioritization); and 5) when systems failures occur that results from technology driving processes rather than processes driving technology (p. 3). Indeed, it is widely recognized that healthcare alarms are poorly designed (ACCE, 2007; Cvach, 2012; Phillips & Barnsteiner, 2005; Siebig et al., 2010; Xiao & Seagull, 1999). The ACCE (2007) points out that "best-practiced cognitive engineering and human factors strategies to improve patient safety are not always followed in current clinical alarm system designs" (p. 22).

Based in large part on this AF phenomenon, in June 2013, the TJC (2013b, 2013c) announced “Reduce[ing] the harm associated with clinical alarm systems” as a 2014 National Patient Safety Goal (i.e. NPSG.06.01.01) (p. 1). STEP 1 of the *Elements of Performance* for NPSG.06.01.01 or “performance elements” (see Appendix G) state that as of July 1, 2014, alarm management should have been made a priority by hospital leaders (TJC, 2013c). STEP 2 performance elements for NPSG.06.01.01 state that: during 2014, hospitals should specifically 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) consider risk to patients if the alarm signal is not attended to or if it malfunctions, 3) determine whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) integrate important published best practices and guidelines (TJC, 2013c, p. 7).

STEP 3 of NPSG.06.01.01 performance element requirements state that by January 1, 2016, hospitals will be expected to establish policies and procedures for managing the alarms identified in STEP 2 that, at minimum, addresses the following conditions: 1) appropriate clinical settings for alarm signals, 2) when alarm signals can be disabled, 3) when alarm parameters can be changed, 4) who in the organization has the authority to set alarm parameters, 5) who in the organization has the authority to change alarm parameters, 6) who in the organization has the authority to set alarm parameters to “off”, 7) who should monitor and respond to alarm signals, and 8) who should check individual alarm signals for accurate settings, proper operation, and detectability (TJC, 2013c, p. 7). Finally, STEP 4 NPSG.06.01.01 performance element requirements state that “as of January 1, 2016”, hospitals should “educate staff and licensed practitioners about the purpose and proper operation of alarm systems for which they are responsible” (TJC, 2013c, p. 7). TJC (2013b) also points out that while safe

alarm system management is bolstered by standardization, specific clinical unit customized solutions may also be necessary.

Background

AF can occur at any time and in any patient care environment in which there are clinical alarms sounding, particularly in areas with multiple alarms such as critical care areas. According to the ACCE (2007), the care of an intensive care unit (ICU) patient will typically involve six or more different alarm sounds with similar sounds having different meanings depending on the clinical device from which it originated. Stanton (1999) points out that humans typically have a difficult time learning more than six alternate alarm types and research has shown that even experienced clinicians cannot identify even 50% of re-played alarms (Cropp et al., 1994). The ACCE (2007) emphasizes that “The number and complexity of alarm systems in critical care environments challenge human limits for recognition and action” (p. 32).

The causes of AF are multi-factorial and may include: frequent false alarms, which can result from electrical artifact, disconnections, inappropriate amplitude settings and/or lead selection, or poor electrode application technique; numerous technical alarms, which can result from disconnections, damaged equipment, dead batteries, and/or poor signal detection; inappropriate or poor protocols regulating inactivation of alarms and/or poor training of healthcare staff related to alarm management protocols; inappropriate alarm limits and settings, which can result from lack of, or poor policies regulating these practices to include the training of healthcare staff; and even due to the overutilization of physiologic monitoring in patients that may not justifiably require such monitoring, which can result from lack of, or poor policies guiding the utilization of physiologic monitoring and lack of knowledge or education on the parts

of ordering providers (ACCE, 2007; AAMI & HTSI, 2012, 2013; ECRI, 2007, 2013; Graham & Cvach, 2010; Patel & Souter, 2008; Siebig et al., 2010; TJC, 2013b).

The AAMI and HTSI (2013) point out that, “Nuisance alarms are either false alarms or technical alarm conditions that have no significant patient health consequence and are non-actionable, requiring a response albeit not in relation to a life threatening event” (p. 5).

Furthermore, according to the ECRI (2013), “any circumstance that results in the failure of staff (1) to be informed of a *valid* alarm condition in a timely manner or (2) to take appropriate action in response to the alarm can be considered a clinical alarm hazard” which can lead to AF and patient harm (p. 3). Such patient safety hazards may specifically include “inappropriate alarm modification, alarm fatigue, modifying alarms without restoring them to their original settings, and improperly relaying alarm signals to the appropriate person” (ACCE, 2007; ECRI, 2010; Cvach, 2012, p. 268).

It is widely recognized that healthcare alarms are poorly designed (ACCE, 2007; Cvach, 2012; Phillips & Barnsteiner, 2005, p. 318; Siebig et al., 2010). Cvach (2012) emphasizes that “Physiologic monitor alarms are purposefully designed for high sensitivity” so that a true event is not missed (p. 269). In fact, Chambrin et al. (1999) found the sensitivity of monitor alarms to be 97% while specificity was only 58% with a positive predictive value of only 27% and a negative predictive value of 99%! What’s more, the ACCE (2007) points out that International Standard IEC 60601-1-8 guidelines, which are the only standards available and intended to be applied to all medical device alarm systems, “are not widely implemented in medical devices and hospitals” (p. 27). The ACCE (2007) describes that International Standard IEC 60601-1-8 is a guideline that “specifically defines the characteristics of visual and audible alarm signals that can be used to prioritize the degree of urgency for all alarming devices”; however, some device

vendors still provide hospitals “with the option to use the IEC-defined alarm tones or the device vendor’s own proprietary alarm scheme” (p. 27). International Standard IEC 60601-1-8 states that “The purpose of alarm systems is to communicate ‘information that requires a response or awareness by the operator’” (ACCE, 2007, p. 22). In light of this information, it is also important to note that AF is typically the leading cause of alarm-related sentinel events and alarm-related deaths are likely ten times higher than current estimates due to the limitations of typical incident reporting systems (AAMI, 2011; TJC, 2013a). Thus, for three years in a row, the ECRI (2011, 2012, 2013) has named “alarm hazards” as number one on their annual list of the “Top 10 Health Technology Hazards”, recognizing it as major patient safety issue.

Significance

Considering the above information, the AF problem is significant to nursing practice because it can directly impact bedside nurses and advanced practice registered nurses (APRNs) in their roles as patient caregivers while subsequently negatively impacting the care, recovery, safety, and health of patients. AF is also a significant problem for APRNs who are tasked with organizational and systems leadership for quality improvement and risk management to include the safe and effective use of patient care technology (American Association of Colleges of Nursing, 2006). Interdisciplinary collaboration in the management of clinical alarm systems is essential to addressing the systemic problem of AF in order to meet the requirements and ultimate goal of NPSG.06.01.01 which is to “Reduce the harm associated with clinical alarm systems” (TJC, 2013c).

Problem Statement

Hospital clinicians, particularly bedside healthcare providers in critical care environments, are vulnerable to AF on a continuous basis while providing patient care, and consequently, their patients are vulnerable to the harms associated with this phenomenon.

Indeed, AF is typically the leading cause of alarm-related sentinel events and is recognized by healthcare governing agencies as a major patient safety hazard (AAMI, 2011, ECRI, 2011, 2012, 2013; TJC, 2013a). The AF phenomenon has prompted TJC (2013b, 2013c) to proclaim alarm management as a 2014 NPSG with the goal of reducing the harm associated with clinical alarm systems. Thus, in accordance with TJC NPSG.06.01.01 requirements, prioritizing hospital alarm system safety and then identifying the most important alarm signals to manage are imperative first steps towards decreasing AF amongst patient care staff and reducing the harm associated with clinical alarm systems.

Project Aims

The overall aims of this project were to assess measures of AF amongst ICU clinical staff and to complete STEP 2 performance elements of NPSG.06.01.01 for the project ICU which are to identify: 1) the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) published best practices and guidelines (TJC, 2013c, p. 7).

Project Objectives

The project objectives were to:

1. Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage.
2. Identify the most important alarm signals to manage in the project ICU based on data gathered from the hospital's administration regarding the potential for patient harm based on internal incident history.

3. Identify the most important alarm signals to manage based on published best practices and guidelines.

Chapter 2: Project Description

Literature Review

World Health Organization recommendations governing noise in hospitals (i.e. 35 decibels [dB] during the day and 30dB at night) are far exceeded in the majority of hospitals which can ultimately create hazards for staff and patients (Bush-Vishniac, West, & Barnhill, 2005; Cvach, 2012; Ryherd, Persson, & Ljungkvist, 2008). Ryherd et al. (2008) found that noise can contribute to symptoms of stress amongst clinical staff including fatigue, problems with concentration, and headaches. A survey conducted by Korniewicz, Clarke, & David (2008), with a goal to “gain reliable information on the extent to which the management of clinical alarms is a problem in hospitals”, showed that the majority of responders “identified nuisance alarms as problematic, with the large majority agreeing or strongly agreeing that they occur frequently (81%), disrupt patient care (77%), and can reduce trust in alarms and cause caregivers to disable them (78%)” (ACCE, 2007, p. 28). One respondent stated that “False alarms take up a large portion of the bedside care provider’s time. If these alarms could be significantly reduced, staff would see the benefit of alarms, respond more readily and quickly, and embrace the technology” (ACCE, 2007, p. 31).

A study by Johns Hopkins Hospital, a 1,051-bed teaching hospital in Baltimore, Maryland, revealed a frequency of 58,764 alarms over one 12-day period, equating to 350 alarms per bed per day (AAMI & HTSI, 2012). The study also showed that the hospital ICUs were the noisiest areas with the average number of alarms per bed per day in one ICU being 771 (AAMI & HTSI, 2012)! Johns Hopkins researchers concluded that the contributing factors to the

excessive alarm conditions were that: 1) Alarm parameters were not set to actionable levels, 2) Alarm thresholds were set too tight resulting in too many false positives, 3) Staff working in large clinical units did not have clear accountability to respond to alarm conditions, 4) Too many duplicate alarm conditions desensitized staff to alarm signals, and 5) Lengthy time-lags between installation of devices and staff training on those devices did not allow for staff to become accustomed to the auditory alarm signals of new equipment (AAMI & HTSI, 2012, p. 4).

Another study conducted by the University of Pittsburgh Medical Center Presbyterian Hospital (UPMC), which is a 737-bed hospital located in Pittsburgh, Pennsylvania, found that alarms consistently pulled nurses away from direct patient care and were often too numerous for a quick response (AAMI & HTSI, 2013). During a 10-day observation period on an 18 bed medical cardiology unit, researchers from the UPMC performed an alarm signal analysis and found that the majority of the alarm signals were “midlevel, non-life-threatening arrhythmia” alarms ranging from 247 to 1565 signals per day with the average being 871 non-life threatening/non-actionable alarm signals per day (AAMI & HTSI, 2013, p. 5). The UPMC researchers found that “most alarm signals...had no significant health consequences” and “had become background noise” for “desensitized” clinical staff members (AAMI & HTSI, 2013, p. 5).

Another UPMC study in a medical cardiology and a progressive care unit showed that non-life threatening arrhythmia alarms occurred on average once every 96 seconds for a total occurrence of 83 times per patient per day (AAMI & HTSI, 2013). A nursing research team reviewed ten days of alarm signal data on all non-life threatening alarm conditions collected from cardiac monitors on the two units and concluded that there were too many alarm signals for nurses to differentiate between (i.e. life threatening versus non-life threatening/nuisance), alarms

occurred too frequently for quick response, and that “workflow was interrupted and inefficient due to the time and attention that nurses had to spend responding to alarm signals” (AAMI & HTSI, 2013, p. 6).

Furthermore, AF can occur in any healthcare setting with clinical alarms and has been found to be the leading contributing factor to alarm-related sentinel events (AAMI, 2011; ECRI, 2007, 2012, 2013; TJC, 2013a). Between January 2009 and June 2012, TJC’s sentinel event database reported 98 alarm-related sentinel events while the US Food and Drug Administration’s (FDA) (2011) Manufacturer and User Facility Device Experience (MAUDE) database showed 566 alarm-related patient deaths between 2005 and 2008; however, as previously described, alarm-related events are underreported (AAMI, 2011; Cvach, 2012; ECRI, 2013; TJC, 2013a). Another review of the MAUDE database from March 2010 to June 2010, showed 73 alarm related deaths, 33 of which were attributed to physiologic monitor alarms (Cvach, 2012). According to the ACCE (2007), “For physiologic monitors, there are numerous reports of critical patient events in which the monitoring system was reported to not produce an alarm. Many of these reports were subsequently investigated...to find that alarms had somehow been inadvertently disabled” (p. 24).

Of the 98 Joint Commission (2013a) alarm-related sentinel events described above, 94 occurred in the hospital setting, mostly within telemetry, ICU, emergency department (ED), and general medicine environments, with 80 leading to death and 13 to permanent loss of function (ECRI, 2013). Common types of alarm-related events that resulted in death or injury involved falls, medication errors, ventilation use, and treatment delays with major contributing factors being “alarm settings inappropriately turned off (36)”, and “improper alarm settings (21)” (TJC, 2013a, p. 2). TJC (2013a) also describes “alarm settings that are not customized to the

individual patient or patient population” as contributing to alarm-related sentinel events (p. 2).

According to Maria Cvach, RN, Assistant Director of Nursing, Clinical Standards at John Hopkins Hospital,

We in healthcare have created the perfect storm with all of these monitoring devices...In hospitals today, we have too many alarming devices. The alarm default settings are not set to actionable levels, and the alarm limits are set too tight. Monitor alarm systems are very sensitive and unlikely to miss a true event; however, this results in too many false positives. We have moved to large clinical units with unclear alarm system accountability...and duplicate alarm conditions which desensitize staff (AAMI & HTSI, 2012, p. 3).

In June 2013, the TJC (2013b, 2013c) announced “clinical alarm safety for hospitals and critical access hospitals” as a 2014 NPSG and as of July 2014, alarm management was required to be made a hospital priority (ECRI, 2013; p. 1, 3). Hospitals were then expected to identify “the most important alarm signals to manage” in their own hospitals based on 1) input from the medical staff and clinical departments; 2) risk to patients if the alarm signal is not attended to or if it malfunctions; 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF; 4) potential for patient harm based on internal incident history; and 5) published best practices and guidelines (TJC, 2013c, p. 7).

By January 1, 2016, hospitals will be expected to establish policies and procedures for managing the alarms identified as clinically important which should address “clinically appropriate settings for alarm signals” and “default alarm settings and the limits appropriate for each care area” particularly “in high-risk areas and for high-risk clinical conditions” amongst other specific requirements (TJC, 2013a, p. 2, 2013b, p.3). TJC (2013b) also points out that safe

alarm system management strategies “may have to be customized for specific clinical units” (p. 3). In cooperation with the AAMI and the ECRI, TJC (2013a) also recommends establishing a multidisciplinary team to tackle the AF problem including stakeholders from patient care, clinical engineering, information technology, and risk management (ECRI, 2013, p. 3).

The project hospital a Joint Commission accredited 276 bed rural community hospital located in the State of Hawaii’s “Big Island” hereafter referred to as The Hospital (HMC, 2014). The Hospital currently has many alarm equipped patient care areas including operating rooms, a post-anesthesia care unit, short-stay unit, cardiovascular unit, obstetrics unit, ICU, and ED; thus, The Hospital will have to abide by TJC NPSG.06.01.01 performance element requirements described herein. However, according to The Hospital’s Director of Quality Management, there were not any specific policies guiding clinical alarm system management in any patient care area, including the ICU, thus, much work was to be accomplished in order to abide by TJC (2013b, 2013c) requirements in a timely manner (personal communication, August 10, 2013). According to The Hospital’s Director of Quality Management, as of August 2013, The Hospital had already established alarm system management as an organizational priority due to the 2014 Joint Commission NPSG.06.01.01 and was in the preliminary stages of tackling this quality improvement project (personal communication, August 10, 2013).

General Clinical Alarm Management Strategies. According to many patient safety authorities, clinical alarm management strategies must first start with the support of leadership who must recognize unmanaged clinical alarms as a major patient safety hazard, establish alarm management as an organizational priority, and dedicate the resources required to manage the issue (AAMI, 2011; AAMI & HTSI, 2012; ACCE, 2007; ECRI, 2007, 2012; TJC, 2013a, 2013b, 2013c). Furthermore, alarm management planning strategies must involve a multidisciplinary

team approach throughout the process to include involvement by industry regulators, key medical staff, nurse managers, frontline patient care staff, patient safety officers, risk management, informatics experts, device vendors, and biomedical/clinical engineering (AACN, 2013; AAMI, 2011; AAMI & HSTI, 2012; ACCE, 2007; ECRI, 2007, 2011, 2013; TJC, 2013a, 2013b; Wiklund & Kendler, 2011).

Furthermore, when alarm-equipped medical devices are evaluated for adoption by organizations, the *needs* important to the healthcare organization's clinical processes should drive the technology choice rather than allowing technology to drive an organization's clinical processes (AAMI, 2011; TJC, 2013a). The ACCE (2007) states that

Healthcare institutions purchasing devices and systems with alarms should carefully evaluate the potential for devices to reduce false alarms and other cited problems through intelligent processing of incoming signals, the use of 'smart alarm' technology, ease of use, usability and human factors design principles, and application of standardization and systems engineering measures (p. 33).

According to the AAMI (2011), alarm equipped healthcare technology should reliably draw attention to and detect true events that require intervention; state the problem, potential consequences, and communicate the important elements and/or corrective action with clear words or simple images and/or animations; and should enable the user to perform the corrective action with ease.

Researchers from Johns Hopkins also recommend gathering data by asking the right questions of unit managers and clinical staff such as: 1) Where are the alarm conditions coming from?, 2) What is the bed number?, 3) Who is the patient?, 4) Why alarm signals are sounding - what is the cause?, 5) How long are alarm signals sounding?, 6) How many alarm signals are

occurring in units?, 7) When an alarm signal goes off, what do you do?, 8) When an alarm goes off, how do you hear it?, 9) What is the average number of patient alarm conditions per bed, per day?, 10) What is the workflow of a clinical unit e.g., backup notification, nurses per unit, assignments, etc.?, and 11) What is the clinical significance of an alarm condition? - Determine high/low priority alarm conditions along with high/low risk alarm conditions (AAMI & HSTI, 2012, p. 7).

Alarm management experts also recommend 1) capturing quantitative baseline data possibly from network frequency logs that have the ability to track device alarm messages in order to analyze alarm conditions and to Compare pre- and post- data for improvement measurements; 2) observing and distinguishing between alarm conditions and patterns and defining alarm condition types (e.g., false, true, nuisance, inactionable, etc.) and assure that definitions are understood by unit staff; 3) incremental unit based revisions of default alarm parameters to actionable levels including implementation of acceptable generation delays prioritizing and differentiating which signals should be visual versus auditory; and 4) implementing alarm setting safety checks (ACCE, 2006; AAMI, 2011; AAMI & HSTI, 2012, p. 7; ECRI, 2007, 2012; Phillips & Barnsteiner, 2005).

Additional alarm management strategies recommended by Johns Hopkins researchers include: 1) focusing on the key metric of average number of alarm conditions per patient per day; 2) recognizing that technologies are not perfect and so new equipment should be tested to ensure proper alarm settings; 3) considering more than one alarm signal notification technology such as a user-based monitor watch group, wireless notification devices/pagers, or split screen monitors since no one technology works in every unit across the hospital; and to 4) develop alarm system management policies (AAMI & HSTI, 2012, p. 8). Alarm management policy and procedures

include recommendations that they be based on clinical evidence and describe which alarms should be activated; default limits and parameters; customizing of alarms based on patient needs; when alarm parameters can be changed from their default settings or can be disabled or turned off and by whom; and when and who is responsible for monitoring, responding to, and ensuring proper settings, detectability, and operation of clinical alarm signals such as the assigned caregiver, including who is responsible for backup response (AAMI, 2011; ACCE, 2006; Cvach, 2012; ECRI, 2007, 2012, 2013; Graham & Cvach, 2010; Phillips & Barnsteiner, 2005; TJC, 2013b, 2013c).

Cvach (2012) emphasizes that “If the alarm that is being generated is considered insignificant, then it should never be activated because the most that it can do is provide noise” (p. 272). Recommendations also include utilization of password protection technology to control alarm system setting modification such as silencing, modification, and disabling of alarm equipped medical devices and that alarms should not be inactivated until the patient has been assessed and the cause of the alarm has been addressed (AAMI & HSTI, 2013; ECRI, 2012). The AAMI (2011) also recommends considering integrating rapid response and code teams into alarm condition response protocols (p. 17). Alarm management experts further recommend development of continuous improvement processes for alarm system policies (AAMI, 2011, p. 7, 15; ECRI, 2012, p. 5).

In addition, experts recommend that the physical layout of each alarm-equipped patient care area; staffing levels, care models, and patterns; and the ability of staff to hear clinical alarms should be assessed to ensure that alarms are audible and can be received wherever clinicians are (ACCE, 2006, 2007; AAMI, 2011; AAMI & HSTI, 2012; ECRI, 2007, 2012; Phillips & Barnsteiner, 2005; TJC, 2013a; Zwieg et al., 1998). Cvach (2012) points out that when the

audibility of alarms could become an issue, such as when patient room doors are closed or when floors are being buffed, additional alarm notification adjuncts should be used. Various alarm notification models could include *on-floor monitoring* in which a responsible caregiver is notified directly via a medical device alarm, pager, and/or via a human monitor watcher as well as *remote monitoring* in which an outside area human monitors alarms (Cvach, 2012; ECRI, 2007).

In addition, pagers or middleware systems can be linked to alarm producing medical devices wirelessly and can be programmed to include delays and alarm escalation (Cvach, 2012, p. 272; Dyell, 2012). The ACCE (2007) points out that alarm pagers can be valuable if well-designed, however, if used as the primary alert method, can lead to problems as previously described (p. 32). Johns Hopkins officials point out the shortcomings of such devices stating that “With mobile wireless devices, caregivers need a [visual] waveform to provide clinical context for the alarm condition” (AAMI & HSTI, 2012, p. 8). The ACCE (2007) points out a Veterans Health Administration July 2, 2004 Patient Safety Alert which stated that “ ‘medical alarm systems using paging technology are not designed or intended to be used as the primary method for alerting clinical staff of critical alarms conditions nor are they approved for this use by the FDA’ ” (p. 27). Furthermore, unless alarm parameters are customized, pagers can actually increase the false alarm rate when compared to a dedicated monitor watcher (ACCE, 2007; Cvach, 2012; Zweig et al., 1998).

