



Impact Of Clinical Alarms On Patient Safety

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FORWARD

Leaders in healthcare technology management and safety established the American College of Clinical Engineering Healthcare Technology Foundation as a private not-for-profit 501c3 organization in late 2002 in order to accelerate deployment of safer healthcare technologies, educate the public and to promote best practices in the field of clinical engineering.

The vision of the Foundation is to improve healthcare delivery by promoting public awareness of, and the development and application of, safe and effective healthcare technologies through the global advancement of clinical engineering research, education, practice and other related activities. The Foundation's commitment to involve users, clinical engineers, regulators, together with its strong relationship with the medical device manufacturing industry, and with the mission to reach out to the public ultimately translates into better-educated community, and thus safer and more efficient healthcare delivery. As a catalyst for the advancement of better and safer clinical technology, the Foundation supports several initiatives including better understanding of the challenging issues associated with the effectiveness of clinical alarms.

In 2004, the Foundation established the clinical alarms improvement project with the goal of collecting and sharing information related to the perception of care providers and engineers about the impact of clinical alarms in the equipment they are working with. The project team leader, Mr. J. Tobey Clark, CCE assembled a task force that was responsible for the data collection and preparation of this report. The task force developed the survey tool that was used in both live forums as well as through an internet application to collect data from 1,327 care givers and engineers. The results of this survey, conducted between August 2005 and January 2006, was integrated with an analysis of data available within the Food and Drug Administration and ECRI databases.

This report is offered as to facilitate the improvement of alarm design, the user interface, alarm uniformity and user education. It is the intention of the ACCE Healthcare Technology Foundation to share this information and highlight the opportunities to improve all aspects of clinical alarm functionality.

The Foundation would like to extend its appreciation to all who contributed and assisted in bringing this important project to completion; especially to J. Tobey Clark, Marvin Shepherd, Bruce Hyndman, William Hyman and Yadin David, and to acknowledge the collaboration of Jeff Heyman and Jim Keller of ECRI in the writing of the manuscript.

ABSTRACT

Clinical alarms warn caregivers of immediate or potential adverse patient conditions. Alarms must be accurate, intuitive, and provide alerts which are readily interpreted and acted on by clinicians in an appropriate fashion. Clinical alarms and their shortcomings have been the topic of numerous studies and analysis in the literature. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) established a National Patient Safety (NPS) goal in 2002 to improve the effectiveness of clinical alarms. This goal was removed for hospital organizations in 2004 and incorporated into the JCAHO standards. Despite the technological and healthcare improvements related to efforts to meet the NPS goal, adverse patient events continue to occur related to alarm system design and performance, care management and the complexity of the patient care environment.

In 2004, the ACCE Healthcare Technology Foundation started an initiative to improve clinical alarms. This paper reviews the literature related to clinical alarm factors and analyzes adverse event databases. Efforts to improve alarms through technological, standards, and regulatory means are reviewed and evaluated. Forums, meetings and a survey of 1,327 clinicians, engineers, technical staff and managers provided considerable feedback regarding alarm issues. Of particular value is the response from nursing who represented the majority of the respondents to the survey. Observations and recommendations have been developed to improve the impact of clinical alarms on patient safety. Future directions are aimed at awareness, a focused effort towards the reduction of false alarms, and soliciting all constituents involved in clinical alarms to meet and develop action plans to address key issues.

Keywords: *Equipment Alarm Systems; Medical Device Safety; Monitoring, Physiological; Patient Care Management, Clinical Engineering*

INTRODUCTION

Alarms on clinical devices are intended to call the attention of caregivers to patient or device conditions that deviate from a predetermined “normal” status. They are generally considered to be a key tool in improving the safety of patients. The purpose of alarm systems is related to “communicating information that requires a response or awareness by the operator.”¹ In some cases the normal conditions are preset in the device, while in others the correct use of the device requires directly setting the parameter limits. The user often has the ability to turn the alarms on or off, and to set the volume of the audible alarm output. Alarm information may also be transmitted away from the bedside to a remote location that can be down the hall, or at some distance away. Such transmission may also be disabled, either intentionally or inadvertently. When an alarm is triggered the caregiver is tasked with noting the alarm, identifying its source, and responding appropriately. Effective alarm setting, noting and responding is a design, user, and systems issue. From the design perspective alarms should be easy to set, their status (e.g. on/off, limit values) should be easily determined if not directly visible, and the identification of and specificity of a triggered alarm should be unambiguous and easy to determine. The alarm system must also be designed for all intended environments of patient care. From the use perspective, users must be adequately trained, and the number of staff must be suitable to the setting and the number of patients. However, it is widely recognized that training is not itself a suitable or effective cure for poorly designed and overly challenging equipment. Best practice cognitive engineering and human factors strategies to improve patient safety are not always followed in current clinical alarm system designs.

It is important to understand that users will come to rely on alarms to call their attention to adverse conditions. Thus clinical alarms, to varying degrees, become substitutes for the degree of

caregiver attention that would be required if there were not an alarm system in place. In this regard alarms are sometimes viewed as a suitable basis for reducing staff levels or skill requirements. In some cases alarms are a primary source of information if the situation triggering the alarm is not directly observable. When caregivers rely on alarms, it becomes essential that the alarms perform to their expectations. When they don't patients may not receive the care they need, with potentially serious adverse consequences. Of course, alarms must be set properly and the settings should be applicable to the clinical setting the device is being used in. While many non-performance issues may be associated with “use error”, the culture of blaming the user is now recognized as both inappropriate and ineffective.

For a clinical alarm to be effective it must be triggered by a problem which adversely affects the patient, personnel must identify the source and meaning of the alarm, and correct the problem prior to an adverse patient event. This deceptively simple set of concepts has not yet resulted in clinical alarm systems that universally meet usability and other performance objectives directed toward improving patient safety. This report presents the work of an ACCE Healthcare Technology Foundation (AHTF) (Appendix A) task force focusing on an initiative to improve the management and integration of clinical alarms. ECRI (Appendix B) provided valuable input into the task force work and contributed to the preparation of this report. The document includes a review of relevant literature, analyzes available adverse event databases, and presents results from a national survey containing constructive feedback from clinical users and other support staff. This information offers valuable insights into current clinical alarm issues, and how clinical alarms can be improved to enhance patient safety.

