Why Clinical Alarms Are a 'Top Ten' Hazard

How You Can Help Reduce the Risk

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Take a look around your hospital for medical devices and systems with alarms. You'll find them on infusion pumps, physiologic monitors, ventilators, anesthesia machines, dialysis units, laparoscopic insufflators, and so on. It's amazing how much the healthcare system has grown to rely on medical device alarms. It would be hard to walk into almost any type of patient room or care area and not find an alarm-based device being used. In critical care areas, it's typical to find a dozen or more such devices, just for one patient. And these devices are now starting to become interconnected and are sharing lots of critical information, including alarm data.

With such widespread use of alarm-based medical devices, you'd think we would have a very effective safety net to warn about serious changes in patient conditions or performance- and safety-related problems with devices. Unfortunately, as many experts agree, there are serious problems with the design and use of device-based clinical alarms. Clinical alarms have been at or near the top of the ECRI Institute's list of "Top 10 Health Technology Hazards" since the annual list was first published in 2007. It remains near the top because alarm-related events are all too common, and the consequence of these problems can be extremely serious.[1,2]

Alarm Fatigue and Confusion

In early 2010 *The Boston Globe* reported on a typical alarm-related problem in which a patient's death may have been due to a critical physiologic monitoring alarm being turned off. That incident was attributed to alarm fatigue, in which caregivers can become overwhelmed by the sheer number of alarms.[3] Alarm fatigue can cause caregivers to unsafely modify alarm settings or silence alarms in order to reduce alarm overload. Or, caregivers can become desensitized to alarms and miss or delay their response to critical patient events.[4]

When you do your look around the hospital, consider how many different types of medical device alarm settings are being used.[5] Often, two different models of the same device type can have slightly different ways to set the same type of alarm. This can confuse caregivers who have to operate and adjust alarms for both models. ECRI Institute has investigated alarm-related incidents in which this type of confusion has had fatal consequences. The risk of this happening is magnified when you consider that many devices have multiple alarms, often with several different ways to adjust them.

Most medical devices with clinical alarms are intended for use on a variety of patients with a variety of medical conditions. As such, their alarm limits and other parameters are adjustable to meet the needs of the many types of

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patients that they will be used on. This level of flexibility can be helpful but is of no value and can even be dangerous if not used properly. For example, a pulse oximeter used in a neonatal intensive care unit should have different oxygen saturation limit settings than the same device used in an adult intensive care unit. Or, the pressure limit settings for a ventilator that is used on an adult vs. an infant must be adjusted to completely different levels. The acceptable limits for the adult patients will likely be lethal for the infant.

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Unfortunately ECRI Institute has seen many examples of alarms not being set according to the appropriate care area or patient type. In some cases this is because hospitals have not established specific alarm setting protocols for their different types of clinical settings and patients. Or the hospitals have established protocols, but they were not followed or understood. We've also seen examples of two or more of the same model device being used to treat patients with similar clinical conditions in the same care area with completely different alarm settings.

Efforts to Improve: An Overview

The problems described have helped to focus attention on the need to improve the design of clinical alarms and how they are used. Medical device manufacturers are working hard to improve features. New products like alarm integration systems can help present alarm data from disparate devices and systems in a more organized and functional manner. Cell phones and other communication devices can now deliver critical alarm data directly to caregivers, thereby potentially increasing their responsiveness to critical changes in patient conditions. Some of these efforts are supported by the resources from various medical device-related standards organizations, most notably from the International Electrotechnical Commission (IEC). Its 60601-1-8 standard provides general requirements for alarm systems and is intended to be applied to all medical devices with alarms.[6]

Many healthcare organizations are a taking a hard look at how clinical alarms are used and managed in their facilities. They typically find the need for significant improvement. Some have identified technology solutions like those described above. Others have chosen to focus on process changes utilizing their existing technologies, sometimes because of financial limitations. Others have implemented a combination of technology- and process-based changes.

The most successful efforts to improve alarm-related safety come about through systematic and critical analysis of how clinical alarms are used across all care areas in the institution. It requires strong commitment and a willingness to change at the highest levels of the organization. The analysis, improvement design, and implementation of an improvement plan must have active participation and buy-in from, at a minimum, clinical (including physicians), risk management, administrative, information technology, and clinical engineering staff.

Safe and effective management of clinical alarms is very complex. It's impacted by the hospital's mix of technologies, its care models, patient population, the physical layout of each care area, staffing patterns, staff education and training models, the hospital's safety-related "cultural" mindset, budget, its history of alarm-related problems, and many other factors. Any new technology will typically bring some new unintended risks or problems. Any initiative to improve the safety and effectiveness of clinical alarms needs to carefully consider all of these factors. All of the parties involved need to come to the table with the understanding that this will involve lots of hard work and will likely result in significant change to existing workflow and processes.