Next, although the use of marquee signs or monitor screens intended to notify clinical staff of patient waveforms and alarms in areas with long hallways and dispersed geography can create issues of patient confidentiality, patient identifiers *can* be removed from such devices (Cvach, 2012, p. 272; ECRI, 2007; Philips, 2006). Johns Hopkins officials also point out the

flaws of such devices including that “Waveform screens in hallways can increase noise...and don’t address lower priority alarm conditions” (AAMI & HSTI, 2012, p. 8). Additionally, alarm notification to patient care givers is best when given in contextual terms and using closed-loop communication (Cvach, 2012; Gee & Moorman, 2011; Moorman & Gee, 2011).

The ACCE (2007) states that, “In general, alarms are a tool in assessing patient conditions and should be used in conjunction with direct clinical measurements and observations” (p. 32). What’s more, alarm management strategies should also include identification of situations when alarm signals are not clinically necessary and developing guidelines for modifying alarm settings for specific patient types to include only monitoring patients with a medical necessity for monitoring based on practice standards (AACN, 2013; AAMI, 2011; Drew et al., 2005; ECRI, 2007; TJC, 2013a, 2013b). Furthermore, the most important alarm signals to manage should be determined based on the risk to patients if the alarm is not heard or malfunctions and based on alarm related hospital incident trends (AAMI, 2011; TJC, 2013b, 2013c). Bliss, Fallon, and Nica (2007) also point out that requiring documentation of alarm parameters in the medical record may improve alarm adjustment compliance amongst clinical staff.

Once alarm management policies are approved, patient care staff must receive initial formal, standardized education and training covering the safe and proper use of the alarm equipped medical devices for which they are responsible. Plans should be in place (or developed) for routine (i.e. such as annual) ongoing education and training, to include new staff such as per diem, temporary, or traveling nurses including when any new alarm-equipped medical devices are purchased (ACCE, 2006, 2007; AACN, 2013; AAMI, 2011; AAMI & HSTI, 2012; ECRI, 2007, 2012; Phillips & Barnsteiner, 2005; TJC, 2013a, 2013b). In order to avoid

the possibility of patient harm, training should be conducted in a simulated environment, similar to the actual patient care environment, and involve interactive, hands on training (ACCE, 2007; AAMI, 2011). The ACCE (2007) points out that plans for the procurement of new alarm-equipped technology must include specific budgeting and time for the training of clinicians who will use the technology including budgeting and time for refresher training of such staff. Education for clinical engineering and nursing staff covering how to assess for malfunctioning equipment that may need to be replaced and/or repaired is also recommended (ECRI, 2007; Patel & Souter, 2008).

Additional strategies for alarm management should also include the regular maintenance and inspection of alarm-equipped medical devices in order to ensure appropriate alarm settings and safe operation based on manufacturer recommendations, current experience, and risk levels (Patel & Souter, 2008; TJC, 2013a). In addition, processes should be in place to identify and respond to actual or potential technology hazards including reporting, tracking, trending and investigation of event reports (ECRI, 2012). Finally, UPMC administrators emphasize that “Even if a health system throws a million dollars in time, expertise or software at the problems associated with alarm management, there is no easy fix or one-size-fits-all solution” (AAMI & HSTI, 2013, p. 8).

Management of Physiologic Monitor Alarms. In the management of physiologic monitors, many patient safety authorities recommend first preparing an inventory of the type of physiologic monitors in use in high-risk clinical areas and for high-risk clinical conditions and then to determine the appropriate default alarm settings, limits, and priority levels (i.e. high, medium, low), with the understanding that safe alarm system management is bolstered by standardization but may have to be customized for specific patient groups, care areas, and even

individual patients (AACN, 2013; AAMI, 2011; Cvach, 2012; ECRI, 2007, 2012; Phillips & Barnsteiner, 2005; TJC, 2013a, 2013b). Indeed, Cvach (2012) points out that “if monitor parameter thresholds are set too tight, true but clinically insignificant alarms may occur” (p. 269).

Additional recommendations from Johns Hopkins researchers, include: first, determining how severe the problem may be by conducting a Fault Tree Analysis in order to understand timely or critical physiologic alarm response failures and/or via accessing and extracting key data such as “bed number, purpose, and timeframe/length of alarm condition” and by identifying and using “a key metric” such as “average number of alarm conditions per bed per day”; setting goals such as eliminating “30% of alarm conditions throughout the hospital”; then, sharing these goals with all stakeholders such as “clinicians, administration, clinical engineers and biomed technicians, and other key staff”; and, finally, understanding the systematic, institution-wide nature of the problem and “the resolution...as long-term and on-going” (AAMI & HSTI, 2012, p. 5).

In a study by Graham and Cvach (2010), conducting “small tests of change” during an 18-day period on a 15-bed medical progressive care unit by altering physiologic monitor alarm parameters and limits to actionable levels showed that the baseline number of high priority alarms decreased by 43% from 16,953 to 9,647 alarms (Cvach, 2012). During the study, duplicate alarms were eliminated (i.e. heart rate high versus tachycardia), alarm limits were adjusted to actionable levels, and patient specific parameter limits were individualized (Cvach, 2012).

Similarly, a study by Gross et al. (2011) found that non-actionable alarms could be substantially decreased by setting appropriate patient population alarm limits such that increasing

the heart rate limit from 120 to 130 would have resulted in a 50% decrease in heart rate alarms!

In an effort to decrease the number of non-actionable clinical alarms, another study conducted by the UPMC on a medical cardiology and progressive care unit set non-life threatening informational alarms on physiologic monitors to “OFF” and allowed only heart rate parameters and life-threatening arrhythmias to produce an alarm signal (AAMI & HSTI, 2013). As a result of these efforts, overall alarm signal time was reduced by approximately 80 percent (AAMI & HSTI, 2013)!

Based on the positive results of this UPMC pilot study and due to a lack of evidence-based protocols for customizing alarm signals for various patient populations, UPMC officials attempted to replicate their efforts across other hospital units. These efforts subsequently resulted in the development of an evaluation tool called the Eight Critical Elements to Monitor Alarm Competency (AAMI & HSTI, 2013). Development of the tool involved a task force that identified common essential elements required for physiologic monitor management competency followed by two alarm management educational sessions attended by a nursing representative from each hospital unit (AAMI & HSTI, 2013). The tool can be used across clinical departments regardless of the type of physiologic monitors used and requires that staff demonstrate how to: 1. Admit a patient in the cardiac monitoring system; 2. Discharge a patient from the cardiac monitoring system; 3. Review alarm settings; 4. Customize alarm settings [based on a patient’s clinical condition] and document these settings in the electronic health record; 5. Properly place leads on a monitored patient; 6. Correctly load ECG paper in the machines; 7. Appropriately put patient monitors in stand-by mode versus alarm signal suspend mode; and 8. Set monitors to correctly identify a pacemaker implanted in a patient (AAMI & HSTI, 2013, p. 8).

The nursing representatives then incorporated the eight essential elements into a unit-based competency process and reviewed the competency process with staff annually (AAMI & HSTI, 2013). Nurses and medical technicians throughout the UPMC are now required to undergo this annual competency review of the eight critical elements as well as to take a written exam, and a hands-on observation exam for those clinicians responsible for managing patients (AAMI & HSTI, 2013). These clinicians must also review how to communicate patient alarm parameter changes from one shift to another (the UPMC process for face-to-face information handoff between shift nurses occurs at the patient's bedside and includes a review of the patient's alarm parameters) (AAMI & HSTI, 2013). The UPMC also began holding Nursing Grand Rounds during which discussion on how to address AF and improve alarm recognition and awareness now takes place (AAMI & HSTI, 2013).

The new UPMC alarm management protocol has not negatively impacted patient care or resulted in an increase in adverse patient events related to the reduction of alarm signals (AAMI & HSTI, 2013). What's more, prior to implementation of the competency training at the UPMC, 33% of hospital nurses rated themselves as "not confident" in one or more aspects of monitor functionality, and less than half of the hospital units had a unit-based monitor competency process (AAMI & HSTI, 2013). Post survey results of UPMC nurses showed a 13% decrease in the number of nurses who rated themselves "not confident" in one or more aspects of monitor functionality (AAMI & HSTI, 2013). Ultimately, UPMC administrators found that "On-going reinforcement and education for nursing staff on customizing heart rate alarm settings specific to a patient's baseline is crucial for reducing the frequency of alarm signals" and "Defaulting non-life threatening alarms to 'OFF' can have a positive effect on unit noise level" (AAMI & HSTI, 2013, p. 10).

In light of their experiences tackling physiologic monitor alarm management, UPMC researchers recommend: 1) measuring the time nurses are spending on responding to alarm signals; 2) deciding on a measure that will determine the number of signals nurses are responding to (e.g., signals per unit - per bed - per day) and then to collect, document, and analyze the data; 3) prioritizing conditions that require an alarm signal and determining those that are non-actionable, non-life threatening and/or nuisance; 4) re-setting alarm parameters according to your priorities; and 5) determining who on your staff has authority to set or re-set alarm parameters (e.g., nursing staff) (AAMI & HSTI, 2013, p. 7). Other experts similarly recommend identifying which clinical alarms are “actionable”, eliminating “no-action” alarm conditions, and also assessing the feasibility of implementing a 10-19 second auditory alarm-signal delay or “hold-off” for self-correcting physiological alarm conditions other than apnea or asystole alarms (AAMI, 2011, p. 7; Gorges, Markewitz & Westenkow, 2009).

Cvach (2012) points out that “alarms often self-correct” and “adding short delays can significantly decrease the number of ignored or ineffective alarms, which are often caused by suctioning, washing, repositioning, and oral care” (p. 271). The AAMI (2011) also recommends developing “a one-step way to tailor alarm limits around a patient’s baseline parameters”, pointing out that the majority of ICU physiologic monitors have this capability but that many clinicians are not trained on many of the functions of the monitors that they use (p. 15). UPMC researchers also recommend: 1) conducting alarm competency classes with a curriculum focused on how alarm signals can be customized; 2) holding Nursing Grand Rounds with a focus on how to address AF and improve alarm recognition and awareness; 3) looking for commonalities across units and departments; and 4) establishing an evaluation protocol of your own or adopting UPMC’s Eight Critical Elements to Monitor Alarm Competency (AAMI & HSTI, 2013, p. 9).

Additional physiologic monitor alarm management recommendations include that alarms be customized to actionable limits and levels within one hour of assuming patient care and as needed thereafter as a patient's condition changes; and that hospital organizations consider a culture of suspending alarms before performing patient care activities that could create false alarms, such as when removing patients from monitors briefly, when providing oral care, when replacing ECG electrodes, or when repositioning, suctioning, or bathing patients (AACN, 2013; Chambrin et al., 1999; ECRI, 2007; Gorges, Markewitz & Westenkow, 2009; Graham & Cvach, 2010; Gross et al., 2011; Phillips & Barnsteiner, 2005; Tsien & Fackler, 1997; Zwieg et al., 1998). The ECRI (2007) points out that the length of time for alarm suspend settings can be programmed into physiologic monitors and that the *monitor standby* function should be used when patients are removed from monitoring for an extended length of time, such as when patients leave a unit to have a procedure, and should be programmed to automatically turn back on when a patient is reconnected if possible.

Furthermore, unless contraindicated, changing disposable sensors, such as electrocardiograph (ECG) electrodes and pulse oximetry sensors, according to manufacturer recommendations will aid in decreasing unnecessary alarms (AAMI, 2011; TJC, 2013a). In addition, many sources recommend considering *smart alarm* technology prior to purchase of any new physiologic monitor systems since such devices take into consideration “multiple parameters, rate of change,...signal quality [and] can reduce the number of false alarms” (ACCE, 2007; AAMI & HSTI, 2012; Biot et al., 2003; Burgess et al., 2009; Cvach, 2012, p. 271; Gross, Dahl, & Nielson, 2011; King et al., 2010; Otero et al., 2009; Schmid, 2011). Johns Hopkins researchers emphasize that “single parameter alarm conditions are simplistic and subject to

artifact...Everyone agrees that multi-parameter ‘smart’ alarm conditions are badly needed” (AAMI & HSTI, 2012, p. 10).

Management of ECG Alarms. The literature points out that ECG monitoring devices are typically sensitive, having single parameter alarm threshold limits, and thus, are not specific, which results in frequent false alarms (Cvach, 2012; Drew et al., 2005). Experts recommend many strategies to improve the quality of ECG monitoring including to ensure that cardiac monitoring parameters are clinically significant, that parameters are set according to patient baselines, and to have dedicated staff to monitor such patients (AAMI & HSTI, 2013; ACCE, 2007; Drew et al., 2005). Drew et al. (2005) points out that having qualified, dedicated monitor watchers on each patient unit is ideal, compared to having one monitor watcher responsible for many patient units, in which case one monitor watcher would have to contact outside units via phone or pager to notify responsible staff of significant cardiac rhythms. Drew et al. (2005) also claims that alarm pagers that display patient rhythms or monitor screens that are visible throughout a unit could also be used if dedicated monitor watchers are infeasible. Another option to a dedicated monitor watcher described by Drew et al. (2005) includes investing in “state-of-the-art” cardiac monitoring and training staff to use such systems to their fullest potential.

Drew et al. (2005) also recommend that medical and nursing leadership of cardiac monitoring units determine the knowledge and skill proficiencies that staff should have for the population served to include formal didactic and hands on orientation and ongoing education, training, and practice to include return demonstration. Experts recommend that staff be competent in basic electrophysiology, cardiac arrhythmias, correct ECG lead application, cardiac monitor functions, and monitoring goals (ACCE, 2007; Drew et al., 2005).

For example, cardiac monitoring electrodes should be placed on the chest rather than on limbs and bony prominences, fatty areas, or major muscles like the diaphragm (AACN, 2013; AAMI, 2011; ECRI, 2007; Patel & Souter, 2008). Drew et al. (2005) explains that right arm electrodes should be placed in the infraclavicular fossa close to the right shoulder, left arm electrodes should be placed in the infraclavicular fossa close to the left shoulder, left leg electrodes should be placed below the rib cage on the left side of the abdomen, and the ground or reference electrode can be placed anywhere, but it is usually placed on the right side of the abdomen (see Appendix F).

Proper ECG lead application is important in order to decrease false technical alarms, which constitute a large proportion of alarms, and should include assessing ECG electrodes for integrity (i.e. that they are not dried out or expired); proper skin preparation to include removing hair, washing with soap and water, and then wiping off with a rough washcloth or gauze to remove dead skin and oil; avoiding alcohol wipes; and drying the skin before applying ECG electrodes (AACN, 2013; AAMI, 2011; ACCE, 2007; AHA, 2005; Clochesy, Cifani, & Howe, 1991; Cvach, 2012; ECRI, 2007; Medina, Clochesy, & Omery, 1989; Patel & Souter, 2008).

Furthermore, ECG lead wires should be positioned to avoid tension (including from patient movement) which could lead to disconnection and false alarms (ECRI, 2007). If significant patient movement is expected, leads should be secondarily secured by taping the lead wire to the patient's skin near the electrode with a single piece of tape and allowing for some slack between the electrode and taped section of the lead wire (ECRI, 2007). In addition, if there are repeatedly *leads-off* alarms, properly re-prepping the patient's skin and applying new ECG electrodes should be considered (ECRI, 2007). If *leads-off* alarms are continually a problem despite correct skin preparation and ECG lead placement and function, hospitals should consider

trialing different brands or types of ECG electrodes to determine if a new product adheres better to patients' skin (ECRI, 2007). Furthermore, lead sets should be replaced if they continually detach from the electrode due to old-age and/or hospitals should consider disposable leads or routinely replacing lead sets (i.e. every one to two years) to avoid false alarms due to old-age (AAMI & HSTI, 2012; ECRI, 2007; Patel & Souter, 2008).

Studies have also shown that changing electrodes and telemetry pack batteries every 24 hours can substantially decrease unnecessary alarms (AAMI & HSTI, 2012, 2013; Cvach, 2011). In addition, ECG monitoring leads should be carefully chosen to ensure a signal amplitude high enough to avoid false asystole alarms due to low signal amplitude and to ensure the highest R-wave amplitudes compared to P- or T-wave amplitudes in order to avoid false high heart rate alarms (AACN, 2013; ECRI, 2007).

Regarding ST segment monitoring specifically, Drew et al. (2005) recommend evaluating the ST segment with the patient in the supine position, using indelible ink to mark where electrodes are placed on the patient so that they can be replaced in the same location, and that if electrodes must be moved from their original location due to skin breakdown, that this information be noted in the patient's medical record and directly onto cardiac rhythm strips. Furthermore, Drew et al. (2005) recommend that for high risk patients, ST segment alarm parameters be set 1 mm above and below the baseline and at 2 mm in more stable, active patients in order to decrease false alarms.

Drew et al. (2005) also provide specific guidelines regarding the patient conditions that warrant *Cardiac Arrhythmia Monitoring*, *ST-segment Ischemia Monitoring*, and *QT Interval and ECG Monitoring for Detection of Proarrhythmia* and guidelines regarding which patients do not require such monitoring. According to Drew et al. (2005), patients in each of these categories

should be separated into *Class I*, *Class II*, and *Class III*. Drew et al. (2005) state that most *Class I* patients require cardiac monitoring; some, but not all, *Class II* patients require cardiac monitoring; and cardiac monitoring is not indicated for *Class III* patients. Drew et al. (2005) claim that *Class I Cardiac Arrhythmia Monitoring* patients “includes all patients at significant risk of an immediate, life-threatening arrhythmia” and so require continuous ECG monitoring including transportation “with a portable, battery-operated monitor-defibrillator used by a healthcare provider who is skilled in ECG interpretation and defibrillation” (p. 78-79).

According to Drew et al. (2005), *Class I Cardiac Arrhythmia Monitoring* patients are divided into 16 subcategories including *Patients Who Have Been Resuscitated From Cardiac Arrest*, *Patients in the Early Phase of Acute Coronary Syndromes* (ST Elevation or Non-ST-Elevation MI), *Unstable Angina ‘Rule-Out’ MI*, *Patients With Unstable Coronary Syndromes and Newly Diagnosed High-Risk Coronary Lesions*, *Adults Who Have Undergone Cardiac Surgery*, *Children Who Have Undergone Cardiac Surgery*, *Patients Who Have Undergone Non-urgent Percutaneous Coronary Intervention With Complications*, *Patients Who Have Undergone Implantation of an Automatic Defibrillator Lead or a Pacemaker Lead and Are Considered Pacemaker Dependent*, *Patients With a Temporary Pacemaker or Transcutaneous Pacing Pads*, *Patients With AV Block*, *Patients With Arrhythmias Complicating Wolff-Parkinson-White Syndrome With Rapid Anterograde Conduction Over an Accessory Pathway*, *Patients With Long-QT Syndrome and Associated Ventricular Arrhythmias*, *Patients Receiving Intra-aortic Balloon Counter-pulsation*, *Patients With Acute Heart Failure/Pulmonary Edema*, *Patients With Indications for Intensive Care*, *Patients Undergoing Diagnostic/Therapeutic Procedures Requiring Conscious Sedation or Anesthesia*, *Patients With Any Other Hemodynamically Unstable Arrhythmia*, and *Diagnosis of Arrhythmias in Pediatric Patients* (p. 79-82).

According to Drew et al. (2005), *Class II Cardiac Arrhythmia Monitoring* patients are typically admitted to telemetry or intermediate care units and are sub-divided into 10 categories including *Patients With Post-acute MI, Patients With Chest Pain Syndromes, Patients Who Have Undergone Uncomplicated, Non-urgent Percutaneous Coronary Interventions, Patients Who Are Administered an Antiarrhythmic Drug or Who Require Adjustment of Drugs for Rate Control With Chronic Atrial Tachyarrhythmias, Patients Who Have Undergone Implantation of a Pacemaker Lead and Are Not Pacemaker Dependent, Patients Who Have Undergone Uncomplicated Ablation of an Arrhythmia, Patients Who Have Undergone Routine Coronary Angiography, Patients With Subacute Heart Failure, Patients Who Are Being Evaluated for Syncope, and Patients With Do-Not-Resuscitate Orders With Arrhythmias That Cause Discomfort* (p. 82-85). For these patients, monitoring is often beneficial to their management, “but is not expected to save lives” (Drew et al., 2005, p. 82).

Class III Cardiac Arrhythmia Monitoring patients typically include young postoperative patients “without heart disease who undergo uncomplicated surgical procedures” and so are low risk for cardiac arrhythmias; obstetric patients without heart disease; permanent rate-controlled atrial fibrillation patients; non-Class I or Class II patients undergoing hemodialysis; and stable patients with chronic premature ventricular contractions (Drew et al., 2005, p. 86).

Next, *Class I ST-Segment Ischemia Monitoring* patients include: *Patients in the Early Phase of Acute Coronary Syndromes (ST-Elevation or Non-ST-Elevation MI, Unstable Angina ‘Rule-Out’ MI), Patients Who Present to the ED With Chest Pain or Anginal Equivalent Symptoms, Patients Who Have Undergone Nonurgent Percutaneous Coronary Intervention With Suboptimal Angiographic Results, and Patients With Possible Variant Angina Resulting From Coronary Vasospasm* (Drew et al., 2005, p. 86-87).

Class II patients in this category include: *Patients With Postacute MI, Patients Who Have Undergone Nonurgent Uncomplicated Percutaneous Coronary Intervention, Patients at High Risk for Ischemia After Cardiac or Noncardiac Surgery, and Pediatric Patients at Risk of Ischemia or Infarction Resulting From Congenital or Acquired Conditions* (Drew et al., 2005, p. 87-88).

Finally, *Class III* patients in this category include: *Patients with Left Bundle-Branch Block, Patients With Ventricular Pacing Rhythm; Patients With Other Confounding Arrhythmias That Obscure the ST Segment; and Patients Who Are Agitated* (Drew et al., 2005, p. 89).