BACKGROUND

Clinical alarm problems have existed since the advent of monitoring and therapy device use in healthcare. ECRI first reported an alert related to alarms in the 1974 issue of *Health Devices*² at a time prior to the 1976 Medical Device Amendments that created the modern era of the Food and Drug Administration (FDA) regulation of medical devices.

Studies published in professional publications have shown a number of limitations of clinical alarm systems.

- Individuals have difficulty in learning more than six different alarm signals.³ A patient in an ICU environment will many times have more than six different alarm sounds associated with their care, as well as the same sound having different meanings when emanating from different devices. A study showed that experienced care givers could not identify even one-half of common ICU critical alarm sounds when played back.⁴
- Care providers have difficulty in discerning between high and low priority alarm sounds in part due to design.⁵ The perceived urgency of audible alarms can be inconsistent with the clinical situation.⁶
- A false alarm is an alarm which occurs in the absence of an intended, valid patient or alarm system trigger. In a 2006 paper in the *American Journal of Emergency Medicine*,⁷ 99.4% of the alarms were determined to be false with less than 1% of all alarms resulting in a change of patient management. False positive rates over 85% have been reported in the past.^{8,9} False alarms may be the most serious shortcoming as the effectiveness of alarms depends upon the alarm system's credibility.¹⁰ High false-positive rates can lead to disabling of alarms by medical personnel.¹¹ Unfortunately, vendors sometimes design equipment with easily defeatable alarms in response to complaints of nuisance alarms. Conversely, designers may adopt the philosophy of "better safe than sorry" incorporating many disruptive and poorly designed alarms into devices.¹² However, an over abundance of alarms does not necessarily result in enhanced safety.

Some improvements have been made by (1) the medical technology industry through design of

intelligent alarm mechanisms, better incorporation of human factors design, and utilizing systems engineering concepts; (2) accreditation and standards organizations developing care management and design guidelines; (3) clinical and allied health organizations providing recommendations and best practices; and (4) healthcare organizations developing better care management procedures, enhanced care giver training, and environment of care design changes. Despite these positive changes, reports of problems with clinical alarms continue.

Figure 1

DEATHS BY YEAR • 2002-2004
Term "Alarm" in Product Problem description

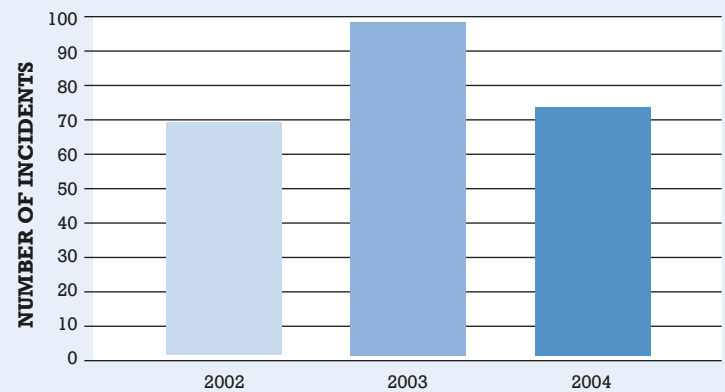


Figure 2

DEATHS BY DEVICE • 2002-2004
Term "Alarm" in Product Problem description

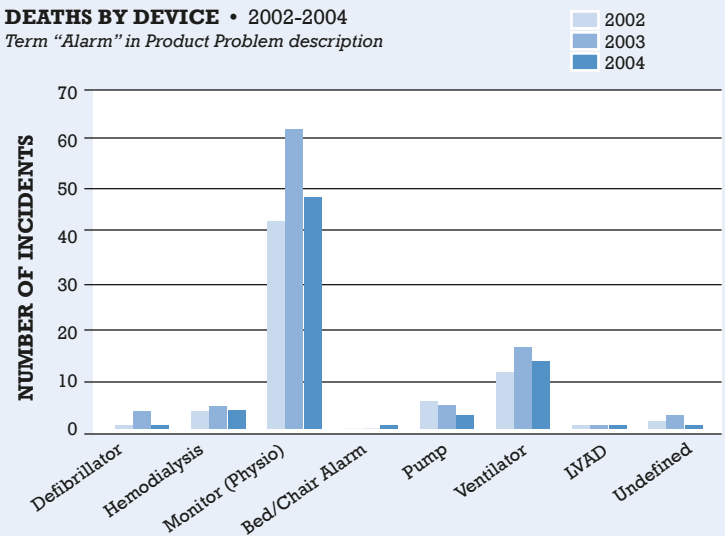


Table 1

FAILURE ANALYSIS

Clinical Alarm Reports Involved in Patient Deaths

Description	SRM Failure Categories ¹²	Total Cases	Percent of Total (%)
Device, unpredictable failure	D2	8	3.4
Device, deterioration	D3	2	0.8
Environment, external	E2	1	0.4
Operator Error, education/training	O1	58	24.5
Operator Error, distracted	O3	67	28.3
Patient, active	P1	3	1.3
Not Analyzable	G	98	41.4
	TOTAL	237	100

REPORTED PROBLEMS

As part of this study the FDA Manufacturer and User Facility Device Experience Database (MAUDE) and ECRI's Problem Report System were reviewed. These databases represent a subset of the total adverse events involving medical devices as has been stated in 2006 by the FDA, "Adverse events related to medical devices are widely under-reported by device users"¹³ This under reporting deters the ability of healthcare providers and the medical device industry in taking appropriate corrective action to improve patient safety where clinical alarms are used.¹⁴

FDA MAUDE Database Review

The FDA MAUDE database was queried over the period of 2002-2004 using the search terms "alarm" in the Product Problem field and "death" as the Event Type selection. Two hundred and thirty-seven reports were found using this search criterion with breakdowns shown in Figure 1 — Deaths by Year and Figure 2 — Deaths by Device Type.

