Reduction of Cardiopulmonary Monitor Alarms in the Special Care Nursery

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Abstract

Background: Health care technology has added benefits for monitoring patients, but many of these devices are associated with alarms and alerts to notify staff when a patient's physiological limits fall outside of set parameters or when there is a machine malfunction. Alarm fatigue occurs when a person is exposed to so many clinical alarms, they eventually become immune to the sound, thus having no or slow responses to alarms. In addition to desensitization, staff exposed to these repetitive sounds may react by silencing alarms, turning them off or changing the parameters to unsafe ranges. These actions, and staff missing clinically relevant alarms, have resulted in adverse patient events and deaths in hospitals nationwide. While the issues surrounding alarm safety are multifaceted, many experts focus on strategies to decrease false or non-actionable alarms. False or non-actionable alarms are alarms that do not require any clinical intervention by staff. Evidence suggests that by changing alarm parameters to fit patient needs, false alarms are minimized, therefore decreasing alarm fatigue.

Purpose: The purpose of this project is to decrease alarm fatigue in the Special Care Nursery, a step-down nursery, at a large academic medical center. In order to achieve this goal, the project aimed to decrease the number of cardiopulmonary alarms that sound throughout the unit by individualizing each patient's alarms to their personal baseline.

Methods: A quality improvement project was completed in the Special Care Nursery in which nurses were instructed on how to change alarm parameters to fit their patient's baseline cardiopulmonary needs. Oxygen saturation was excluded from the project due to the narrow margin of acceptability for a neonate's oxygenation status. During the one week intervention, staff were reminded of the importance of alarm parameter changes and the impact of alarm fatigue twice daily before starting their shift. In accordance with current hospital standards, prior to alarm parameter changes, a physician order was required. A job aid on how to change alarm parameters was provided to staff and available on the unit at all times.

Results: Utilizing the Mann Whitney U for analysis, there was no statistically significant difference in the number of alarms that sounded prior to the intervention and following the intervention. No orders were placed for alarm parameter changes following the intervention period.

Discussion: Although the intervention in this project did not result in a statistically significant change (p value=0.974) in cardiopulmonary alarms, the project brought to the forefront the discussion of alarm fatigue within the unit. Further focused work on this unit should involve analysis of current baseline settings to determine if changes can result in decreased nuisance cardiopulmonary alarms. Additional work should focus on achieving support from the front line staff on the criticality of alarm fatigue on patient safety and the role of the nursing staff in decreasing false alarms and alarm fatigue.

Background of the Problem

With developments in health care technology, there have been significant increases in the way health care staff can monitor their patients. Many of these monitoring devices are associated with alarms and alerts to notify staff when a patient's physiological limits fall outside of set parameters or when there is a machine malfunction. Some common alarms staff are exposed to on a daily basis include pulse oximetry readings, electrocardiogram lead alerts such as PVCs, PACs, tachycardia, ventricular fibrillation, asystole; tube feeding pumps, IV pumps, tube stations, sequential compression devices, bed alarms, call bells and ventilators (Purbaugh, 2013;ECRI Risk Analysis, 2008). Some research counts approximately 40 patient care alarm sources not including infusion pumps (Chambrin, 2001).

Research indicates that staff is exposed to a staggering number of alarms on a daily basis. This increase in sensory input may cause staff and family members to suffer from alarm fatigue (Sykes, Barach, Belojevic, Bushc-Vishniac, Cavanaugh, et al, 2011). At Johns Hopkins Hospital (JHH) in 12 days there were 58,764 alarms or 350 alarms per bed per day (JHH, 2012). Boston Medical Center estimated their total audible alarms to be 87,823 (Covelle, Piepenbrink, Whalen, 2013). Alarm fatigue occurs when

a person is exposed to so many clinical alarms, they eventually become immune to the sound, thus having no or slow responses to alarms (TJC Sentinel Event Alert, 2013; Horkan, 2014). This over sensitization can cause people to miss clinically significant alarms (Welch, 2012). In addition, staff exposed to these repetitive sounds may react by silencing alarms, turning them off or changing the parameters to unsafe measurements (ECRI, 2011). These actions and staff missing clinically relevant alarms, can and have, resulted in adverse patient events and deaths in hospitals nationwide. Not only does this barrage of alarms affect patient safety, it can increase anxiety for family members and decrease patient satisfaction (Purbaugh, 2013).

The pediatric population is not immune to these issues. TJC's (TJC) National Patient Safety goal is aimed at all populations, adult and pediatric. Many children's hospitals have started to evaluate their clinical alarms and have published their results in decreasing alarm fatigue. Children's Hospitals such as Cincinnati, Duke University and Children's Hospital of Philadelphia have led the effort in decreasing alarm fatigue in pediatrics. The Special Care Nursery of a local large system hospital was the unit chosen for this project since this unit has the technological capability to obtain alarm data from the unit hardware. Additionally, this unit has many children on cardiopulmonary monitoring and the leadership on the unit is interested in addressing alarm fatigue with staff.

Statement of the problem

Alarm safety is a complex issue that has been brought to the forefront by numerous esteemed healthcare groups including Association for the Advancement of Medical Instrumentation (AAMI), Emergency Care Research Institute (ECRI) and TJC (AAMI, 2012, ECRI, 2013, TJC, 2014). Currently, a large not for profit hospital in Eastern North Carolina is interested in improving the safety of alarms within the institution along with pursuing compliance with The TJC National Patient Safety Goal Number six which states "reduce the harm associated with clinical alarms" (TJC 2015). The first Element of Performance

(EP) associated with this goal is for leaders to establish alarm system safety as a hospital priority. The second EP addresses identifying the most important alarm signals. The third EP set forth by TJC states that by 2016 hospitals will have developed and established policies for managing alarms. This includes the following: addressing when alarms can be disabled, when the parameters can be changed, who has the authority to change parameters, who can set parameters to off, and monitoring as well as responding to alarm signals. As a part of fourth EP, staff must be educated on the purpose and correct operation of alarm systems (TJC, 2015). The frequency, duration and type of education to meet this standard is individually determined by each facility accredited by TJC.

The hospital involved in this project has developed an Alarm Safety Committee that is dedicated to making alarm safety a priority. The Alarm Safety Committee is interdisciplinary, including nurses, physicians, respiratory therapists, biomedical engineers, former hospital patients and leadership. This committee meets on a monthly basis. They focus on ensuring the hospital is on target to meet the standards set forth by TJC. They review any alarm concerns that arise within the institution and review any changes made to alarm policies, parameters and practices. The Alarm Safety Committee is also part of a larger committee lead by the hospital's corporate office, who ensures consistency with alarm policies across the hospital system. Recently, the hospital had a serious event related to alarm safety. Prior to that time, the hospital had not experienced any serious safety events related to alarms. To track patient events and near misses, all units of the hospital utilize an event self-reporting system, which is accessed through any hospital computer. This database, Safety Intelligence (SI), is managed by the hospital Patient Safety Department. A system query provided from the Safety Department, from January 1, 2012 through March 31, 2014 using the terms: alarm, monitor, ECG, pulse ox, oximetry, electrode, ventilator and telemetry resulted in 794 hospital events. Of these events, 403 were related to alarm safety. The vast majority of the events, 131, were related to telemetry alarms.

Like many other facilities across the country, frequently occurring alarms is an issue within the institution chosen for this project. One can walk onto any unit in the hospital and hear a cacophony of beeps as the alarms ring at nurses' stations. While the hospital has started focused work on alarm parameters with the adult population, little work has been completed with the pediatric population at the hospital.

There are five pediatric units within the hospital including the neonatal intensive care unit (NICU) a pediatric floor, a pediatric intensive care unit (PICU), a kids immunocompromised specialty unit (KISU) and a neonatal step down unit or special care nursery (SCN). The hospital utilizes Phillips monitors of varying models depending on when the units were built. The ECG alarms are managed differently in each unit. The PICU and NICU staff respond to their own patient monitors which are located at the bedside with central displays at each nurses' station. The KISU and the pediatric floor previously employed monitor technicians to continuously observe the monitors in an off the unit central station. The monitor technicians were responsible for calling nurses with any ECG monitoring issues such as low oxygen saturation, tachycardia or unattached leads. A recent modification, has led to a practice change on the pediatric floor and the KISU. Unit nurses are now responsible for monitoring their own alarms.