According to Drew et al. (2005),

Patients with left bundle-branch block[s] have ST-T waves that markedly deviate in a positive or negative direction, depending on the ECG lead. The steeply sloping ST segments in these patients cause ST amplitude...to vary with heart rate. Because ST-segment monitoring software triggers an alarm for a change in ST amplitude, such patients have frequent false ST alarms, and this leads to staff fatigue and disenchantment with the technology. Patients with right bundle-branch block usually can be monitored successfully because the ST-T wave is not so extremely deviated; however, patients with frequent intermittent right bundle-branch block should not be monitored because of false ST alarms whenever the block appears or disappears (p. 89).

Furthermore, Drew et al. (2005) state that the in patients with a ventricular pacing rhythm the QRS morphology in right ventricular pacing rhythms is similar to the pattern of left bundle-branch blocks. Thus, the same rationale for not monitoring patients with left bundle-branch blocks applies to patients with ventricular pacemakers, especially those with rate-adaptive pacing (i.e. variable heart rates). Furthermore, patients especially prone to false ST alarms are those

who fluctuate between spontaneous rhythm (with a more typical ST segment) and pacing rhythm (with a deviated ST segment).

In addition, according to Drew et al. (2005), *Patients With Other Confounding Arrhythmias That Obscure the ST Segment*, including those with coarse atrial fibrillation, atrial flutter, or accelerated ventricular rhythms and *Patients Who Are Agitated* (i.e. restless and confused), can cause the ST-segment to fluctuate and created frequent false alarms.

Next, *Class I QT Interval and ECG Monitoring for Detection of Proarrhythmia* patients include: *Patients Administered an Antiarrhythmic Drug Known to Cause Torsades de Pointes*, *Patients Who Overdose From a Potentially Proarrhythmic Agent*, *Patients With New-Onset Bradyarrhythmias*, and *Patients With Severe Hypokalemia or Hypomagnesemia* (Drew et al., 2005, p 91-92). *Class II* patients in this category include: *Patients Who Require Treatment With Antipsychotics or Other Drugs With Possible Risk of Torsades de Pointes*, and *Patients With Acute Neurological Events* (Drew et al., 2005, p. 92). Finally, *Class III* patients in this category only include *Healthy Patients Administered Drugs That Pose Little Risk for Torsades de Pointes* (Drew et al., 2005, p. 92).

Management of Pulse Oximetry Alarms. Recommendations regarding the management of pulse oximetry alarms include that when possible, pulse-oximetry sensors should not be placed on the same limb as a non-invasive blood pressure (NIBP) cuff, intravenous (IV) or arterial catheter lines, and/or monitoring technology that automatically inactivates pulse-oximetry alarms during NIBP measurement should be considered for use (ECRI, 2007). False nails, nail polish, and any other nail coloring agents should be removed from the fingers before application of pulse-oximetry sensors and sensors should be protected from bright ambient light (ECRI, 2007). Adhesive, disposable pulse oximetry sensors should be used when possible and

replaced when they no longer adhere appropriately to patients' skin (more testing is needed to determine the best length of time before routine replacement of disposable pulse oximeters is needed (AACN, 2013; AAMI, 2011; ECRI, 2007). In addition, pressure against the skin from pulse oximetry sensors as well as perfusion to the pulse oximetry site should be assessed periodically via evaluation of the monitor's perfusion index and pulse oximetry waveform quality (ECRI, 2007). If perfusion to the pulse oximetry site is poor, moving the sensor may be indicated (ECRI, 2007). What's more, delay and threshold settings should be customized, settings should be adjusted according to patients' baselines, and healthcare organizations should consider utilizing *next-generation* pulse-oximetry technology (AACN, 2013; AAMI & HSTI, 2013; ECRI, 2007; Gorges, Markewitz & Westenkow, 2009).

Summary

After an extensive literature review covering AF and alarm management, it appears that there is abundant evidence regarding the importance of organizational leadership support as the initial step in clinical alarm management efforts. In addition, the importance of involving a multidisciplinary team of stakeholders, including end-users, in the development of alarm management improvement strategies was also repeatedly discussed. In addition, many sources point out the significance of evaluating the specific environment of care, to include current alarm management processes, in which alarm management improvement strategies are to be implemented. The importance of thoroughly evaluating any new alarm-equipped clinical devices prior to purchase was also repeatedly discussed. Additionally, determining current alarm-capable devices and systems in use, alarm parameter settings, and default alarm settings appropriate for specific care areas, patient populations, and patient conditions, was repeatedly suggested in the literature.

What's more, repeated recommendations from experts included that policies and procedures should be developed in order to guide clinical staff in their adjustment of alarm settings, including naming who is responsible for monitoring, responding to and/or adjusting alarms and settings. In addition, the literature strongly points out the importance of routinely educating the clinical staff who are responsible for managing alarm equipped clinical devices regarding any newly developed alarm management policies and procedures including education on the proper use and function of alarm equipped devices. There is also robust literature evidence regarding the significance of properly preparing patients' skin prior to ECG electrode application, proper ECG electrode placement, and regularly changing ECG electrodes. There is also much evidence in support of utilizing disposable pulse oximetry probes. An expert panel from the American Heart Association also provides specific evidence-based guidelines covering which patient diagnoses' and clinical conditions warrant ECG monitoring initiation and the best methods to institute such monitoring (Drew et al., 2005).

The major gaps and limitations in the literature regarding AF and alarm management appear to include lack of any specific guidelines on which clinical alarms are most important to manage. There is also little guidance in the literature regarding appropriate default alarm parameter settings and exactly how often disposable pulse oximetry probes should be changed. Moreover, there have been no patient care staff AF measurement methods described in the literature, which is interesting since the literature has shown that AF is the leading cause of patient harm related to clinical alarms. Furthermore, there also appears to be a gap in the literature regarding which strategies have proven to actually reduce AF amongst patient care staff, however, AF measurement tools would be required first in order to measure any such reductions in AF following alarm management efforts. In other words, many studies have shown

and recommended quantitative alarm reduction strategies; however, few have studied what alarm management strategies specifically reduce AF amongst patient care staff nor have any studies described any proven measures of AF.

Conceptual and Theoretical Frameworks

Alarm Fatigue Conceptual Framework. The major concept involved in this practice improvement project (PIP) is AF. The concept of AF is rather abstract because it is a phenomenon that occurs when healthcare providers become overwhelmed and desensitized by a multitude of alarm *noises* from various clinical devices which can result in patient harm when *important* alarm signals are inadvertently ignored or inappropriately adjusted (AACN, 2013; AAMI, 2011; ECRI, 2007, 2012; Graham & Cvach, 2010; TJC, 2013a, 2013b). Thus, no standard measurement or definition of AF exists in the literature. However, since AF has been repeatedly cited in the literature as a major patient safety hazard and as the leading cause of alarm related sentinel events (AAMI, 2011; TJC, 2013a), it is important to define the concept more clearly for purposes of this PIP via a conceptual framework or *map* (see Appendix A).

Alarm management, alarm system design, alarm noise, overwhelmed clinician, desensitization, clinician complacency, and mismanaged alarms, are all terms that are closely associated with the AF concept since all of these individual concepts interrelate in some way to result in the overarching phenomenon or *primary concept* that is AF. For example, *alarm management* refers to the organizational protocols and system-processes that are in place, or *not* in place, aimed at managing clinical alarms in the patient care environment. *Alarm system design* refers to the functions, or non-functions, of the clinical alarm systems that are utilized in patient care monitoring within the patient care environment, such as cardiac, pulse oximetry, respiratory, exhaled CO₂, and blood pressure monitoring systems. Clinical alarm systems

utilized in the patient care environment could also include bed exit alarms, ventilators, SCDs, tube feeding and IV infusion pumps, and wound vacuum devices amongst others. *Alarm noise* refers to the multitude of competing alarms from various clinical devices which can combine to create confusion rather than clarity as to what patient care actions should be carried out.

Overwhelmed clinician refers to the bedside caregiver who cannot *keep up* with the multitude of competing alarms from various patients' clinical devices which can result in desensitization and complacency in response to these *alarm noises*. *Desensitization* refers to the *tuning out* of the multitude of clinical alarms from various patients' clinical devices while *clinician complacency* refers to the *ignoring* of clinical alarms which are deemed *unimportant* by the individual clinician due to the various terms described previously, such as *alarm management*, *alarm system design*, *alarm noise*, *desensitization*, and due to feeling *overwhelmed*. *Mismanaged alarms* refers to the bedside clinician's independent decision to silence, adjust, or ignore clinical alarms due to a combination of all of the previous concepts described above such as *alarm management*, *alarm system design*, *alarm noise*, *overwhelmed* and *desensitized* clinician, and *clinician complacency*, which ultimately culminates in the conceptual phenomenon of AF and potential patient harm.

AF was chosen as the PIP topic of inquiry and major concept instead of one of the closely associated terms described above because AF is the conceptual phenomenon which involves and describes all of these interrelated terms which can potentially culminate in patient harm. One of the most important components of patient care, if not the most important component of patient care, is to ensure patient safety and to prevent harm (i.e. "first do no harm"). AF is a phenomenon which can ultimately result in patient harm if not managed properly. Based off of an extensive literature review on the AF topic, I have created the "Alarm Fatigue Conceptual

Framework” as the source for an AF measurement tool/questionnaire for clinical staff (see Appendices A & C). This AF measurement tool was used to accomplish a portion of the aims and objectives of this project.

The Iowa Model of Evidence-Based Practice to Promote Quality of Care. The Iowa Model of Evidence-Based Practice to Promote Quality of Care (see Appendix B) or the *Iowa Model*, was also used to guide the project; first, because it is a model that is structured for purposes of healthcare project development, implementation, and evaluation, and second, because “the model is based on the problem-solving steps in the scientific process and is widely recognized for its applicability and ease of use by multidisciplinary healthcare teams” (Melnik & Fineout-Overholt, 2011, p. 251). Indeed, the setting of the PIP was within a hospital and involved an interdisciplinary team to include ICU nurse managers, nursing unit staff, biomedical personnel, risk management, and quality improvement administration.

The first step in the Iowa Model begins with identifying a *trigger* or practice question which can be either *problem focused*, such as from identification of a clinical problem, or *knowledge focused*, such as stemming from national agencies or organizational standards and guidelines (Titler et al., 2001). Thus, the Iowa Model pertained to this PIP since the primary concept of the project was AF, which is a clinical problem that TJC (2013a, 2013b) is requiring that all hospitals prioritize addressing via completion of NPSG.06.01.01 performance elements.

After identifying a trigger, the next step in the Iowa Model is to assess whether the trigger is a priority for the organization (Titler et al., 2001). This point in the Iowa Model was also fitting for this PIP since as of July 2014, TJC’s (2013b) NPSG.06.01.01 required that all hospitals ensure that clinical alarm safety and alarm management was made a hospital-organization priority. Thus, *alarm management* was already established as an organizational

priority at The Hospital prior to beginning the PIP. Furthermore, according to the Iowa Model, “once there is commitment to addressing the topic, a team is formed to develop, implement, and evaluate the practice change” (Melnik & Fineout-Overholt, 2011, p. 253). This step involved multiple interdisciplinary meetings with hospital staff, including with quality improvement administration; ICU unit managers, staff nurses, and educators; biomedical department management; and a physiologic monitor vendor during the course of the PIP.

The next step in the Iowa Model process is to “assemble relevant research and related literature” and “critique and synthesize research for use in practice” (Titler et al., 2001). This portion of the Iowa Model coincides with the aims and objectives of the project and was completed via a comprehensive literature review. These literature review sources are cited in various chapters herein and within the references section.

The next step in the Iowa Model process is to determine if the evidence found through research is high-quality or sufficient for determining practice. If not, the team may choose to use lower levels of evidence or conduct their own research for these purposes. Based on the literature synthesis and analysis, which showed gaps in the literature relating to a lack of AF measurement tools as well as which clinical alarms are most important to manage, research was conducted during this PIP with the aims and objectives previously described herein.

The next step in the Iowa Model process is to “pilot the change in practice” which includes selecting outcomes to be achieved, collecting baseline data, designing evidence-based practice (EBP) guidelines, implementing EBP guidelines on pilot units, evaluating processes and outcomes, and then possibly modifying the practice guideline after pilot outcome evaluation (Titler et al., 2001). Because the aims of this PIP were to assess measures of AF amongst The Hospital’s ICU clinical staff and to complete the STEP 2 performance elements of

NPSG.06.01.01 for The Hospital's ICU which include to 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, and 4) potential for patient harm based on internal incident history (TJC, 2013c, p. 7), this is the baseline data that will be collected during this project via an ICU clinical staff survey (see Appendix C).

All other components involved in this step of the Iowa Model are outside of the scope and timeframe of this PIP and will be conducted during STEP 3 and STEP 4 of NPSG.06.01.01 performance elements which calls for hospitals to establish policies and procedures for managing the alarms identified in STEP 2 and to “educate staff and licensed practitioners about the purpose and proper operation of alarm systems for which they are responsible” (TJC, 2013, p. 7). At minimum, the new policies and education must address the following: 1) clinically appropriate settings for alarm signals, 2) when alarm signals can be disabled, 3) when alarm parameters can be changed, 4) who in the organization has the authority to set alarm parameters, 5) who in the organization has the authority to change alarm parameters, 6) who in the organization has the authority to set alarm parameters to “off”, 7) monitoring and responding to alarm signals, and 8) checking individual alarm signals for accurate settings, proper operation, and detectability (TJC, 2013c, p. 7). The literature review section of this PIP manuscript may assist The Hospital's administration with these steps at a later date.

The final step of the Iowa Model involves dissemination of project results (Titler et al., 2001). This step coincided with a final PIP presentation at the University of Hawaii at Hilo (UHH) at the conclusion of my Doctor of Nursing Practice program studies. This step will also

involve dissemination of PIP information and findings at The Hospital and through submission to various professional organizations such as the AACN and AAMI for possible publication.

Chapter 3: Project Design and Evaluation Plan

In this chapter, the project design and methods that were used to accomplish the project's objectives will be discussed. The project design and methods were derived from an AF Conceptual Framework (see Appendix A) and the Iowa Model (see Appendix B) as described in Chapter 2.

Project Design and Methods. The steps of this project were based on the Iowa Model (see Appendix B) which included:

1. Determine a project *trigger*: This project's *trigger* was a knowledge-focused trigger in the form of a National Agency or Organizational Standard and Guideline, specifically TJC (2013b, 2013c) NPSG.06.01.01.
2. Determine if the project trigger was an organization priority: Addressing clinical alarm safety was already determined to be a Joint Commission accredited hospital priority according to The Hospital's Quality Director due to the 2014 Joint Commission NPSG.06.01.01. STEP 1 of NPSG.06.01.01 specifically requires that hospitals first ensure that clinical alarm safety and management is made a priority.
3. Form a project team: The team tasked with improving clinical alarm safety at The Hospital includes myself, the Quality Director (who was also a PIP committee member), The Hospital's ICU nurse manager, ICU clinical coordinator staff nurses (i.e. charge nurses), ICU clinical educator, biomedical engineering management, and a physiologic monitor vendor representative.

4. Assemble relevant research and related literature: Assembling relevant research and literature for analysis and synthesis in order to meet the PIP's objectives to "Identify the most important alarm signals to manage in the project ICU based on data gathered from The Hospital's administration regarding the potential for patient harm based on internal incident history", and to "Identify the most important alarm signals to manage based on published best practices and guidelines" involved speaking with The Hospital's Risk Manager regarding internal incident history related to clinical alarms and performing a comprehensive literature search. Performing a comprehensive literature review involved use of databases including: Cochrane Reviews, National Guideline Clearinghouse, Agency for Healthcare Research and Quality, Dynamed, PubMed, CINAHL, and MEDLINE, using the search terms of AF, alarm systems, clinical alarms, healthcare alarms, health care alarms, alarm management, and alarm protocols. Additional pertinent literature sources were found via the reference sections of articles discovered through the primary database research. Attention was given to evidence-based guidelines, systematic research reviews, meta-analyses, and clinical studies on the topic.
5. Critique and synthesis of research: This step involved determining the scientific merit of the studies found via the literature review, generalizability of the study findings to The Hospital's ICU, and relevance of the study findings to this project's objectives which included to "Identify the most important alarm signals to manage in the project ICU based on data gathered from The Hospital's administration regarding the potential for patient harm based on internal incident history", and to "Identify the most important alarm signals to manage based on published best practices and guidelines".

6. Determine if there is sufficient research to guide practice: Via the research critique and synthesis, which involved determining the relevance of findings to this project's aims and objectives and the generalizability of the research findings to The Hospital's ICU, it was determined that there was not sufficient research to fulfill the aims and objectives of this specific project, thus, additional methods were used.
7. Survey The Hospital's ICU clinical staff: A clinical staff survey (see Appendix C) was developed based on the AF Conceptual Framework (see Appendix A) and NPSG.06.01.01 performance elements (see Appendix G). The survey was implemented in order to meet this project's objective to: "Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage".
8. Utilize research to create EBP guidelines: This step of the Iowa Model coincides with STEP 3 and STEP 4 of NPSG.06.01.01, which were outside of the scope of this project.
9. Pilot the change in practice: This step of the Iowa Model coincides with STEP 3 and STEP 4 of NPSG.06.01.01, which were outside of the scope of this project. This step would involve incrementally implementing a new evidence-based alarm management practice guideline in The Hospital's ICU as well as selecting outcomes to be achieved, collecting additional baseline data, evaluating the process and outcomes of the trial, and possibly modifying the guideline based on the process and outcome data.
10. Pilot outcomes to be achieved: This step of the Iowa Model coincides with STEP 3 and STEP 4 of NPSG.06.01.01, which were outside of the scope of this project. This step would involve determining pilot outcomes to be achieved in collaboration with The Hospital's interdisciplinary team. A possible pilot outcome goal could include: A 20% reduction in the

perception of AF amongst The Hospital's ICU clinical staff after alarm management policy changes had been in place for one year or longer and/or a 20% reduction in the number of alarm conditions per patient per day during the pilot timeframe.

11. Pilot collecting baseline data: Collecting baseline data partially coincided with this PIP's objectives which included to: "Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage" (see Appendix C). This PIP's survey was intended to gather baseline quantitative data on the sense of AF amongst ICU clinical staff prior to implementation of later policy and procedure changes that will take place during STEP 3 and STEP 4 of NPSG.06.01.01. Quantitative survey data was also gathered regarding which ICU clinical alarms are most important to manage. There was one open-ended survey question where qualitative data could have been entered by participants. Anonymity was assured by having participants type their responses electronically into a computer that could not be linked to the individual participant. *Survey Monkey*, which allows for anonymity, was used.
12. Pilot implementation of the guideline: Pilot implementation of the guideline in The Hospital's ICU would be included in STEP 3 and STEP 4 of NPSG.06.01.01, which were outside of the scope of this project.
13. Pilot evaluation of the process and outcome data: Pilot evaluation of the process and outcome data in The Hospital's ICU would be included in STEP 3 and STEP 4 of NPSG.06.01.01, which were outside of the scope of this project.
14. Modifying the guideline post-pilot: This step would be included in STEP 3 and STEP 4 of the NPSG.06.01.01 criteria, which were outside of the scope of this project.

Project Participants. A convenience sample of 28 adult ICU clinical staff members, including registered nurses and telemetry technicians/nursing assistants, were included in this PIP for survey completion. These participants were identified by collaborating with The Hospital's ICU nurse manager and ICU clinical educator. The PIP was explained to participants by placing a recruitment flyer in their staff mailboxes and by reading the flyer to clinical staff during unit meetings (see Appendix D). No compensation was offered for project participation.

Project Setting. The project setting was at The Hospital and specifically, within The Hospital's ICU. The Hospital is a Joint Commission accredited 276 bed community hospital located in the State of Hawaii (HMC, 2014). The Hospital ICU is an 11-bed general medical-surgical ICU which cares for a mix of "primary" and "secondary" ICU patients and rarely cares for pediatric patients.

Data Collection Tools. The purpose of the following data collection tools were to meet the project objectives including to "Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage" and to "Identify the most important alarm signals to manage based on published best practices and guidelines". The project data collection tools included:

1. National Patient Safety Goal.06.01.01 Clinical Alarm Management Questionnaire (see Appendix C). This questionnaire (i.e. survey) was pre-viewed by The Hospital's ICU nurse manager, ICU clinical educator, Quality Director, project committee members, as well as an expert in the field from John Hopkins Hospital in order to gather input for improvement and to determine survey content validity. Input from The Hospital's biomedical department manager and the ICU clinical educator regarding the types of alarm-capable clinical devices in current use in the ICU were also utilized in the survey

development in order to ensure content validity. The AF survey measure-questions were derived from an extensive literature review culminating in the development of the AF Conceptual Framework (see Appendix A). The survey's intent was to gather quantitative data on the sense of AF amongst The Hospital's ICU clinical staff prior to implementation of later policy and procedure changes that will take place during STEP 3 and STEP 4 of the NPSG.06.01.01 (see Appendix G). Quantitative survey data was also gathered with the aim of identifying which ICU clinical alarms are most important to manage. There was one open-ended survey question where qualitative data could have been entered. Anonymity was assured by having survey participants type their responses electronically into a computer that could not be linked to the individual participant. A *Survey Monkey* link, which allows for anonymity, was used.

2. Electronic databases including Cochrane Reviews, National Guideline Clearinghouse, Agency for Healthcare Research and Quality, Dynamed, PubMed, CINAHL, and MEDLINE were used for the literature review.