Cause Analysis

Due to the limitations of the search process, the presence of the term "alarm" in the Product Problem field does not necessarily mean that an

alarm was related to the cause of the adverse event. For this reason, a focused analysis was undertaken to attempt to determine the causes of the events.

The two hundred and thirty-seven adverse event reports generated were analyzed using cause definitions found in the Shepherd System's Risk Model¹⁵ (Appendix D). Of these event reports, 98 (41%) could not be analyzed because of the limited information provided in the Product Problem field. Based on the material contained in the descriptions, 58 (25%) were determined to be related to education and training of the operator; 67 (28%) were related to work conditions or personal problems of the operator, and 14 (6%) were determined to be due to other causes. (See Table 1 for a breakdown of events)

It is of particular interest that of the 139 events that could be analyzed, 58 (42%) were related to operator education and training, and 67 (48%) were related to work conditions or personal problems. Unfortunately, the work conditions or personal problem factors cannot be further identified retrospectively. However, this does suggest the need for asking questions that would elicit this information in future studies.

ECRI Problem Reporting System Database Review

Of more than 2,200 reports of medical-device-related incidents and deficiencies received through ECRI's Problem Reporting System since March 2000, approximately 12% include the word "alarm" in the Problem Description field. (These include reports of alarm malfunction, as well as discussion of alarms in the context of the reported incident.) 64% of the reports involved one of three types of devices—physiologic monitors, ventilators, and infusion pumps - 11%, 39%, and 14%, respectively. The remainder of the reports are distributed between various other types of devices with alarms.

For physiologic monitors, there are numerous reports of critical patient events in which the monitoring system was reported to not produce an alarm. Many of these reports were subsequently investigated by ECRI staff to find that alarms had somehow been inadvertently disabled. Many of both the ventilator and infusion pump reports discuss device failures that put the patient at risk, but that did not result in an alarm to alert caregivers to the failure. However, for both devices, many reports describe other types of device failures for which appropriate alarms did occur.

IMPROVEMENT EFFORTS AND ISSUES

Technology

As the capabilities of medical devices have evolved, so has the sophistication of their respective alarms. Physiologic monitoring system alarms evolved from simple, ECG-only devices with heart rate limit alarms to multi-parameter devices with real-time arrhythmia analysis capability and an array of alarms for rates, pressures, saturations, and concentrations. Anesthesia machines have advanced from having entirely manual "on/off" controls to alarms that automatically reconfigure based on the mode of operation. For example, entering cardiopulmonary bypass mode on some anesthesia machines automatically disables alarms that are no longer relevant and would otherwise create nuisance alarms (e.g., end-tidal carbon dioxide alarms), while exiting this mode

automatically re-enables these alarms. Some devices include alarms that monitor human interaction with the device, such as dose error reduction systems on infusion pumps (i.e., "smart pumps") that can alarm if a nurse accidentally sets dosing parameters outside of prescribed limits. Additionally, schemes like alarm prioritization have been introduced in an attempt to aid management of the growing numbers of alarms that staff are responsible for by providing different visual alerts and audible tones depending on the urgency of the alarm. In addition, devices increasingly offer highly configurable and flexible alarm systems, allowing hospitals to implement alarms in ways that best meet their broader practices and protocols.

The medical device industry has begun responding to the need for technologies that help hospital's efforts to improve clinical alarms management. Products continually come to market in response to specific clinical problems or needs, either in the form of devices with improved acquisition techniques and alarms design, or supplemental products that facilitates how clinicians deal with alarms. For example, one challenge for nurses is to effectively respond to the multitude of alarms and alerts emitted by the systems and devices under their purview—e.g., physiologic monitoring systems, nurse call systems, infusion pumps, ventilators, bed-exit alarms, etc. Various solutions are now available that are intended to consolidate and organize alarm information so that it is more manageable for staff, such as integrating ventilator and other bedside device alarms into a physiologic monitoring system or implementing a communication system that accepts and automatically disseminates data from various sources.

Nuisance alarms are annoying alarms that may interfere with patient care, and typically do not result from an adverse or potentially adverse patient conditions. To reduce the frequency of nuisance alarms, device manufacturers have both sought to improve parameter acquisition techniques (e.g., motion-tolerant pulse oximetry) and improve alarm system design to avoid burdening staff with alarms that are not clinically significant. For the latter, some manufacturers have implemented what are sometimes termed "smart alarms," in which the alarm system takes into account multiple parameters, rate of change of parameters, signal quality, etc. By doing so, the system may be able, for example, to avoid alarming for a high

pulse rate caused by pulse oximetry sensor motion if the heart rate determined by the ECG signal remains stable.

Ensuring audibility of clinical alarms can be particularly challenging in intermediate and general care areas which, compared to critical care areas, are often large, have long hallways, and in the interest of patient and family privacy, may have doors to patient rooms closed. Despite this challenge, alarming devices such as physiologic monitoring systems and ventilators are increasingly used in such areas as hospitals deal with the trend of rising patient acuity. In response, a variety of alarm enhancement solutions have become available that are intended to complement or extend device alarms. Examples include technologies that route device alarms through a nurse call or paging system or enunciator devices (e.g., buzzers).

