Initiatives in Safe Patient Care

Enhancing patient safety through improved surveillance

Clinical alarms warn caregivers of immediate or potential adverse patient conditions. Alarms and their shortcomings have been the topic of numerous studies and analysis. In 2002, the Joint Commission on Accreditation of Health Care Organizations reviewed 23 reports of death or injury that were related to mechanical ventilation. Nineteen of those events resulted in death, and 4 resulted in coma; 65% were related to alarms. More recently, the ECRI Institute identified alarm hazards as the number one device-related risk on its 2008 list of top 10 health technology hazards. The severity and frequency of alarm-related incidents pushed them to the top of the ECRI Institute's list.

In her article, Maria Cvach and colleagues examines the many aspects of alarms including goals of an alarm, false alarms, perceived nuisance alarms, alarm audibility, the risk of alarms to patient safety, and recommendations on how to improve alarm management based on best evidence and alarm management innovations.

In our panel discussion, we have recruited clinical experts to help address the issues facing clinicians regarding alarms including which parameters should be monitored, the sensitivity of the alarms as well as what we could expect from future alarm systems.

Clinical Alarms and the Impact on Patient Safety

Continuing Education for Nurses (CE) and Respiratory Therapists (CRCE)

By Maria Cvach MS, RN, CCRN, Deborah Dang, PhD, RN, NEA BC, Jan Foster, PhD, APRN, CNS, and Janice Irechukwu, BSN, RN, MSN (c)

Technologic advances in hospitals have increased substantially over the past 25 years. With these advances come sophisticated and complicated monitoring equipment, many of which are manufactured with built-in audible alarms. These alarms are intended to alert the clinician regarding a deviation from a predetermined "normal" status and are considered to be a key tool to improving the safety of patients by communicating information that requires a response or awareness by the operator.[1]

Twenty-five years ago, few hospital devices had alarm capability. Today most devices are manufactured with a functioning alarm. Alarms on acute care units are generated from any number of devices – infusion pumps, respiratory monitoring equipment, feeding pumps, bed or chair alarms, wound vacuum devices, sequential compression devices, cardiac monitors, ventilators, and patient call systems. However, there is no standardization of alarm sounds among manufacturers, so caregivers must be able to distinguish these audible alarms and react based on the perceived importance of the sound. It is ironic that the very alarms that are meant to protect patients have instead led to increased unit noise, alarm fatigue and a false sense of security regarding patient safety.

This article will examine many aspects of alarms including goals of an alarm, false alarms, perceived nuisance alarms, alarm audibility and the risk of alarms to patient safety. We will also suggest ways to improve alarm management based on best evidence and alarm management innovations.

Goals of Clinical Alarms

An alarm is an automatic warning aimed at getting the caregivers' attention. Device alarms may have levels (or catagories) of alarms which

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may or may not follow a hierarchical order.[2] An example of this hierarchical order can be seen in a physiologic monitor: detection of life-threatening situations (crisis alarm), detection of life-threatening device malfunction (system failure), detection of imminent danger (warning alarm), detection of potential device malfunction (system warning), and detection of unsafe situation (advisory alarm). The severity of the alarm can be determined by the type of sound emitted. For instance, a crisis alarm is distinctly different from an advisory alarm. The caregiver uses the sound of the alarm to determine how to respond. There are also alarms in therapeutic devices that may not have hierarchical order so the alarm sounds the same regardless of the situation. For example, an IV pump alarm may sound the same regardless of the situation that triggers the alarm. The caregiver is expected to hear the alarm, register the meaning of the alarm, and react. Patient safety relies upon alarms being eas-

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Panel Discussion:

Clinical Alarms: Where are we today — What more can be done.

Moderator: Thomas Aherns DNS, RN, CCNS, FAAN
Panelists: Richard Branson Ms, RRT, FAARC
Marjorie Funk RN, PhD, FAAN
Jeff Frank MS, CET, CBET

Patient alarms are one of the most essential means by which clinicians are alerted to potential dangers facing patients. Alarms have saved incalculable numbers of patients by alerting clinicians prior to a catastrophic event. While everyone agrees that alarms are essential, problems still remain concerning the ideal alarm design and physiologic parameter to monitor. Alarms can neither be set too rigid (due to increasing false alarms) nor too lax (alarm fails to alert the clinician in time).

In this panel discussion, we have selected three clinical experts to help address the issues that clinicians face with regard to alarms. They discuss which parameters should be monitored as well as how sensitive alarms should be. We look into solving the problem of false alarms as well as what we can expect from future alarm systems. We hope this information is of value to you in your practice.