Data Analysis Methods

Data analysis methods were aimed at achieving the project objective to "Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage". Data analysis methods involved the use of simple descriptive statistics including quantitative analysis of: 1) demographic data, 2) nine separate 6-point likert-scale survey questions aimed at measuring AF amongst participants, as well as 3) four separate questions with 6-point likert-scale survey measures aimed at identification from participants of the most important alarm signals to manage in The Hospital's ICU (see Appendix C). For the nine AF survey questions, the 6-point likert scale included six

possible responses including: *Strongly*, *Moderately*, or *Slightly Disagree* or *Agree* (see Appendix C). Data analysis methods included separation and combination of the 3 possible *Disagree* scale choices and the 3 possible *Agree* scale choices whereas if more than 50% of participants combined *Strongly*, *Moderately*, or *Slightly Agreed* with the AF measure question, then this was considered significant that the “majority” (i.e. more than 50%) of participants were likely suffering from AF on those measures. On the other hand, if more than 50% of participants combined *Strongly*, *Moderately*, or *Slightly Disagreed* with the AF measure question, then this was considered significant that participants were likely *not* suffering from AF on those measures.

Next, the four separate questions with corresponding 6-point likert-scale survey measures aimed at the project objective of identification of the most important alarm signals to manage in The Hospital’s ICU included a listing of 18 different alarm capable clinical devices in use in the ICU. The four separate questions were: 1) Rate the following clinical devices according to how important they are to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms, 2) Rate the following clinical devices according to how necessary their alarms are, 3) Rate the following clinical devices according to how often they produce false or non-actionable alarm noise, and 4) Rate the following clinical devices according to which carry the greatest safety risk to patients if the alarm signal is not attended to or if it malfunctions (see Appendix C).

Question #1) above included the 6-point likert-scale choices of *Extremely*, *Moderately*, or *Slightly Important* or *Unimportant*. Data analysis methods included separation and combination of the 3 possible *Important* choices and the 3 possible *Unimportant* choices whereas if more than 50% of participants combined felt that the clinical device was *Strongly*, *Moderately*, or *Slightly Important* to manage, then this was considered significant for the “majority” (i.e. more than

50%) of staff who felt that the clinical device was *Important* to manage. On the other hand, if more than 50% of participants combined felt that the clinical device was Strongly, Moderately, or Slightly *Unimportant* to manage, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device was *Unimportant* to manage.

Question #2) above included the 6-point likert-scale choices of *Extremely*, *Moderately*, or *Slightly Necessary* or *Unnecessary*. Data analysis methods included separation and combination of the 3 possible *Necessary* choices and the 3 possible *Unnecessary* choices whereas if more than 50% of participants combined felt that the clinical device was Strongly, Moderately, or Slightly *Necessary* to manage, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device was *Necessary* to manage. On the other hand, if more than 50% of participants combined felt that the clinical device was Strongly, Moderately, or Slightly *Unnecessary* to manage, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device was *Unnecessary* to manage.

Question #3) above included the 6-point likert-scale choices of *Never*, *Rarely*, *Occasionally*, *Often*, *Very Often*, or *Extremely Often*. Data analysis methods included separation and combination of the *Never*, *Rarely*, and *Occasionally* choices and the *Often*, *Very Often*, and *Extremely Often* choices whereas if more than 50% of participants combined felt that the clinical device produced false or non-actionable alarm noise *Never*, *Rarely*, or *Occasionally*, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device *did not* produce significant numbers of nuisance alarms, and thus, was not a high priority for management. On the other hand, if more than 50% of participants combined felt that the clinical device produced false or non-actionable alarm noise *Often*, *Very Often*, or *Extremely Often*, then this was considered significant for the “majority” (i.e. more than 50%) of staff who

felt that the clinical device *did* produce significant numbers of nuisance alarms, and thus required managing.

Question #4) above included the 6-point likert-scale choices of *No*, *Rare*, *Minimum*, *Moderate*, *High*, or *Extremely High Safety Risk*. Data analysis methods included separation and combination of the *No*, *Rare*, and *Minimum Safety Risk* choices and the *Moderate*, *High*, and *Extremely High Safety Risk* choices whereas if more than 50% of participants combined felt that the clinical device posed *No*, *Rare*, or a *Minimum Safety Risk* to patients if the alarm signal was not attended to or malfunctioned, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device did not necessarily require management due to the *Minimum* to *No* Safety Risk to patients. On the other hand, if more than 50% of participants combined felt that the clinical device posed a *Moderate*, *High*, or *Extremely High Safety Risk* to patients if the alarm signal was not attended to or malfunctioned, then this was considered significant for the “majority” (i.e. more than 50%) of staff who felt that the clinical device required management.

Survey Monkey was used to analyze the percentage of participant responses to the quantitative survey measures described (see Appendices H to R). These survey measure percentages were intended to provide the interdisciplinary team a greater understanding of the sense of AF amongst The Hospital’s ICU clinical staff before implementation of any NPSG.06.01.01 STEP 3 performance element policy changes as well as providing the data required in order to progress to STEP 3 and STEP 4 of NPSG.06.01.01 (see Appendix G).

Human Subjects Protection

Participants who were asked to complete the NPSG.06.01.01 Clinical Alarm Management Questionnaire were provided with a consent to participate in research (see

Appendix E). No personally identifiable information was requested by or gathered in the surveys. Only non-identifiable demographic information was requested in the surveys and participants were asked to “not include any additional personal information” in their survey. The surveys were electronic and were completed from a non-identifiable survey link.

The only ethical concern may include that The Hospital’s ICU clinical staff could have felt obligated to participate in the survey due to senior nursing staff (i.e. myself, the ICU clinical educator, and clinical coordinators) asking for their participation, in which case it is possible that it could affect their choice to participate. See Appendix R for UHH Institutional Review Board Approval stating that the project was “exempt” as a human subjects research project. See Appendix S for The Hospital’s project approval.

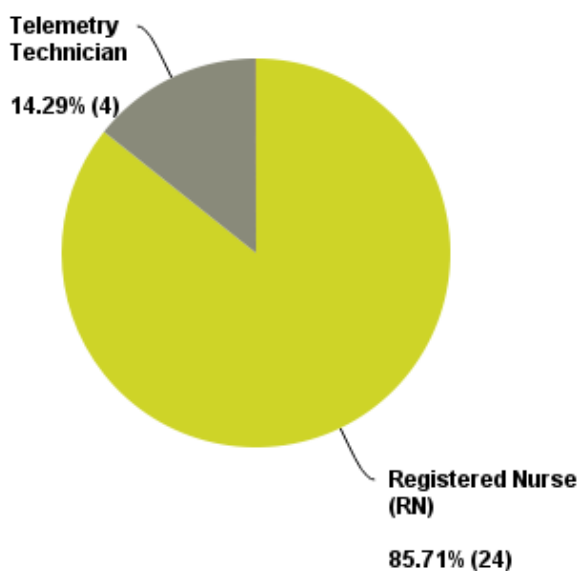
Chapter 4: Results

In this chapter, the project results in relation to accomplishment of the project’s aims objectives will be discussed. The aims of this project were to assess measures of AF amongst The Hospital’s ICU clinical staff and to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital’s ICU which are to 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) published best practices and guidelines (TJC, 2013c, p. 7).

The project objectives were to: 1) Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage, 2) Identify the most important alarm signals to manage in the project ICU based on data gathered from The Hospital’s administration regarding the potential for patient

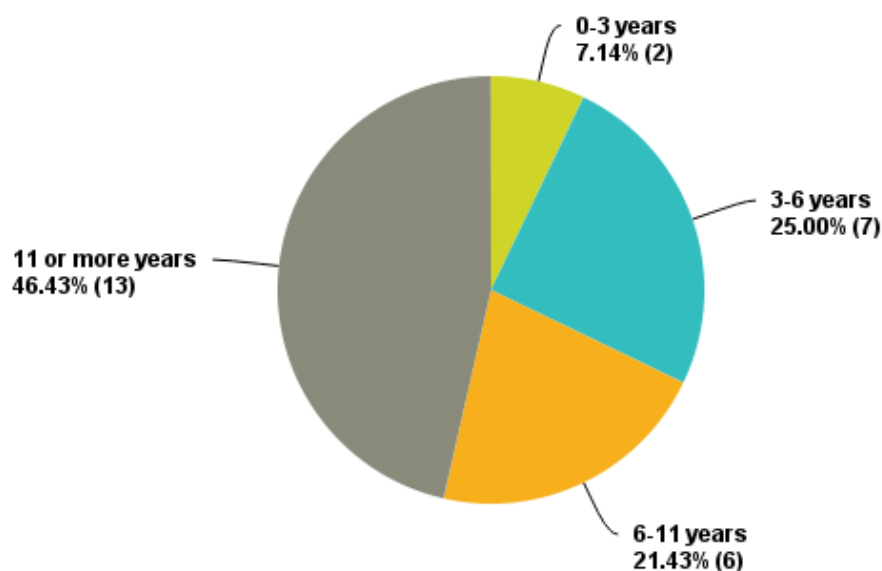
harm based on internal incident history, and to 3) Identify the most important alarm signals to manage based on published best practices and guidelines.

In all, 33 ICU clinical staff members participated in the NPSG.06.01.01 Clinical Alarm Management Questionnaire which equates to 82.5% participation from the ICU clinical staff! However, 5 participants entered demographic data only and so were excluded from survey data analysis which brought the participation rate down to 70% or 28 participants (see Appendix H for data table). Final demographic data results included participants' job titles, which included 85.71% (24) Registered Nurses and 14.29% (4) Telemetry Technicians (i.e. monitor watchers) (see Appendix H for full data table).

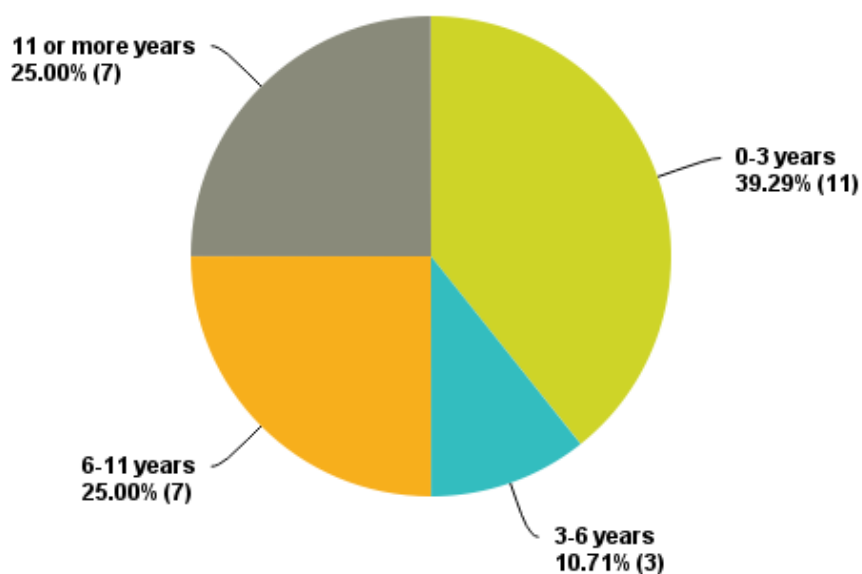


Next, years of experience in the participants' job titles included 46.43% (13) with 11 or more years, 21.43% (6) with 6-11 years, 25.00% (7) with 3-6 years, and 7.14% (2) with 0-3

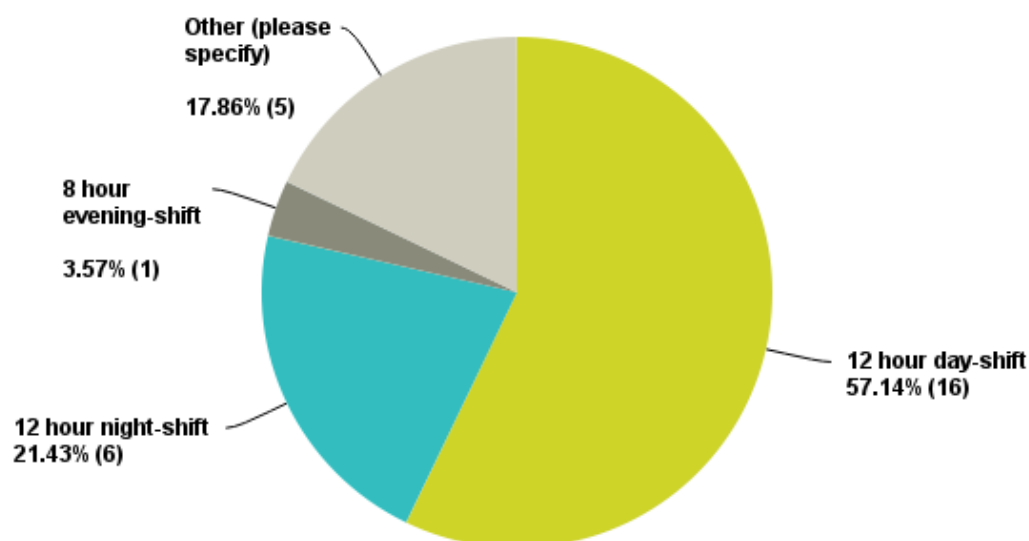
years (see Appendix I for full data table).



Next, in response to the question: How many years have you worked in this unit?, 25.00% (7) responded with “11 or more years”, 25.00% (7) responded with “6-11 years”, 10.71% (3) responded with “3-6 years”, and 39.29% (11) responded with “0-3 years” (see Appendix J for data table).

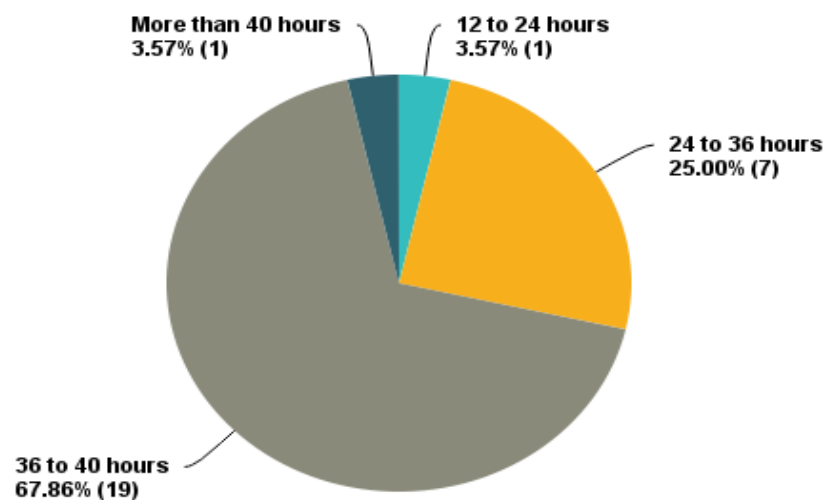


Next, in response to the question: Which one of the following best describes your work schedule?, 57.14% (16) responded with “12 hour day-shift”, 21.43% (6) responded with “12 hour night-shift”, 3.57% (1) responded “8 hour evening-shift”, and 17.86% (5) responded “Other” explaining that their shifts varied (see Appendix K for full data table).



Next, when asked the question “Typically, how many hours per week do you work in this unit?”, 67.86% (19) responded with “36 to 40 hours”, 25.00% (7) responded with “24 to 36 hours”, 3.57% (1) responded with “12 to 24 hours”, and 3.57% (1) responded with “More than

40 hours” (see Appendix L for full data table).

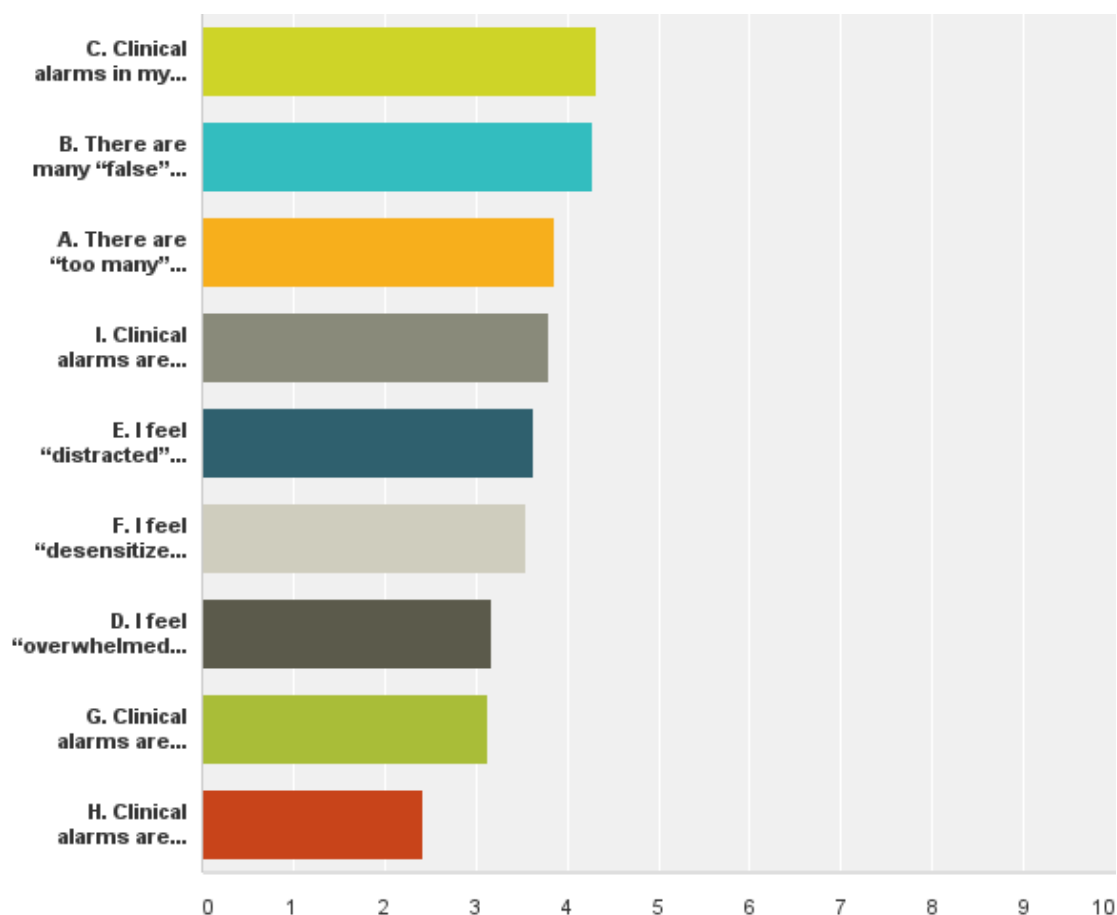


Objective #1

Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage. The first aim and objective of this project was to develop and implement a survey in order to assess measures of AF amongst The Hospital’s ICU clinical staff. All included participants responded to the AF survey measures, which equates to 70% of The Hospital’s ICU clinical staff.

Based on the project’s data analysis methodology described in Chapter 3, the AF survey results showed that 67.86% (19) of participants *Agreed* while 32.14% *Disagreed* that there are *too many* clinical alarms in The Hospital’s ICU; 78.57% (22) of participants *Agreed* while 21.43% (6) *Disagreed* that there are many *false* or *non-actionable* clinical alarms in The Hospital’s ICU; 89.28% (25) of participants *Agreed* while 10.72% (3) *Disagreed* that clinical alarms in The Hospital’s ICU make the work area noisy; 53.57% (15) of participants *Agreed* while 46.43% (13) *Disagreed* that they feel *overwhelmed* by the number of clinical alarms in The Hospital’s ICU; 67.85% (19) of participants *Agreed* while 32.15% (9) *Disagreed* that they feel *distracted* by the number of clinical alarms in The Hospital’s ICU; 60.72% (17) of participants

Agreed while 39.28% (11) *Disagreed* that they feel *desensitized* by the number of clinical alarms in The Hospital's ICU; 46.43% (13) of participants *Agreed* while 53.57% (15) *Disagreed* that clinical alarms in The Hospital's ICU are *ignored* due to the number of false and non-actionable alarm signals; 28.58% (8) of participants *Agreed* while 71.42% (20) *Disagreed* that clinical alarms in The Hospital's ICU are *turned off* due to the number of false and non-actionable alarm signals; and 67.86% (19) of participants *Agreed* while 32.14% (9) *Disagreed* that clinical alarms in The Hospital's ICU are *adjusted* due to the number of false and non-actionable alarm signals (see Appendix M for full data table).

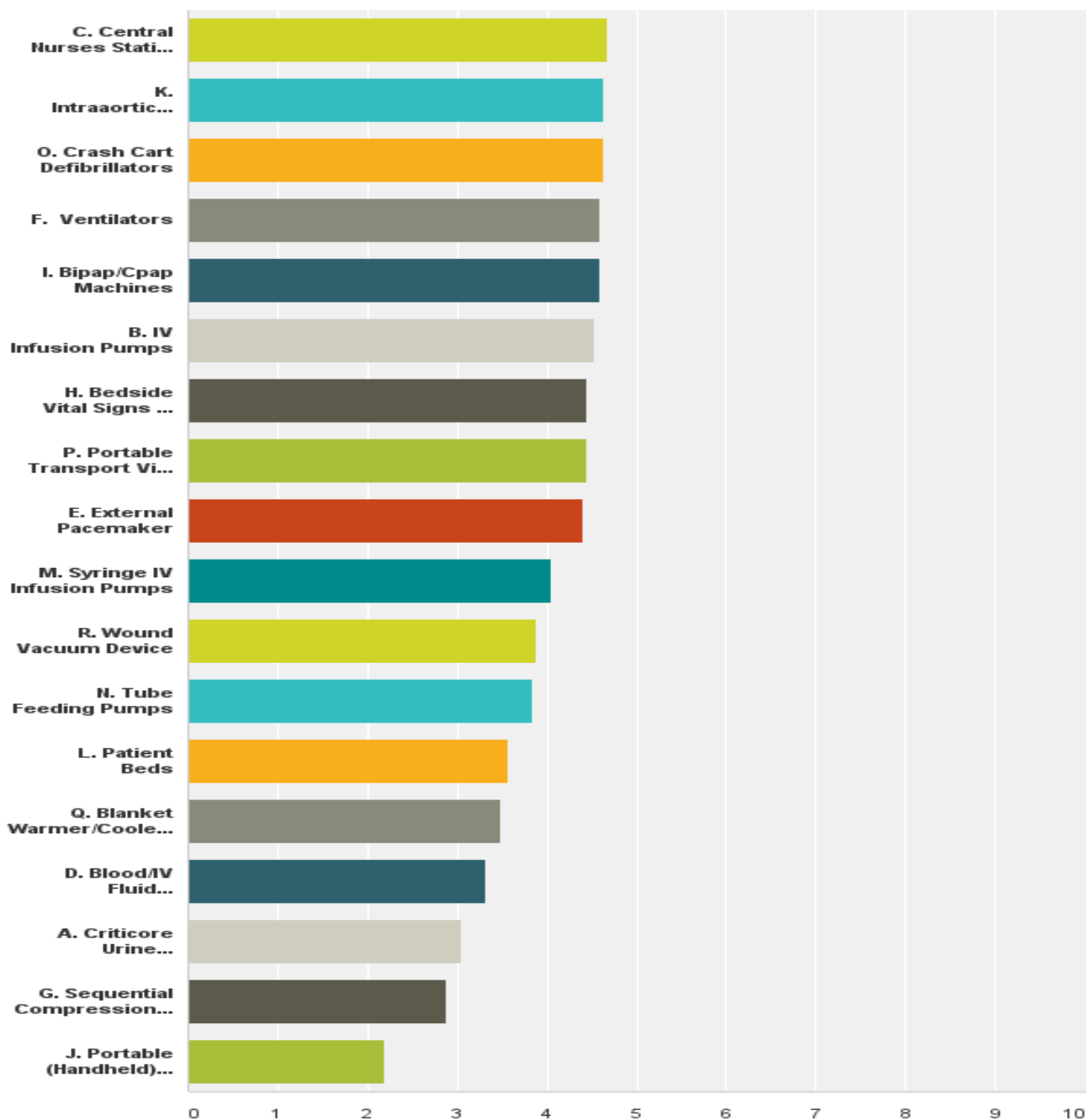


Next, the project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which included to "identify the most important alarm

signals to manage based on...input from the medical staff and clinical departments” was fulfilled by asking survey participants to rate 18 different alarm-capable ICU devices according to 4 different questions on a 6-point likert scale. The 18 devices that staff were asked to rate included: Criticare Monitors, IV Pumps, Nurses Station Monitors, Blood/IV Fluid Warmer/Coolers, External Pacemakers, Ventilators, SCDs, Bedside Monitors, Bipap/Cpap Machines, Handheld Thermometers, Intraaortic Balloon Pumps, Patient Beds, Syringe IV Pumps, Tube Feeding Pumps, Defibrillators, Portable Monitors, Blanket Warmer/Coolers, and Wound Vacuum Devices.