Despite manufacturers' efforts to create products that facilitate safer and more effective alarm management, there are many cases where alarm management technologies actually create additional problems. For example:

- ECRI's January 2005 Health Devices evaluation of physiologic monitoring systems examined interfaces that allowed ventilator alarms to appear on the monitoring systems' central station monitors. ECRI's study found that none of the evaluated systems provided completely safe and reliable notification of ventilator alarms, falling short in areas such as alarm prioritization and identification from the central station.
- Many hospitals have reported to ECRI that a popular alarm paging system used to deliver physiologic monitoring system alarms directly to the caregiver has the negative "side-effect" of compounding the effect of false and nuisance alarms. That is, alarm pages are issued in addition to the alarms issued by the monitoring system itself.
- The Veterans Health Administration published a Patient Safety Alert on July 2, 2004 related to the failure of medical alarm systems using paging technology to notify clinical staff. The VA recommendations states that "medical alarm systems using paging technology are not designed or intended to be used as the primary method for alerting clinical staff of critical alarms conditions or are they approved for this use by the FDA."

JCAHO's Alarm-Safety Goal

Shortly following JCAHO's February 2002 Sentinel Event Alert discussing 23 ventilator-related deaths and injuries, 65% of which involved problems with alarms, the JCAHO set six National Patient Safety Goals for 2003. Among these was a goal to improve the effectiveness of clinical alarms. JCAHO's focus on this issue was effective in raising awareness of deaths and injuries that continue to occur due to ineffective alarm coverage and inappropriate alarm use, and promoting a better understanding of the importance of effective alarm management strategies in general. This goal remained as a National Patient Safety Goal for 2004, after which it was removed from the list and became part of JCAHO's Accreditation Participation Requirements (APRs). Despite the two year focus by JCAHO on clinical alarm improvement, the continued high level of alarm-related adverse events reported to FDA and ECRI illustrate that clinical alarm management still requires attention from hospitals.

Design Standards

Alarms are currently addressed in some way or another in a number of medical device standards. IEC 60601-1-8, which provides general requirements for alarm systems, is the only focused alarm standard intended to be applied to all medical devices with alarms. Among other things, this standard specifically defines characteristics of visual and audible alarms signals that can be used to prioritize the degree of urgency for all alarming devices. Despite this opportunity for harmonization of alarms for disparate devices, these guidelines are not widely implemented in medical devices and hospitals. Some devices provide the hospital with the option to employ the IEC-defined alarm tones or the device vendor's own proprietary alarm scheme.

Current AAMI/ANSI standards include some discussion of alarm requirements, but do not currently address the need for prioritization of alarms emitted from different devices. That is, alarms are generally handled on a device-specific basis, and primarily cover interaction between the device and the alarm system. For example, in the ANSI/AAMI EC13 standard discussing cardiac monitors, requirements include alarm limit ranges for heart rate and allowable alarm delays when there is a limit violation.

FDA Device Regulation

The FDA, in its regulatory review of new devices, focuses on individual device performance with relatively little attention to the integration of the device into the clinical environment. Furthermore add-on, multi-device communications systems have received little attention from the FDA, in part because they are currently in the gray zone of whether or not they are themselves medical devices. On the positive side, the FDA has been paying increasing attention to human factors issues such that user interface issues are receiving more attention. The FDA has adopted the 60601-1-8 as a reference standards.

AHTF INITIATIVE

AHTF put forth an initiative in 2005:

- To improve patient safety by identifying issues and opportunities for enhancements in clinical alarm design, operation, response, communication, and appropriate actions to resolve alarm-related events.

To pursue this initiative a task force was formed to focus on clinical alarms management and integration. Activities have included open forums, audio conferences, literature and hazard reviews, the design, implementation and analysis of a clinical alarms survey, and development of educational materials including materials on the AHTF website <http://www.acce-htf.org/> and the publication of this paper.

The kickoff event was the 2005 AAMI annual meeting where a "Town Meeting" on clinical alarms was attended by nearly 100. The discussion included the role of alarm standards, developing alarm management and prioritization systems, the difficulty in training clinical staff on alarms, environmental issues, and even defining "What is an alarm?" Based on a raise of hands vote, the assembly believed that care management and standards were critical, but the majority stressed that improving alarms requires a systems approach. A subsequent ACCE audio conference included questions from the audience on the availability of alarm system upgrades and manufacturer use of standards. Other presentations and discussion sessions took place at the 2005 FDA MedSun annual meetings in Baltimore and San Diego and at several biomedical technology society meetings.

A major focus of the task force has been on the development, delivery and analysis of a national survey on clinical alarm usage, issues, and priorities for solution. The American Association for Critical-Care Nurses offered valuable input into the development of the survey. Many other clinical, technical and engineering organizations contributed to the initiative (Appendix B) and posted a link to the survey on their website. A goal of the survey was to help gain reliable information on the extent to which the management of clinical alarms is a problem in hospitals so that equipment manufacturers and caregivers can take appropriate corrective actions.

The survey (Appendix C) was divided into four main sections. The first section (A through D) requested demographic information from the respondent e.g. type of facility, job type. The second section (E) provided a number of general statements about clinical alarms and prompted the respondent to rate their level of agreement with the statement with options for Strongly Agree, Agree, Neutral, Disagree, and Strongly Disagree. The third section (F) presented a listing of nine issues that inhibit effective clinical alarm management and asked the respondent to rank them on a scale of 1 (most important) to 9 (least important). The final section (G) requested commentary on what is needed to improve clinical alarm recognition and response.

The survey was implemented on-line via Survey-Monkey™ on August 15, 2005 with a close date of January 15, 2006. It was also made available in a paper version which was utilized by many health-care institutions. The completed paper survey forms were reviewed internally at the healthcare institutions and then faxed for loading into the online database for analysis. The paper surveys were beneficial to institutions as they could review feedback and focus on clinical alarms problems at the hospital level.

Clinical Alarm Survey Results

The survey was completed by 1,327 respondents, the large majority (94%) of which worked in acute care hospitals. Over half of respondents were Registered Nurses (51%), with a sizable portion of surveys completed by Respiratory Therapists (14%), Clinical Engineers and Biomedical Equipment Technicians (6% and 9%, respectively), and Clinical Managers (6%). Almost one-third of respondents (31%) work in an intensive care unit,

with the remainder of respondents fairly dispersed among various other departments. 66% of respondents had more than 11 years of experience and only 8% had less than three years.