The focused unit of this project is the SCN, where preterm and term infants who require additional support or monitoring are admitted. Per policy, all of the patients located in the SCN should have continuous cardiovascular monitoring. The nurses in the SCN carry pagers that alert them to any alarms in their patient's rooms. Alarms can also be seen on the bedside monitor or viewed and heard at two central nurses' stations. Currently, these alarms are set to default parameters based on patient's gestational age and the limits are rarely changed. On this unit there are no practice standards regarding EKG lead placement or pulse oximetry lead placement. Broad default alarm settings and lack of a focus

on alarms in the SCN has led to numerous alarms sounding on this unit where young, vulnerable children are hospitalized. As common on many units, the vast majority of these alarms are non-actionable alarms. A focused review of the SI report showed one safety event occurred on the SCN related to alarms. Since this report is confidential, it is unknown what details were involved.

Significance of the Problem

The Institute of Medicine's (IOM) publication "To Err is Human." in 1999, discussed the human contribution in many health care deaths. This IOM report concentrated on how mistakes are a leading cause of death in healthcare (IOM, 1999). Alarm fatigue and human error surrounding ignoring and not responding to alarms contribute to the harm and deaths caused by humans in healthcare. In 2011, a Boston Globe article brought to the attention of the lay media this additional human factor related to hospital deaths which is termed, alarm fatigue (Kowalzyk, 2011). As highlighted in the Globe's article, a patient at St. Elizabeth's Medical Center died after her EKG leads became detached from the monitor. While the monitor alerted staff that the leads were no longer reading appropriately, the staff did not notice the alarm. The patient coded and later died. In 2008, at Tobey Hospital, an alarm from a dying cardiac monitor battery was ignored for hours. The patient later suffered a heart attack that went undetected (Kowalzyk, 2011). From January 2005 to June of 2010, the deaths of 200 hospitalized patients were blamed on alarm fatigue (Kowalzyk, 2011). At Massachusetts General Hospital, alarms signifying tachycardia, tachypnea and low oxygen saturations in a patient went without response for approximately one hour. The staff later responded when the alarms finally alerted apnea, but the patient was unable to be revived (Purbaugh, 2013). Over a 6 year time frame in Pennsylvania, The Pennsylvania Patient Safety Authority received 35 reported monitor related deaths. Of these deaths, 31 were attributed to human error and involved telemetry monitors (Lacker, 2011). The Joint Commission's database shows 98 reported sentinel events related to alarms between January 2009 and

June 2012. Of those 98 reports, 80 patients died and 13 suffered permanent loss of function (TJC Sentinel Event Alert, 2013). Even with these staggering statistics, it is noted that alarm related events are underreported and not often recognized, suggesting these numbers underrepresent the true scope of the problem (TJC Sentinel Event Alert 2013).

The concerns surrounding alarm fatigue affect all patient populations, regardless of age. While statistics regarding alarm deaths and events of harm do not break out the patients into age, the lay literature discusses alarm related events for the pediatric population as well as adults. In 2013 an article written by the Washington Post addressed alarm fatigue and referenced the death of a 17 year old female who suffered an anoxic brain injury and subsequent death following a tonsillectomy. After being given pain medications, the patient developed bradypnea, the alarms on the respiratory monitor were muted and the patient went 25 minutes without intervention (Crites, 2013).

The issues surrounding alarm fatigue are multifactorial. The literature suggest contributing factors to alarm fatigue including the monitoring of too many patients (Drew, 2004), interfering noise on the unit (Kokani, 2014), unit layout making alarms difficult to hear (Walsh, 2015), inaccurate alarm settings, inaccurate lead placement and insufficient replacement of leads (AAMI, 2011). Therefore, many expert groups have made clinical alarms a focus of patient safety. At the AAMI (Association for the Advancement of Medical Instrumentation) Summit in 2011, leaders from the clinical arena, research, acoustical experts, regulators and patient safety advocates collaborated and shared data regarding alarm safety and called facilities to action (AAMI, 2011). Due to patient safety concerns surrounding alarms, alarm safety has topped The Emergency Care Research Institute's (ECRI) "Top 10 Technology Hazards" in 2011, 2012, 2013, 2014 and 2015 (ECRI Institute, 2011,2012,2013,2014, 2015) Alarm fatigue is not a new issue; it was first recognized by ERCI in 1974 (Sendelbach and Funk, 2013). Since that time alarms have increased in number therefore increasing the possibility of alarm fatigue (Sendelbach and

Funk, 2013). Recently the concerns surrounding alarms have gained national attention from many patient safety groups. TJC developed a National Patient Safety Goal Standard which has a phased effect with the first and second element of performance mandated by 2014 including identification of the most important alarms. The third and fourth elements of performance are mandated to be in effect by 2016, which include the development of policies defining who can manage clinical alarms and providing education based on these policies (TJC, 2015).

The concerns regarding alarm fatigue apply to all patient populations, but the pediatric patient may pose additional concerns. Some research indicates that nonactionable alarms may be more frequent in the PICU versus the Adult Intensive Care Unit creating a higher risk of alarm fatigue among the PICU staff (Bonafide, Lin, Zander, Graham, Paine, et al, 2015). Many pediatric patients are placed on SpO2 monitors. These monitors can give frequent false alarms due to motion artifact, which is common in the pediatric population (Salyer, 2003). In addition, the layout of some units, where staff are far from their young, vulnerable patients, may lead staff to choose narrow alarm parameters aimed at reassuring staff of the patient's safety (Walsh, Powers, and Fanaroff, 2015). The increased noise that results from multiple alarms can negatively affect the neonate. Increased noise can cause increased heartrate, respiratory rate and desaturations in the neonate (Ranganna and Bustani, 2011). Sensorineural hearing loss has been linked to repeated exposure to loud sound in the NICU (Ranganna and Bustani, 2011). Therefore is it critical to decrease alarms in the SCN, not only to decrease alarm fatigue for family and staff, but to also decrease the neonates expose to ambient noise.

Theoretical Framework

Patricia Benner's theory of From Novice to Expert provides a framework for understanding a nurse's knowledge and how the nurse progresses in their knowledge and development of clinical skills.

Benner's theory is based on the Dreyfus Model of Skill Acquisition and outlines five stages of clinical competence (Benner, 1982). The stages of clinical competence are: novice, advanced beginner, competent, proficient and expert. As a person develops more experience they transition from a novice through the other phases of competence and may finally reach the level of expert. Novice nurses have no experience. They use rules to guide their practice and cannot relate rules and policies to real world experiences or determine when to provide an exception to a rule. In situations, they are unable to identify what information is critical to a process over what is not important or necessary. Advanced beginners have some clinical experience. They operate off of guidelines, but are unable to fully assess clinical priorities. Advanced beginners still need assistance in the clinical arena and the support of other nurses. Benner states competent nurses have usually worked in the same area one to three years. Competent nurses feel they have grasped their nursing roles and many nurses do not progress past this level of mastery. Proficient nurses are more flexible than competent nurses and see the holistic nature of situations, rather than fragments. Proficient nurses are able to discern important information from other data. Expert clinicians rely on their experience to guide their practice rather than rules and algorithms and are able to analyze and synthesize a situation in its entirety (Benner, 1982). As nurses progress through the stages of competency, they develop and improve time management and prioritization skills. A nurse may not fluidly move from one stage to the next and the progression from novice to expert is not linear (Butts and Rich, 2011).

Applying Benner's theory to the concern of monitor attention, the vast majority of hospital staff are competent with the monitor system. Hospital Staff members know to respond to alarms, check on a patients and intervene if necessary when an alarm sounds. With the advances in knowledge and literature regarding alarm fatigue and the high rate of false alarms, few people are experts or even proficient in this arena. Through this quality improvement project, staff will gain more knowledge regarding alarm fatigue. Staff's knowledge will progress from competent to proficient through an

educational intervention. Consistent with Brenner's theory, which states that the majority of in-services are aimed at the competent staff, this educational intervention will target the competent level staff. Increasing the staff's knowledge with the algorithm which details the default parameters for alarms and informing them that exceptions to these rules may occur and empowering staff to recognize these exceptions and act on them by changing alarm parameters fits the progression of the nursing learner through the competent to proficient phase of learning. The skills of the proficient level nurse enable her/him to analyze the vital signs of the patient in conjunction with their diagnosis and physiological needs in order to develop a holistic view of the patient and any needed changes in the alarm parameter settings.

Once staff are able to progress to the proficient level with alarms, they will be able to use the unique skillset of the proficient level nurse which involves seeing the problem in a holistic fashion to aid in understanding of the patient's physiological changes and the patient's physiological needs.