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- Branson -

What monitors should be used to assess ventilation, arterial oxygenation, tissue oxygenation, and blood flow?

Branson: Ventilation can no longer simply mean adequate elimination of CO2. Although PaCO2 remains the standard-of-care for monitoring ventilation, tidal volume and plateau pressures are perhaps more important. Respiratory rate is often overlooked, but it is a sensitive indicator of patient distress and excessive workload. ETCO2 has some promise, but it rarely reflects PaCO2. Volumetric capnography may be useful, but this is unproven. Pulse oximetry remains a standard for monitoring oxygenation, despite the large randomized controlled trials which have failed to demonstrate the efficacy of continuous oximetry. However, oximetry does not provide data related to oxygen delivery or perfusion. Tissue oxygenation measures include invasive monitoring of lactate and base deficit as well as non-invasive measures including transcutaneous monitoring and a variety of methods evaluating tissue beds (i.e. gastrointestinal, thenar eminence, etc). At present, a global monitor of tissue oxygenation is not available and individual monitoring of tissue beds are invasive and unproven. Blood flow measures are subject to changes related to preload, contractility, and afterload as well as pharmacologic therapy, disease, and environment. Pulse pressure variation and heart rate variability remain variables which may prove useful. Blood pressure is the standard, but is one of the least sensitive measures. Rather than new monitors, I think it may be important to develop techniques to integrate information from a variety of devices to make a more global assessment of patient status.

Frank: In my opinion, monitoring of patient ventilation should be done by monitoring ETCO2. Capnography can indicate proper ventilation and also provide assurance of a good airway connection. Monitoring of arterial oxygenation can be done most conveniently using a pulse oximeter. However, there is much concern about the potential inaccuracies of SPO2 due to the inability of the device to accurately count dysfunctional hemoglobin and the inability to filter out small pulsations of venous blood, both of which make SPO2 readings inaccurate. Blood gas readings are more accurate but obviously less convenient. I have no strong opinions about tissue oxygenation monitoring. NIRS seems to be most popular method. There are quite a few options to monitor blood flow, depending on the specific patient's diagnostic needs, but for general blood flow analysis, Doppler Ultrasound is a very simple and dependable method.

If you had to pick only the essential monitoring parameters, what would they be? Also, how would you set alarm limits to avoid nuisance alarms?

Branson: It depends on the type of patient. In a ventilated patient in ARDS monitoring, tidal volume and airway pressures are paramount. Here, alarms can be set within 20% of desired values. Volume is delivered reliably in volume control ventilation. In these cases airway pressure monitoring is crucial. During pressure control ventilation, volume monitoring is critical. Pulse oximetry is clearly a standard of care. In adults, only hypoxemia needs to trigger an alarm so values above 90% seem well tolerated. Blood pressure is important, despite the fact that it remains one of the last variables to fall by the wayside during shock. Heart rate in conjunction with blood pressure and R-R variability may become more important.

Funk: Essential monitoring parameters should be dictated by the clinical status of the patient and include only those parameters that are likely to become abnormal if the patient's condition deteriorates. At a minimum, monitoring of heart rate and rhythm is indicated for many patients in hospitals. Given that cardiac monitors – either in the form of hardwire or telemetry monitors – are ubiquitous in hospitals, there are strategies that can be used to minimize nuisance alarms. These include:

- Ensure that electrodes adhere to the skin by taking the time to prepare the skin. This includes cutting excessive hair, using a washcloth to abrade the skin, and if the patient is excessively diaphoretic, applying tincture of benzoin. These simple strategies will help prevent electrodes from becoming loose and falling off and help avoid artifact that could mimic a tachycardia and set off an alarm.
- Customize alarm settings to the individual patient. For example, if a patient is being monitored for myocardial ischemia and has a chronic depressed ST-segment, the nurse should set the alarm limits 1 or 2 mm above and below the patient's baseline ST-segment, not the isoelectric line.
- To avoid unnecessary monitoring and nuisance alarms, discontinue monitoring when it is no longer clinically indicated. The American Heart Association Practice Standards for Electrocardiographic Monitoring in Hospital Settings specify who should be monitored and for how long.[1] In addition, litigation-wary physicians may order cardiac monitoring for patients who have no clinical indication for it. In an era of less than adequate staffing, alarms from monitors may substitute for direct human surveillance.