Answers to section E yielded some similarities and some differences between respondents. The large majority of respondents (>90%) agreed or strongly agreed with the statements, covering the purpose of clinical alarms, and the need for prioritized and easily-differentiated audible and visual alarms. Likewise, a large portion of respondents identified nuisance alarms as problematic, with the large majority agreeing or strongly agreeing that they occur frequently (81%), disrupt patient care (77%), and can reduce trust in alarms and cause caregivers to disable them (78%). 80% of respondents support smart alarms which can help minimize some types of nuisance alarms.

Responses were split on whether properly setting alarm parameters is overly complex on existing systems. 49% of respondents disagreed or strongly disagreed with this statement, while 28% agreed or strongly agreed and 23% responded as neutral on the issue. 72% of respondents agreed or strongly agreed that alarms are adequate to alert staff to changes in the patient's condition.

Two survey statements in section E addressed how alarms are conveyed to staff. 49% of respondents believe that a dedicated central alarm management staff (i.e., monitor watchers) for disseminating alarm information to caregivers is helpful, while 34% were neutral; 54% of respondents see utility in integrating alarm information with communications systems (e.g., pagers, cell phones), while 30% were neutral.

Section F provided insight into how staff rate the relative contributions of various challenges faced with clinical alarm management. For most of the items, responses were well-distributed across the range of importance. That is, a sizeable portion of respondents selected each rating, from 1 to 9, for the item. Items with such responses include:

- Difficulty in setting alarms properly
- Difficulty in hearing alarms when they occur
- Difficulty in identifying the source of an alarm
- Inadequate staff to respond to alarms as they occur
- Over-reliance on alarms to call attention to patient problems

Two items showed more consistency among respondents. 42% of respondents consider "frequent false alarms reducing attention" and "response to alarms" as the most important of the presented issues, and 78% rated false alarms in the top four rankings. Conversely, 25% of respondents believe lack of training on alarms is the least important issue, and 63% rated it at the lowest ranking - 6 through 9.

Perspectives On The Clinical Alarm Survey

ECRI staff review of the data shows that the most salient result of the survey was the frustration among staff with the high level of false and nuisance alarms. The quantitative results were echoed in respondents' commentary in section G, with one respondent stating, "False alarms take up a large portion of the bedside care provider's time. If these alarms could be significantly reduced, staff would see the benefit of alarms, respond more readily and quickly, and embrace the technology."

ECRI's investigations of adverse patient events continually show a causative contribution that frequent nuisance alarms have to alarm-related patient incidents. At minimum, they are distracting and can interfere with clinicians effectively performing other critical tasks. They also contribute to nurse desensitization to alarms, such that alarms for "real" events are less likely to catch the attention of staff. This is of particular concern for seemingly low-priority alarms—e.g., ECG leads-off, or SpO₂ sensor-off—which typically employ less ear-catching audible tones than higher-priority alarms. Nurses may fail to notice, and thus, not respond to such alarms. If the low-priority alarms are disabled for the particular parameter, critical patient conditions may not be detected. Additionally, clinicians will sometimes take inappropriate actions to gain relief from frequent nuisance alarms, such as lowering alarm volume, extending alarm limits outside of a reasonable range, or disabling alarms altogether.

Some amount of false and nuisance alarming is inevitable. Mitigating the problem posed by them lies in the hands of both device manufacturers and clinicians. Clearly, designs incorporating "smart alarms" and pulse oximetry that avoids loss-of-signal alarms by reading through artifact are steps in the right direction from a technology standpoint. Equally important is for clinicians to work to minimize nuisance alarms through

effective use of equipment. For example, heart rate limit settings should be chosen that provide sufficient protection for the patient while not allowing rate changes that are not clinically significant to set off nuisance alarms. Proper ECG electrode application technique must be employed to limit ECG leads-off alarms. Furthermore, alarms must be addressed promptly, since patient conditions that are left unresolved typically result on ongoing alarms.

As devices become more sophisticated the complexity increases. Nurses currently are charged with effectively managing a host of bedside devices, each with alarm capability. Nurses are responsible for setting alarms properly and responding to each alarm promptly—for each device and for each patient—while still managing all other non-alarm-related tasks. Furthermore, nursing staff must deal with a high frequency of false alarms (e.g., a tachycardia alarm triggered by the effect of patient movement on the ECG) and “nuisance alarms,” alarms that do not indicate a clinically significant patient condition requiring attention. One example of a nuisance alarm is a “high pressure” ventilator alarm caused by a patient cough. Operationally, hospitals must ensure proper training for nursing staff on a broad range of devices and alarm systems. Policies and procedures must be in place for nurses to effectively respond to alarms. Care unit geography and staffing must be such that all alarms can always be heard by staff. Failure to meet any of these challenges can allow alarms to be missed by clinicians, and as a result, a critical patient condition can go unnoticed. The complexity of clinical alarm management explains why, despite the abundance of device alarms, alarm-related adverse events still occur with worrisome frequency.

A large portion of the survey responses indicated that (1) alarm settings are not overly complex and (2) lack of training on alarms, compared to other alarm management issues, is not a significant concern. Yet in ECRI’s reported experience, problems often stem from alarms being improperly configured or inadvertently defeated by staff. These are impacted both by the human factors design of the device’s alarm system, as well as the nursing staff’s level of proficiency with configuring and managing alarms. Thus, effective initial and ongoing training is still of vital importance. While on the surface, many alarm systems seem straightforward, the intricacies are often not well understood by staff. A common example is the many ways one can defeat an alarm on a physiologic

monitoring system. One action may silence an existing alarm. Another may disable all alarms for a period of time. Still another may indefinitely disable alarms. Not understanding these differences can lead to inappropriate actions for the given circumstances, which can and do lead to adverse events.