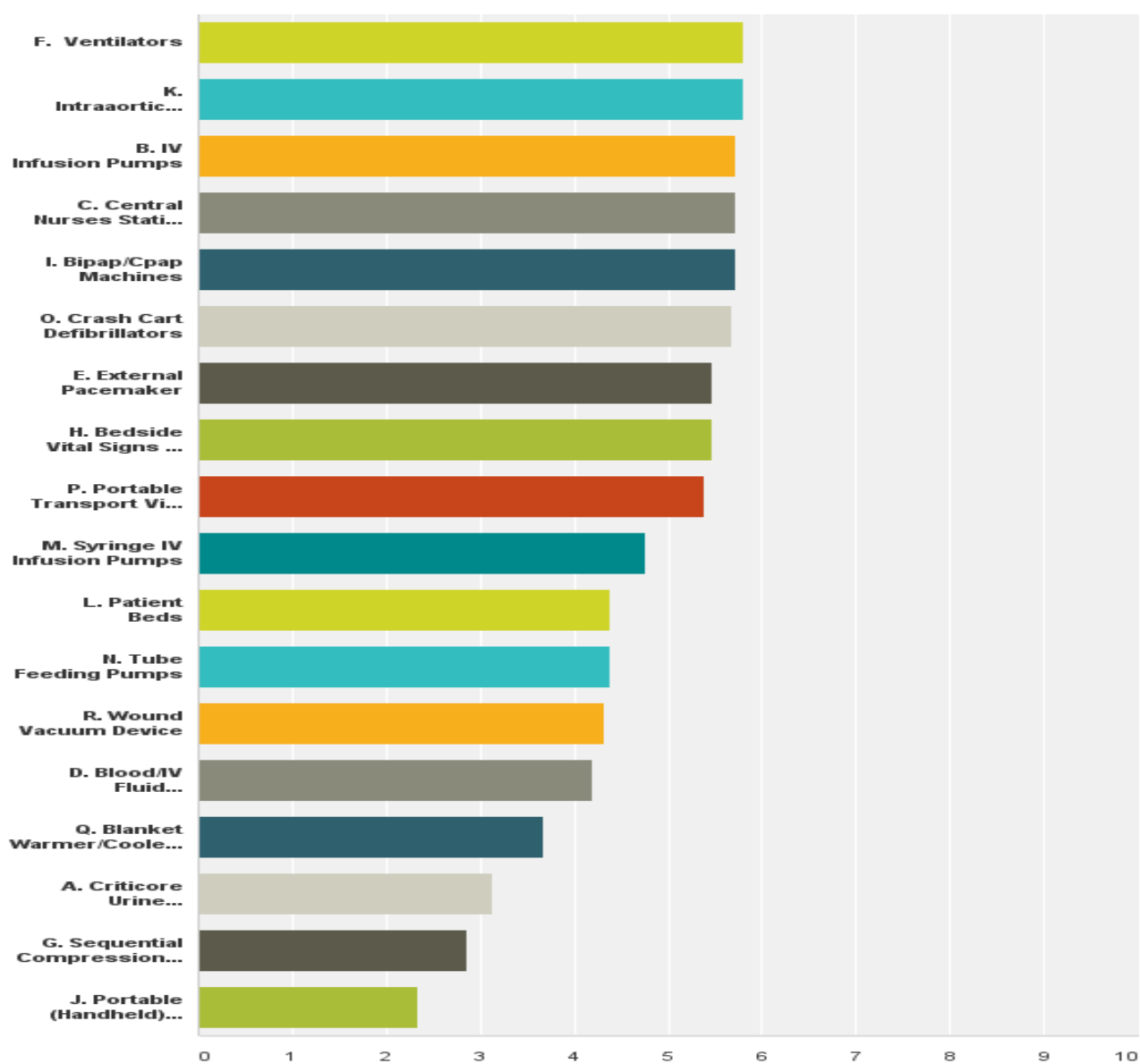
The first of these questions asked participants to “Rate the following clinical devices according to how important they are to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms”. Twenty-five participants responded, which equates to 62.5% of The Hospital’s ICU clinical staff. Based on the project’s data analysis methodology described in Chapter 3, this survey question’s results showed that more than 50% of participants indicated that *all* of the devices, except for *Criticare Monitors*, *SCDs*, and *Thermometers* are *important* to

manage in order to decrease unnecessary alarms (see Appendix N for full data table).

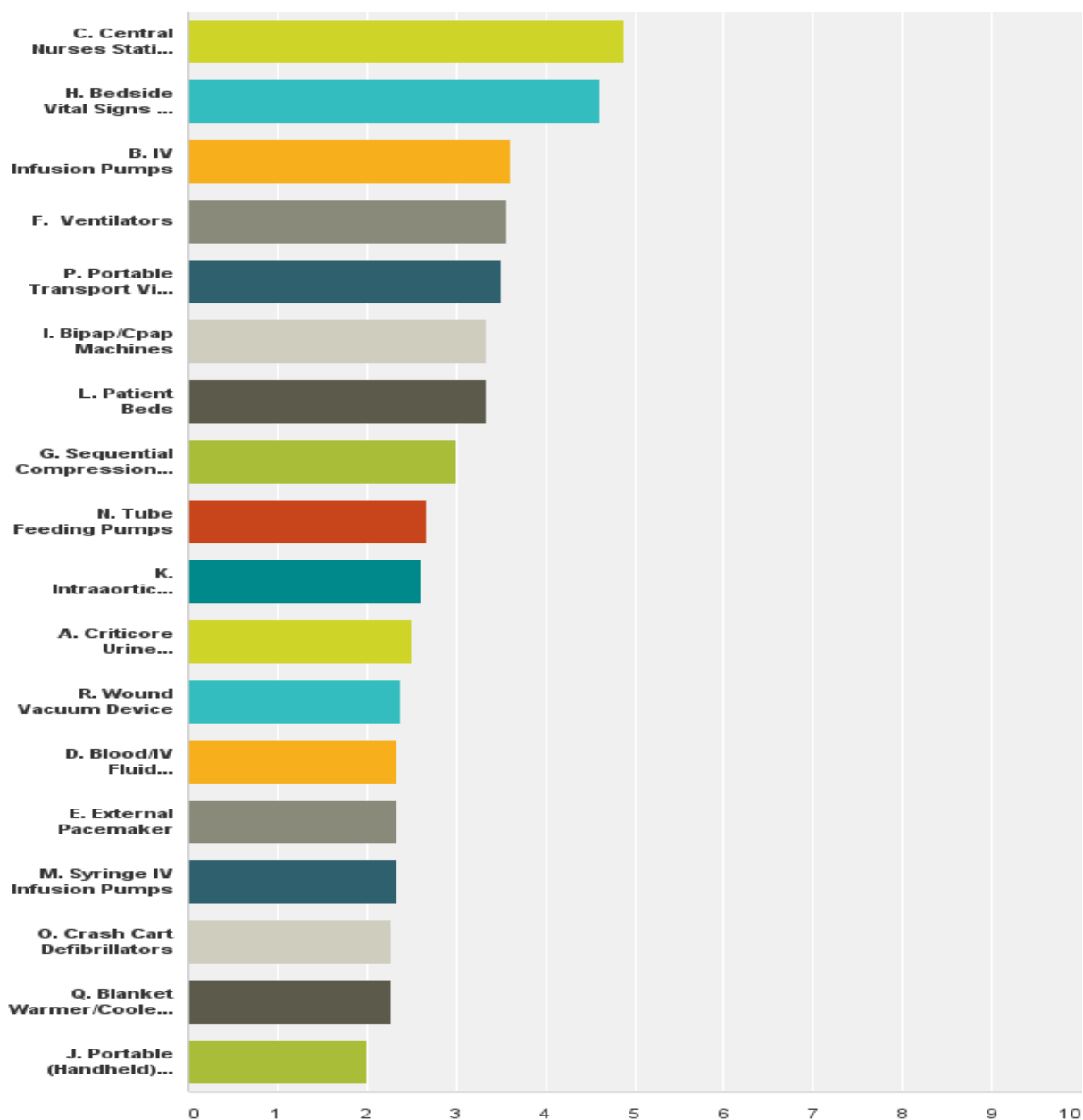


The project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which included to "identify the most important alarm signals to manage based on...input from the medical staff and clinical departments" and "whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm

fatigue”, was fulfilled by the next survey question which asked participants to “Rate the following clinical devices according to how necessary their alarms are”. Twenty-one participants responded, which equates to 52.5% of The Hospital’s ICU clinical staff. Based on the project’s data analysis methodology described in Chapter 3, this survey question’s results showed that more than 50% of participants indicated that *Thermometers*, *Criticare Monitors*, and *SCDs* have *unnecessary* alarms while the remainder of the devices have *necessary* alarms (see Appendix O for full data table).



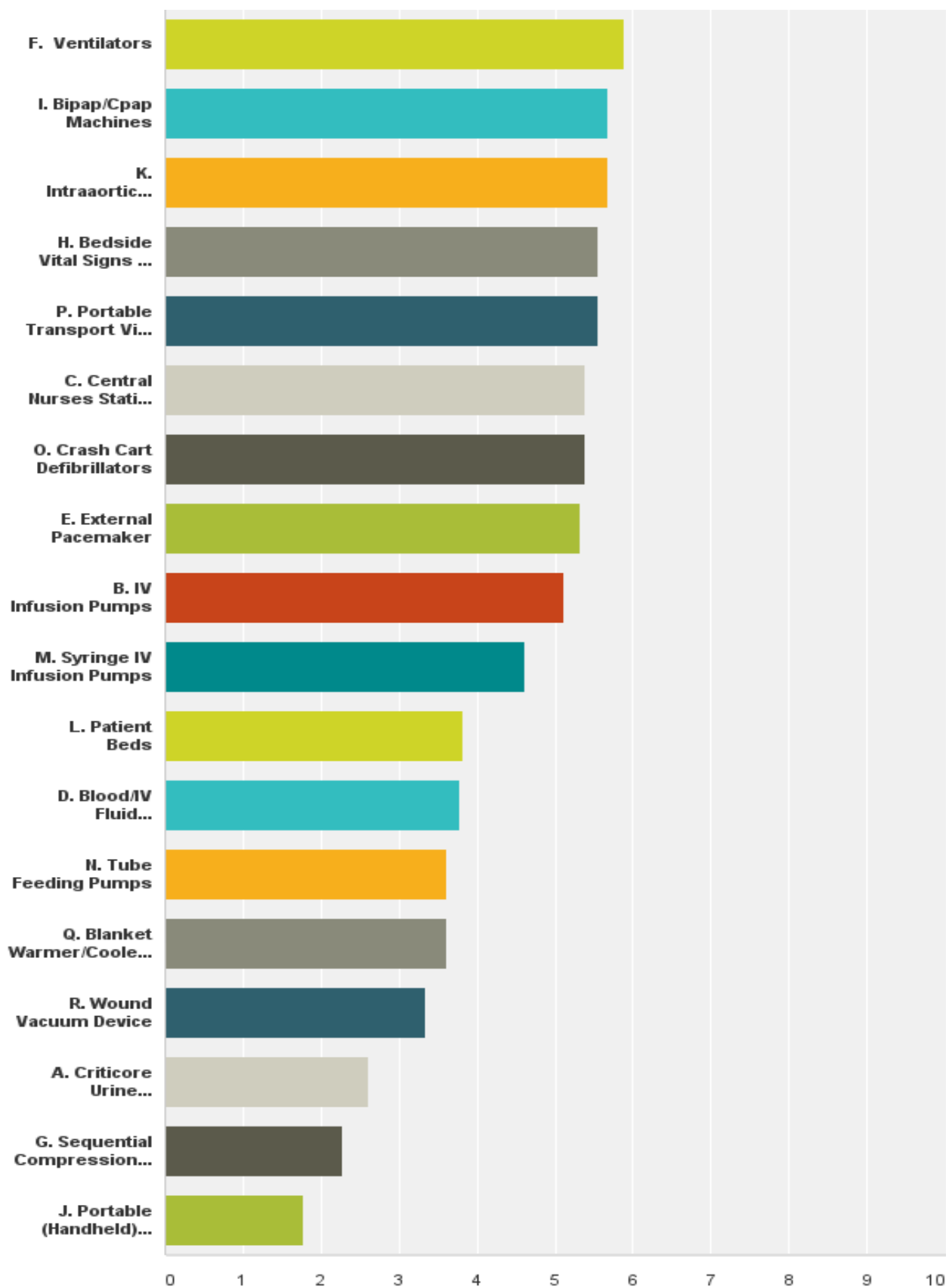
Next, the project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which included to "identify the most important alarm signals to manage based on...input from the medical staff and clinical departments" and "whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF", was fulfilled by asking the next question of survey participants to "Rate the following clinical devices according to how often they produce false or non-actionable alarm noise". Eighteen participants responded, which equates to 45% of The Hospital's ICU clinical staff. Based on the project's data analysis methodology described in Chapter 3, this survey question's results showed that more than 50% of participants indicated that *Nurses Station Monitors*, *Bedside Monitors* and *Ventilators* produce false or non-actionable alarm noise *Often* to *Extremely Often*, while the remainder of the devices produce false or non-actionable alarms *Never* to *Occasionally* (see Appendix P for full data table).



The project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which included to "identify the most important alarm signals to manage based on...input from the medical staff and clinical departments" and "risk to patients if the alarm signal is not attended to or if it malfunctions" was fulfilled by asking the next question of survey participants to "Rate the following clinical devices according to which carry the greatest safety risk to patients if the alarm signal is not attended to or if it

malfunctions”. Eighteen participants responded, which equates to 45% of The Hospital’s ICU clinical staff. More than 50% of participants indicated that *Thermometers*, *Criticore Monitors*, *SCDs*, *Wound Vacuum Devices*, and *Patient Beds* pose *Minimum to No* safety risk to patients while the remainder of the devices pose a *Moderate to Extremely High* safety risk to patients if

the alarm is not attended to or malfunctions (see Appendix Q for full data table).



The survey results included only a single qualitative survey comment. The participant stated: “central tele unit in ICU makes for continual alarm distractions which ICU nurses are not responsible for attending/ responding to. We are listening to alarms for other units that don't apply to our patients. This is a huge source of alarm fatigue”.

Objective #2

Identify the most important alarm signals to manage in the project ICU based on data gathered from the hospital's administration regarding the potential for patient harm based on internal incident history. The next aim and objective of this project was to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU including to “identify the most important alarm signals to manage based on...potential for patient harm based on internal incident history” via data gathered from The Hospital's administration. According to The Hospital's Risk Manager, internal incident history related to clinical alarms in The Hospital shows only that clinicians' management of bed exit alarms have possibly resulted in patient harm related to subsequent patient falls.

Objective #3

Identify the most important alarm signals to manage based on published best practices and guidelines. The final aim and objective of this project was to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU including to “identify the most important alarm signals to manage based on...published best practices and guidelines” (TJC, 2013c, p. 7). This aim and objective was completed via a comprehensive literature review. Literature review findings showed that although the literature does not explicitly state which types of clinical alarms are most important to manage, there were many literature sources showing the great numbers of false and clinically insignificant (i.e. non-actionable) alarms

produced by physiologic monitoring devices including pulse oximetry and cardiac rhythm monitors, which have been shown to be contributors to AF and subsequent patient harm (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI, 2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O'Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997).

The AAMI (2011) describes that in 2010, the FDA MAUDE database showed that there were “more than 2,500 adverse event reports associated with ventilator use” and “about a third of the ventilator events indicated an alarm system-related issue” (p. 8) while Phillips and Barnsteiner (2005) describe that “One of the most essential alarms in a critical care setting is the ventilator alarm” (p. 320). In addition, a study conducted by ACCE (2007) queried the FDA MAUDE adverse event database from 2002 to 2004 “using the search terms ‘alarm’ in the Product Problem field” and found that “physiological monitoring systems along with ventilators and infusion pumps” came up most commonly (p. 24, 32). Other studies also point out the false and clinically insignificant alarms produced by ventilators (Gorges, Markewitz, & Westenskow, 2009) as well as IV infusion pumps (Chopra & McMahon, 2014). Thus, the literature indicates that physiologic monitor alarm systems including pulse oximetry and cardiac rhythm alarms are currently the most important clinical alarms to manage followed by ventilators and IV infusion pumps.

Summary

In this chapter, the project results in relation to accomplishment of the project's aims and objectives was discussed. The aims of this project were to assess measures of AF amongst The

Hospital's ICU clinical staff and to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which are to 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) published best practices and guidelines (TJC, 2013c, p. 7).

The project objectives were to: 1) Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage, to 2) Identify the most important alarm signals to manage in the project ICU based on data gathered from the hospital's administration regarding the potential for patient harm based on internal incident history, and to 3) Identify the most important alarm signals to manage based on published best practices and guidelines.

The results showed that overall, the majority of participants appear to be affected by AF on 78% or 7 out of 9 of the AF survey measures. The results also showed that when the project survey results, internal incident history, and evidence-based literature are combined, overall, physiologic monitors including pulse oximetry and cardiac rhythm alarms are currently the most important to manage in The Hospital's ICU followed by ventilators, IV pumps, and patient bed exit alarms. Project participants also identified Bipap/Cpap Machines, Crash Cart Defibrillators, Intraaortic Balloon Pumps, Wound Vacuum Devices, External Pacemakers, Tube Feeding Pumps, Blanket Warmer/Coolers (BAIR Hugger), and Blood/IV Fluid Warmer/Coolers as important to manage due to frequent false and non-actionable alarms, their alarm necessity, and/or their importance relative to patient safety, although these devices were not discussed as specific contributors to AF or patient harm in the literature. Participants also indicated that

Portable (Handheld) Thermometers, SCDs, and Criticare Urine Output/Temperature Monitors have Unnecessary clinical alarms and pose Minimum to No safety risk to patients if the alarm signal is not attended to or malfunctions.

Chapter 5: Recommendations and Conclusions

In this chapter, accomplishment of the project's aims objectives will be discussed based upon the project results and the significance of the results. Literature comparisons to the project results and the project strengths and limitations will also be discussed. The aims of this project were to assess measures of AF amongst The Hospital's ICU clinical staff and to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which are to 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) published best practices and guidelines (TJC, 2013c, p. 7).

The project objectives were to: 1) Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage, to 2) Identify the most important alarm signals to manage in the project ICU based on data gathered from The Hospital's administration regarding the potential for patient harm based on internal incident history, and to 3) Identify the most important alarm signals to manage based on published best practices and guidelines.

Objective #1

Develop and implement a survey to gather input from the ICU clinical staff regarding AF measures and to identify the most important alarm signals to manage. The

project successfully accomplished the first aim and objective of this project which was to develop and implement a survey in order to assess measures of AF amongst The Hospital's ICU clinical staff. Based on the data analysis methodology described in Chapter 3, the AF survey results showed that more than 50% of The Hospital's ICU clinical staff participants *Agreed* that clinical alarms in the ICU make the work area noisy (89.28%); that there are many *false* or *non-actionable* clinical alarms in the ICU (78.57%); that there are *too many* clinical alarms in the ICU (67.86%); that clinical alarms in the ICU are *adjusted* due to the number of *false* or *non-actionable* alarm signals (67.86%); and that they feel *distracted* (67.85%), *desensitized* (60.72%) and *overwhelmed* (53.57%) by the number of clinical alarms in the ICU. The AF survey results also showed that more than 50% of the ICU clinical staff participants *Disagreed* that clinical alarms in the ICU are *turned off* (71.42%) or are *ignored* (53.57%) due to the number of *false* or *non-actionable* alarm signals.

Thus, the significance of these results includes that the majority of The Hospital's ICU clinical staff participants appear to be affected by AF on 78% (7 out of 9) of the AF survey measures! The survey results indicating that the majority of ICU clinical staff participants *Disagree* that clinical alarms are *turned-off* or are *ignored* in the ICU is significant since these "negative" survey findings are likely contributing to the "positive" survey findings of AF amongst the clinical staff including the findings that the majority of participants feel that the ICU work area is *noisy*, that there are many *false* or *non-actionable* and *too many* clinical alarms that then are *adjusted* and cause the clinical staff to feel *distracted*, *overwhelmed*, and *desensitized*.