Not only will the educational sessions serve as a way to increase knowledge regarding alarm fatigue, staff's knowledge regarding the intricacies of the alarm system will improve by learning how to change monitor settings and bringing these settings to the forefront of staff attention.

Review of the Literature

Patient deaths and sentinel events related to missed alarms have brought the issue of clinical alarms to the attention of the patient safety community throughout the country (TJC, 2013; AAMI 2011; ECRI, 2008). Numerous alarms alert staff to changing patient conditions, but due to the frequency of alarms and similar tone, alarms can go unrecognized resulting in catastrophic events (Chambrin, 2001). A comprehensive literature review was conducted using PubMed. The terms "Alarm Fatigue" were searched and limited to English articles within the past 5 years. The search generated 102 articles. The articles were reviewed for relevance to the topic and duplicity of information. Older articles were

reviewed on an individual basis for relevance to the topic. Other terms searched included "alarm fatigue" and "patient safety," "alarm fatigue" and "pediat*" CINAHL was also searched using the same terms for articles within the last 5 years. Duplicate articles were removed from the review. The resources from articles were reviewed for pertinent information. Additionally, lay literature was reviewed to find references to alarm fatigue in news outlets. The review of literature will address the evolution of alarm fatigue, the impact of alarm fatigue, alarm tones, types of alarms and recommendations from the literature to address alarm fatigue.

Evolution of Alarm Fatigue

Alarm fatigue was first mentioned in the literature in 1974 when ECRI recognized an alarm on a hypothermia machine was ignored for an extended period of time resulting in severe patient burns (Sendelbach and Funk, 2013). This phenomena is not unique to nursing or the health care field, although the term may be coined alert fatigue in other fields. Alarm fatigue was cited as a contributing factor in a Washington DC metro subway crash that killed nine people in 2009. Prior to the crash, the metro staff had been ignoring over 9,000 alarms a week (Wald, 2010). Employees on Oil Rigs have also suffered from alarm fatigue. The Oil spill that occurred in the Gulf of Mexico in 2010 was attributed to an alarm that had been disabled due to frequent false alarms (Wald, 2010). The 1997 crash of a Korean jumbo Jet was attributed to alarm fatigue. Air traffic controllers felt an alarm notifying them of a low altitude warning sounded too often and had the alarm disabled (Wald, 2010). The jumbo jet later flew into the ground. Alarm fatigue has been cited in many concerning areas. Health care providers suffer not only from alarm fatigue on the unit, but may also suffer from alert fatigue with the electronic health record. In 2013, a 16 year old patient was administered 38.5 Septra pills in a medication overdose attributed to alert fatigue during the medication ordering process (Wachter, 2014). If Alarm and Alert fatigue contribute to death or significant disability, there is most definitely a concern to study the problem.

The Impact of Alarm Fatigue

The frequency of which staff are exposed to alerts and alarms can pose a patient safety risk with staff ignoring alarms, being slow to respond or turning the alarms off (Horkan, 2014). Alarms rarely malfunction. Actual issues with alarms are most often due to poor set up, staff actions or inability to hear alarms (ECRI, 2008). Many esteemed healthcare groups, including AAMI, TJC, ERCI and AACN, have determined the frequency with which alarms sound contribute to staff having slow responses or ignoring alarms. While this phenomenon has been accepted in the literature, Bonafide and colleagues (2015) studied nursing response time to nonactionable alarms and determined that a nurses' response time was longer when responding to an alarm that had been nonactionable in the preceding 120 minutes, reinforcing the concept of alarm fatigue. With units containing on average over 120 alarmed devices, the number of alarms that sound on a unit are staggering (Blum and Blike, 2011). Cincinnati Children's experienced 475,143 alarms over 3 months or 250 alarms per monitor per day (Dandoy, Davies, Flesch, Hayward, Koons, et al, 2014). A medical progressive unit experienced 16, 953 alarms over an 18 day study time period (Graham and Cvach, 2010). With this amount of sensory input coming just from alarms, the human mind must adapt. Gazarian et al (2014) describes alarm fatigue as an adaptive mechanism that is not voluntarily controlled by which staff are trying to reduce their cognitive burden. Staff begin to tone out nonactionable alarms to reduce this cognitive burden (Gazarian et al, 2014). With research showing somewhere between 70 and 90% of alarms are nonactionable, staff are conditioned to not respond to alarms (Karnik and Bonafide, 2014).

The phenomena of alarm fatigue is costly and has been blamed for many patient deaths and events of harm. In a five year period, the Emergency Care Research Institute attributed 216 patient deaths to alarm fatigue (Dandoy, Davies, Flesch, Hayward, Koons, et al, 2014). TJC Sentinel Event database contains over 98 alarm related events for a three year period (TJC, 2013). Alarm fatigue was a

contributing factor in the death of a patient who suffered head trauma from a fallen tree branch but later died when his clinical condition deteriorated and alarms alerting staff to the event went unnoticed (TJC, 2013). Other deaths attributed to alarm fatigue include a patient who's ventilator was turned off in the operating room for an x-ray and the ventilator was never restarted. The alarms on the ventilator were silenced. A 17 year old passed away from an anoxic brain injury when staff were not alerted to her desaturation due to the alarms being turned off (Sendelbach and Funk, 2013). It is also recognized that alarm related events are likely 10 times higher than the data shows since alarm related events are likely underreported (Sendelbach and Funk, 2013).

Alarm Tones

Although a comprehensive review is beyond the scope of this paper, auditory science is an element affecting alarm fatigue. Alarm tones should indicate the criticality of a patient's condition. For example, a sequential compression pump malfunction tone should be distinctly different than a ventilator occlusion tone. The International Electrotechnical Commission has written standards that specifically address alarm sounds. IEC 60601-1-8 is a standard to which most medical alarms voluntarily adhere. This document addresses the Hz and pitch standard for alarm sounds (O'Brien, 2013). Edworthy (2013) suggest that the contour of sounds is what defines them and suggests that short sequences that have the same contour may easily be confused, as is the standard with medical alarms. It is important for staff to be able to discern what different tones indicate and the criticality of those tones. While staff may think they can recognize alarms by their sounds, Cropp (1994) and colleagues demonstrated that nurses can only recognize 38% of vital alarms, putting them at risk for missing a critical event.

An additional concern is the inability of staff to hear alarm sounds (ECRI Institute, 2008). Ambient unit noise can contribute to staff not hearing alarms. Ambient noise arises from ventilation

systems, locking mechanism associated with automatic doors, closing of doors, communication devices (phones, beepers, overhead pages), televisions, linen and meal carts, floor cleaning equipment, human conversation and more (Kokani, 2014). The average unit noise ranges from 50-60 dB (Blum and Blike, 2011). Alarms contribute to unit noise pollution and are capable of producing sounds of greater than 80dB. Sounds of this strength have demonstrated a relation to sleep deprivation and stress while greatly exceeding the World Health Organizations (WHO) recommendation of noise levels being 35dB during the day (Chambrin, 2001 & Cvach, 2012). Research has shown increased noise levels can physiologically and psychologically affect not only staff but patients as well. ICU nurses recognize noise levels in the environment to be a work hazard (Kokani, 2014). A behavioral based approach completed by Konkani and colleagues did not significantly decrease noise on the patient unit and led them to recommend noise reduction related to medical alarms on the unit (Kokani, 2014).

Types of Alarms

Alarm sounds can be classified into numerous categories and there is no standardization of classification throughout the literature. False alarms are often deemed nonactionable alarms. Imhoff and colleagues (2006) break the term false alarms into further descriptions, defining technically false alarms as when alarms read false due to a patient condition. For example, when SpO2 reads low due to poor profusion or hypothermia the alarm is technically false. Clinically false alarms are those alarms that sound when a preset value is passed, but this may have no clinical relevance. For example, when a patient has a known arrhythmia and has intermittent tachycardia that exceeds the alarm limits. Finally, there are false alarms with poor readings due to nursing interventions, such positioning or bathing of a patient (Imhoff and Kuhls, 2006). Phillips (2006), classifies alarms as true and clinically relevant. These alarms are true and require an intervention such as a baby who needs stimulation to raise his oxygen saturation. True and clinically irrelevant alarms are alarms that are accurate, but do not require an

intervention such as when a baby develops tachycardia from crying. Additionally, there are false alarms. Which are similar to 'true and clinically irrelevant alarms' due to a violation of alarm parameters, but do not necessarily indicate a significant clinical change (Phillips, 2006).