Given that more than half of respondents were nurses, the fact that survey responses both highlighted the burden of nuisance alarms and deemphasized need for clinical alarms training is not altogether surprising. This illustrates the current state of clinical alarms management in hospitals: Many nurses see alarms as one item on a long list of tasks to be managed, rather than as an enabling tool that improves the nursing staff’s ability to stay informed of their patients’ conditions. By not recognizing the importance of training, the results indicate that nurses may underestimate their role in alarm management and see the “burden” of clinical alarms as solely a technology problem. Clearly, frequent nuisance alarms have played a role in breeding this mindset, and technology improvements are a necessary component in addressing this problem. However, nursing staff must recognize that effective alarm management relies on how the technology and the human elements intersect. Compounding the “alarm burden” felt by nurses, alarm management is often “thrown” at nursing staff without enough consideration by the hospital for the challenge at hand. For example:

- Are alarms sufficiently audible to alert nurses wherever they may be, especially in an environment with many competing alarms?
- Do current staff levels allow enough time to manage the large number of alarms?
- Have devices been configured to minimize nuisance alarms?
- Have nurses received adequate training?
- Are adequate methods of communication between nurses available to exchange alarm information and facilitate response?

Thus, effective clinical alarm management relies on (1) equipment designs that promote appropriate use (e.g., easy to set, obvious visual indicators when alarms have been disabled), (2) clinicians taking an active role in learning how to use equipment safely over its full range of capabilities, and (3) hospitals recognizing the complexities of clinical alarm management and devoting the necessary

resources to develop effective management schemes. As stated by one survey respondent, a “combination of technology and nursing process adjustments need to be implemented in order to effectively address this issue. Smart alarms, improved communication systems, directing alarms to the caregivers, training, accountability regarding alarm response policies, etc, all should be helpful in reducing the risk.”

OBSERVATIONS

The studies presented revealed several themes:

- The number and complexity of alarm systems in critical care environments challenge human limits for recognition and action.
- Alarms in critical care environments may not significantly affect care management decisions.
- In general, alarms are a tool in assessing patient conditions should be used in conjunction with direct clinical measurements and observations.
- The term “alarm” was found in the FDA MAUDE adverse event report Product Problem field most commonly for physiological monitoring systems along with ventilators and infusion pumps.
- Parameter acquisition improvements (e.g. pulse oximetry) are important in improving alarm accuracy and value.
- Remote alarm communication devices (e.g. pagers) if well designed can be of value but problems have occurred when used as the primary alert method.
- The IEC/ISO standards are viewed by many as a way to improve alarms by standardizing audible and visual alarms, priority and parameter differentiation.
- The alarm problem is a systems issue and actions toward specific areas must consider their impact on the system.
- There is disagreement about the role of user operation of alarm systems in alarm system performance. Caregivers de-emphasize the need for alarm configuration and operation training while adverse event analysts find many instances of improper setup and subsequent action when alarms do occur.
- False alarms have been consistently reported as a major issue with alarm systems. They reduce staff confidence in alarms which may result in deactivation of alarm systems and detract from care management.

RECOMMENDATIONS

Medical Device Industry

Manufacturers should consider the complexity of the healthcare environment in order to design alarm systems that are operationally intuitive, and effective given the care tasks of users, and which are focused on the true need for intervention. False alarms must be reduced for alarm systems to be effective. There must be additional emphasis on accurate parameter acquisition, human factors design and a systems approach to alarm systems. The IEC/ISO standards for alarm systems represent an improvement in design and should be considered for implementation in the U.S. Standardization offers the opportunity to eliminate some elements of confusion over what different alarms mean, as well as how they are operated. The actual use of recognized standards by various manufacturers must become the norm rather than the exception. Additional standards and standardization are also necessary so that devices that are commonly used together operate as a system rather than as a collection of individual components. Furthermore, how devices are configured must also reach a greater level of commonality so that, for example, every manufacturer’s monitor, or infusion pump, or ventilator does not require unique operator knowledge.

Healthcare

Healthcare organizations and clinicians should recognize the limitations of alarm systems and utilize them only as a tool in the overall assessment of patient condition. It should be recognized that improper configuration and operation can result in adverse events in the complex patient care environment. Effective education and training must take place to better understand proper operation, the implications of mis-configuration or defeating alarms, and the limitations of current alarm systems. False alarms will occur, but should not result in reduced alarm vigilance and deactivation of alarms. The care of patients where clinical alarms are used should be planned with input from clinical staff, biomedical/clinical engineers, facilities staff and others involved in the environment of care so that alarm use is well integrated with other procedures and requirements.

Healthcare institutions purchasing devices and systems with alarms should carefully evaluate the potential for devices to reduce false alarms and other cited problems through intelligent processing of incoming signals, the use of “smart

alarm” technology, ease of use, usability and human factors design principles, and application of standardization and systems engineering measures. Consideration of the implications, interfacing and environmental factors in adding remote enunciator systems.

Education

Effective education for clinicians is a critical part of the process that needs to be considered when working to improve alarm-related safety. Clinicians need to be provided with plenty of opportunities to learn about the details of the alarm-based medical devices they are expected to operate. Such learning must reach the level of operational effectiveness rather than just intellectual knowledge. Planning for this education needs to start during the technology planning and procurement process. Specifically, the cost for training clinicians on how to use devices with alarms needs to be included in the budgeting and implementation timeline for new technology procurement. This needs to consider training of clinicians on devices once they arrive and an appropriate level of refresher courses, for example on an annual basis, and for training of per diem or other staff that miss the initial training. Training should be designed so that devices are operated in their normal clinical environments and should include information on the institution’s alarm setting and response protocols.