Frank: The most essential parameters would be ECG, BP, ETCO2, and SPO2 (where BP is IBP when clinically reasonable). Exact limits are always patient-dependent and certainly require adjustment throughout the patient's stay. The biggest issue I see is moving set limits farther and farther from the normal reading until finally the point is reached where clinical action is required. Why not start the limit at the "action required" point, thereby eliminating the need for repeated adjustments? It seems this ritual is used for record keeping purposes even though today's monitors have trending capabilities that are better suited for this purpose.

How have nuisance alarms affected clinical performance and patient care on the floors? How do you train the clinician to distinguish between a real alarm versus a nuisance alarm?

Branson: Nuisance alarms clearly have desensitized bedside caregivers. The simplest answer is to teach clinicians to compare alarm variables with the clinical observation of the patient. A patient with an SpO2 of 70%, while talking on their cell phone, likely represents a false alarm. This is an area ripe for innovation. The monitor should monitor its own operation, providing the caregiver with information regarding status. An alarm with a high degree of reliability. An alarm

> **Clinicians take inappropriate actions from nuisance alarms, such as lowering the alarm volume, extending alarm limits outside a reasonable range, or disabling alarms.** FUNK -

related to device function. As an example, the monitor should be able to distinguish between a real problem and a misplaced sensor. The first is a priority alarm, the second is an alert of device status.

Funk: All health care workers in the patient care environment need to react to alarms – whether it is assessing the patient directly or notifying the appropriate professional to do so. Often nonprofessionals – including patients and visitors – simply silence annoying alarms, without notifying a professional to assess the patient and determine why the alarm was sounding. In addition, health care workers may think they are silencing an alarm for a brief time period, but are actually silencing multiply alarms or disabling them indefinitely.

Frank: Nuisance alarms have created two dangerous situations. First, we have the issue of slowly moving the alarm limit to the "action required" level. This method creates a potential "cry wolf" situation where a fast change in the patient's condition may not be acted upon quickly, because the caregiver may think it is just another minor violation of a limit that is not "actionable." Secondly, the abundance of alarms can be overwhelming and can mask the occurrence of true "actionable" alarms. We need alarms that look for patterns over multiple parameters to indicate "real" problems. If we can create these multi-parameter analysis alarms dependable, we can push those limit alarms out to the "actionable" limit. Follow-up education is important for the clinician.

What education would you suggest clinicians receive regarding the essential monitors in order to use them most effectively?

Branson: A strong foundation in physiology is the basis for understanding monitoring and patient assessment. In the past decade or more, there seems to be a move away from teaching the underlying physiology, which makes interpretation at the bedside more difficult. It also opens the door for industry to provide educational initiatives. While many of these efforts are helpful, many also present the newest widget as the absolute answer. The clinician, without a strong physiology background, then has trouble separating the marketing plan from the reality. I believe that simulation is grossly underused in these situations. While physiology can be taught in lecture form, there is no substitute for clinical experience. Simulation allows the clinical experience to occur in a safe, controlled environment.

Funk: Part of learning any technology is learning about the alarms. This includes the visual and auditory alerts, how to set the limits, how to ensure that the alarm status is easily determined and making sure that the alarms are within the staff's range of hearing and sight. As with most types of education, a variety of approaches works best. These include alarm drills and testing competencies related to clinical alarms. Competencies include identifying clinically significant alarms, stratifying responsibility for setting and responding to clinical alarms, optimizing patient placement for audibility (especially for stand-alone alarms), participating in testing of alarms, and responding appropriately to any clinical alarm.[2] Clinicians sometimes take inappropriate actions to gain relief from nuisance alarms, such as lowering the alarm volume, extending alarm limits outside a reasonable range, or disabling alarms.[3] These actions may result in alarm-related adverse events. It may be useful to have regularly scheduled discussions of adverse events associated with alarms.

Frank: "Hands on" is best for veteran clinicians using a new model, it allows the clinicians to quickly become familiar with the new model device and generate questions to the items they find relevant. For new devices or new clinicians, virtual reality or simulations are best. They still get a "hands on" experience during this process and the proctor can incorporate "bugs" into the system, giving the clinician an opportunity to become familiar with the equipment in a controlled environment. Lectures are usually a waste of time, and attendance usually needs to be mandatory to get people to come. Quick info sheets of one paragraph or less also receive positive responses; these usually address just one item and act as reinforcement for information previously sent out.

When discussing the effectiveness of technology, describe how information should be tied to clinical actions to demonstrate a clinical outcome improvement.