False alarms

False alarms are often deemed non actionable alarms and nuisance alarms. Nuisance alarms occur frequently in hospital settings. They disrupt patient care and reduce clinician trust in alarms resulting in the alarms being inappropriately turned off (2011 National Clinical Alarms Survey). High number of alarms contribute to alarm desensitization and missed alarms (Cvach, 2012; Covelle, Piepenbrink, Whale, 2013). Boston Medical Center has an average of 87,823 alarms a week (Covelle, Piepenbrink, Whale, 2013) while JHH has approximately 58,764 a day or 350 alarms per patient per day (AAMI, 2012). Data suggest that false alarms occur as often as 80-99% of the time (Cvach, 2012) making false alarms the main contributor to excessive alarms (ECRI, 2008). With this number of alarms, nurses spend a significant amount of their time hearing and responding to false alarms. Bitan and colleagues (2004), suggest that nurses spend approximately 35% of their time responding to patient alarms. With such a high false alarm rate, staff is likely to become desensitized and not respond to alarms. Research conducted by Bliss and colleagues (1995) revealed that alarm response correlates with alarm accuracy. For example, alarms that are accurate 90% of the time will be responded to 90% of the time. Alarms that are accurate 10% of the time will be responded to 10% of the time (Bliss, Gilson, Deaton, 1995). With such a high false alarm rate, it is imperative to improve alarm accuracy and decrease the number of false or nonactionable clinical alarms.

Recommendations from the Literature

First, the literature recommends being selective in which patients have continuous cardiopulmonary monitoring. The American Heart Association states that a small number of pediatric

patients outside of the intensive care unit warrant continuous cardiopulmonary monitoring. This population of patients includes patients with heart disease or cardiac surgery. Other patients who potentially warrant monitoring include children with chest pain, chest trauma, neurologic events, severe asthma exacerbation, Kawasaki disease, or those who have been given medications that cause prolonged QT and infants with prenatal exposure to cocaine (Drew, Califf, Funk, Kaufman, Krucoff, et al, 2004). It is also recommended to not place all patients on pulse oximeter monitoring, even those with respiratory illness (Bonafide, 2014). The literature recommends developing protocols for which patients should be placed on continuous cardiopulmonary monitoring and algorithms on how to discontinue this monitoring (Bonafide, 2014).

Expert recommendation also addresses strategies to decrease false or nonactionable alarms. By widening alarm parameters or adjusting alarms to fit patient needs, units have been able to decrease their false alarm rates (Whalen, Covelle, Piepenbrink, Villaova, Cueno, et al, 2013; Gross, Dahl, Neilson, 2011; Guardia-LaBar, Scruth, Edworthy, Foss-Durant Burgoon, 2014; AAMI, 2012; Graham & Cvach, 2010; TJC, 2013; Sendelbach & Funk, 2013). Gross and his colleagues audited a 79 bed subacute floor and discovered that the alarm settings, programmed for a critical care unit were too sensitive and resulted in numerous false alarms (Gross, Dahl, Neilson, 2011). The literature does not support any specific standards when it comes to setting alarms, but recommends evaluating your own patient population. Recent research completed by Bonafide and colleagues developed new standards for respiratory and cardiac rates for hospitalized children (Bonafide, Brady, Keren, Conway, Marsolo, et al, 2013). These parameters could serve as a starting point for setting alarm parameters in a pediatric institution. At JHH minimal changes in alarm parameters reduced alarms between 24% and 74% (AAMI, 2012). By changing alarm settings for heart rate and changing some alarm limits to crisis, one telemetry unit was able to reduce their nonactionable alarms by 89% (Whalen, Covelle, Piepenbrink, Villaova, Cueno, et al, 2013). By increasing the cardiac limits on one unit, more than 50% of alarms were

reduced. When the same unit lowered the SpO2 to 85%, SpO2 alarms were reduced by 35% (Gross, Dahl, Nielsen, 2011). A small test of change was completed on a medical intermediate unit where cardiac alarm parameters were edited to include a range of 20 beats above and 20 beats below the patient's baseline resulting in a 43% reduction of alarms (Graham and Cvach, 2010). Leaders in the field recommend changing alarm parameters to meet patient needs. Johns Hopkins, who has initiated a successful alarm management program recommends starting safety checks on alarm settings and editing alarm settings to make all alarms actionable (AAMI, 2012). The American Association of Critical Care Nurses (AACN) also recommends changing alarm parameters to meet patient needs (Sendelbach & Jepsen, 2013). One of the priority actions identified during the AAMI clinical alarm summit was to suppress alarms and signals that did not require action (AAMI, 2011). To aid in the process of changing alarms to patient needs, the ECRI Institute recommends the development of protocols for setting alarms (ECRI, 2008).

In addition to changing alarm limits to fit the patient population, research recommends changing daily EKG electrodes (Sendelbach & Jepsen, 2013; Cvach Biggs, Rothwell, Charles-Hudson, 2013). Electrodes can malfunction due to drying out of the gel, patient perspiration and hair (Cvach, Biggs, Rothwell, Charles-Hudson, 2013). Electrodes that are placed with appropriate skin preparation experience less artifact. Literature supports using soap, water and gauze or sandpaper on the skin prior to applying EKG leads. Daily changing of leads in conjunction with appropriate skin preparation decreased alarms per bed by 46% (Cvach, Biggs, Rothwell, Charles-Hudson, 2013).

Finally, experts recommend education on clinical alarms (AAMI, 2011). In a survey completed by clinical staff, responders ranked lack of training on alarm systems as a top most important issue when related to clinical alarms (AAMI, 2011). ECRI (2008) recommends educating staff on alarm use. It is important to communicate alarm concerns and education with staff and unit managers (AAMI,

2012). As alarms become less frequent, it will be important for staff to recognize the need to quickly respond to alarms. Alarm education is also an element of performance set forth by TJC in the NPSG addressing alarm fatigue (TJC, 2015).

Moving forward with this project it will be important to garner support from hospital staff to address the concerns related to alarm fatigue. While the hospital has made alarm fatigue a priority, this information may not get translated to the front line staff. Gaining the support and interest of front line staff will make this project successful. Also, while not monitoring all patients, and changing alarm parameters is supported in the literature, it would be a significant practice change for the project institution. Therefore, having a complete understanding of the expert recommendations and results in the literature will aid in persuading staff to support this initiative.

Synthesis of the Evidence

As the number of patient monitoring devices have increased in the hospital setting, so have the number of alarms (Gazarian, Carrier, Cohen, Schram, Shiromani, 2014). The sheer volume of alarms on units have created alarm fatigue which results when staff unintentionally tune out alarms (Gazarian, Carrier, Cohen, Schram, Shiromani, 2014), change alarm parameters to unsafe values or disable alarms (AAMI, 2011). The number of alarms, volume of alarms and unit design contribute to alarm fatigue (AAMI, 2011). Alarm fatigue has resulted in multiple events of patient harm and patient deaths. Patient advocacy groups have called hospitals to action and asked that they address alarm fatigue (TJC, 2015). Expert recommendations developed by AAMI, surround garnering hospital support and developing crossfunctional teams to address alarm fatigue (AAMI, 2011). The practice changes supported by the literature involve decreasing the number of patients being inappropriately monitored (Drew, Califf, Funk, Kaufman, Krucoff, et al, 2004), decreasing nonactionable alarms by widening alarm parameters

and personalizing alarm limits, reducing false alarms by changing EKG pads and using skin preparation for lead changes and finally providing alarm education to staff (Karnik, Bonafide, 2014).

Methods

Purpose

The literature shows that hospital staff suffers from alarm fatigue related to numerous alerts throughout the hospital (AAMI, 2011). Alarm fatigue is common among all patients and false alarms may be even more prevalent in the pediatric population (Karnik, Bonafide, 2014). Alarm fatigue increases the risk that staff may miss a patient safety event and the increased ambient noise can have an effect on newborn infants in addition to staff. Based on the literature review, a decrease in nuisance and nonactionable alarms would decrease alarm fatigue on this unit as well as decrease newborn exposure to ambient noise. In addition, an increase in staff awareness and knowledge regarding the setting of alarm parameters would aid staff in changing alarm settings and decrease excessive alarms. The current policy for the SCN sets alarm parameters at 100-200 beats per minute, respirations greater than 80 and apnea greater than 15 seconds. Oxygenation, measured by pulse oximetry is set at 90-100% for infants less than 35 weeks gestation at birth who are on room air. For those less than 35 weeks gestation at birth who are on oxygen, their settings are 90-95%. Infants greater than 35 weeks gestation have oxygenation saturation alarms set at 95-100%.