FUTURE DIRECTIONS

The results of this study lay the groundwork for future efforts towards improving the area of clinical alarms. These efforts will include:

- Developing awareness of the need to improve clinical alarms through the publication of this report in media read by the various constituents – industry, regulatory, clinical, risk management, healthcare leadership, and clinical engineering.
- Soliciting the constituents to meet at focused forums to develop action plans to improve identified problem areas.
- Promote to the medical device industry the critical need to reduce false alarms by:
 - enhanced parameter acquisition accuracy and employment of proven “smart alarms” technology to reduce false alarms.
 - better human factors engineering in alarm systems such as the use of more intuitive graphical user interfaces.
 - improved alarm integration and intelligence.
- Bringing forth the data to standards bodies to promote alarm standardization improvements including the use of scientific research data in developing alarm standards such as a uniform method of annunciation (tone, display, etc.) for life critical versus other types of alarms.
- Developing a better awareness by clinical staff of the criticality of alarms and deleterious effects of operational problems so that there can be an enhanced emphasis of the importance of training and preparation in the area of alarms.
- Re-evaluate the area of clinical alarms in 1-2 years by administering a similar survey and other measures to determine progress in clinical alarm improvement.

APPENDIX A

ACCE Healthcare Technology Foundation (AHTF)
5200 Butler Pike
Plymouth Meeting, PA 19461-1298
Telephone: 610.825.6067
<http://www.acce-htf.org>

Mission:

Improving healthcare delivery by promoting the development and application of safe and effective healthcare technologies through the global advancement of clinical engineering research, education, practice and their related activities.

Major Programs And Initiatives:

- **Public Awareness** - The Public and Education Program for Healthcare Technology provides programs for improving our community's use of safer and better health technologies.
- **Certification for clinical engineers** - The Healthcare Technology Certification Commission provides the infrastructure for the United States Board of Examiners Certification.
- **Clinical Engineering Excellence Institute** - The institute provides focus on and the promotion of excellence in the clinical engineering field through recognition programs and awards.
- **Patient Safety** - The patient safety program will develop recommendations on proper safety labeling of medical devices and will provide lists of which devices are properly labeled regarding it's safe use.
- **Clinical Alarms Management and Integration** - This program is identifying issues and opportunities to improve clinical alarm design, integration, operation, response and actions.

APPENDIX B

ECRI (formerly the Emergency Care Research Institute) is a nonprofit health services research agency and a Collaborating Center of the World Health Organization (WHO). It is designated as an Evidence-based Practice Center (EPC) by the U.S. Agency for Healthcare Research and Quality. ECRI's mission is to improve the safety, quality, and cost-effectiveness of healthcare. It is widely recognized as one of the world's leading independent organizations committed to advancing the quality of healthcare.

ECRI's Focus

ECRI's focus is healthcare technology, healthcare risk and quality management, patient safety improvement and healthcare environmental management. It provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, voluntary sector organizations, associations, and accrediting agencies worldwide. Its more than 30 databases, publications, information services, and technical assistance services set the standard for the healthcare community.

ECRI's services alert readers to healthcare system and technology-related hazards with strategies to correct them; disseminate the results of medical product evaluations and health technology assessments; provide expert advice on technology acquisitions, staffing, and management; report on hazardous materials management policy and practices; and supply authoritative information on risk control in healthcare facilities and clinical practice guidelines and standards.

APPENDIX C



ACCE Healthcare Technology Foundation
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Clinical Alarms Survey

Please insert only one response for each question

A)	Facility	Acute Care Hospital		Ambulatory Care Facility or Surgery Center		Sub Acute Care				
		Nursing Home		Assisted Living/Rehabilitation		Other (write in)				
B)	Hospital department (if applicable)	ICU		Nursery		ER	Support			
		OR/Anes		General Floor		Progressive Care	Other (write in)			
C)	Job Title	Physician		RN		LPN	Clinical manager			
		Nurses aide or Orderly		Respiratory therapy		Clinical Engineer	BMET			
		Paramedical e.g. Rad/Lab/Resp		Administrator/Non-clinical manager		Transport	Other (write in)			
D)	Years Experience	0-3		3-6		6-11	11+			
E)	Alarm-Related Information:					Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
1.	The purpose of clinical alarms is to alert staff of an existing or potentially hazardous patient condition									
2.	Alarm sounds and/or visual displays should differentiate the priority of alarm									
3.	Alarm sounds and/or visual displays should be distinct based on the parameter or source (e.g. device)									
4.	Alarms should impact multiple senses (audible, visual, proprioceptive, etc.)									
5.	Nuisance alarms occur frequently									
6.	Nuisance alarms disrupt patient care									
7.	Nuisance alarms reduce trust in alarms and cause care givers to turn alarms off at times other than setup or procedural events									
8.	Properly setting alarm parameters and alerts is overly complex in existing devices									
9.	New (less than three years old) monitoring systems have solved most of the previous problems we experienced with clinical alarms									
10.	Since the implementation of the JCAHO Patient Safety Goal #6, now part of the overall JCAHO standards, patient adverse events related to clinical alarms have been reduced to an acceptable level.									

E)	Alarm-Related Information (cont)	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree				
11.	The alarms used on my floor/area of the hospital are adequate to alert staff of potential or actual changes in a patient's condition									
12.	There have been frequent instances where alarms could not be heard and were missed									
13.	The staff is sensitive to alarms and responds quickly									
14.	The medical equipment used on my unit/floor all have distinct outputs (sounds, repetition rates, visual displays, etc.) that allow differentiation of the source of the alarm									
15.	When a number of devices with alarms are used with a patient, it can be confusing to determine which device is in alarm									
16.	Environmental background noise has interfered with alarm recognition									
17.	A central alarm management staff that receives alarm messages and notifies the appropriate staff is helpful									
18.	Alarm integration and communication systems via pager, cell phone, other wireless device are useful in improving alarms management and response									
19.	Smart alarms, where multiple parameters, rate of change of parameters, and signal quality, are automatically assessed in their entirety would be effective in reducing false alarms									
20.	Smart alarms, where multiple parameters, rate of change of parameters, and signal quality, are automatically assessed in their entirety would be effective in improving clinical response to important patient alarms									
21.	Policies and procedures exist within the facility to regulate alarms and they are followed									
22.	There is a requirement in your institution to document that the alarms are set and are appropriate for each patient									
F)	Please rank the following issues below concerning alarms; 1 = most important, 9 = least important. <i>Read all issues first, then rank each issue with <u>only one</u> ranking.</i>									
		1	2	3	4	5	6	7	8	9
1.	Difficulty in setting alarms properly.									
2.	Difficulty in hearing alarms when they occur.									
3.	Difficulty in identifying the source of an alarm.									
4.	Difficulty in understanding the priority of an alarm									
5.	Frequent false alarms, which lead to reduced attention or response to alarms when they occur.									
6.	Inadequate staff to respond to alarms as they occur.									
7.	Over reliance on alarms to call attention to patient problems.									
8.	Noise competition from non-clinical alarms and pages.									
9.	Lack of training on alarm systems									
G. Please comment on what is needed to improve clinical alarm recognition and response. Also if there are specific equipment items which "strongly" influenced your answers above, please list them and why.										