Step 1: A Safety Assessment

The first step in any institution-wide alarm safety improvement project involves setting up a multidisciplinary team. This team should be responsible for understanding the hospital's history of alarm-related events and near misses, how alarms are used throughout the institution, its existing clinical alarm-related policies and procedures, technology-related capabilities and limitations, actual practices, and probably most importantly, how clinical staff feels about alarm-related performance and response in the hospital.

The history of the hospital's alarm-related events and near misses can be identified from the hospital's incident reporting system, incident reports filed to manufacturers, FDA, insurance companies, and independent reporting organizations such as ECRI Institute. It can also come from review of alarm-related root cause analyses, results from clinical alarm problem remediation projects, and summaries of alarm trending data from physiologic monitors and other alarm-based medical devices. It's likely that this review will identify problems in many if not all of the hospital's care areas. Solving all alarm-related problems at once is probably an unrealistic task. This type of analysis can help hospitals identify where problems are most serious and can provide ideas on care areas or alarm problems to focus on first.

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An assessment of alarm use should include mapping the processes for alarm notification and response, discussions with clinical staff about their alarm-related concerns, and observations of how alarms are set and used in different care areas. The assessment should keep an eye out for problems with alarm

responsiveness or desensitization, difficulties with clinical staff's ability to hear alarms, large numbers of nuisance alarms, the frustration level of clinical staff during alarm conditions, or general signs of trouble like alarm pagers not being worn.

Information from the historical analysis and assessment of alarm use can be used to identify key institution-wide alarm vulnerabilities and potential failures. Examples include alarm fatigue, apathy to alarms that are incorrectly perceived to be "low priority" such as leads-off, or breakdowns in transport communications. This may help point to problem causes such as diffuse responsibilities for alarm response, competing staff priorities, infrastructure limitation, inadequate training, a weak safety culture among clinical staff, or specific technology limitations. Once the problem causes have been identified, the committee can begin to develop its improvement plan. [7,8]

Step 2: Improvement Planning

The interdisciplinary alarm improvement team should plan to develop realistic, implementable strategies to address underlying causes of the alarm problems it identified. The plan should start with strategies that apply to most hospitals. They may include:

- Establishing protocols for proper electrode skin preparation and placement
- Setting alarm limits to the specific patient population
- Tailoring alarm limits to the individual patient care area
- Elevating the response priorities for critical alarms like those identifying a leads-off condition

Strategies that require more in-depth process analysis include:

- Delineating responsibility for alarm response
- Developing plans for tiers of coverage
- Delineating responsibility for back-up response
- Implementing technology solutions such as two-way pagers for providing alarm notification directly to the caregivers
- Establishing policies for meeting alarm-specific safety criteria during the technology selection process

Whichever strategies are implemented, it is essential to provide staff education and training including why the strategy is important and how it should be implemented. Whichever specific plans are developed, a key goal is to have alarms that are actionable so that, as much as possible, staff are being alerted to only clinically significant alarms, thereby minimizing the risk of alarm fatigue.[9,10]

Success Stories

ECRI Institute gives out an annual award called the Health Devices Achievement Award. It is designed to recognize technology-related initiatives that our member hospitals undertake to improve patient safety, improve overall healthcare quality, or reduce costs. Two of its award honorees (William Beaumont Hospital and Boston Medical Center) were recognized for projects that had significant impacts on improving alarm safety. The Johns Hopkins Hospital is another example of an organization that put serious effort into finding ways to improve how alarms are managed and used.

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William Beaumont Hospital

William Beaumont Hospital in Detroit, MI undertook an alarm improvement project because of general complaints with the responsiveness of its clinical staff to critical alarms from a newly installed telemetry monitoring system.

Beaumont assigned a multidisciplinary team to further investigate the problem. It first decided to measure the time it took for clinical staff to respond to alarms. It was found that the mean response time was 9.5 minutes, which was clearly a dangerous situation. This led to a critical review of how alarms were being communicated by the telemetry system and the clinical staff on the telemetry ward. At that time, specially trained telemetry technicians were assigned to verify alarms and then page the patient's nurse. The nurse would then call to confirm receipt of the page and to request any additional information. If the nurse did not respond within 3 minutes, the technician would reissue the page. If necessary, the page would be directed to other personnel following the specified "chain of command." Unfortunately, pages were frequently missed and then had to be reissued, which led to the nurses becoming

desensitized to the pages and contributed to the unacceptably long alarm response times.