Due to the lack of evidence to support any specific process to address minimizing alarms in the special care nursery, and thus decreasing alarm fatigue, this project was developed. Therefore, the purpose of this quality improvement project is to answer the question: In the special care nursery, does increasing staff knowledge regarding alarm fatigue result in staff changing alarm parameters to fit a patient's baseline and therefore decrease nonactionable alarms in this unit? Knowledge gained from this project may aid in developing hospital policies for other pediatric and potentially adult units within the facility.

Setting and Sample

This quality improvement project was completed in a large (approximately 900 bed) hospital situated in rural eastern North Carolina. The intervention was focused on the 32 bed SCN where the patient population includes vulnerable infants. This unit is an intermediate unit and often contains patients who are progressing from the NICU. The convenience sample consisted of all patients admitted to the SCN unit during the project time frame, between September 18th, 2015 and October 8th, 2015. Exclusion criteria were patients admitted to the unit who were not on a cardiopulmonary monitor during the project timeframe but all patients in the study were on cardiac monitors Since the turnover of patients in this unit is low, some of the same patients were part of the pre-test and post-test groups.

Project Design

Application to the Institutional Review Board (IRB) of both the school, University of Maryland and the hospital was made to complete this Quality Improvement project. The project was deemed exempt from the IRB process. Following IRB clearance, a pre-test post-test, non-experimental design quality improvement project was conducted to determine if personalizing alarm parameters and increasing nursing knowledge regarding alarm fatigue and alarm monitor settings decreased alarms in the SCN.

Procedures

During the intervention period, which lasted seven days, the primary investigator attended, via conference call, twice daily unit meetings. These twice daily unit meetings were held immediately prior to nurse's starting their shift at 7am and 7pm. The unit manager requires all nurses working for the next 12 hours to be present during these meetings and time was allotted to the PI out of interest in improving alarms on the unit. At this time, the PI discussed the role of alarm fatigue and the importance of personalizing cardiopulmonary monitor settings in decreasing alarms and therefore decreasing alarm

fatigue. Staff was encouraged to monitor their patients for baselines that fell outside of the standard alarm parameters set forth in the SCN policy. If a patient's baseline alarm settings were outside of these presets, then the staff was encouraged to ask providers for an order to change alarm parameters during provider rounding. Since there is no standardization on exactly how alarm parameters should be set and the current practice requires provider order for alarm parameters, it was determined for patient safety and compliance with hospital standards, that orders would be needed prior to changing alarms. In some studies, nurses were able to change alarm parameters with the verification of another RN and later obtain a provider's order (Whale, Covelle, Piepenbrink, Villanova, Cuneo, et al, 2013). Staff was then oriented to the process of changing alarm parameters on the bedside monitor. In addition, a job aid complete with screen shots detailing how to change alarm parameters on the bedside monitor was provided to staff on the unit (see Appendix B). A period of time was left for staff questions.

Data Collection

Data was collected for three days prior to the project intervention to establish a baseline for the number and types of alarms sounding within the unit. The project intervention took place for seven days. Following the intervention, a period of seven days elapsed to evaluate for a practice change. After the seven days passed, post intervention data was obtained for a period of three days.

Data was pulled from the Phillips Monitor central processing unit by the PI. This data contained all alarms for the project time frame separated by date and room. This de-identified data was maintained in an excel spreadsheet. In addition, a chart review was conducted retrospectively on each patient in the pre and post intervention group. Demographic data was obtained including the patient's gestational age, gender, oxygen status and age. If a patient had an order for any form of continuous oxygen, they were flagged as having an order for oxygen during the data abstraction. Oxygen status was used to denote infant stability. Also collected, was the patient's alarm parameter settings and if the

patient had a provider order to change their alarm parameter settings. In this unit, alarm parameters are preset based on infant gestational age, so any variation of these settings was documented.

Data Analysis

After data was collated according to date and room number, the types of alarms were analyzed. Alarms types that sounded during the project included: asystole, yellow alarms, red alarms, In Op (which most often indicates leads off), bradycardia: <100, <80, <70, Tachycardia: >200, >210, >220 and >230, respirations <20, <15 and >100. Desaturation alarms included saturation <85%, <92%, <90%, <87%. Blood pressure alarms included diastolic >90. No alarms were set to include systolic parameters. Yellow alarms and red alarms occur when a patient's vital signs reach a preset limit. Yellow alarms and red alarms have different auditory tones and when they sound, the numbers on the screen turn yellow or red, respective to the alarm. Prior to the intervention, there were a total of 21,039 alarms in the SCN over a three day period. The pre-intervention alarms per bed per day were 390, 400 and 229. Following the intervention, there were 19,810 alarms over three days. This calculated out to an alarm per bed per day value of 289, 306 and 348. Following this basic analysis on the data means, the data was again edited and all alarms referencing oxygen saturation and blood pressure were excluded from analysis. The exclusion of oxygen saturation alarms is due to the narrow safety parameters for infant oxygenation. Red and yellow alarms were also excluded from further analysis as these were seen as double counts of alarms. Data was then analyzed using Minitab version 17.

Results

Demographic data showed greater than 50% of the project sample identified their race as white with 36.8% African American and the remainder of the sample was Hispanic (Figure 1). Patient gestational age was grouped into preterm and term infants. Term infant was defined as patients equal to or greater than 37 weeks gestation at delivery. Approximately 80% of the sample was a preterm

infant (Figure 2). The patient ages ranged from one day to 9 weeks. Age data was recoded to weeks for ease of graphing. Approximately 63% of the infants in the sample were one week or less in age (Figure 3). There were six instances of patients on continuous oxygen in the project sample.

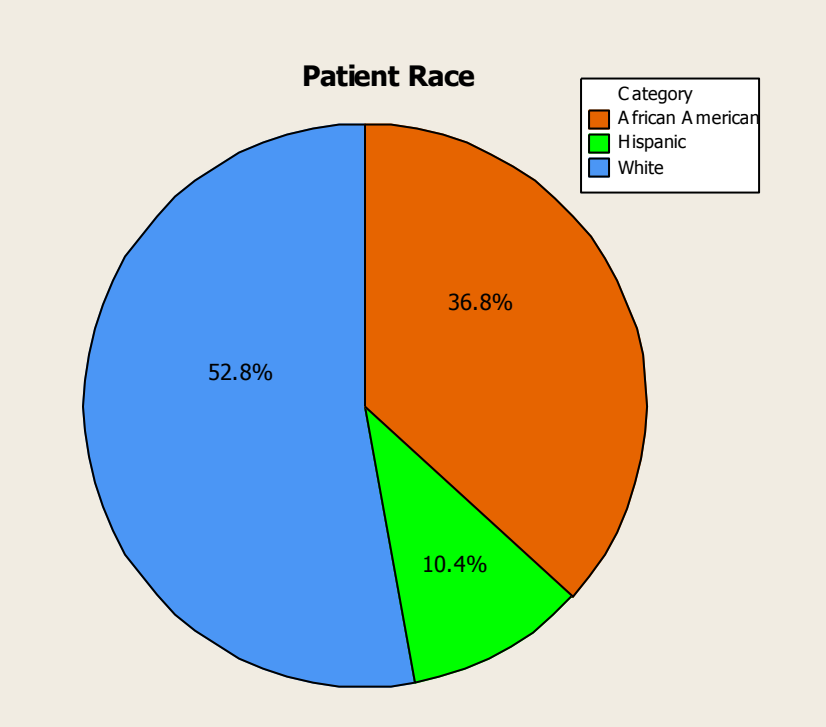

Figure 1. Patient Race. This graph displays the race of patients included in the QI project.