Thank you!

Return this survey to: AHTF FAX NUMBER (832) 825-1850

APPENDIX D

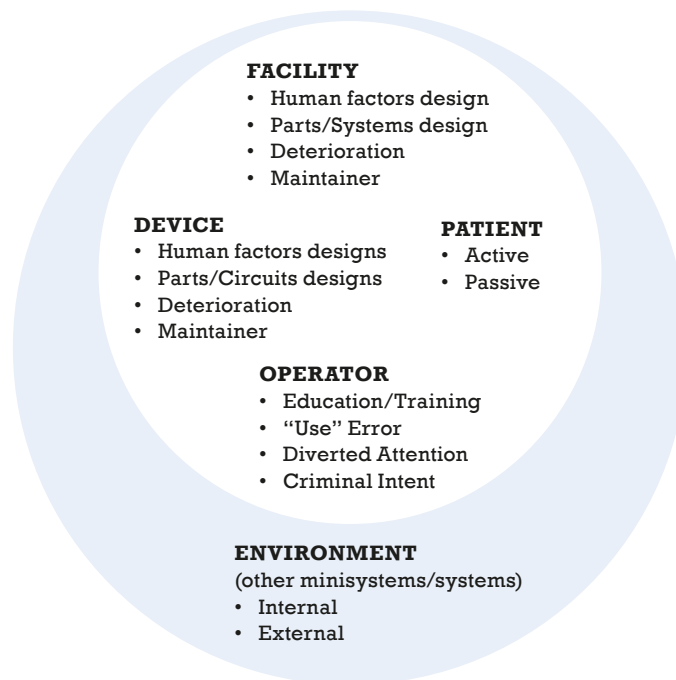
Shepherd's System Risk Model

Systems Safety Engineering Model
(Systems Risk Model)
(5-component, 16-Subcomponents)

Notes:

• Failures of any one of the 5 components — Device, Facility, Patient, Environment or Operator — are called direct causes of a system's failure. The subcomponents are the first level of root causes and can and should lead to additional and lower levels of root cause(s).

• Failure codes are intended to identify "causes" at the time an event occurs and the causes are associated with the conditions that prevailed only at that time. Specifically, why did the conditions that prevailed not accomplish the expected or intended results and which of the system's components or subcomponents failed to meet expectations. With the exception of "education and training," corrective actions to prevent a future event are generally not the causes of a specific adverse event.



System's Risk Model Failure Classifications And Definitions

(Updated 3/23/06)

Direct Causes (Failure Codes)	Root Causes (Failure Codes)	Root Causes (Failure Codes)
<p>D = Device Failure</p> <p>E = Environmental Failure</p> <p>F = Facility Failure</p> <p>O = Operator Failure</p> <p>P = Patient Failure</p>	<p>D1 = Device-Human Factors Design</p> <p>D2 = Device-component/circuit design (unexpected failure)</p> <p>D3 = Device- Deterioration (slow, predictable deterioration that requires a PM) (Includes battery failures, worn brushes, etc.)</p> <p>D4 = Device-Maintainer Error</p> <p>E1 = Environment (within hospital); internal minisystem affected outcome, i.e., EMI, etc.,</p> <p>E2 = Environment (external to hospital); external minisystem affected outcome, i.e., EMI, etc.,</p> <p>F1 = Facility-Human Factors Design</p> <p>F2 = Facility-Parts/System (unexpected failure; electrical, systems, etc.)</p> <p>F3 = Facility-Deterioration (slow, predictable deterioration that requires a PM)</p> <p>F4 = Facility-Maintainer Error</p>	<p>O1 = Operator Error (desirable human factor's design but operator education/training was inadequate)</p> <p>O2 = Operator Error (human factor's design predisposes operator to make an error ("use" error)</p> <p>O3 = Operator Error-Distracted Attention (operator is well versed in the HFDs but other conditions prevailed to cause an error, i.e., work load, long hours, personal problems, drugs, etc)</p> <p>O4 = Operator Error-Criminal Intent (the operator intends to use the device in such a manner as to cause harm to the patient). Note that an operator can be a nurse, doctor, technician, patient, family member, or even the patient.</p> <p>P1 = Patient, Active; patient action affected the outcome</p> <p>P2 = Patient, Passive; patient condition affected outcome</p> <p>G = Can't analyze the event</p>

APPENDIX E

Organizations contributing to the survey design and/or initiative:

- MedSun – Social & Scientific Systems
- AORN - Assoc. of periOperative Registered Nurses
- AACN – Amer. Assoc. of Critical-care Nurses
- ECRI – Emergency Care Research Institute
- ACCE - American College of Clinical Engineering
- META – Medical Equipment & Technology Assoc.
- AAMI – Association for the Advancement for Medical Instrumentation
- NECES – New England Clinical Engineering Society
- Virginia Biomedical Society
- Supporting publications: 24x7, J. of Clinical Engineering, Biomedical Safety & Standards

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