Branson: The current economic conditions press manufacturers to provide evidence for improved outcomes with their devices. Real changes in outcomes are difficult to attain, even with large studies and grand budgets. This unrealistic push for outcomes data drives poor research, extended claims, and disappointing results. This is where I believe integration of variables may prove more helpful. Monitors, which perform like a skilled clinician, and integration of a group of variables could prove worthwhile. We rarely look at the blood pressure without considering the heart rate, and SpO2 is of little value without knowing if there is adequate perfusion for accurate monitoring. A monitor which uses logic to predict impending problems has the best chance of demonstrating efficacy.

The display of data is also an opportunity for advancement. For the current generation of caregivers who use email, video games, or text messaging, we must design products that speak to them through these modalities. Graphic images demonstrating changes in patient condition may prove to be particularly instructive.[4,5] This has been demonstrated by Westenskow's group in a number of environments.[6]

Funk: The information provided by any health care technology should be clinically useful and have an effect on the care of patients and their clinical outcomes. If a particular piece of equipment is providing information that is not important and is also causing nuisance alarms, consideration should be given to its possible elimination from clinical care. This may result in cost savings.

Frank: In today's "information rich" society, I often find myself skimming through most of the information I am presented with and throwing away much of it. We need to be extremely careful with what gets automatically forwarded to the clinician. Alarms and notifications need to be actionable items. Any alarm that is not of value will just congest the clinician information highway and cause real events to be lost or ignored. I'm not sure if trying to record a "link" between information and actions taken is part of the solution or the problem. It seems the extra documentation, although minor, would simply be adding to the workload creep already current in our "information rich" society. Wouldn't we just be creating another lengthy report for someone else to skim or throw away? Technology needs to make our lives easier! If the information automatically sent could be filtered to only the relevant actionable items, we would save ourselves an enormous amount of time, which would allow us to spend more time on the important items. This would mean better patient care, happier employees, and less adverse events, which all add up to savings.

What are the most important technologies for the near future?

A monitor which uses logic to predict impending problems has the best chance of demonstrating efficacy.

Branson: I think integrated data from a variety of monitors coupled with the graphic display of data into easily understood graphics is near. It is a simple truth that a picture is worth a thousand words —in monitoring, a picture is worth 20 numbers. Instead of providing signal quality, SpO2, pulse volume, pulse variability and heart rate from the oximeter; along with systolic, diastolic, and mean blood pressure, what if the monitor just displayed a picture that would convey the patient status in a single image? Given the shortage of caregivers, cost reductions, sicker patients, and a graying of the critical care team, there will indeed be changes. We do not need more monitors, with more information, and more alarms, we need smart alarms and smart displays.

Funk: No currently available ECG monitors are capable of continuous monitoring of QTc intervals or alarming for prolongation above the upper limit of normal (47 msecs for men and 48 msecs for women). Many antiarrhythmics, antibiotics, and antipsychotics, commonly given to hospitalized patients, prolong the QTc interval and put them at risk of the life-threatening arrhythmia of torsades de pointes.

Frank: I have been looking at monitoring technology, specifically alarm management. We have had some success with the "less is better" approach and continue to look for ways of filtering out useless alarms. I am concerned that sometimes we go too far in attempts to monitor patients' parameters with equipment that is not as accurate as clinicians expect them to be. Most of today's technologies use elaborate algorithms, noise canceling software, and estimation templates to calculate parameters. While these methods usually produce good results, sometimes the readings we get from devices are not even close to correct. We need to be sure the staff using these devices understands the complexity, so they can accurately use these devices to give safe patient care. I'm looking forward to multiparameter alarm analysis as a new technology and hope to see it well-developed in the near future.

As you can see from the experts opinions, there are both better ways of monitoring and better ways of teaching and implementing alarm systems. For example, capnography is an excellent monitor of ventilation if used as a trend. Hands on education about alarms, discontinuation of alarms when no longer clinically useful and development of smart alarms to identify relevant versus nuisance alarms are all part of ways to reduce the false alarms but not lose the value of the alarm systems. It is imperative that clinicians work with manufacturers to make these improvements happen, and not remain just opinions or ideas. Without improvements like suggested by these authors, alarms will continue to both a blessing and curse to clinicians.

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ily distinguished and on clinicians reacting in a timely manner.