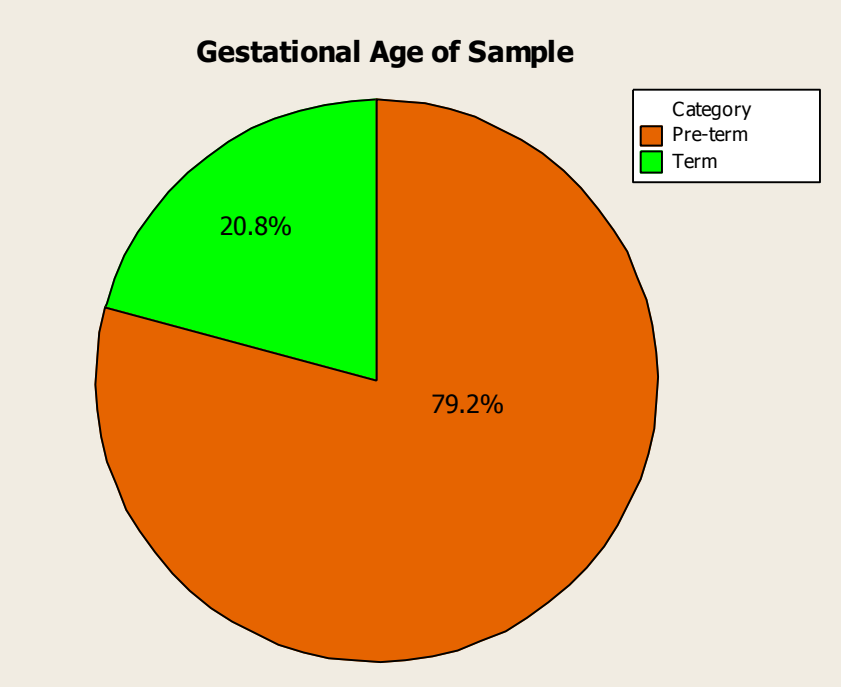

Figure 2. Gestational Age of Sample. This graph depicts the gestational age of the patients in the QI project. Term was defined as greater than or equal to 37 weeks.

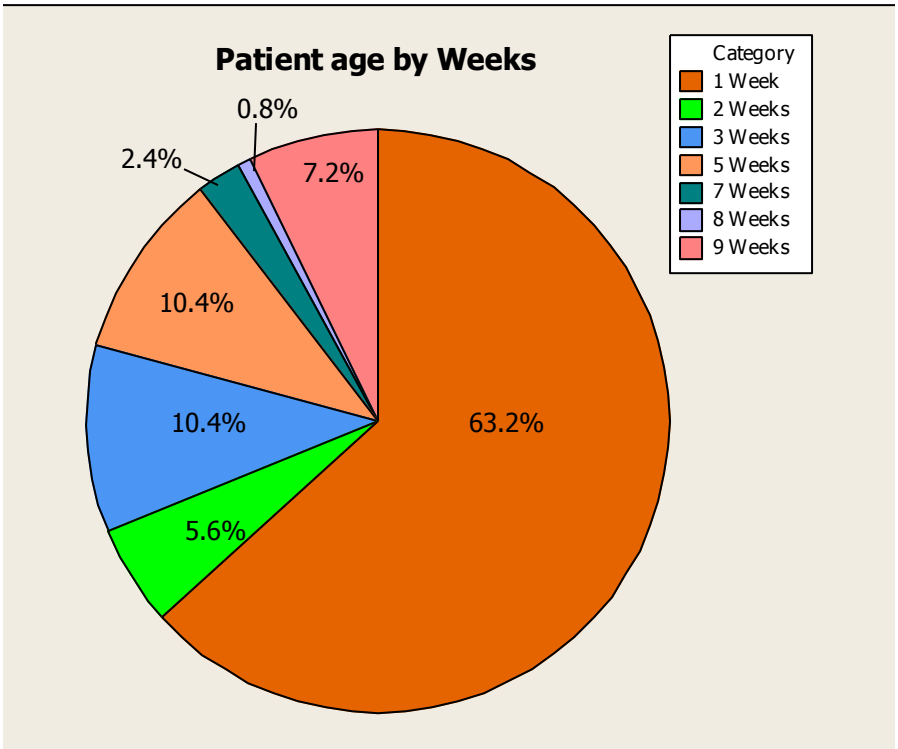

Figure 3. Patient Age by Weeks. This figure depicts the age of the patients in the QI project.

A two proportions test was run on the fields, 'alarm parameters set on default' and on the field 'is there an order for alarm parameter change.' A two proportions test was run because the population sample was not the exact same prior to and after the intervention. For 'alarm parameters set on default,' at a p-value of 0.05, there was no statistically significant difference between the two populations (P-Value = 0.151). No orders were found for alarm parameter changes during chart audits. Although no alarm parameter orders were submitted, three charts had heartrate alarm parameters that were not set on default. This was noted during the chart review. Therefore, one can conclude that the intervention had no impact on the behaviors of the nurses in the Special Care Nursery.

Statistical analyses were completed to determine if there was a statistically significant difference in the number of alarms that sounded prior to and following the intervention. An Anderson Darling test was completed to determine if the data had a normal distribution. The p-value was <0.05 indicating the data was not normally distributed. A histogram of pre-intervention and post-intervention data is available below (Figure 4). The histogram shows the data is skewed to the right. Since the data did not have a normal distribution, nonparametric test were utilized for further analysis. The Mann Whitney U was run on the sum of all alarms (excluding afore mentioned alarms) over the project timeframe. Median alarm sounds were 111.0 and 112.0. The distributions of the two groups did not differ significantly with the median difference between the two groups at -1.00 with a 95% CI (P-Value = 0.9744). Therefore one can conclude there was no statistical difference in the total number of alarms that sounded prior to and following the intervention.

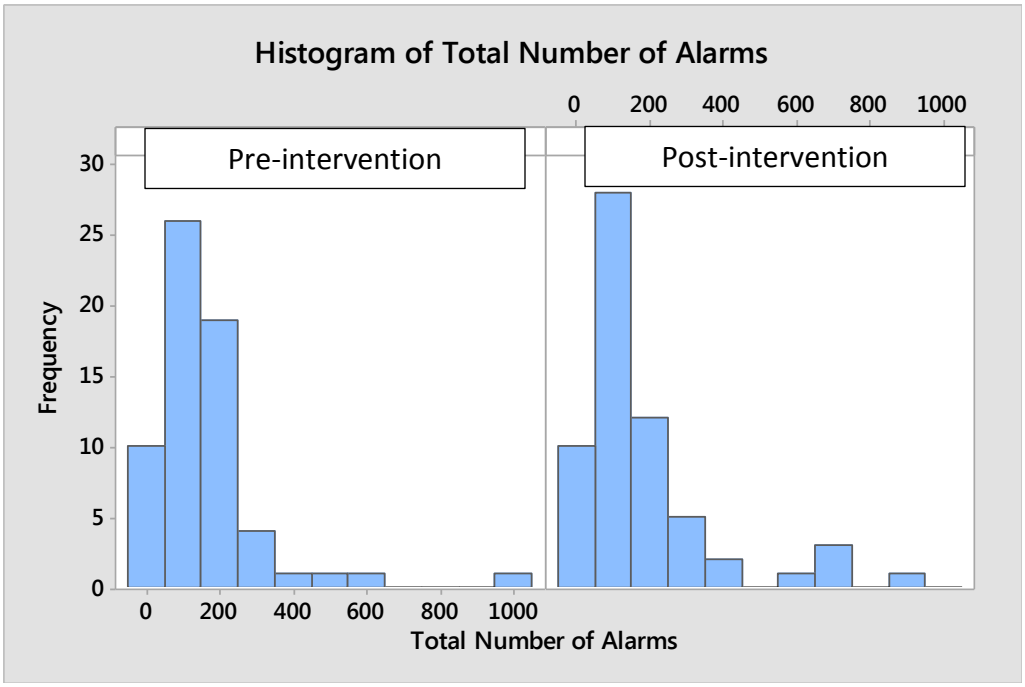

Figure 4. Total Number of Alarms on SCN. This graph depicts the total number of alarms pre-intervention and post-intervention.

Conclusion

This project was completed to address the frequency of alarms in the SCN. While the intervention did not deliver the desired results, it did allow for data analysis of alarms in the unit. It also further engaged leadership in the need to address alarms with this patient population. Finally, the project validated the belief that staff do not currently change alarm parameters based on patient baseline status.

Discussion

Alarm fatigue is an issue in hospitals nationwide that has resulted in sentinel events and patient deaths. The increase in monitored patients increases the potential for frequent alarms. Alarm frequency must be addressed to decrease alarm fatigue. The intervention during this project did not result in a practice change for the nursing staff. No orders were written for alarm parameter changes.

While the intervention did not produce a change in the nurse's behaviors, this project demonstrated the significant alarm frequency on the SCN unit. This project served as a discovery to hospital leadership and nursing staff how frequently alarms sound on the unit. Prior to this project, the staff felt alarm fatigue was an issue only mentioned in the literature and believed the SCN unit had appropriately configured alarm parameters. A review of the raw data shows, many alarms sound due to one or two points outside of the preset ranges. The literature does recommend personalizing the alarm parameters to patient needs, but through this project the unit may choose to widen their alarm parameters to decrease non-actionable alarms as some of the facilities referenced in the review of the literature.