These AF survey measure results support that AF is likely a problem in The Hospital's ICU just as it has been found to be a problem for clinical staff in many other studies. Furthermore, these results indicate that The Hospital's ICU patient's are thus vulnerable to the

harms associated with the AF phenomenon (ACCE, 2007; AACN, 2013; AAMI, 2011; AAMI & HTSI, 2012, 2013; Atzema & Schull, 2006; Bush-Vishniac, West, & Barnhill, 2005; Chambrin et al., 1999; Cvach, 2012; Drews et al., 2007; ECRI, 2007, 2010, 2011, 2012, 2013; Graham & Cvach, 2010; Korniewicz, Clarke, & David, 2008; Lawless, 1994; TJC, 2013a; Ryherd, Persson, & Ljungkvist, 2008; Schmid et al., 2011; Siebig et al., 2010; TJC, 2013a, 2013b; Tsien & Fackler, 1997).

Indeed, many studies point out that while alarm signals in hospitals are essential to providing safe patient care, clinical alarms can also create numerous challenges due to multiple similar sounds, mismanaged settings and equipment, and failure to respond, which can lead to patient harm rather than safety (ACCE, 2007; AACN, 2013; AAMI, 2011; AAMI & HTSI, 2012, 2013; Aztema & Schull, 2006; Chambrin et al., 1999; Cvach, 2012; Drew, Musters, Markham, & Samore, 2007; ECRI, 2007, 2011, 2012; Kowalcusk, 2010a, 2010b; Lawless, 1994; Schmid et al., 2011; Siebig et al., 2010; TJC, 2013a; Tsien & Fackler, 1997). These “AF” data results also signify the importance for The Hospital’s compliance with NPSG.06.01.01!

Next, the project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital’s ICU which included to “identify the most important alarm signals to manage based on...input from the medical staff and clinical departments” was fulfilled by asking survey participants to rate alarm-capable ICU devices according to 4 different questions on a 6-point likert scale. There were 18 devices that staff were asked to rate including: Criticare Monitors, IV Pumps, Nurses Station Monitors, Blood/IV Fluid Warmer/Coolers, External Pacemakers, Ventilators, SCDs, Bedside Monitors, Bipap/Cpap Machines, Handheld Thermometers, Intraaortic Balloon Pumps, Patient Beds, Syringe IV Pumps, Tube Feeding

Pumps, Defibrillators, Portable Monitors, Blanket Warmer/Coolers, and Wound Vacuum Devices.

The first of these questions asked participants to “Rate the following clinical devices according to how important they are to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms”. Based on the project’s data analysis methodology described in Chapter 3, this survey question’s results showed that more than 80% of the survey participants indicated that *IV Infusion Pumps* (100%), *Central Nurses Station Vital Signs and Rhythm Monitors* (100%), *Bedside Vital Signs and Rhythm Monitors* (96.00%), *Portable Transport Vital Signs and Rhythm Monitors* (96.00%), *Ventilators* (96.00%), and *Syringe IV Infusion Pumps* (84.00%) are important to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms.

Management of clinical alarms according to STEP 3 NPSG.06.01.01 performance elements include *establish[ing] policies and procedures for managing the alarms identified in EP 2 [i.e. in STEP 2] that, at a minimum, address the following: Clinically appropriate settings for alarm signals, When alarm signals can be disabled, When alarm parameters can be changed, Who in the organization has the authority to set alarm parameters, Who in the organization has the authority to change alarm parameters, Who in the organization has the authority to set alarm parameters to “off”, Monitoring and responding to alarm signals, and Checking individual alarm signals for accurate settings, proper operation, and detectability* (TJC, 2013c, p. 7).

These survey results are significant since they are consistent with the many publications showing the great numbers of false and clinically insignificant (i.e. non-actionable) alarms produced by physiologic monitoring devices including pulse oximetry and cardiac rhythm monitors, ventilators, and IV infusion pumps and the safety issues associated with

mismanagement of these device alarms (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI, 2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O'Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997).

For example, during a 10-day observation period on an 18 bed medical cardiology unit, researchers from the UPMC performed a cardiac rhythm alarm signal analysis and found that the majority of the alarm signals were “midlevel, non-life-threatening arrhythmia” alarms ranging from 247 to 1565 signals per day with the average being 871 non-life threatening/non-actionable alarm signals per day (AAMI & HTSI, 2013, p. 5). The UPMC researchers found that “most alarm signals...had no significant health consequences” and “had become background noise” for “desensitized” clinical staff members (AAMI & HTSI, 2013, p. 5).

Another UPMC study in a medical cardiology and a progressive care unit showed that non-life threatening arrhythmia alarms occurred on average once every 96 seconds for a total occurrence of 83 times per patient per day (AAMI & HTSI, 2013). A UPMC nursing research team reviewed ten days of alarm signal data on all non-life threatening alarm conditions collected from cardiac monitors on the two units and concluded that there were too many alarm signals for nurses to differentiate between (i.e. life threatening versus non-life threatening/nuisance), alarms occurred too frequently for quick response, and that “workflow was interrupted and inefficient due to the time and attention that nurses had to spend responding to alarm signals” (AAMI & HTSI, 2013, p. 6).

Furthermore, a review of the FDA's MAUDE database from March 2010 to June 2010, showed 73 alarm related deaths, 33 of which were attributed to physiologic monitor alarms (Cvach, 2012). In addition, according to the ACCE (2007), "For physiologic monitors, there are numerous reports of critical patient events in which the monitoring system was reported to not produce an alarm. Many of these reports were subsequently investigated...to find that alarms had somehow been inadvertently disabled" (p. 24). The AAMI (2011) also described that in 2010 the FDA MAUDE database showed that there were "more than 2,500 adverse event reports associated with ventilator use" and "about a third of the ventilator events indicated an alarm system-related issue" (p. 8) while Phillips and Barnsteiner (2005) described that "One of the most essential alarms in a critical care setting is the ventilator alarm" (p. 320).

In addition, a study conducted by ACCE (2007) queried the FDA MAUDE adverse event database from 2002 to 2004 "using the search terms 'alarm' in the Product Problem field" and found that "physiological monitoring systems along with ventilators and infusion pumps" came up most commonly (p. 24, 32). Other studies also point out the false and clinically insignificant alarms produced by ventilators (Gorges, Markewitz, & Westenskow, 2009) as well as IV infusion pumps (Chopra & McMahon, 2014).

Moreover, TJC reports that common types of alarm-related events that resulted in death or injury involved medication errors, ventilation use, and treatment delays with major contributing factors being "alarm settings inappropriately turned off (36)", and "improper alarm settings (21)" (TJC, 2013a, p. 2). According to Maria Cvach, RN, Assistant Director of Nursing, Clinical Standards at John Hopkins Hospital, "Monitor alarm systems are very sensitive and unlikely to miss a true event; however, this results in too many false positives" (AAMI & HTSI, 2012, p. 3). Chopra and McMahon (2014) also point out that "cardiac monitors frequently alarm

for bradycardia in patients with low normal (often, sleeping) heart rates, just as intravenous pumps sound a repetitive signal when an infusion is complete” (p. 1199) while a study by Gorges, Markewitz, and Westenkow (2009) found that only 23% of the 1214 alarms that occurred during a 200-hour observation period, which included ventilator, physiologic monitor, and IV infusion pump alarms, were actually effective.

In addition, the survey results showed that more than 50% of the ICU participants indicated that *Bipap/Cpap Machines* (100%), *Crash Cart Defibrillators* (96.00%), *Intraaortic Balloon Pumps* (96.00%), *Wound Vacuum Devices* (88.00%), *External Pacemakers* (84.00%), *Tube Feeding Pumps* (84.00%), *Blanket Warmer/Coolers (BAIR Hugger)* (68.00%), *Patient Beds* (64.00%), and *Blood/IV Fluid Warmer/Coolers* (56.00%) are also important to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms.

Although there has not been any substantial literature naming these specific clinical devices in relation to the phenomenon of AF and subsequent patient harm, these results are still significant since they indicate that the ICU staff feel that these devices are important to manage and thus should be considered by hospital management in alarm management policies.

In addition, the majority of survey participants indicated that *Portable (Handheld) Thermometers* (76.00%), *Criticore Urine Output/Temperature Monitors* (64.00%), and *SCDs* (60.00%) are *Unimportant* to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms. These results are also significant since they indicate that the ICU staff feel that these devices are *Unimportant* to manage and thus hospital management may not need to focus on these devices in future alarm management policies.

Next, the project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital’s ICU which included to “identify the most important alarm

signals to manage based on...input from the medical staff and clinical departments” and “whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue”, was fulfilled by the next survey question which asked participants to “Rate the following clinical devices according to how necessary their alarms are”.

Based on the project’s data analysis methodology described in Chapter 3, this survey question’s results showed that more than 80% of survey participants indicated that *Central Nurses Station Vital Signs and Rhythm Monitors* (100%), *Portable Transport Vital Signs and Rhythm Monitors* (100%), *Ventilators* (100%), *Bedside Vital Signs and Rhythm Monitors* (95.24%), *IV Infusion Pumps* (85.72%), and *Syringe IV Infusion Pumps* (84.00%) have necessary clinical alarms. These findings echo the literature support described previously within this chapter and the importance of managing these *Necessary* clinical alarms that when unmanaged, are potential contributors to AF and subsequent patient harm (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI, 2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O’Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997).

In response to this question, the majority of participants also indicated that *Bipap/Cpap Machines* (100%), *Intraaortic Balloon Pumps* (100%), *Crash Cart Defibrillators* (100%), *External Pacemakers* (90.48%), *Tube Feeding Pumps* (80.95%), *Patient Beds* (80.95%), *Wound Vacuum Devices* (76.19%), *Blood/IV Fluid Warmer/Coolers* (61.91%), and *Blanket Warmer/Coolers (BAIR Hugger)* (57.14%) also have *Necessary* clinical alarms while the majority of survey participants indicated that *Portable (Handheld) Thermometers* (71.42%),

SCDs (61.91%), and *Criticore Urine Output/Temperature Monitors* (52.39%) have *Unnecessary* clinical alarms.

Although the literature has not specifically described the necessity of these device's clinical alarms in relation to AF and clinical alarm management, these results are still significant as a guide to The Hospital's future alarm management efforts. For example, hospital management may want to consider including all of the above clinical devices in future alarm management policies. Hospital management may also want to consider changing audible alarm signals on *Portable (Handheld) Thermometers*, *SCDs*, and *Criticore Urine Output/Temperature Monitors* to visual type alarms if possible, since the majority of ICU clinical staff participants believe that these devices have *Unnecessary* clinical alarms.

Next, the project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which included to "identify the most important alarm signals to manage based on...input from the medical staff and clinical departments" and "whether specific alarm signals are needed or unnecessarily contribute to alarm noise and AF", was fulfilled by asking the next question of survey participants which was to "Rate the following clinical devices according to how often they produce false or non-actionable alarm noise".

Based on the project's data analysis methodology described in Chapter 3, this survey question's results showed that more than 50% of participants indicated that *Central Nurses Station Vital Signs and Rhythm Monitors* (83.33%), *Bedside Vital Signs and Rhythm Monitors* (83.33%), and *Ventilators* (55.55%) produces false or non-actionable alarm noise *Often* to *Extremely Often*, which is supported by the literature described previously within this chapter (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI,

2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O’Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997).

Additionally, more than 50% of survey participants indicated that *Criticore Urine Output/Temperature Monitors* (94.45%), *Portable (Handheld) Thermometers* (94.44%), *Blanket Warmer/Cooler (BAIR Hugger)* (94.44%), *Wound Vacuum Devices* (94.44%), *Tube Feeding Pumps* (88.89%), *External Pacemakers* (88.88%), *Syringe IV Infusion Pumps* (83.34%), *Crash Cart Defibrillators* (83.34%), *Blood/IV Fluid Warmer/Coolers* (83.33%), *Intraaortic Balloon Pump* (77.77%), *Patient Beds* (72.22%), *SCDs* (66.67%), *IV Infusion Pumps* (55.56%), *Portable Transport Vital Signs and Rhythm Monitors* (55.56%), and *Bipap/Cpap Machines* (55.55%) produce false or non-actionable alarm noise *Never to Occassionally*.

Besides the literature support discussed within this chapter describing physiologic monitors, ventilators, and IV infusion pumps relative to their high production of false or non-actionable alarm noise and potential for contribution to AF and patient harm when mismanaged, the literature does not specifically discuss the remainder of these clinical alarms relative to their production of false or non-actionable alarms or relationship to AF. These results are significant since they show that *Central Nurses Station* and *Bedside Vital Signs and Rhythm Monitors* and *Ventilators* likely produce the most false or non-actionable alarm noise, which is also supported by the literature, thus supporting the need for their management.

The project aim and objective to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital’s ICU which included to “identify the most important alarm signals to manage based on...input from the medical staff and clinical departments” and “risk to patients if the alarm signal is not attended to or if it malfunctions” was fulfilled by asking the

fourth question of survey participants to “Rate the following clinical devices according to which carry the greatest safety risk to patients if the alarm signal is not attended to or if it malfunctions”.

More than 70% of survey participants indicated that *Ventilators* (100%), *IV Infusion Pumps* (100%), *Bedside Vital Signs and Rhythm Monitors* (100%), *Portable Transport Vital Signs and Rhythm Monitors* (94.44%), *Central Nurses Station Vital Signs and Rhythm Monitors* (88.90%), and *Syringe IV Infusion Pumps* (72.22%) poses a *Moderate to Extremely High* safety risk to patients if the alarm signal is not attended to or malfunctions which is also supported by literature findings relative to AF and the patient safety incidents related to mis-management of these devices as described previously within this chapter (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI, 2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O’Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997).

The majority of survey participants also indicated that *Bipap/Cpap Machines* (94.44%), *Intraaortic Balloon Pumps* (94.44%), *External Pacemakers* (88.88%), *Crash Cart Defibrillators* (83.33%), *Blood/IV Fluid Warmer/Coolers* (61.11%), and *Blanket Warmer/Coolers (BAIR Hugger)* (55.56%) also pose a *Moderate to Extremely High* safety risk to patients if the alarm signal is not attended to or malfunctions. These devices have not been described in the literature relative to AF and clinical alarm management, however, this information is important since it signifies the need for management to include these devices in future alarm management policies.

In addition, the majority of survey participants indicated that *Portable (Handheld) Thermometers* (94.44%), *SCDs* (88.89%), *Criticare Urine Output/Temperature Monitors* (72.23%), *Wound Vacuum Devices* (61.11%), and *Patient Beds* (55.55%) poses *Minimum* to *No* safety risk to patients if the alarm signal is not attended to or malfunctions. These results are significant since they possibly show the lesser degree of importance of the audible alarms of these clinical devices and/or the lesser need for inclusion of these devices in future alarm management efforts and policies. The opinion regarding the safety risk to patients if *Tube Feeding Pump* (50.00%) alarm signals are not attended to or malfunction was split 50:50 amongst survey participants, thus, significance regarding the management of this device in relation to patient safety cannot necessarily be determined.

Objective #2

Identify the most important alarm signals to manage in the project ICU based on data gathered from the hospital's administration regarding the potential for patient harm based on internal incident history. The next aim and objective of this project was to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU including to "identify the most important alarm signals to manage based on...potential for patient harm based on internal incident history" via data gathered from The Hospital's administration. This was accomplished by speaking with The Hospital's Risk Manager who manages The Hospital's incident reporting system.

The Hospital Risk Manager stated that internal incident history related to clinical alarms showed only that staff's management of patient bed exit alarms have possibly resulted in patient harm related to subsequent patient falls. The patient safety issues related to the management of bed exit alarms have been described in the literature, although there is conflicting evidence

regarding whether proper use of such devices actually reduces patient fall-related safety incidents (Anderson, Boshier, & Hanna, 2012; Capezuti et al., 2009; Coussement, et al., 2008; ECRI, 2009; Guarascio-Howard, 2011; Hempel et al., 2013; Hilbe et al., 2010; Johnson, George, & Tran, 2011; Sahota et al., 2013; Shorr et al., 2012; Shrikant Kulkarni, 2013; Veluswamy & Price, 2010).

For example, Capezuti et al. (2009) state that TJC has endorsed bed exit alarms as a valuable tool in fall prevention but that “the overall reliability of bed exit alarms in detecting resident movements out of bed has not been well established” (p. 27). Furthermore, Coussement, et al. (2008) conducted a meta-analysis which “found no conclusive evidence that hospital fall prevention programs [including those that use bed exit alarms] can reduce the number of falls or fallers” (p. 29). In addition, Hempel et al. (2013) state that “in-hospital falls are a significant clinical, legal, and regulatory problem, but information on effective fall reduction is lacking” (p. 483). What’s more, Guarascio-Howard (2011) and Hilbe et al. (2010) state that bed exit alarms do help to control patient fall rates while a study by Schorr et al. (2012) found that increased bed alarm use did not prove to decrease falls in hospitalized patients. Additionally, Johnson, George, and Tran (2011) state that “In the absence of staff or family to provide adequate supervision, alarm devices are encouraged” to assist in preventing patient falls (p. 65) and Veluswamy and Price (2010) state that bed exit alarms are effective in reducing patient falls when they are in proper working order. The Hospital’s ICU survey participants in this project indicated that *Patient Beds* likely pose *Minimum* to *No* safety risk to patients if the alarm signal is not attended to or malfunctions. These results may ultimately be due to the fact that many ICU patients are often less mobile than less acutely ill patients who are typically more mobile.

Objective #3

Identify the most important alarm signals to manage based on published best practices and guidelines. Finally, the aim and objective of this project to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU including to "identify the most important alarm signals to manage based on...published best practices and guidelines" (TJC, 2013c, p. 7) was completed via a comprehensive literature review as described previously within Chapter 4 and within this chapter.

The review showed that although the literature does not explicitly state which types of clinical alarms are *most important to manage*, the literature consistently describes the great numbers of false and clinically insignificant (i.e. non-actionable) alarms produced by physiologic monitoring devices including pulse oximetry and cardiac rhythm monitors which can lead to subsequent AF and patient harm. The literature also shows evidence of the actual patient safety incidents related to mis-management of these devices (AAMI, 2011; ACCE, 2007; AAMI & HSTI, 20012, 2013; Atzema et al., 2006; Borowski et al., 2011; Chambrin, et al., 1999; Chopra & McMahon, 2014; Cvach, 2012; Drew et al., 2005; ECRI, 2007, 2012, 2013; Gorges, Markewitz, & Westenskow, 2009; Graham & Cvach, 2010; Gross, Dahl, & Nielsen, 2011; Lawless, 1994; Kowalcsk, 2010b; O'Carroll, 1986; Patel & Souter, 2008; Seibig et al., 2009, 2010; Tsien & Fackler, 1997). The literature also included some studies pointing out the potential safety issues relative to ventilator and IV infusion pumps alarms (AAMI, 2011; ACCE, 2007; Chopra & McMahon, 2014; Phillips & Barnsteiner, 2005). These literature findings were also supported by the project survey results described within this chapter. Overall, these project findings are significant since they indicate that physiologic monitors including pulse oximetry and cardiac rhythm alarms are currently the most important to manage according to the literature, followed by ventilators, IV pumps, and patient bed exit alarms.

Strengths and Limitations

A great strength of this project is that the survey data collection tool that was used was pre-viewed by The Hospital's ICU nurse manager, ICU clinical educator, Quality Director, project committee members, as well as an expert in the field from John Hopkins Hospital in order to gather input for improvement and to determine survey content validity. Input from The Hospital's biomedical department manager and the ICU clinical educator regarding the types of ICU alarm-capable clinical devices in current use were also utilized in the survey development in order to ensure content validity. Part of the survey design was also based on NPSG.06.01.01 STEP 2 performance elements. Thus, data gathered from the ICU participants allowed for completion of STEP 2 NPSG performance elements. Feedback from an ICU charge nurse who "tested" the survey showed that it was "quick" and "easy" to complete. Furthermore, the majority of the data results came straight from the ICU clinical staff via the survey results. These ICU survey participants will be affected by the later policy and procedure changes related to the survey results and as required by TJC NPSG.06.01.01.

Additional strengths and facilitators to accomplishing the aims and objectives of this project were certainly the collaboration and assistance provided by The Hospital's ICU clinical leadership including the clinical educator and charge nurses. The Hospital's ICU leaders assisted in reminding the ICU clinical staff to complete the surveys during any work down-time as it was impossible for me to be present in the ICU at all times. Project limitations and barriers to accomplishing full survey participation by the ICU clinical staff possibly included the project time constraints and that the surveys could potentially be perceived as "lengthy" at first glance. Furthermore, the surveys had to be completed during the ICU clinical staffs' patient care shifts. Thus, completing the surveys during work-time may have contributed to some staff not

participating in completing the surveys or not completing the surveys completely due to potential work related interruptions or distractions. However, this could also have been a strength of the project design since the survey was conveniently available for the staff to take when they had any work down-time.

It also appears from the survey results that the ICU night-shift staff did not participate in equal proportion to the day-shift staff which may be due to the fact that the ICU clinical educator was not available throughout the night-shift to remind staff about the surveys, which was a barrier and limitation of this project. Finally, 50% (2) of the Telemetry Technicians who participated in the survey completed only the AF survey measures. This may indicate that the Telemetry Technicians did not feel confident completing the remainder of the survey in which it asks staff to rate *all* of the clinical devices with alarms. This finding may be because the telemetry technicians/nurse aids do not work directly with *all* of these clinical devices, such as intra-aortic balloon pumps. However, 29% (7) of the Registered Nurses also did not fully complete the survey, which could possibly be due to time constraints related to having to complete the survey during work-time.