Novel displays and alarms are being explored for use on medical equipment in critical care environments, but little is known about their effectiveness. The International Electrotechnical Commission (IEC) 60601-1-8 standard for medical equipment alarms for international use offers equipment manufacturers an option to create melodic alarms that distinguish the physical or physiological system that each alarm represents.[1] Sanderson studied the ability of undergraduate students to learn the IEC melodic alarm looking at the alarm effectiveness.[3] Melodic alarms were distinguished by the number of notes, a 3-note melody played once for medium priority alarms and a 5-note version of the melody played twice for high priority alarms. During two training sessions, spaced one week apart (training sessions were about the time of a standard in-service training period for new equipment), 33 participants where asked to recognize 16 melodic medical alarms. Only 30% of the participants were able to correctly identify all of the alarms. Unexpectedly, participants were faster and more accurate at recognizing medium priority alarms than high priority alarms. This study raises concern about the caregiver's ability to recognize and distinguish the type of clinical alarms occurring on a typical hospital unit.

"Nuisance" Alarms

Although alarms are important and sometimes life-saving, frequent nuisance alarms —defined as false-positive alarms and/or clinically irrelevant alarms —can compromise patient safety. The problem of excessive alarms has been recognized and studied extensively over the past 20 years in various settings, particularly in the intensive care unit (ICU). Studies done in the 1990's showed that the rate of false alarms is high.[4,5] In a multicenter study, Chambrin recorded alarm data on 131 mechanically ventilated critically ill patients over 1971 hours of care distributed over all 3 shifts.[6] There were 3188 alarms with an average of 1 alarm every 37 minutes. The alarms originated from ventilators, cardiac monitors, pulse oximeters and capnography machines. One quarter of the alarms had a consequence such as sensor repositioning, suctioning, or titration of a medication. Only 5.9% of alarms led to a physician being called. The positive predictive value of an alarm in this study was 27% and its negative predictive value was 99%. The sensitivity of the alarm was calculated to be 97%, but the specificity was only 58%. The authors concluded that a great number of false-positive alarms are generated in the ICUs. Tsion and Fackler studied the occurrence rate, cause and appropriateness of alarms in a children's hospital ICU over 298 monitored hours.[7] The alarms were monitored by a trained observer and validated by a bedside nurse. A total of 86% of the 2942 alarms were found to be false-positive, while an additional 6% were classified as clinically irrelevant true alarms. Only 8% of the alarms tracked during the study were thought to be true alarms with clinical significance. Nearly all monitored signals had false positive alarm rates exceeding 90% with two exceptions: respiratory rate (75%) and mean arterial pressure (46%). More recently, Atzema reported on 72 stable emergency department patients with chest pain and suspected ischemia.[8] During the 371 monitored hours, there were 1726 recorded alarms with an average of 4.7 alarms per hour. The researchers measured the rate of adverse events associated with each alarm, defining an adverse event as a vital sign or arrhythmia event. Of the alarms recorded, only 11 were true adverse events. The false alarm rate was calculated as 99.4%. Only 0.62% of alarms occurred because of an adverse event and none of them were hemodynamically significant. Of all the alarms that occurred, only 3 alarms (0.2%) resulted in a change in patient management. The researchers concluded that routine continuous electrocardiographic monitoring result in excessive alarms, most of which require no change in management. The alarms are not only annoying, but result in nursing interruptions, distractions, and likely waste nursing time. In addition, the frequency of alarms likely decreases both nurse and physician sensitivity to alarms.

In the general care units, where alarms may provide the greatest benefit, few physiologic alarms are utilized and less opportunity for direct visualization of patients.

In summary, these studies tell us that, (1) device alarms are far too frequent, (2) they are often false alarms, (3) when alarms are true, they are often clinically insignificant, and (4) inefficient alarms increase the risk of adverse patient outcomes and medical costs.

Perception of Nuisance Alarms, Reaction Time and Impact on Patient Safety

Nuisance alarms are alarms that may interfere with patient care and typically do not result from an adverse patient condition.[9] Alarm fatigue or desensitization may occur when the sheer number of alarms causes the caregiver to become desensitized such that a real event may be unrecognized or ignored by the caregiver, or the speed with which the caregiver reacts to an alarm is hampered. Literature supports this notion that a multitude of alarms leads to dangerous desensitization of the staff toward true alarms.[10] Biton and colleagues studied nurses' reaction time to alarms in a neonatal ICU by measuring the occurrence of alarms from different causes, recording the nurses' reaction, and analyzing the relationship between alarms and actions.[11] The results demonstrated that nurses often do not respond directly to alarms, but use them in conjunction with other sources of information. The probability of responding to an alarm depended on the cause of the alarm, its duration and the characteristics of the patient. The researchers concluded that nurses were more likely to respond to a longer alarm (>5 sec) or a rare alarm rather than a short duration alarm or a frequently occurring alarm.

In an experimental study of psychology students in a laboratory setting, Bliss et al. found that subjects responded significantly faster and more often to alarms of longer (4 sec) versus shorter (1 sec) duration.[12] The measurement of response frequency and reaction time was measured using a gauge monitoring and tracking battery program hosted by an IBM compatible computer. In addition, Bliss's team measured perception of reaction time using a 5-point Likert scale opinion questionnaire with items designed to assess how alarm duration and true alarm rate affected each participants perception of alarm signal validity. Previous studies by this group also showed that if an alarm system is perceived to be reliable, subjects responded significantly faster to the alarm than alarm systems that are perceived to be less reliable.[13] The American College of Clinical Engineering (ACCE) established a Clinical Alarms Improvement Project in 2004. They surveyed 1327 clinicians, engineers, technical staff and managers.[9] The large majority of respondents (94%) worked in an acute care setting. Over half of the respondents were nurses (51%) and almost one-third of the respondents (31%) worked in an intensive care setting. A large portion of respondents identified that nuisance alarms occur frequently (81%), disrupt patient care (77%), and can reduce trust in alarms thereby causing caregivers to disable them (78%).

Audibility of Alarms

The audibility of alarms directly impacts patient safety. Activated alarms must be sufficiently audible with respect to distance and competing noises on the unit. There have been few studies on the audibility of alarms in a hospital environment. Sobieraj et al. studied alarm audibility of an infusion pump on a medical surgical unit with room doors open and closed.[14] Their findings indicated that alarms are sufficiently audible and can compete with environmental background noises when patient room doors are open at distances of about 95 feet. Alarm audibility was significantly reduced when patient room doors were closed with maximal audibility of only up to 45 feet. In addition, alarm audibility was affected by floor buffing activities. The authors suggest establishing guidelines for when it is safe to close the door to a patient room. Many patients want their doors closed for privacy or other reasons, yet this may pose a patient safety risk in being able to hear alarms.

On monitored units, where alarms are triggered either in the room, central monitoring station, or both, alarm audibility is a serious safety concern. Units must have alarm annunciation systems in place to allow audibility of alarms at all times. This may be done in many different ways. Physiologic monitors may have an autoview on the alarm feature or the alarm can be sent through the patient call system. In addition, secondary alarm notification systems such as pagers, phones, marquee signs, LCD screens can all ensure alarm audibility. Finally, a unit may institute a unit-based or central monitor watch system to assure physiologic monitor vigilance. There is little published on the benefits of monitor watch. Unit-based watch enables staff to become highly proficient in rhythm interpretation and troubleshooting alarms. Central monitor rooms (sometimes referred to as War Rooms) enables multiple units to be viewed in one location which may or may not be onsite. Trained observers who are highly proficient in rhythm interpretation and troubleshooting work with nursing staff or dedicated monitor nurses to handle monitor alarms. Research on the best method to ensure audibility of alarms is lacking.

Sentinel Events Related to Alarms

Shortly after The Joint Commission (TJC) February 2002 Sentinel Event Alert (Issue 25) regarding 23 ventilator-related deaths and injuries of which 65% involved malfunction or misuse of an alarm or an inadequate alarm, the TJC identified 6 national patient safety goals.[15] One of these goals was to improve the effectiveness of clinical alarms. In 2005, the goal was incorporated into the TJC environment of care standards. This was an important step in raising awareness of adverse events related to ineffective alarm coverage, inappropriate alarm use and promoting effective alarm management strategies.

The Clinical Alarms Improvement Project analyzed the number of reported deaths by year and device in the FDA Manufacturer and User Facility Device Experience Database (MAUDE) from 2002 to 2004.[9] The database was queried using the search term "alarm" and "death." A total of 237 reports were found using these search criteria. Of the death events reported, 98 could not be analyzed because of limited information

Figure 1. New Alarm Management System (AMS) for Nellcor™OxiMax™N-600x™

in the report; 58 were determined to be operator error due to poor education and training; 67 were related to operator distraction and 14 were due to other causes such as environmental factors, device deterioration or an unpredictable device failure. In addition, the report looked at 2,200 reports of medical-device related incidents and deficiencies in the Emergency Care Research Institute (ECRI) Problem Reporting System since the year 2000. ECRI is an independent, nonprofit organization that researches best approaches to improving patient care. Approximately 12% of the reports included the word "alarm" in the problem/description field. Sixty-four percent of the reports involved one of three types of devices: physiologic monitors (11%), ventilators (39%) and infusion pumps (14%). For physiologic monitors, there were numerous reports of critical adverse events in which an alarm was not produced. Upon further investigation, it was found that the alarm had somehow been disabled.[9]

Effective Clinical Alarm Management

Key sources for alarm overload are false-positive alarms, technical alarms, inappropriate protocols for alarm inactivation, inappropriate alarm limits and settings, overutilization of patient monitoring in some instances, and underutilization of alarms in other settings. For example, many physiological parameters are routinely monitored in the ICU, some in duplication with different methods, i.e. non-invasive and invasive blood pressures. However, in the general care units, where alarms may provide the greatest benefit, few physiologic alarms are utilized and less opportunity for direct visualization of patients.

Hospitals can incorporate technology and clinical policies to enhance an audible alarm system. Units should determine the types of alarms that frequently occur, and determine if the alarms are truly actionable in order to reduce alarm burden. Clinical engineering can provide guidance on alarm defaults and ensure standardization among like units. A uniform approach to assigning priority to alarms and alarm annunciation is important. Uniformity in priority of alarms and associated sound patterns across various kinds of technology would assist with proper interpretation and a timely response by caregivers. Uniformity would also reduce the stress of not knowing the significance of the alarm without viewing the patient or monitor. However, there is currently no requirement of vendors to have uniform alarms.

No matter what the capabilities of the alarm system, users must comply with manufacturer and other expert guidelines for maximum benefit of the system. To optimize effective clinical alarm systems, the ECRI Institute recommends reducing occurrences of false and technical alarms by following good practices for monitoring electrode/sensor placement and application, training staff in appropriate protocols for alarm inactivation, and properly configuring alarm settings. For example, monitoring patients who do not medically require it can add to the quantity of alarms and increase staff desensitization. Developing guidelines for monitor use and overseeing compliance can help facilities avoid these problems.[16]

The American Heart Association (AHA) Practice Standards for Electrocardiographic Monitoring in Hospital Settings provides evidence-based practice guidelines that should be incorporated into hospital physiologic monitoring and alarm management policies.[17] Alarm management policies should include: adequate skin preparation prior to electrode placement, proper electrode positioning, changing electrodes based on manufacturer recommendations; individualizing patient alarms each shift; ensuring that alarm defaults are standardized and set wide enough to minimize nuisance alarms, but are still within a safe notification threshold, alarm audibility, documentation of alarms, and most importantly accountability for rectifying alarms.

In summary, factors that contribute to an effective alarm system include best use of technology, application of standards, and proper procedures by users of the devices. Only when all of these variables are addressed can an alarm system be of true value as a clinical decision support system.

Trends for the Future

The perfect alarm system should signal clinically relevant data exclusively and contribute to clinical decision-making.[18] In order to accomplish this, several features must be present (Figure 1). First, the alarm should signal only when the event is real, a feature of instrument sensitivity. Secondly, the alarm should not be activated in the absence of the event, which represents specificity of the instrument. Thirdly, the alarm signal should offer positive/negative predictive value, which reflects accuracy of the instrument. Next, the alarm should trigger in conjunction with real-time events. Ideally, the alarm should be detectable by the appropriate caregiver at all times and under all circumstances. The caregiver should be able to determine the problem by the nature of the alarm, which allows for decision support by the system. Finally, an alarm system that does not disturb the healing/recovery process of the patient would provide the greatest benefit to caregivers and patients alike.

Decision support using an alarm management system will help reduce the number of false alarms and improve alarm specificity. Multivariate detection of parameters, for example, of both hypotension and differences in blood pressure during the respiratory cycle may lead to recognition of a cardiac tamponade, allowing for immediate, lifesaving intervention (i.e. chest tube insertion). Time delay technology also has the potential for improving alarm sensitivity and specificity. Monitoring, then, is pattern recognition over a time series. Patterns first need to be recognized via machine learning techniques. Then the patterns need to be described using artificial intelligence technology. This can be accomplished with computer algorithms that produce intelligent warnings of impending problems using different time axes within the algorithm. This in turn allows for a decision support system. For example, a capnography innovation uses software that detects respiratory rate and calculates a new rate after every cycle. Additionally, all significant events are recognized. With longer time for averaging methods and trending of patient data, deviations in patterns are detected, real events are better captured, and false alarming is reduced.[19] Correct problem identification and timely intervention becomes feasible with an effective alarm system.

The technological landscape is rich with offerings designed to achieve these goals. Middleware technology that integrates software applications so that data is exchanged will be important in alarm technology in the future. It allows uncomplicated import and export of data through a single access point. Although this technology has been used for several decades in other industries, its use will broaden in patient care for the efficiency it affords.[20]

Video equipped patient monitoring offers an interactive component that enables clinicians to identify and even correct patient instabilities from remote points.[21] Perhaps we can envision this technology extending to patient homes in the future. Robotics may also become a part of alarm monitoring and management as we look forward to the future.

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1. A frequent nuisance alarm is defined as:

a. A false positive or clinically irrelevant alarm
b. An alarm with high specificity
c. A crisis alarm
d. An alarm with low sensitivity

2. All device alarms follow a hierarchical order (i.e. alarm sound can be relied on to determine alarm urgency).

a. True
b. False

3. Alarm fatigue or desensitization may lead to:

a. Decreased speed reacting to alarms
b. Silencing of alarms
c. Disabling of alarms
d. All of the above

4. Research indicates that a person is more likely to respond to an alarm that is:

a. Of short duration
b. Frequently occurring
c. A rare alarm
d. All of the above

5. Key sources of alarm overload include:

a. Inappropriate alarm limits
b. Over utilization of patient monitoring
c. Inappropriate protocols for alarm inactivation
d. All of the above

6. If an alarm system is perceived as reliable most of the time, response to alarms will be significantly slower than if the alarm system is perceived to be inaccurate or false most of the time.

a. True
B. False

7. When an alarm is real each time it signals, this is known as alarm:

a. Sensitivity
b. Specificity
c. Positive predictive value
d. Desensitization

8. Positive predictive value reflects instrument accuracy.

a. True
b. False

9. Research has shown that despite the frequency of monitor alarms, the actual number of times that an alarm results in a clinical action is usually:

a. Less than 10% of the time
b. More than 90% of the time
c. Every time it alarms
d. Never

10. ECRI recommends reducing false alarms by following good practices for monitoring electrode/sensor placement and application, training staff in appropriate protocols for alarm inactivation and properly configuring alarm settings.

a. True
b. False

11. Skin preparation is not important in reducing false alarms

a. True
b. False

12. Research findings indicate that alarms are sufficiently audible and can compete with environmental background noises when patient room doors are closed at distances up to 95 feet

a. True
b. False

Participant's Evaluation

This program has been approved for 1.5 contact hours of continuing education (CRCE) by the American Association for Respiratory Care (AARC). AARC is accredited as an approver of continuing education in respiratory care.

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To earn credit, do the following:

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5. Upon completion, you may print out your certificate immediately. If you are an AARC member, your results are automatically forwarded to the AARC.
6. Accreditation expires May 15, 2018. (RTs) and May 15, 2018 (Nurses)

The goal of this program is to educate healthcare professionals on the management of OSA

1. What is the highest degree you have earned? Circle one. 1. Diploma 2. Associate 3. Bachelor 4. Masters 5. Doctorate

   Strongly Agree **Strongly Disagree**
   1 2 3 4 5 6

2. Indicate to what degree the program met the objectives:

   Strongly Agree **Strongly Disagree**
   1 2 3 4 5 6

3. Describe nuisance alarms and the implication for patient safety

   Strongly Agree **Strongly Disagree**
   1 2 3 4 5 6

4. Describe the criterion for sufficient level of alarm audibility and factors that reduce audibility.

   Strongly Agree **Strongly Disagree**
   1 2 3 4 5 6

5. Identify effective alarm management techniques based on best evidence

   Strongly Agree **Strongly Disagree**
   1 2 3 4 5 6

Answers

1	A ☐	B ☐	C ☐	D ☐	9	A ☐	B ☐	C ☐	D ☐
2	A ☐	B ☐	C ☐	D ☐	10	A ☐	B ☐	C ☐	D ☐
3	A ☐	B ☐	C ☐	D ☐	11	A ☐	B ☐	C ☐	D ☐
4	A ☐	B ☐	C ☐	D ☐	12	A ☐	B ☐	C ☐	D ☐
5	A ☐	B ☐	C ☐	D ☐	13	A ☐	B ☐	C ☐	D ☐
6	A ☐	B ☐	C ☐	D ☐	14	A ☐	B ☐	C ☐	D ☐
7	A ☐	B ☐	C ☐	D ☐	15	A ☐	B ☐	C ☐	D ☐
8	A ☐	B ☐	C ☐	D ☐	16	A ☐	B ☐	C ☐	D ☐

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