A few potential reasons that the intervention did not result in alarm parameter changes are staffing concerns, workflow and lack of buy in. During this intervention, the hospital as well as the SCN had insufficient staffing and staff were being asked to work additional shifts. This level of fatigue could decrease the staff's willingness to participate in the project and complete alarm parameter changes, which may appear to be added work.

Work flow issues could also contribute to the lack of alarm parameter changes. Due to current hospital standard and a need to protect the vulnerable patient population, in the design of the project, nurses were required to get a provider order prior to changing alarm parameters. The need for an order could be seen as a barrier and too difficult for already busy staff to obtain. Additionally, staff were asked to obtain orders during provider rounds. Nurses may have missed the providers during rounds or forgotten about the need for an alarm parameter change during the provider rounds. The fact that the providers are not physically located on the unit throughout the day could also contribute to the lack of orders for alarm parameter changes.

Another potential cause of the lack of alarm parameter changes could be due to lack of buy in from the bedside nurses to change alarm parameters. Prior to the project, key leadership stake holders including the unit manager, medical director and quality staff were invested in the project, but with

many projects the change begins at the bedside. The purpose of the intervention was to obtain support from the bedside staff. While the staff was attentive during the meetings and the PI was available for questions, the project did not change common practice. Bedside champions who could be available during shifts and work with staff will need to be enlisted in the change.

Limitations

Some limitations of this project include the sample, which was a convenience sample at a large academic medical center, not representative of all SCN nurses. Also, there is no capture of request for alarm parameter changes made by staff that were not granted by providers. Therefore, if nurses requested an alarm parameter change, but the providers forgot or did not feel it was necessary, that information is not available. Other limitations of this project relate to the lack of alarm parameter order changes. Although, some alarm parameters were changed, there were no orders placed for these changes. It is unclear why these alarm settings were changed without an order. Additional challenges exist with this patient population. It can be difficult to personalize alarm parameters for the pediatric population due to the variability of their heart rate and respiration rate. While significant pulse changes and respiration rate changes do not commonly occur in the adult, this can happen many times a day in the pediatric patient due to crying or excitement. Finally, it is unclear how much staff felt that changing alarm parameters may result in missing a precursor to an event, although this is not supported in the literature.

Recommendations

Three major recommendations resulted from this quality improvement project. One, the raw data will be reviewed with physician leadership to determine if alarm parameters can safely be widened for the overall patient population. Also during the raw data review, it was noticed that the SCN had a total of 1560 red alarms. Red alarms are triggered when a patient meets multiple criteria, for example, increased respirations and increased heart rate. Red alarms and yellow alarms have different auditory

tones. In the SCN, red alarms are called 'latching alarms.' Latching alarms require a nurse intervention to stop the alarm sound, even after vital signs recover to baseline. With 1560 red alarms over a period of 6 days, nurses were being required to intervene on the monitor frequently to stop alarms even if their patient has returned to baseline. One patient had 53 red alarms in one day. This significantly increases a nurse's workload in addition to contributing to alarm fatigue. The SCN leadership may want to consider making red alarms not latching.

The second recommendation surrounds obtaining support for this practice change from front line nursing staff and provider staff on the criticality of alarm fatigue. While upper leadership has recognized this patient care concern, bedside nursing staff have not made changes in their practice. Exploring why this is an issue is an important next step.

With adequate staffing, obtaining bedside champions for the project to help coach their peers in alarm parameter changes is likely to assist with compliance. Once the practice change has begun, providers could make it a part of their daily rounds to ask each patient's nurse if there was any need for alarm parameter changes. Once nurses recognize that a few additional steps at the start of the shift/day could decrease the need for their intervention and free additional nursing care time, the project goals may be better recognized.

Finally, the stakeholders in this area should address the other recommendations in the literature aimed at decreasing alarms. These recommendations include EKG lead replacements, tailored to the needs of the neonate's fragile skin and evaluating the decibels of alarms within the unit.

Translation Plan

This project did not result in a practice change for the staff in the SCN, but it did discover that the staff in the SCN is vulnerable to alarm fatigue due to the number of alarms they are exposed to on a daily basis. The data obtained during this project showed if alarm parameters for respirations were decreased to alarm less than 18, heartrate were set to alarm at less than 98 and greater than 202, and

then the SCN could have decreased their alarms during the project timeframe by 48% (6,020 alarms). This information will be shared with leadership in the Children's Hospital with hopes of making a policy change. To further this project, data should be collected on all units within the pediatric hospital and education on alarm fatigue should be formally completed with nursing and physician staff on these units. Once the staff recognize the importance of alarm fatigue, leadership should develop protocols on what patients should be monitored and develop protocols for nursing to discontinue monitors.

Conclusion

This quality improvement project did not demonstrate that increasing nursing knowledge regarding alarm fatigue and alarm monitor settings will result in personalization of alarm parameters and a decrease in alarms in the SCN. The data collected and analyzed in this project will be used to evaluate the current alarm parameter settings in the SCN. In addition, the support garnered from leadership through the development and implementation of this project will be used to further address changes at the bedside related to alarm fatigue.

References

AAMI, FDA, TJC, ACCE, ECRI Institute (2011). Clinical Alarms 2011 Summit.

AAMI (2012). Using Data to Drive Alarm Improvement Efforts. The Johns Hopkins Hospital.

American Association of Critical Care Nurses. (April 2013). Alarm management. Retrieved from http://www.aacn.org/wd/practice/content/practicealerts/alarm-management-practice-alert.pcms?menu=practice

Benner, P. (1982). From Novice to Expert. The American Journal of Nursing, 82(3), 402-407.

Bitan, Y., Meyer, J., Shinar, D., Zmora, D.(2004). Nurses reaction to alarms in the neonatal intensive care unit. Cognition, Technology & Work, 6(4),

Bliss, J., Gilson, R., Deaton, J. (1995). Human probability matching behavior in response to alarms of varying reliability. Ergonomics, 38(11), 2300-2312.

Bonafide, C., Lin, R., Zander, M., Graham, C., Pain, C., et al (2015). Association Between Exposure to Nonactionable Physiologic Monitor Alarms and Response Time in a Children's Hospital. Journal of Hospital Medicine, 10(6), 345-349.

Blum, J., Blike, G. (2011) Clinical Alarms & fatalities resulting from 'alarm fatigue' in hospitals: perspectives from clinical medicine, acoustical science, signal processing, noise control engineering & human factors. White paper.

Butts, J., Rich, K. (2011). Philosophies and Theories for Advanced Nursing Practice (Second Edition). Sudbury, MA: Jones & Bartlett Learning.

Chambrin, M.(2001). Alarms in the intensive care unit: how can the number of false alarms be reduced. Critical Care, 5(4), 184-188.

Christensen, M., Dodds, A., Sauer, J., Watts, N. (2014). Alarm Setting for the Critically Ill Patient: A descriptive Pilot Survey of Nurses' Perceptions of Current Practice in An Australian Regional Critical Care Unit. Intensive and Critical Care Nursing, 30, 204-210.

Covelle, P., Piepenbrink, J., Whalen, D. (2013). A Novel Approach to Cardiac Alarm Management on

Telemetry Units. Webinar.

Crites, A. (2013). Too Much Noise from Hospital Alarms Poses a Risk for Patients. The Washington Post. Retrieved from: http://www.washingtonpost.com/sf/feature/wp/2013/07/07/too-much-noise-from-hospital-alarms-poses-risk-for-patients/

Cropp, A., Woods, L., Raney, D., Bredle, D (1994). Name that tone: The proliferation of alarms in the intensive care unit. Chest (105) 1217-1220.

Cvach, M. (2012). Monitor Alarm Fatigue: An Integrative Review. Biomedical Instrumentation & Technology, 268-277.

Cvach, M., Biggs, M., Rothwell, K., Charles-Hudson, C. (2013). Daily Electrode Change and Effect on Cardiac Monitor Alarms: An Evidence Based Practice Approach. Journal of Nursing Care Quality, 28(3), 265-271.