A detailed failure mode and effects analysis led to a solution to the problem based on implementation of a two-way, voice-activated wireless communication system. The system allowed telemetry monitoring technicians to speak directly to nurses through the communication device, and the nurses could speak directly to the technicians to ask questions. The new technology significantly streamlined Beaumont's alarm notification protocol and drastically shortened alarm response times. Mean alarm response time dropped from 9.5 minutes to 39 seconds, well under a planned improvement target of 3 minutes. Also, use of the two-way communication devices led to a 100% closure of the communication loop, compared with an average of 35% before the project began.[1]

Boston Medical Center

Boston Medical Center (BMC) had recently observed a wide disparity in how alarm limits were being set, particularly in its telemetry wards. It was also experiencing a large number of low-level alarms that contributed to the noise levels in these areas and probably alarm fatigue.

After careful analysis it implemented a program to standardize the alarm setting defaults in the telemetry wards. It also instituted an enhanced version of its telemetry order set that helped ensure that patients receiving telemetry really needed it. BMC also created a telemetry training course for its nurses and interns that helped reinforce its alarm setting standardization and order set enhancement efforts. This project has helped to reduce the number of nuisance alarms at BMC.[12]

The Johns Hopkins Hospital

The Johns Hopkins Hospital in Baltimore, MD completed a study on overall alarm management in its Medical Progressive Care Unit. The medical step-down, which had a diverse patient population, commonly saw fluctuating vital signs with sudden changes in hemodynamic status. Its pre-implementation data revealed bradycardia, low heart rate, high heart rate, oxygen saturation and leads fail as their most common alarms.

The hospital's interventions included a pre- and postnursing survey on alarm management and noise level, education on best practices, troubleshooting methods and customizing of parameters, and patient monitoring software enhancements that included a split screen view that allowed crisis alarms to sound at the central station as well as every bedside monitor. A hospital-wide Monitor Alarm Taskforce team was also started and involved the Medical Progressive Care Unit's Comprehensive Unit-Based Safety Program

(CUSP Team). This team helped revise alarm limit default parameters by analyzing the patient population to determine the best and safest settings for that particular unit. In making these adjustments the team focused on frequent, duplicate, and nuisance alarms. Data were collected approximately a year later and revealed a 43% decrease in critical alarms that led to a hospital-wide initiative for improving and standardizing alarm management.[13]

New Directions

New products like alarm integration systems can help present alarm data from disparate devices and systems in a more organized and functional manner. And cell phones and other communication devices can now help caregivers at facilities such as Beaumont Hospital improve their responsiveness to critical changes in patient conditions. So what will or should the next generation of clinical alarm technology improvements be like?

They should first address how the patient is doing from a holistic point-of-view. Most of today's monitors or other alarm-based medical devices have one or more discrete alarms that trigger when a specific limit is reached. They don't consider for example how pulse rate, ECG heart rate, and oxygen saturation relate to one another. The next-generation alarm systems will need to serve as smart or intelligent monitors that integrate a variety of patient parameters and warn of serious changes to a patient's overall condition. In some cases one of these "collective" alarms will sound earlier than on today's discrete devices (e.g., because several physiologic parameters are trending together in a negative direction). In other cases, the number of nuisance alarms will decrease because "outlier" conditions will be classified as being not clinically significant. The new system will be smart enough to not sound for the outlier condition because other physiologic parameters will be trending just fine.

Two-way communication devices like the one used at William Beaumont will evolve so that all pertinent alarm information is presented in a clear and organized way, eventually in a heads-up display. The alarm data will include information on the patient's current location, possibly a video feed of the actual patient, and appropriate trending information that holistically shows how the patient is doing based on a range of physiologic parameters.

On a shorter term improvement timeline, medical device manufacturers should design their alarm features so that their limits cannot be adjusted to clinically unsafe levels. Their alarms off or silence features should not allow for conditions where patients are not being fully monitored for minutes at a time. When alarms have been defeated or silenced, devices need to provide a very clear indication that they are in a disabled state. And, as alarm data is transmitted from one device to another (e.g., via wireless networks) safeguards will need to be put in place to make sure that the information is transmitted accurately, and without interruption or delay.

Conclusion

Clinical alarms are a serious problem. About a year after its initial story on alarms, *The Boston Globe* reported in February 2011 on more than 200 alarm-related patient deaths from January 2005 through the middle of 2010.[14,15] Considering the underreporting of medical device incidents, the number is likely much higher. A survey during a recent ECRI Institute webinar on clinical alarms found that almost 75% of its listening audience had experienced at least one serious alarm incident in the two years prior to the program.[16] Many hospitals have taken notice and have undertaken significant efforts to improve alarm safety. Some have identified technology-focused solutions and others implemented clinical process changes or a combination of both.

Hospitals that still need significant improvement should conduct a comprehensive assessment of the state of their alarm-based technologies and processes. Regardless of the solutions identified, nothing will work without full participation and cooperation of clinical users. And the clinical users need full support from their hospitals' leaders. One of the most important ways to provide that support is to make sure that all users fully understand the hospital's clinical alarm protocols and how to use and respond to the alarm features of all alarm-based medical devices. Clinical and biomedical engineering professionals should play an important role in making sure this happens and ideally should be the lead or major contributor to any healthcare organization's alarm improvement initiatives. ■

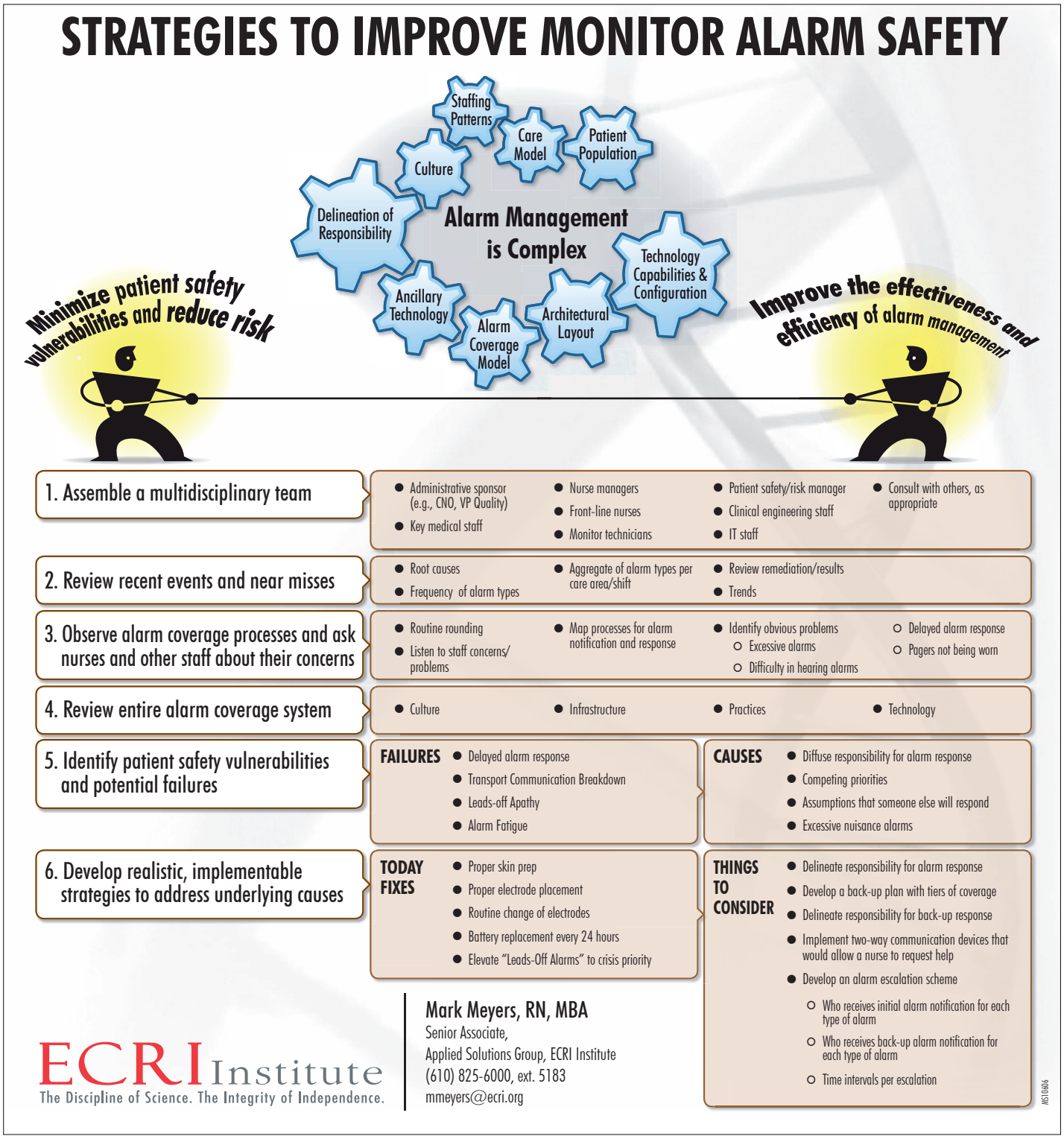

Figure 1. Strategies to Improve Monitor Alarm Safety. ©2011 ECRI Institute. Reprinted with permission.

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