Summary

In this chapter, accomplishment of the project's aims objectives was discussed along with the significance of the project results and literature comparisons. The project strengths and limitations were also discussed. The aims of this project were to assess measures of AF amongst The Hospital's ICU clinical staff and to complete STEP 2 performance elements of NPSG.06.01.01 for The Hospital's ICU which are to 1) identify the most important alarm signals to manage based on...input from the medical staff and clinical departments, 2) risk to patients if the alarm signal is not attended to or if it malfunctions, 3) whether specific alarm signals are

needed or unnecessarily contribute to alarm noise and AF, 4) potential for patient harm based on internal incident history, and 5) published best practices and guidelines (TJC, 2013c, p. 7).

The results showed that overall, the majority of participants appear to be affected by AF on 78% or 7 out of 9 of the AF survey measures which was supported by abundant literature evidence showing that many other clinicians, particularly critical care clinicians, are also affected by AF. Hence the reason for this AF phenomenon culminating in the development of NPSG.06.01.01. The results also showed that when the project survey findings, The Hospital's internal incident history and evidence-based literature are combined, overall, physiologic monitors including pulse oximetry and cardiac rhythm alarms are currently the most important to manage in The Hospital's ICU followed by ventilators, IV pumps, and patient bed exit alarms.

Finally, ICU project participants also identified Bipap/Cpap Machines, Crash Cart Defibrillators, Intraaortic Balloon Pumps, Wound Vacuum Devices, External Pacemakers, Tube Feeding Pumps, Blanket Warmer/Coolers (BAIR Hugger), and Blood/IV Fluid Warmer/Coolers as important to manage due to frequent false and non-actionable alarms, their alarm necessity, and/or their importance relative to patient safety. However, these devices were not discussed in the literature as specific contributors to AF or patient harm due to mismanagement. Participants also indicated that Portable (Handheld) Thermometers, SCDs, and Criticore Urine Output/Temperature Monitors have *Unnecessary* clinical alarms and pose *Minimum to No* safety risk to patients if the alarm signal is not attended to or malfunctions. Thus, these devices auditory alarms may not be necessary.

Chapter 6: Implications for Practice

With the completion of NPSG.06.01.01 STEP 2 performance elements for The Hospital's ICU, The Hospital's administrators and management can proceed towards completing STEP 3

and STEP 4 NPSG.06.01.01 performance elements for the ICU which are due by January 1, 2016. STEP 3 NPSG.06.01.01 performance elements include *establish[ing] policies and procedures for managing the alarms identified in EP 2 [i.e. in STEP 2] that, at a minimum, address the following: Clinically appropriate settings for alarm signals, When alarm signals can be disabled, When alarm parameters can be changed, Who in the organization has the authority to set alarm parameters, Who in the organization has the authority to change alarm parameters, Who in the organization has the authority to set alarm parameters to “off”, Monitoring and responding to alarm signals, and Checking individual alarm signals for accurate settings, proper operation, and detectability* (TJC, 2013c, p. 7).

STEP 4 NPSG.06.01.01 performance elements include *educat[ing] staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible* (TJC, 2013c, p. 7). Thus, the policies and procedures created during STEP 3 can address the *purpose and proper operation* of the alarm systems that The Hospital’s ICU staff are responsible for managing and can be used as educational tools for the ICU clinical staff. In addition, after NPSG.06.01.01 STEP 3 and STEP 4 alarm management changes have been instituted, The Hospital’s ICU patient satisfaction scores relative to environmental noise could possibly be re-assessed to determine if patient satisfaction scores in this category have improved following institution of these new alarm management strategies.

Finally, the AF measurement survey tool used in this project could possibly be used to assess for decreased AF amongst The Hospital’s ICU clinical staff after NPSG.06.01.01 STEP 3 policy and procedure changes and STEP 4 staff education performance elements have been instituted. Using this tool may allow Hospital administration and ICU management to assess if implementation of alarm management changes have resulted in decreased AF amongst the

clinical staff! Dissemination of this project's results included distribution of the project results to The Hospital's ICU staff and management as well as to The Hospital's Quality Director. The project findings will also be disseminated to various professional clinical organizations such as the AACN and AAMI for possible publication.

Summary

In summary, based on the project results, including the literature review findings, The Hospital ICU clinical devices that produce *false* and *non-actionable* alarm noise *Often*, yet still have *Necessary* clinical alarms that carry a *Moderate to Extremely High Safety Risk* to patients if the alarms are not attended to or malfunction, include physiologic monitors, ventilators, IV infusion pumps, and patient bed exit alarms. Thus, these devices appear to be most important to manage first when creating these new STEP 3 NPSG.06.01.01 policies followed by the remainder of the clinical devices that were not necessarily discussed in the literature, but that the majority of The Hospital's ICU clinical staff participants identified as important to manage due to frequent *false* and *non-actionable* alarms, their alarm *Necessity*, and/or their importance relative to patient *Safety Risk*. These additional devices included: Bipap/Cpap Machines, Crash Cart Defibrillators, Intraaortic Balloon Pumps, Wound Vacuum Devices, External Pacemakers, Tube Feeding Pumps, Blanket Warmer/Coolers (BAIR Hugger), and Blood/IV Fluid Warmer/Coolers.

In addition, The Hospital's administration and ICU management may want to consider changing Portable (Handheld) Thermometers, SCDs, and Criticore Urine Output/Temperature Monitors auditory alarms to visual type alarms if possible since the majority of ICU clinical staff project participants indicated that these devices have *Unnecessary* clinical alarms and pose *Minimum to No* safety risk to patients if the alarm signal is not attended to or malfunctions.

Hopefully these new alarm management strategies will decrease AF amongst The Hospital's ICU clinicians, thereby achieving the aim of NPSG.06.01.01 to reduce the harm associated with clinical alarm systems!

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Appendix A

Concept Map: ALARM FATIGUE

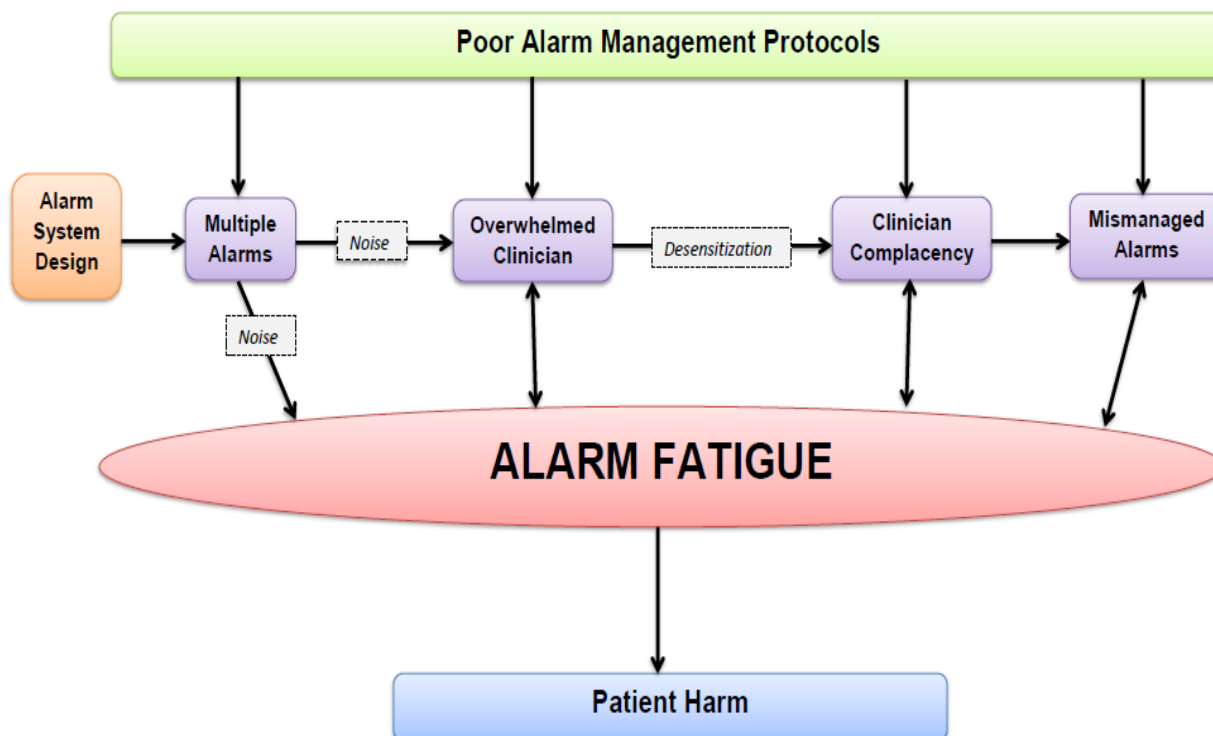
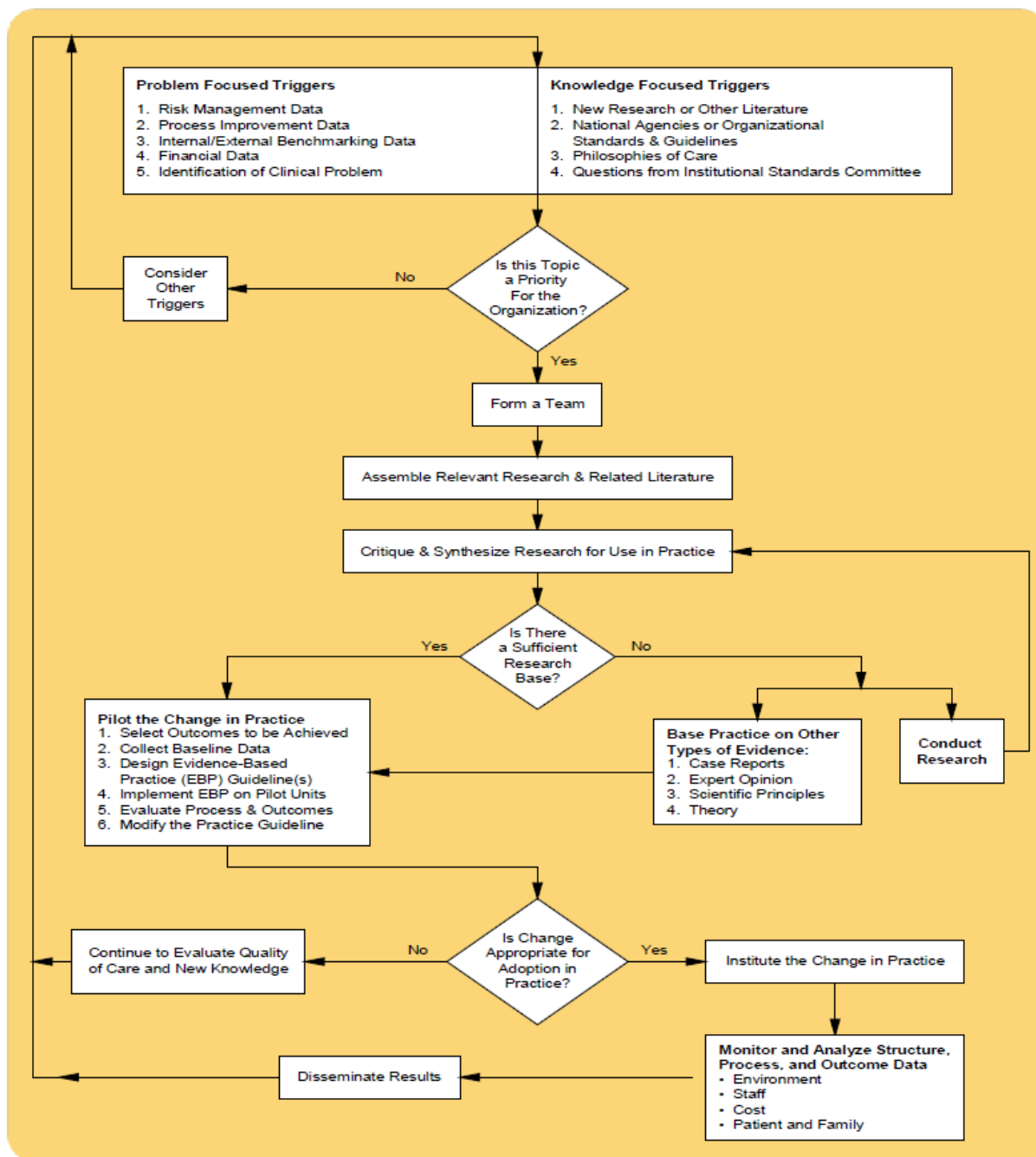


Figure 1. Concept Map: ALARM FATIGUE (primary concept); Poor Alarm Management Protocols, Alarm System Design, Multiple Alarms, Noise, Overwhelmed Clinician, Desensitization, Clinician Complacency, Mismanaged Alarms, Patient Harm (supporting concepts).
Patricia Hensley, N612, Fall 2013

Appendix B

The Iowa Model of Evidence-Based Practice to Promote Quality Care



◊ = a decision point

Titler, M.G., C., Steelman, V.J., Rakel, B. A., Budreau, G., Everett, L.Q., Buckwalter, K.C., Tripp-Reimer, T., & Goode C. (2001). The Iowa Model Of Evidence-Based Practice to Promote Quality Care. *Critical Care Nursing Clinics of North America*, 13(4), 497-509.

REQUESTS TO:
Department of Nursing
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Appendix C

Welcome to the Hilo Medical Center Clinical Alarm Management Questionnaire

On January 1, 2014, the Joint Commission announced a Hospital National Patient Safety Goal to "Reduce the harm associated with clinical alarm systems/Improve the safety of clinical alarm systems".

According to the Joint Commission: "Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multifaceted problem. In some situations, individual alarm signals are difficult to detect. At the same time, many patient care areas have numerous alarm signals and the resulting noise and displayed information tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. Other issues associated with effective clinical alarm system management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among hospitals and even within different units in a single hospital. "

In order to abide by Joint Commission requirements, during 2014, Hilo Medical Center must "identify the most important alarm signals to manage based on the following:

- Input from the medical staff and clinical departments
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue"

Important Definitions:

False alarms occur when there is no valid alarm triggering event.

For example, pulse oximetry or ECG leads with poor signals due to disconnections or artifact may lead to false alarms.

Non-actionable alarms correctly sound, but for an event that has no clinical relevance.

For example, if a patient is sleeping causing their heart rate to decrease to less than 60 beats per minute, a non-actionable bradycardia alarm may be triggered which requires no intervention; or if a patient with chronic obstructive pulmonary disease has a pulse oximetry reading of 93%, a non-actionable "low saturation" alarm may be triggered which requires no intervention.

Confidentiality and Privacy: You will not be asked for any personal information, such as your name or address. Only non-identifiable demographic information will be requested. Please do not include any personal information in your survey.

***Please be truthful and complete to ensure accurate survey results.**

Thank you for participating in our survey.

Demographic Information

Please answer truthfully. All demographic information and survey data collected is anonymous.

***1. Which of the following best describes your job title?**

- ☐ Registered Nurse (RN)
- ☐ Licensed Practical Nurse (LPN)
- ☐ Certified Nursing Assistant (CNA)
- ☐ Telemetry Technician
- ☐ Respiratory Therapist
- ☐ Physician (MD, DO)
- ☐ Advanced Practice Registered Nurse (APRN)
- ☐ Physician Assistant (PA)
- ☐ Other (please specify)

***2. How many years of experience do you have in your job title?**

- ☐ 0-3 years
- ☐ 3-6 years
- ☐ 6-11 years
- ☐ 11 or more years

***3. What clinical department do you work in?**

- ☐ Intensive Care Unit
- ☐ Emergency Department
- ☐ Operating Room/Anesthesia
- ☐ Post-Anesthesia Care Unit
- ☐ Short-Stay
- ☐ Medical Unit
- ☐ Surgical Unit
- ☐ Obstetrics
- ☐ Other

***4. How many years have you worked in this unit?**

- ☐ 0-3 years
- ☐ 3-6 years
- ☐ 6-11 years
- ☐ 11 or more years

***5. Which one of the following best describes your work schedule?**

- ☐ 12 hour day-shift
- ☐ 12 hour night-shift
- ☐ 8 hour day-shift
- ☐ 8 hour evening-shift
- ☐ 8 hour night-shift
- ☐ Other (please specify)

***6. Typically, how many hours per week do you work in this unit?**

- ☐ Less than 12 hours
- ☐ 12 to 24 hours
- ☐ 24 to 36 hours
- ☐ 36 to 40 hours
- ☐ More than 40 hours

Clinical Alarms Fatigue Survey

Important Definitions:

False alarms occur when there is no valid alarm triggering event.

Non-actionable alarms correctly sound, but for an event that has no clinical relevance.

***7. Please mark each statement below according to how much you agree or disagree.**

[illegible]

Clinical Alarms Management Importance Rating

***8. Rate the following clinical devices according to how important they are to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms.**

Important Definitions:

False alarms occur when there is no valid alarm triggering event.

Non-actionable alarms correctly sound, but for an event that has no clinical relevance.

[illegible]

Clinical Alarms Necessity Rating

***9. Rate the following clinical devices according to how necessary their alarms are.**

[illegible]

***10. Rate the following clinical devices according to how often they produce false or non-actionable alarm noise.**

False alarms occur when there is no valid alarm triggering event.

[illegible]

***11. Rate the following clinical devices according to which carry the greatest safety risk to patients if the alarm signal is not attended to or if it malfunctions.**

	No Safety Risk	Rare Safety Risk	Minimum Safety Risk	Moderate Safety Risk	High Safety Risk	Extremely High Safety Risk
A. Criticore Urine Output/Temperature Monitors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
B. IV Infusion Pumps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
C. Central Nurses Station Vital Signs and Rhythm Monitors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
D. Blood/IV Fluid Warmer/Cooler	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
E. External Pacemaker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F. Ventilators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
G. Sequential Compression Devices (SCDs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
H. Bedside Vital Signs and Rhythm Monitors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I. Bipap/Cpap Machines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
J. Portable (Handheld) Thermometers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
K. Intraaortic Balloon Pump	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
L. Patient Beds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
M. Syringe IV Infusion Pumps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
N. Tube Feeding Pumps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
O. Crash Cart Defibrillators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
P. Portable Transport Vital Signs and Rhythm Monitors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Q. Blanket Warmer/Cooler (BAIR Hugger)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
R. Wound Vacuum Device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. Any other comments or suggestions?

Appendix D

The University of Hawai'i at Hilo is conducting a study:

Reducing the Harm Associated with Clinical Alarm Systems: Meeting the Joint Commission National Patient Safety Goal.06.01.01 Performance Elements

Are you a Hilo Medical Center (HMC) ICU patient care or clinical staff member?

If the answer is **YES**...

Doctor of Nursing Practice student Patricia Hensley, RN, BSN, CCRN would like to invite you to participate in a research study.

The purpose of this study is to conduct a survey of “alarm fatigue” amongst HMC ICU clinical staff members and to complete Joint Commission National Patient Safety Goal (NPSG) .06.01.01 “Step 2” performance element criteria which are to “identify the most important alarm signals to manage based on...input from the medical staff and clinical departments”, “risk to patients if the alarm signal is not attended to or if it malfunctions”, and “whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue” (The Joint Commission, 2013).

- Surveys are completely anonymous and can be easily completed by clicking a link on a HMC ICU education room computer.
- Surveys should take approximately 10 minutes to complete.
- A summary of the HMC ICU survey results will be provided to you upon completion of the study.

To learn more about the study, please contact Patricia Hensley at 808.557.0884 or 808.333.5500.

Appendix E

University of Hawai'i at Hilo: Consent to Participate in Research
**Reducing the Harm Associated with Clinical Alarm Systems: Meeting the Joint
Commission National Patient Safety Goal.06.01.01 Performance Elements**

My name is Patricia Hensley, RN, BSN, CCRN. I am a graduate student at the University of Hawai'i at Hilo (UHH). As part of my degree program, I am conducting a research project. One of the purposes of my project is to assess clinical staff's opinions about the clinical alarms in the Hilo Medical Center (HMC) Intensive Care Unit (ICU). I am asking that you participate in this project because you are at least 18 years old and you are a clinical staff member in the HMC ICU.

Project Description – Activities and Time Commitment: If you decide to take part in this project, you will be asked to fill out a survey. The survey questions are mainly multiple choice or on a "likert-scale". There will be one question where you may add an open-ended response. The survey is accessed via the survey monkey website and you can take the survey anonymously on a computer in the HMC ICU "education room" at any time when myself, the unit educator, or a charge nurse is available to open the survey-link. Completing the survey will take approximately 10 minutes. I expect that all HMC ICU clinical staff will take part in this project.

Benefits and Risks: There will be no direct benefit to you for taking part in this project, however, the findings from this project may help to create a better understanding of the wishes and needs of HMC ICU clinical staff regarding the management of clinical alarms in the HMC ICU. There is little risk to you for participating in this project. All survey results are completely anonymous.

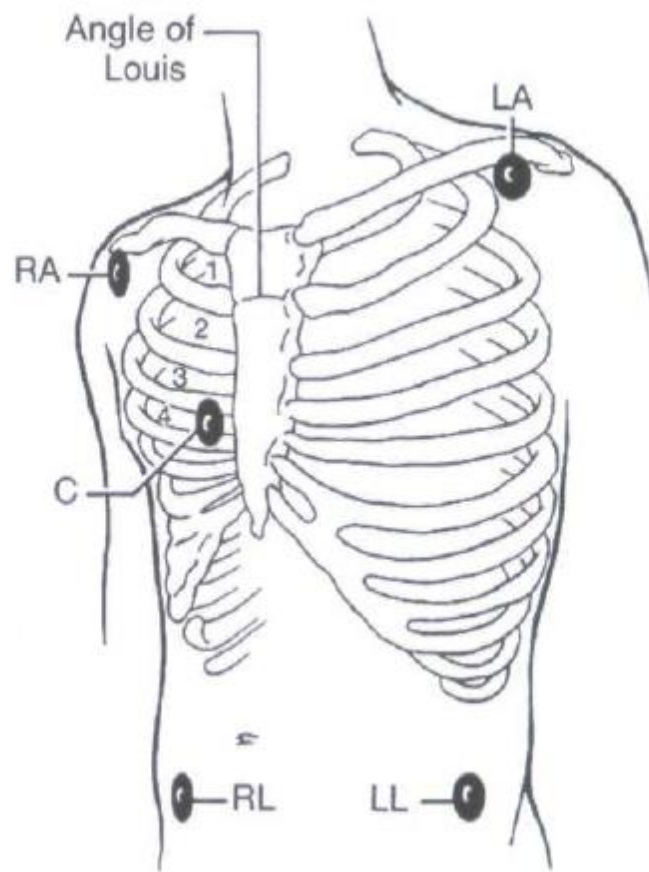
Confidentiality and Privacy: I will not ask you for any personal information, such as your name or address. Only non-identifiable demographic information will be requested. Please do not include any personal information in your survey responses.

Voluntary Participation: You can freely choose to take part or to not take part in this survey. There will be no penalty or loss of benefits for either decision. If you do agree to participate, you can stop at any time.

Questions: If you have any questions about this study, please contact me at 808-333-5500 or 808-557-0884 or email me at hensleyp@hawaii.edu. You may also contact my advisor, Dr. Cecelia Mukai, at 808-932-7067 or cmukai@hawaii.edu. If you have questions about your rights as a research participant, you may contact the UH Human Studies Program at 808.956.5007 or uhirb@hawaii.edu.

To Access the Survey: Please see myself, the HMC ICU clinical educator, or charge nurse who will provide you with a link to the survey. Completing the survey will be considered as your consent to participate in this study.

Appendix F



Appendix G

Hospital National Patient Safety Goals

Effective January 1, 2014

Goal 6

Reduce the harm associated with clinical alarm systems.

NPSG.06.01.01

Improve the safety of clinical alarm systems.

--Rationale for NPSG.06.01.01--

Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multifaceted problem. In some situations, individual alarm signals are difficult to detect. At the same time, many patient care areas have numerous alarm signals and the resulting noise and displayed information tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. Other issues associated with effective clinical alarm system management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among hospitals and even within different units in a single hospital.

There is general agreement that this is an important safety issue. Universal solutions have yet to be identified, but it is important for a hospital to understand its own situation and to develop a systematic, coordinated approach to clinical alarm system management. Standardization contributes to safe alarm system management, but it is recognized that solutions may have to be customized for specific clinical units, groups of patients, or individual patients. This NPSG focuses on managing clinical alarm systems that have the most direct relationship to patient safety. As alarm system management solutions are identified, this NPSG will be updated to reflect best practices. *

Footnote *: Additional information on alarm safety can be found on the AAMI website <http://www.aami.org/htsi/alarms/>. Also, the ECRI Institute has identified alarm hazards as one of the top technology hazards for 2013; more information on this hazard list can be found at http://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Elements of Performance for NPSG.06.01.01

- | | | | | | | |
|--|---|----------|----------|---|--|--|
| 1. As of July 1, 2014, leaders establish alarm system safety as a hospital priority. | <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; text-align: center;">R</td> <td style="width: 20px; text-align: center;">A</td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | R | A | | | |
| R | A | | | | | |
| 2. During 2014, identify the most important alarm signals to manage based on the following: <ul style="list-style-type: none"> - Input from the medical staff and clinical departments - Risk to patients if the alarm signal is not attended to or if it malfunctions - Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue - Potential for patient harm based on internal incident history - Published best practices and guidelines (For more information on managing medical equipment risks, refer to Standard EC.02.04.01.) | <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; text-align: center;">R</td> <td style="width: 20px; text-align: center;">A</td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | R | A | | | |
| R | A | | | | | |
| 3. As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following: <ul style="list-style-type: none"> - Clinically appropriate settings for alarm signals - When alarm signals can be disabled - When alarm parameters can be changed - Who in the organization has the authority to set alarm parameters - Who in the organization has the authority to change alarm parameters - Who in the organization has the authority to set alarm parameters to "off" - Monitoring and responding to alarm signals - Checking individual alarm signals for accurate settings, proper operation, and detectability (For more information, refer to Standard EC.02.04.03) | <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; text-align: center;">R</td> <td style="width: 20px; text-align: center;">A</td> <td style="width: 20px; text-align: center;">Ⓢ</td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | R | A | Ⓢ | | |
| R | A | Ⓢ | | | | |
| 4. As of January 1, 2016, educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible. | <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; text-align: center;">R</td> <td style="width: 20px; text-align: center;">C</td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | R | C | | | |
| R | C | | | | | |

Appendix H

Q1: Which of the following best describes your job title?

Answer Choices	Responses	
Registered Nurse (RN)	85.71%	24
Licensed Practical Nurse (LPN)	0.00%	0
Certified Nursing Assistant (CNA)	0.00%	0
Telemetry Technician	14.29%	4
Respiratory Therapist	0.00%	0
Physician (MD, DO)	0.00%	0
Advanced Practice Registered Nurse (APRN)	0.00%	0
Physician Assistant (PA)	0.00%	0
Other (please specify)	0.00%	0
Total		28

Appendix I

Q2: How many years of experience do you have in your job title?

Answer Choices	Responses	
0-3 years	7.14%	2
3-6 years	25.00%	7
6-11 years	21.43%	6
11 or more years	46.43%	13
Total		28

Appendix J

Q4: How many years have you worked in this unit?

Answer Choices	Responses	
0-3 years	39.29%	11
3-6 years	10.71%	3
6-11 years	25.00%	7
11 or more years	25.00%	7
Total		28

Appendix K

Q5: Which one of the following best describes your work schedule?

Answer Choices	Responses	
12 hour day-shift	57.14%	16
12 hour night-shift	21.43%	6
8 hour day-shift	0.00%	0
8 hour evening-shift	3.57%	1
8 hour night-shift	0.00%	0
Other (please specify)	17.86%	5
Total		28

Appendix L

Q6: Typically, how many hours per week do you work in this unit?

Answer Choices	Responses	
Less than 12 hours	0.00%	0
12 to 24 hours	3.57%	1
24 to 36 hours	25.00%	7
36 to 40 hours	67.86%	19
More than 40 hours	3.57%	1
Total		28

Appendix M

Q7: Please mark each statement below according to how much you agree or disagree.

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree	Total	Weighted Average
C. Clinical alarms in my department make my work area "noisy".	3.57% 1	3.57% 1	3.57% 1	35.71% 10	21.43% 6	32.14% 9	28	4.32
B. There are many "false" or "non-actionable" clinical alarms in my work area.	3.57% 1	3.57% 1	14.29% 4	17.86% 5	28.57% 8	32.14% 9	28	4.29
A. There are "too many" clinical alarms in my work area.	14.29% 4	0.00% 0	17.86% 5	21.43% 6	28.57% 8	17.86% 5	28	3.86
I. Clinical alarms are "adjusted" in my work area due to the number of false or non-actionable alarm signals.	10.71% 3	10.71% 3	10.71% 3	25.00% 7	21.43% 6	21.43% 6	28	3.79
E. I feel "distracted" by the number of clinical alarms in my work area.	17.86% 5	0.00% 0	14.29% 4	35.71% 10	25.00% 7	7.14% 2	28	3.64
F. I feel "desensitized" by the number of clinical alarms in my work area.	21.43% 6	3.57% 1	14.29% 4	21.43% 6	25.00% 7	14.29% 4	28	3.54
D. I feel "overwhelmed" by the number of clinical alarms in my work area.	25.00% 7	3.57% 1	17.86% 5	35.71% 10	17.86% 5	0.00% 0	28	3.18
G. Clinical alarms are "ignored" in my work area due to the number of false and non-actionable alarm signals.	28.57% 8	3.57% 1	21.43% 6	17.86% 5	25.00% 7	3.57% 1	28	3.14
H. Clinical alarms are "turned off" in my work area due to the number of false or non-actionable alarm signals.	42.86% 12	14.29% 4	14.29% 4	14.29% 4	14.29% 4	0.00% 0	28	2.43

Appendix N

Q8: Rate the following clinical devices according to how important they are to manage in order to decrease unnecessary (i.e. false and non-actionable) clinical alarms.

	Extremely Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Extremely Important	Total	Weighted Average
C. Central Nurses Station Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	0.00% 0	4.00% 1	28.00% 7	68.00% 17	25	4.68
K. Intraaortic Balloon Pump	4.00% 1	0.00% 0	0.00% 0	4.00% 1	16.00% 4	76.00% 19	25	4.64
O. Crash Cart Defibrillators	0.00% 0	0.00% 0	4.00% 1	4.00% 1	24.00% 6	68.00% 17	25	4.64
F. Ventilators	0.00% 0	0.00% 0	4.00% 1	4.00% 1	28.00% 7	64.00% 16	25	4.60
I. Bipap/Cpap Machines	0.00% 0	0.00% 0	0.00% 0	4.00% 1	36.00% 9	60.00% 15	25	4.60
B. IV Infusion Pumps	0.00% 0	0.00% 0	0.00% 0	0.00% 0	48.00% 12	52.00% 13	25	4.52
H. Bedside Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	4.00% 1	12.00% 3	36.00% 9	48.00% 12	25	4.44
P. Portable Transport Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	4.00% 1	12.00% 3	36.00% 9	48.00% 12	25	4.44
E. External Pacemaker	8.00% 2	0.00% 0	8.00% 2	0.00% 0	12.00% 3	72.00% 18	25	4.40
M. Syringe IV Infusion Pumps	4.00% 1	8.00% 2	4.00% 1	20.00% 5	28.00% 7	36.00% 9	25	4.04
R. Wound Vacuum Device	4.00% 1	4.00% 1	4.00% 1	36.00% 9	40.00% 10	12.00% 3	25	3.88
N. Tube Feeding Pumps	4.00% 1	8.00% 2	4.00% 1	36.00% 9	32.00% 8	16.00% 4	25	3.84
L. Patient Beds	4.00% 1	12.00% 3	20.00% 5	24.00% 6	28.00% 7	12.00% 3	25	3.56
Q. Blanket Warmer/Cooler (BAIR Hugger)	12.00% 3	8.00% 2	12.00% 3	12.00% 3	44.00% 11	12.00% 3	25	3.48
D. Blood/IV Fluid Warmer/Cooler	12.00% 3	16.00% 4	16.00% 4	16.00% 4	24.00% 6	16.00% 4	25	3.32
A. Criticare Urine Output/Temperature Monitors	8.00% 2	20.00% 5	36.00% 9	16.00% 4	16.00% 4	4.00% 1	25	3.04
G. Sequential Compression Devices (SCDs)	16.00% 4	24.00% 6	20.00% 5	20.00% 5	16.00% 4	4.00% 1	25	2.88
J. Portable (Handheld) Thermometers	44.00% 11	24.00% 6	8.00% 2	12.00% 3	4.00% 1	8.00% 2	25	2.20

Appendix O

Q9: Rate the following clinical devices according to how necessary their alarms are.

	Extremely Unnecessary	Moderately Unnecessary	Slightly Unnecessary	Slightly Necessary	Moderately Necessary	Extremely Necessary	Total	Weighted Average
F. Ventilators	0.00% 0	0.00% 0	0.00% 0	0.00% 0	19.05% 4	80.95% 17	21	5.81
K. Intraaortic Balloon Pump	0.00% 0	0.00% 0	0.00% 0	0.00% 0	19.05% 4	80.95% 17	21	5.81
B. IV Infusion Pumps	0.00% 0	0.00% 0	0.00% 0	0.00% 0	28.57% 6	71.43% 15	21	5.71
C. Central Nurses Station Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	0.00% 0	4.76% 1	19.05% 4	76.19% 16	21	5.71
I. Bipap/Cpap Machines	0.00% 0	0.00% 0	0.00% 0	4.76% 1	19.05% 4	76.19% 16	21	5.71
O. Crash Cart Defibrillators	0.00% 0	0.00% 0	0.00% 0	9.52% 2	14.29% 3	76.19% 16	21	5.67
E. External Pacemaker	0.00% 0	4.76% 1	4.76% 1	4.76% 1	9.52% 2	76.19% 16	21	5.48
H. Bedside Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	4.76% 1	0.00% 0	38.10% 8	57.14% 12	21	5.48
P. Portable Transport Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	0.00% 0	14.29% 3	33.33% 7	52.38% 11	21	5.38
M. Syringe IV Infusion Pumps	4.76% 1	0.00% 0	9.52% 2	19.05% 4	33.33% 7	33.33% 7	21	4.76
L. Patient Beds	4.76% 1	9.52% 2	4.76% 1	28.57% 6	28.57% 6	23.81% 5	21	4.38
N. Tube Feeding Pumps	0.00% 0	4.76% 1	14.29% 3	33.33% 7	33.33% 7	14.29% 3	21	4.38
R. Wound Vacuum Device	0.00% 0	0.00% 0	23.81% 5	28.57% 6	38.10% 8	9.52% 2	21	4.33
D. Blood/IV Fluid Warmer/Cooler	4.76% 1	9.52% 2	23.81% 5	4.76% 1	38.10% 8	19.05% 4	21	4.19
Q. Blanket Warmer/Cooler (BAIR Hugger)	19.05% 4	4.76% 1	19.05% 4	9.52% 2	42.86% 9	4.76% 1	21	3.67
A. Criticare Urine Output/Temperature Monitors	19.05% 4	19.05% 4	14.29% 3	23.81% 5	23.81% 5	0.00% 0	21	3.14
G. Sequential Compression Devices (SCDs)	19.05% 4	28.57% 6	14.29% 3	23.81% 5	14.29% 3	0.00% 0	21	2.86
J. Portable (Handheld) Thermometers	52.38% 11	9.52% 2	9.52% 2	9.52% 2	19.05% 4	0.00% 0	21	2.33

Appendix P

Q10: Rate the following clinical devices according to how often they produce false or non-actionable alarm noise.

	Never	Rarely	Occasionally	Often	Very Often	Extremely Often	Total	Weighted Average
C. Central Nurses Station Vital Signs and Rhythm Monitors	5.56% 1	0.00% 0	11.11% 2	5.56% 1	38.89% 7	38.89% 7	18	4.89
H. Bedside Vital Signs and Rhythm Monitors	5.56% 1	0.00% 0	11.11% 2	27.78% 5	22.22% 4	33.33% 6	18	4.61
B. IV Infusion Pumps	5.56% 1	16.67% 3	33.33% 6	11.11% 2	22.22% 4	11.11% 2	18	3.61
F. Ventilators	16.67% 3	11.11% 2	16.67% 3	11.11% 2	44.44% 8	0.00% 0	18	3.56
P. Portable Transport Vital Signs and Rhythm Monitors	5.56% 1	22.22% 4	27.78% 5	16.67% 3	16.67% 3	11.11% 2	18	3.50
I. Bipap/Cpap Machines	11.11% 2	22.22% 4	22.22% 4	11.11% 2	33.33% 6	0.00% 0	18	3.33
L. Patient Beds	0.00% 0	11.11% 2	61.11% 11	16.67% 3	5.56% 1	5.56% 1	18	3.33
G. Sequential Compression Devices (SCDs)	5.56% 1	38.89% 7	22.22% 4	22.22% 4	5.56% 1	5.56% 1	18	3.00
N. Tube Feeding Pumps	5.56% 1	38.89% 7	44.44% 8	5.56% 1	5.56% 1	0.00% 0	18	2.67
K. Intraaortic Balloon Pump	22.22% 4	33.33% 6	22.22% 4	11.11% 2	5.56% 1	5.56% 1	18	2.61
A. Criticare Urine Output/Temperature Monitors	0.00% 0	55.56% 10	38.89% 7	5.56% 1	0.00% 0	0.00% 0	18	2.50
R. Wound Vacuum Device	11.11% 2	50.00% 9	33.33% 6	0.00% 0	5.56% 1	0.00% 0	18	2.39
D. Blood/IV Fluid Warmer/Cooler	11.11% 2	61.11% 11	11.11% 2	16.67% 3	0.00% 0	0.00% 0	18	2.33
E. External Pacemaker	22.22% 4	44.44% 8	22.22% 4	5.56% 1	0.00% 0	5.56% 1	18	2.33
M. Syringe IV Infusion Pumps	16.67% 3	50.00% 9	16.67% 3	16.67% 3	0.00% 0	0.00% 0	18	2.33
O. Crash Cart Defibrillators	27.78% 5	38.89% 7	16.67% 3	11.11% 2	5.56% 1	0.00% 0	18	2.28
Q. Blanket Warmer/Cooler (BAIR Hugger)	16.67% 3	44.44% 8	33.33% 6	5.56% 1	0.00% 0	0.00% 0	18	2.28
J. Portable (Handheld) Thermometers	33.33% 6	38.89% 7	22.22% 4	5.56% 1	0.00% 0	0.00% 0	18	2.00

Appendix Q

Q11: Rate the following clinical devices according to which carry the greatest safety risk to patients if the alarm signal is not attended to or if it malfunctions.

	No Safety Risk	Rare Safety Risk	Minimum Safety Risk	Moderate Safety Risk	High Safety Risk	Extremely High Safety Risk	Total	Weighted Average
F. Ventilators	0.00% 0	0.00% 0	0.00% 0	0.00% 0	11.11% 2	88.89% 16	18	5.89
I. Bipap/Cpap Machines	0.00% 0	0.00% 0	5.56% 1	0.00% 0	16.67% 3	77.78% 14	18	5.67
K. Intraaortic Balloon Pump	0.00% 0	0.00% 0	5.56% 1	5.56% 1	5.56% 1	83.33% 15	18	5.67
H. Bedside Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	0.00% 0	5.56% 1	33.33% 6	61.11% 11	18	5.56
P. Portable Transport Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	5.56% 1	5.56% 1	16.67% 3	72.22% 13	18	5.56
C. Central Nurses Station Vital Signs and Rhythm Monitors	0.00% 0	0.00% 0	11.11% 2	5.56% 1	16.67% 3	66.67% 12	18	5.39
O. Crash Cart Defibrillators	0.00% 0	5.56% 1	11.11% 2	0.00% 0	5.56% 1	77.78% 14	18	5.39
E. External Pacemaker	0.00% 0	5.56% 1	5.56% 1	0.00% 0	27.78% 5	61.11% 11	18	5.33
B. IV Infusion Pumps	0.00% 0	0.00% 0	0.00% 0	22.22% 4	44.44% 8	33.33% 6	18	5.11
M. Syringe IV Infusion Pumps	0.00% 0	11.11% 2	16.67% 3	11.11% 2	22.22% 4	38.89% 7	18	4.61
L. Patient Beds	0.00% 0	11.11% 2	44.44% 8	11.11% 2	16.67% 3	16.67% 3	18	3.83
D. Blood/IV Fluid Warmer/Cooler	0.00% 0	16.67% 3	22.22% 4	38.89% 7	11.11% 2	11.11% 2	18	3.78
N. Tube Feeding Pumps	0.00% 0	22.22% 4	27.78% 5	22.22% 4	22.22% 4	5.56% 1	18	3.61
Q. Blanket Warmer/Cooler (BAIR Hugger)	0.00% 0	22.22% 4	22.22% 4	33.33% 6	16.67% 3	5.56% 1	18	3.61
R. Wound Vacuum Device	5.56% 1	22.22% 4	33.33% 6	22.22% 4	5.56% 1	11.11% 2	18	3.33
A. Criticare Urine Output/Temperature Monitors	5.56% 1	55.56% 10	11.11% 2	27.78% 5	0.00% 0	0.00% 0	18	2.61
G. Sequential Compression Devices (SCDs)	22.22% 4	50.00% 9	16.67% 3	0.00% 0	11.11% 2	0.00% 0	18	2.28
J. Portable (Handheld) Thermometers	50.00% 9	33.33% 6	11.11% 2	0.00% 0	5.56% 1	0.00% 0	18	1.78

Appendix R



UNIVERSITY
of HAWAII[®]
MĀNOA

Office of Research Compliance
Human Studies Program

February 2, 2015

TO: Patricia Hensley
Principal Investigator
Nursing

FROM: Denise A. Lin-DeShetler, MPH, MA
Director

A handwritten signature in black ink, appearing to read 'Denise A. Lin-DeShetler'.

SUBJECT: CHS #22772 - "Reducing the Harm Associated with Clinical Alarm Systems: Meeting the Joint Commission National Patient Safety Goal.06.01.01 Performance Elements"

This letter is your record of the Human Studies Program approval of this study as exempt.

On February 2, 2015, the University of Hawai'i (UH) Human Studies Program approved this study as exempt from federal regulations pertaining to the protection of human research participants. The authority for the exemption applicable to your study is documented in the Code of Federal Regulations at 45 CFR 46.101(b) (Category 2).

Exempt studies are subject to the ethical principles articulated in The Belmont Report, found at <http://www.hawaii.edu/irb/html/manual/appendices/A/belmont.html>

Exempt studies do not require regular continuing review by the Human Studies Program. However, if you propose to modify your study, you must receive approval from the Human Studies Program prior to implementing any changes. You can submit your proposed changes via email at uhirb@hawaii.edu. (The subject line should read: Exempt Study Modification.) The Human Studies Program may review the exempt status at that time and request an application for approval as non-exempt research.

In order to protect the confidentiality of research participants, we encourage you to destroy private information which can be linked to the identities of individuals as soon as it is reasonable to do so. Signed consent forms, as applicable to your study, should be maintained for at least the duration of your project.

This approval does not expire. However, please notify the Human Studies Program when your study is complete. Upon notification, we will close our files pertaining to your study.

If you have any questions relating to the protection of human research participants, please contact the Human Studies Program at 956-5007 or uhirb@hawaii.edu. We wish you success in carrying out your research project.

1960 East-West Road
Biomedical Sciences Building B104
Honolulu, Hawai'i 96822
Telephone: (808) 956-5007
Fax: (808) 956-8683

An Equal Opportunity/Affirmative Action Institution

Appendix S



Stephen Palmore RN
Risk and Compliance Officer
Hilo Medical Center
1190 Waiianuenue Ave.
Hilo, HI 96720
(808) 932-3181 (phone)
(808) 933-9901 (fax)
spalmore@hhsc.org

February 18, 2015

Patricia Hensley DNP Student
Principal Investigator Nursing
University of Hawaii at Hilo

Dear Miss, Hensley,

Re: University of Hawaii (Manoa) IRB approval

Based upon your submittal of the approved IRB from the University of Hawaii (Manoa) dated February 2, 2015, I am pleased to inform you that Hilo Medical Center approves your research project.

Please call on us if we can be of assistance to you. Thank you.

Sincerely,

Stephen Palmore RN
Compliance Officer