Drew, B., Califf, R., Funk, M., Kaufman, E., Krucoff, M., et al (2004). Practice Standards for Electrocardiographic Monitoring in Hospital Settings An American Heart Association Scientific Statement From the Councils on Cardiovascular Nursing, Clinical Cardiology, and Cardiovascular Disease in the Young. Circulation, 110(6), 2721-2746

Edworthy, J. (2013) Medical Audible Alarms: A Review. Journal of American Medical Informatics Association, 20(3), 584-589.

ERCI Institute. (2015). Top 10 Technology Hazards for 2015. Health Devices, 43 (11), 1-31.

ECRI Institute. (2010) Top 10 Technology Hazards for 2011. Health Devices, 39 (11), 389-390.

ECRI Institute. (2011). Top 10 Technology Hazards for 2012. Health Devices, 40 (11), 2-4.

ECRI Institute. (2012). Top 10 Technology Hazards for 2013. Health Devices, 41 (11), 4-6.

ECRI Institute. (2013). Top 10 Technology Hazards for 2014. Health Devices, 42 (11), 3.

ECRI Institute. (2008). Health Risk Control Executive Summary.

Gazarian, P., Carrier, N., Cohen, R., Schram, H., Shiromani, S. (2014). A Description of Nurses' Decision-Making in Managing Electrocardiographic Monitor Alarms. Journal of Clincial Nursing, 24, 151-

159.

Guardia-LaBar, L., Scruth, E., Edworthy, J., Foss-Durant, A, Burgoon, D. (2014). Alarm Fatigue: The Human Interface. Clinical Nurse Specialist, 28(3), 135-137.

Graham, K., Cvach, M. (2010). Monitor Alarm Fatigue: Standardizing use of physiological monitors and decreasing nuisance alarms. American Journal of Critical Care, 19(1), 28-34.

Horkan, A. (2014). Alarm Fatigue and Patient Safety. Nephrology Nursing Journal, 41(1), 83-85.

Imhoff, M., Kuhls, S. (2006). Alarm Algorithms in Critical Care Monitoring. The International Anesthesia Research Society, 102, 1525-1537.

Kokani, A., Oakley, B., Penprase, B. (2014). Reducing Hospital ICU Noise: A Behavior-Based Approach. Journal of Healthcare Engineering, 5(2), 229-246.

Kowalczyk, L.(February 13, 2011). Patient alarms often unheard, unheeded: The incessant din of beeping monitors can numb or distract hospital staff; the consequences can be deadly. Retrieved from http://www.boston.com/lifestyle/health/articles/2011/02/13/patient_alarms_often_unheard_unheeded/

Lacker, C. Physiologic Alarm Management. Pennsylvania Patient Safety Advisory. 2011; 8(3): 105-108.

O'Brien, D. (2013). Using Audible alarms in Medical Equipment (IEC 60601-1-8). Mallory Sonalert Products. Retrieved from: http://www.cs.au.dk/~dsound/DigitalAudio.dir/Papers/ Audible%20Alarms %20in%2 0Medical%20Equipment.pdf

Pennsylvania Patient Safety Advisory (2008). Alarm Interventions during medical telemetry monitoring A failure mode and effects analysis.

Purbaugh, T. (2013). Alarm Fatigue A Roadmap for Mitigating the Cacophony of Beeps. Dimensions of Critical Care Nursing, 33 (1), 4-7.

Ranganna, R., Bustani, P. Reducing Noise on the Neonatal Unit. Infant, 7(1), 25-27.

Salyer, J. (2003). Neonatal and Pediatric Pulse Oximetry. Respiratory Care, 48(4), 386-398.

Sendelback, S., Funk, M. (2013). Alarm Fatigue: A patient safety concern. American Association of Critical Care Nurses, 24(4), 378-386.

Sykes, D., Barach, P., Belojevic, G., Bushc-Vishniac, P., Cavanaugh, W., et al (2011). Clinical alarms and fatalities resulting from 'alarm fatigue' in hospitals: perspectives from clinical medicine, acoustical science, signal processing, noise control engineering and human factors. White Paper.

The Joint Commission, (2013), Joint Commission Sentinel Event Alert. Medical device alarm safety in hospitals, 50.

Joint Commission Resource Handbook (2013)

Wald, M. (2010). For No signs of Trouble, Kill the Alarm. New York Times. Accessed from: http://www.nytimes.com/2010/08/01/weekinreview/01wald.html?_r=0

Walsh, M., Power, E., Fanaroff, J. (2015). Potential for Harm from Alarm Fatigue in Single-Room NICU. Acta Paediatrica, 104, 436-437.

Watcher, B (2014). The Overdose – Harm in a wired hospital. Backchannel. Retrieved from https://medium.com/backchannel/how-technology-led-a-hospital-to-give-a-patient-38-times-his-dosage-ded7b3688558#.skv69ja7x

Welch, J. (2012). Alarm Fatigue Hazards: The Sirens Are Calling. Patent Safety and Quality Healthcare. Retrieved from: http://psqh.com/alarm-fatigue-hazards-the-sirens-are-calling.

Whale, D., Covelle,P., Piepenbrink, J., Villanova, K., Cuneo, C., Awtry, E.(2013). Novel Approach to cardiac alarm management on telemetry units. Journal of cardiovascular Nursing, 29(5), 1-9.

EAST CAROLINA UNIVERSITY
Office of Research Integrity and Compliance (ORIC)
University & Medical Center Institutional Review Board (UMCIRB)
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Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**

TO: Leah Barefoot, CPNP-PC, MSN, QNS III, Vidant Medical Center
FROM: Office for Research Integrity & Compliance (ORIC)
DATE: June 25, 2015

RE: Activity Outside UMCIRB Jurisdiction

TITLE: Use of a data collection tool that will gather pertinent information to help decrease the frequency of nonactionable alarms from Phillips Cardiovascular Monitors in the special care nursery at VMC.

This activity has undergone review on 6/25/15 by the ORIC. Vidant Medical Center employee/DNP student at University of Maryland is carrying out a quality improvement project titled above with no intention for use as human research. As such, this activity is deemed outside of UMCIRB jurisdiction because it does not meet the current federal descriptions for human subject research. Therefore, this activity does not require UMCIRB approval. Contact the office if there are any changes to the activity that may require additional UMCIRB review or before conducting any human research activities.

Relevant Definitions for Human Subject Research:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:
  (1) Data through intervention or interaction with the individual, or
  (2) Identifiable private information.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

Appendix B

Alarm parameters should not be changed without a provider's order. To change settings, tap on the value/character by the heartrate or respiration rate. The set up box below will appear (Image 1). Tap the limit that needs to be changed (Image 2). Change to the desired limit by tapping the correct number.

Image 1:

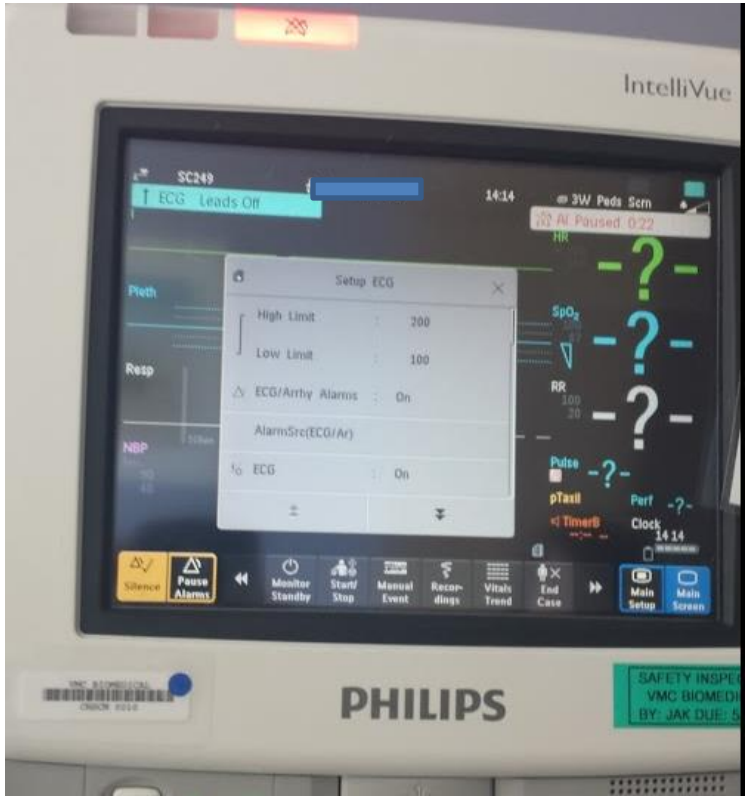

Image 2: