AAMI
Advancing Safety in Medical Technology

Clinical Alarms

2011 Summit

Convened by AAMI, FDA, TJC, ACCE, and ECRI Institute

Clinical Alarms Summit Conveners

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A *Siren Call* for Action

PRIORITY ISSUES FROM THE MEDICAL DEVICE ALARMS SUMMIT

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"We will do our part to help keep the passion alive. And, we look forward to a celebration in 2017, as we share a toast for the achievement of our common goal: no patient will be harmed by adverse alarm events."

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A Call to Action

Dear Colleagues,

On October 5–6, 2011, 300 talented and energized multidisciplinary stakeholders came together and dared to challenge the norm. They coalesced around the common goal of addressing the challenging issue of alarm system safety. They shared freely, learned from one another, and most importantly knew that a big door had been opened to address the hazard and frustration of alarm "noise".

In Henry Ford's words, "Coming together is a beginning. Keeping together is progress. Working together is success." We're going for success with this call to action!

Some people have asked whether we came up with a definition of alarm fatigue at the event. It's a great question—and one that is not yet resolved with a standard definition. The following answer, which encompasses a variety of interpretations of alarm fatigue as it is experienced in the field, should entice those who didn't attend the event to read this entire publication:

- Alarm fatigue is when a nurse or other caregiver is overwhelmed with 350 alarm conditions per patient per day.
- Alarm fatigue is when a patient can't rest with the multitude of alarm signals going off in the room.
- Alarm fatigue is when a true life-threatening event is lost in a cacophony of noise because of the multitude of devices with competing alarm signals, all trying to capture someone's attention, without clarity around *what* that someone is supposed to do.
- Alarm fatigue is compounded by inconsistent alarm system functions (alerting, providing information, suggesting action, directing action, or taking action) or inconsistent alarm system characteristics (information provided, integration, degree of processing, prioritization).
- Alarm fatigue is a systems failure that results from technology driving processes rather than processes driving technology.

While this incredible group of people went home exhausted from two days of intense discussion, they also went home re-energized knowing that together we all can solve these issues. This committed and diverse community of stakeholders is ready to take ownership of the issues and solve this problem.

There are short-term follow-up items that everyone can start to tackle now (see "Top 10" list). There are long-term issues that will take time (see research agenda in the appendix). And, the list of priorities includes everything in between.

The summit was a multidisciplinary community event, and this publication belongs to the community. Whether you attended the summit or not, we hope you will take time to review and reflect on this post-summit publication. Use it as a tool to ignite a call to action in your own organization. Use it to help garner support for a research project. Use it to set new policies. Most importantly, use it and share it with others.

As always, the challenge will be to keep the momentum going, to feed that call. Please share your stories so we can continue the conversation. Please share your successes and lessons learned so others can replicate or make adjustments.

We will do our part to help keep the passion alive. And, we look forward to a celebration in 2017, as we share a toast for the achievement of our common goal: no patient will be harmed by adverse alarm events.

Thank you again; and a special thanks to the other co-conveyers of the Summit—The Joint Commission, ECRI Institute and the American College of Clinical Engineering.

Sincerely,

Mary Logan
AAMI President

Scott A. Colburn
Lieutenant Commander
United States Public Health Service
Acting Director, Standards Program
Center for Devices and Radiological Health
U.S. Food and Drug Administration

(With the support of the FDA's Felipe Aguel, Ph.D. and Shawn Forrest)

Executive Summary

"This event coalesced all stakeholders around a common goal and energized end users to dare to challenge the norm. The balance and diversity of the audience—with industry, end users and regulators—was spectacular."

— Nat Sims, M.D., anesthesiologist and physician advisor in biomedical engineering at Massachusetts General Hospital and co-chair of AAMI's Infusion Device Standards Committee

Imagine a world in which, by 2017, no patient is harmed by an adverse alarm event. This is the powerful vision laid out by AAMI President Mary Logan at the opening of the Medical Device Alarm Summit held in October 2011 in Herndon, VA.

Logan opened the summit by likening the challenge to the story of the blind men and the elephant. In this tale, a group of blind men touch an elephant to try to figure out what it is. One man feels a leg and says the elephant is a pillar; another feels the belly and says it is a wall; one feels the tail and says it is a rope; another feels a tusk and says it is a solid pipe. One man feels the trunk and says the elephant is a tree branch; another feels an ear and says it is a fan. All of them are right—but none of them has a full conception of the beast before them.

Clinicians, manufacturers, biomedical professionals, researchers, acoustical experts, regulators, and patient safety advocates brought different perspectives to the elephant in the room at the summit. Taken together, their deep knowledge of many aspects of alarm system hazards forms a comprehensive picture of a systemic challenge.

Summit participants pooled their collective experiences to identify and prioritize a range of issues with medical alarms, which AAMI's Alarm Standards Committee grouped into seven clarion themes after the summit.

Seven Clarion Themes

1. Deepen all stakeholders' understanding of use environments.
2. Improve alarm system management.
3. Innovate to improve alarm system integration.
4. Reconcile challenges and differences in use environments.
5. Strengthen medical electrical equipment standards and contracting language to promote success in all intended use environments.
6. Clarify regulatory requirements.
7. Share illuminating practices and lessons learned with all stakeholders.

This report summarizes the clarion themes and the priority actions for addressing them. Summit participants assigned a short- or long-term time horizon for accountable stakeholders for each priority action. The clarion themes are a call to action to achieve the vision of eliminating alarm system-related hazards and hazardous situations in healthcare.

Several key messages recurred throughout the summit. Keeping these ideas at the forefront of initiatives to improve alarm systems could accelerate progress:

- A "patient safety first" lens is essential to create a sense of urgency, sustain momentum, and focus on results that matter.
- Technology is driving healthcare processes. This needs to be reversed so that people "own" the technology and human processes drive technology use.
- An increased focus on human factors throughout will drive improvement.
- Problem solving by interdisciplinary teams, and clinical leadership and support, are essential for success.
- Clinicians need to be involved in every step of the process to make progress on the priority actions.
- All stakeholders have an opportunity to contribute to research, share exemplary practices, and develop innovative alarm systems that serve as "trusted sentinels" to clinicians—and that improve the environment of care and patient outcomes.

About This Report

This publication reports on the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional context from experts. The clarion themes, challenges, and priority actions have not been endorsed by AAMI, the FDA, TJC, ACCE, ECRI Institute or any of the summit sponsors or supporting organizations. The views expressed by individuals in summit presentations and expert perspectives do not necessarily represent these organizations' views.

More Summit Information on AAMI Website

The summit agenda, PowerPoint presentations of summit speakers, reference materials, and updates are posted on the AAMI website.
www.aami.org/alarms

Gaining Clarity

Vocabulary is an important part of gaining clarity on the nature of alarm system issues. This publication uses the vocabulary that has been intentionally set by international standards for medical devices, in part to help with clarity and in part for consistency in how the community talks about the issues. For example, saying we have an "alarms problem" isn't sufficiently clear. We may be talking about alarm signals, alarm conditions, alarm settings, or alarm systems. These and other key terms are defined in the Vocabulary Appendix.

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TOP 10 ACTIONS YOU CAN TAKE NOW

10 Things You Can Do Now to Improve Alarm Conditions in Your Healthcare Organization

1 **Gain cross-disciplinary leadership support.**

› Example: Share summit proceedings widely to help show compelling need.

2 **Establish a cross-functional team with clinical leadership to address alarm fatigue across all environments of care.**

› Example: Use 80001-1 model; include clinical engineering and informatics experts.

3 **Re-establish priorities: Process should drive technology adoption rather than allowing technology to drive the process.**

› Example: Technology assessment and planning based on clinical needs.

4 **Develop a continuous improvement process for constantly optimizing alarm system policies and configurations.**

› Example: Improvement strategy based on crawl–walk–run.

5 **Conduct clinical testing and analyze alarm data to implement optimized alarm limits and delays (both alarm condition and alarm signal generation delays) and to reduce clinically non-actionable alarm conditions.**

› Example: Assess the feasibility of implementing 10-second auditory alarm signal "hold-off" (alarm signal generation delay) for all physiologic parameters to eliminate auditory alarm signals from self-correcting physiological alarm conditions (especially ECG and SpO2).

6 **Test acoustics on clinical floors: Environmental noise impacts patient and staff well-being and patient safety.**

› Example: Implement existing standards and guidelines: IEC-ISO 60601-1-8; the AHA's 2010 FGI Guidelines; The Joint Commission's *Planning, Design and Construction of Health Care Facilities* (Second edition, 2009).

7 **Implement an alarm system configuration policy based on clinical evidence.**

› Example: Don't just accept default alarm *preset* configurations; eliminate no-action alarm conditions.

8 **Change single-use sensors more frequently to reduce nuisance alarm conditions (except in pediatric units).**

› Example: Data from summit suggests 24 hours for ECG; conduct testing for SpO2.

9 **Mandate alarm system management training for all clinical *operators*.**

10 **Share experiences with AAMI, the FDA, TJC, ECRI Institute, and others with problem reporting systems so everyone can benefit from your efforts in a cross-disciplinary way.**

› Example: What is working well in your facility? What lessons have you learned?

This top 10 list came out of the audience discussion, and from follow up input received by AAMI about the top things attendees were going to do following the summit. They are not intended to be "should" suggestions from AAMI. They are intended to be inspiring, to give hope that there are at least 10 things that an organization can begin to do now if they want to start on organizational projects, without waiting for longer term standards, research, etc. Organizations will need to decide for themselves which of these items can and should be tackled, based on organizational culture and other priorities.

Clarion Themes, Challenges, and Priority Actions

"Bringing industry, regulators, outside experts, patient safety officers, healthcare technology management professionals, and clinicians together in the same room helps everyone gain a better understanding of the complexity of technology issues. We are more and more convinced that these tough technology challenges are systems issues that cannot be solved well by any single stakeholder group in the system."

—Mary Logan, AAMI President

Defining the Problem: The Top Health Technology Hazard for 2012

Medical alarm systems are out of control. Every day, around the clock, hundreds of auditory alarm signals sound for every patient, thousands of alarm signals chime in every unit, tens of thousands of alarm signals blare throughout every hospital. Clinicians are fatigued, confused, and overloaded with sensory alerts—or left in the dark without actionable information—from this cacophony of sounds and signals.

Alarm systems are built into many medical technologies, such as physiological monitors, infusion devices, and ventilators, to protect patients. When they work as intended, alarm systems alert clinical operators to changes in patients' conditions or problem states that require some decision or action. Sometimes, alarm systems contribute to patient harm instead. Thousands of alarm system-related patient injuries and deaths have been reported. Over a recent four-year period, for example, the FDA received more than 500 reports of patient deaths related to alarm systems on monitoring devices and, in 2010, more than 2,500 adverse event reports associated with ventilator use; about a third of the ventilator events indicated an alarm system-related issue. Summit participants believe these data are grossly underreported and getting worse.

Alarm system-related hazardous situations rank number 1 on ECRI Institute's 2012 Top 10 Health Technology Hazards list of widespread, high-profile problems—up from number 2 in 2010 and 2011. The FDA and The Joint Commission announced in 2011 that they are working on developing a systematic strategy to address alarm fatigue. The Medical Device Alarms Summit complemented this effort by identifying a broad range of alarm system challenges.

Redirecting Attention from the Noise to the Signal

"Alarm [signals] should be about redirecting our attention from something that's less important to something that's more important," said George Blike, Quality and Patient Safety Officer at Dartmouth-Hitchcock Medical Center, the keynote speaker at the summit. In today's healthcare settings, that is proving to be a complicated challenge.

Clinicians face a daunting array of challenges. Alarm signals can be perceived as "nuisances"—mere background noises that compete with environmental noise and patient care responsibilities for clinicians' attention. Alarm systems can overwhelm clinicians with data, but underwhelm them with information that is sufficiently sensitive or specific about critical changes in patient conditions. Multiple

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alarm systems with different interfaces and alarm signals compound the challenges. Clinicians are dealing with a "signal to noise" problem: True clinically actionable messages are drowned out by a din of clinically non-actionable or self-correcting alarm conditions.

Further, alarm systems exist in increasingly complex healthcare systems, with more diagnostic and treatment options, technology, and diversity in clinical settings and staff. "Alarm [system] management is complex," Blike said. "Complexity bites us."

Managing this complexity must be a shared enterprise that encompasses every aspect of patient safety—people, technology, the environment of care, and the organizational culture—as well as systems thinking and human factors. The greatest emphasis should be on human factors. The good news, he said, is that there are recognized levers for managing complexity—but there is no magic bullet.

A Call to Action: Seven Clarion Themes

Blike framed the alarms summit as an opportunity to focus on the shared goal of delivering patient safety by:

- Using available science and wisdom to identify and prioritize the problems with today's alarm systems
- Exploring opportunities and solutions that address alarm system problems

Responsible organizations need to approach the problems, opportunities, and solutions to alarm system management by considering the needs of their own patients and operators, which can vary substantially from facility to facility and even unit to unit. The goal should be to create alarm systems that fulfill their intended purpose of detecting problems, alerting operators to redirect their attention to problems that require action, and empowering clinicians to diagnose and treat patients appropriately.

Blike offered a case in point: an initiative at the Dartmouth-Hitchcock Medical Center. To manage nuisance alarm signals and improve patient outcomes in 2008, the medical center piloted a patient surveillance system in an orthopedic unit to monitor specific changes and trends in heart rate and oxygen saturation (SpO2) vital signs and to page individual nurses with valid alarm conditions. Realizing that nuisance alarm signals desensitizes nursing staff, the medical center broke with conventional practice and set alarm limits to wider thresholds, and implemented auditory alarm signal generation delays so only actionable rescue events produced auditory alarm signals. The results? Early detection of patient distress, early intervention, reduced rescue events, and reduced transfers to the intensive care unit (ICU). The patient surveillance system has since been expanded to 10 other units in the medical center.

By way of comparison, Blike, who is also a professor of anesthesiology at Dartmouth College of Medicine, cited the dramatic improvement in patient safety in anesthesia that resulted from the same kind of concerted, multidisciplinary effort envisioned now for solving alarm system challenges. In the 1970s, anesthesiology was a high-hazard, high-risk practice. By 2000, with sustained attention to a host of contributing factors, the safety profile of anesthesiology rivaled that of the "ultra safe" civil aviation and nuclear power industries. Blike quoted patient safety advocate Lucian Leape, who wrote in 2002: "Anesthesiology is the only system in healthcare that begins to approach the vaunted 'six-sigma' level of perfection that other industries strive for."

"This story suggests that reducing [system-related] alarm hazards is doable," Blike said. "It foreshadows what we can achieve."

In that spirit, summit participants offered a sweeping list of alarm system challenges, reached consensus on short- and long-term priority actions needed to address them, and identified accountable stakeholders to take ownership of them.

The clarion themes and priority issues follow, with highlights from summit presenters and expert perspectives on the issues and potential solutions.

Expert Perspective: Scaling Alarm System Solutions

Frank Block, M.D.
Co-Chairman, AAMI Alarms Committee

Q. Does every hospital need to take on its own study of its alarm systems?

A. There is a conundrum in the claim that the patients in every ward of a hospital aren't like the patients in any other ward in any other hospital. This attitude will result in a constant duplication of effort, if all 5,000 hospitals in the United States would try to come up with their own optimum solutions for alarm systems. The outcome will be that some of the 5,000 hospitals will do it very well, some will do very poorly, and most will be somewhere in the middle.

Q. How can hospitals scale innovative solutions?

A. The truth is that there are more similarities in patient problems than there are differences. This point gets back to the idea of sharing information and best practices.

Clarion Theme 1: Deepen all stakeholders' understanding of use environments

"It's important to identify all possible perspectives in defining alarm [system] issues, so that the solution is not driven by simply reducing the nuisance of alarm signals. It's more than a nuisance issue."

— Barbara Drew, professor of critical care nursing and clinical professor of medicine in cardiology at the University of California, San Francisco

Challenge	Priority Action	Accountability
A lack of documentation and data to analyze reported events and "near misses", understand root problems, or support changes	Compile complete sets of standardized, annotated (and minimal) data—comparable to the "black box" data used in the aviation industry—collected after events and disseminated widely.*	Manufacturers, researchers, and clinicians
A lack of evidence-based rationale for the configurations of alarm settings	Develop a generic methodology by which clinicians can set alarm system policies based on environment of use and medical electrical equipment constraints.*	Clinicians
Insufficient attention to human factors and usability issues	Pay early, iterative, and comprehensive attention to human factors and usability issues, beginning at the front end of alarm system design.*	Manufacturers
Technology drives healthcare processes	Use healthcare processes to drive technology development.* Develop tools to assist responsible organizations in framing functional requirement specifications backed by formal use case analysis and risk assessment. Develop exemplary contracting language to assist responsible organizations in purchasing medical device systems that assure patient safety. **Long-term (three- to five-year) horizon*	All stakeholders

Understanding the Issues: It's More Than A "Nuisance"

Summit presenters made a convincing case that alarm signals, and signal-to-noise nuisances, are burdensome to clinicians. They also cautioned against narrowing the scope of the problem to the impact of noise alone. A deeper understanding of use environments by all stakeholders is required to rectify alarm system-related hazards. The overarching challenges pertaining to use environments reverberate in all of the clarion themes.

"It's important to identify all possible perspectives in defining alarm system issues, so that the solution is not driven by simply reducing the nuisance of alarm signals," said Barbara Drew, professor of critical care nursing and clinical professor of medicine in cardiology at the University of California, San Francisco. "It's more than a nuisance issue."

Drew and her colleagues conducted a study of the "alarm burden," or number of daily alarm conditions from cardiac monitors, to understand a particular use environment: the Stanford University Medical Center. Among the findings:

- Over a two-month period, more than 318,000 cardiac arrhythmia monitor alarm signals went off in six units with 154 beds, which produced a burden of 883 alarm signals per unit per day.

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- 43 percent of alarm conditions indicated non-critical, and "generally non-actionable," events; 38 percent of alarm conditions indicated premature ventricular complexes (PVCs), which, since a landmark 1988 Cardiac Arrhythmic Suppression Trial (CAST) study, are no longer treated; and 3.6 percent of alarm conditions indicated critical events. Just 19 alarm conditions indicated "Code Blue" events, seven of which resulted in deaths.
- 99.8 percent of alarm conditions were not "Code Blue" signals.

"A high volume of monitor alarm signals, mostly false, leads to adverse hospital outcomes," Drew said. Alarm fatigue leads clinicians to ignore or inactivate alarm signals, underutilize extra monitor features, and miss critical events. For example, ST-segment monitor leads that could have signaled silent ischemia (a lack of blood flow and oxygen to the heart), either were not selected for visual display on monitors or were not in use for at least two patients who died. Other adverse outcomes for patients on cardiac monitors include misdiagnosis of arrhythmia, unnecessary diagnostic tests, inappropriate treatment, increased risk, length of stay, and use of resources.

The data and documentation collected in this study informed an analysis of critical events and root problems—and could influence improvements in cardiac monitoring at Stanford University Medical Center.

But in general, this data and documentation to analyze "near misses" and understand root problems is sorely lacking throughout the healthcare community, summit participants said. In fact, some experts believe adverse alarm system-related incidents are underreported. Clinicians, manufacturers, and regulators need this information to develop better practices, products, and policies. Summit participants advocated building a "black box" into alarm systems, akin to those used in the transportation industry, with complete and standardized data sets to analyze incidents.

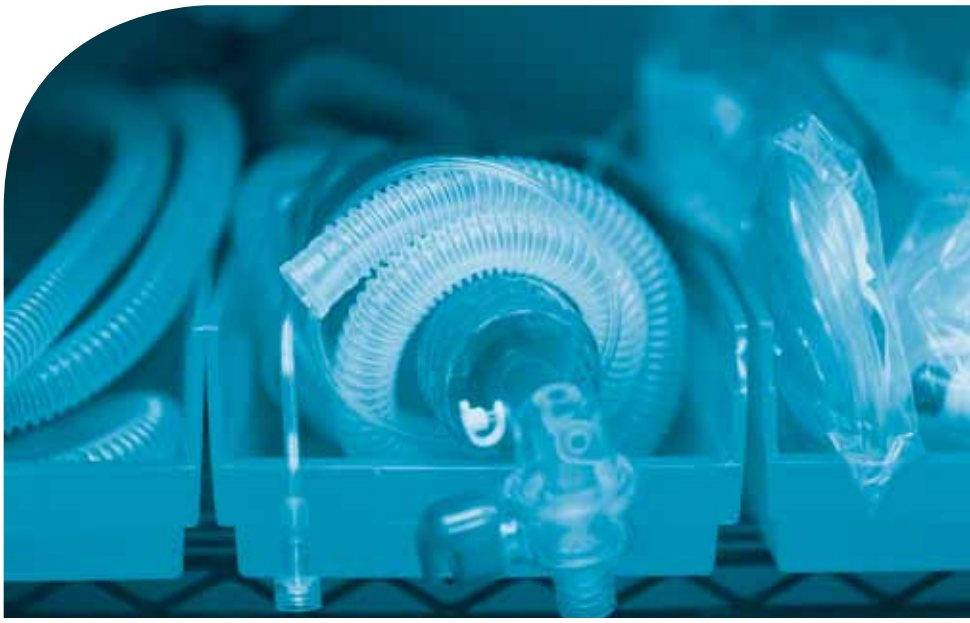
Also missing in understanding use environments is an evidence-based rationale for configuring alarm settings in general or for specific patient populations or units. For example, despite the CAST study, some summit participants said that clinicians would be reluctant to stop PVC cardiac monitoring.

In addition, usability testing reveals that alarm systems can be configured incorrectly, reflexively inactivated and overridden, misinterpreted, and simply not heard, according to Michael Wiklund, president of Wiklund Research & Design, a human factors consulting firm. Yet usability testing in healthcare settings is an underused tool for developing alarm systems that meet clinicians' needs, summit participants said. Likewise, consideration of the human factors in the use of devices with alarm systems gets short shrift.

Neglecting human experiences with alarm systems has contributed to a systemic problem decried by clinicians: Technology is driving healthcare processes. Summit participants want to flip that model.

"Alarm [signal] enunciation should not be stress-inducing. In fact, if alarm [signal] enunciation induces a startle or stress response, then the most likely reaction will either be an immediate 'turn it off!' or some other automated response, rather than more thoughtful deliberation about the situation. Rather, the goal of an alarm [signal] should be to inform and then move the recipient to an appropriate action."

— Matthew B. Weinger, M.D., Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, biomedical informatics, and medical education at Vanderbilt University School of Medicine



THE HUMAN TOLL OF ALARM SIGNALS

"One thing I can't stand is the noise, noise, noise, noise!"
— Dr. Seuss's Grinch

The effect of alarm signals and environmental noise on patients and clinicians is underexplored territory, according to Ilene Busch-Vishniac, provost and vice-president, academic, at McMaster University.

Noise levels in hospitals are escalating. Daytime and nighttime levels of noise exceed the World Health Organization's (WHO) recommended upper limits. "Background noise is doubling about every 10 years. As background noise gets higher, auditory alarm signals have to get louder."

At a minimum, hospital noise is an annoyance—it interferes with patients' sleep and speech and contributes to staff fatigue and burnout, Busch-Vishniac, an acoustician, said. Worse, there is some evidence suggesting that high noise levels can be a health and safety hazard. Patients might take longer to heal, use more pain and sleep medications, and stay in recovery rooms and in the hospital longer in noisy environments. Some staff members experience noise-induced hearing loss.

"There is lots of evidence that alarm [signals] are a growing problem," she said. "Alarm [signals] cause anxiety in patients," both for those whose alarm systems are sounding and for every other patient and visitor who can hear the alarm signals. "The vast majority of alarm [signals] result in no action. We've lost balance. Alarm [signals] alert, but they are difficult to recognize. We've not used human factors data to help us design the sounds. We've not contextualized alarm [signals] adequately."

"Sleep is important for a healthy person—and it is more important for recuperating patients," said Mathias Basner, assistant professor of sleep and chronobiology in psychiatry at the University of Pennsylvania Perelman School of Medicine. Basner is co-chair of the sleep team of the International Commission on Biological Effects of Noise (ICBEN), which has conducted scientific research on noise-induced effects on human beings.

"Undisturbed sleep of sufficient length is a prerequisite for the maintenance of performance and health," he said. The most potent disruptors of sleep are electronic sounds intentionally designed to be alerting, even when the signaling devices are on a quiet setting, according to recent research (Solet et al., 2010; Ellenbogen et al., 2011). Chronic sleep disturbances contribute to a range of performance and health issues, including:

Impaired performance
- Mentally slow and inaccurate
- Emotionally unpredictable
- Unrealistic and pessimistic
- Unreliable memory
- More risky and risk-taking
- Feeling tired, stressed, exhausted
- Weak executive decision making
- No insights or creative solutions

Disease
- Obesity
- Hypertension
- Diabetes
- Increased mortality
- Increased morbidity

Physiological changes
- Impaired glucose tolerance
- Increased inflammatory markers
- Lower antibody blood levels after immunization

Busch-Vishniac and Basner offered research agendas to study the human factors of alarm signals, which are included with research recommendations from other summit presenters and participants in the Research Appendix of this report.

Lead User Profile: Children's National Medical Center

The experts at Children's National Medical Center in Washington, DC know that clinical alarm conditions should be accurate, intuitive, and readily interpreted and acted upon. Yet, their experience has proven that the opposite is true: most alarm conditions are clinically insignificant. Their studies have found that their clinicians are dealing with false positive rates of 85 to 99 percent. In one medical progressive care unit, 942 auditory alarm signals sound every day, or one alarm every 92 seconds. In their neonatal intensive care unit (NICU), clinicians encounter 1,300 alarm signals per day, which translates to one auditory alarm signal every 66 seconds.

"In this alarm-heavy environment, clinicians develop unsafe, subjective ways of responding to alarm [conditions]," reports Linda Talley, vice president of nursing services and neonatal services at Children's. "When clinicians are exposed to such overwhelming numbers of false positive alarm [conditions], they tend to ignore them, develop unsafe ways to prioritize or adjust alarm [limits], and become less likely to respond to any alarm [condition]."

To begin to understand and address the alarm system problem, Talley headed up a group of experts at Children's who undertook a study of cardiopulmonary monitors (CPM) used for 98 children in the pediatric ICU. They recorded 2,245 alarm conditions during the study, of which 68 were deemed to indicate clinically significant events. They also uncovered several technology problems through the study, including problems with recording of events, investigational time stamps, and medical record numbers.

They concluded that while most clinically significant events can be detected with current CPMs, improved awareness is needed of CPM alarm settings, associated false positive alarm conditions, and the impact of false positive alarm conditions on quality care delivery. They also concluded that information gained through the study should be used to update annual CPM education for all nurses and improve alarm settings throughout the hospital.

Lead User Profile: Boston Medical Center

When the clinical engineering and the nursing education departments at Boston Medical Center (BMC) teamed up to improve alarm system management in their telemetry processes, they knew it was an area ripe for improvement. A critical review of alarm system technologies at the 508-bed academic medical center found wide disparities between where they were and where they wanted to be. Their evaluation of areas and alarm systems found problems with alarm signal, volume of alarm signals, types of alarm conditions, specificity, sensitivity, acuity/prioritizing, and recognition of alarms conditions.

To resolve the problems, they formed a multidisciplinary team headed by the chief medical officer with the goal of improving both alarm system performance and staff competency. "The biggest thing we had to do was have governance and ownership of the process," says James Piepenbrink, director of the facility's clinical engineering department. The team focused on:

- Understanding technology utilization, including insignificant arrhythmias and rate violations
- Understanding staffing levels and gaps in both training and technology
- Evaluating opportunities to improve alarm system response through technology enhancements.

Their review of rapidly evolving alarm system technologies confirmed that they already had in place on-unit capabilities for local alarm system management, distribution, and integration, and that middleware technology now exists to push alarm conditions out to caregivers. However, they also confirmed that technology is not a solution in and of itself. "Technology adds complexity to an already complex system," says Piepenbrink. "Optimizing parts is not always the best solution to a complex system. Layering technology does not always fix the solution if the process is poor."

From here, alarm system improvements efforts at BMC are focusing on simulation, situational awareness, and working with vendor partners to leverage human capital. Piepenbrink is also calling for the creation of a database of default alarm presets for research and discussion purposes. "Data warehousing from middleware devices can be used to build better systems and processes," he says.

"Technology adds complexity to an already complex system. Optimizing parts is not always the best solution to a complex system. Layering technology does not always fix the solution if the process is poor."

— James Piepenbrink, director of clinical engineering, Boston Medical Center

Lead User Profile: University of Miami

Simulation in medicine holds great promise to resolve complex systems problems and improve medical practice in alarms management. Richard McNeer, an anaesthesiologist with the University of Miami, and his colleagues have developed a software tool that promises to help with simulation education, simulation-based assessment, and simulation-based research on alarms performance.

"Many of the questions surrounding alarms can be addressed rigorously in a safe, controlled, highly realistic simulated setting," he says.

The team has developed a software tool called PT-SAFE, which stands for Patient-Tracking Software for Audible Alarm Formulation and Evaluation. It is simulation software designed to allow researchers to develop and rapidly deploy novel audible alarms to a simulation or clinical setting for evaluation.

The system allows users to log all of the vital signs coming directly from patient monitors. Logged cases can then be "re-run" through a simulation using the PT-SAFE system, which makes it possible to review elements of the case and evaluate the effects of different alarms or alarm thresholds.

"The goal of simulation is to facilitate testing of new alarms and strategies among diverse researchers," he says. "This is open-source software and we are interested in hearing about desired functionality and obtaining researcher feedback." For more information, visit http://ptsafe.wordpress.com/.

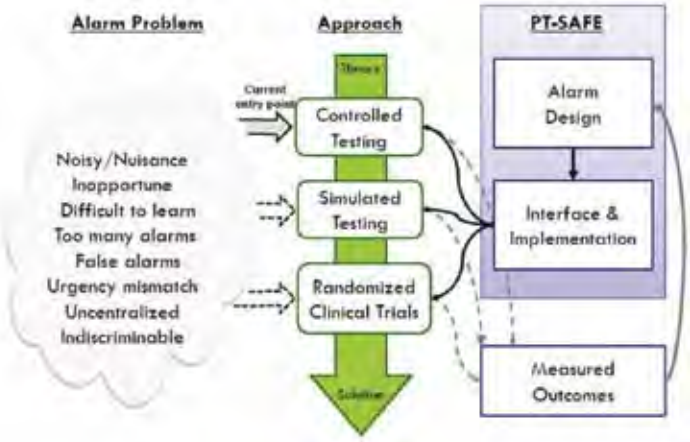


Figure 1. An Approach to Testing Alarm Management Questions

Source: Richard McNeer, "Simulation Testing for Medical Device Alarms." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 4, 2011.

An Opportunity For Collaboration: The Bioengineering Research Partnership

What is needed to improve alarm systems performance? According to Joseph J. Frassica, chief medical information officer of Philips Healthcare, one key is to develop a "gold standard" data set for alarm system algorithm development and testing, which contains reliable data from different patient care environments and reliable clinical annotation.

He reported that such a data set is already being developed by the Bioengineering Research Partnership, an interdisciplinary team from academia (MIT), industry (Philips Healthcare) and a provider organization (Beth Israel Deaconess Medical Center). The effort is being funded by the National Institute of Biomedical Imaging and Bioengineering.

The team is working to develop and evaluate advanced ICU patient monitoring systems that will substantially improve the efficiency, accuracy, and timeliness of clinical decision making in intensive care.

The team has developed the MIMIC-II research database (Multiparameter Intelligent Monitoring in Intensive Care). This database is publicly and freely available and encompasses a diverse and very large population of intensive care unit (ICU) patients as well as high temporal resolution data including lab results, electronic documentation, and bedside monitor trends and waveforms. Substantial progress in this effort has already been achieved, including the development of this massive new research database containing data from more than 30,000 ICU patients, as well as development of a number of promising advanced monitoring concepts and algorithms. The database can support a diverse range of analytic studies spanning epidemiology, clinical decision-rule improvement, and electronic tool development.

This ongoing effort is seeking more annotated data from various patient populations and settings, including inpatient; neonatal; pediatric; and obstetrical populations. To learn more or to contribute, visit http://mimic.physionet.org/.

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Clarion Theme 2: Improve alarm system management

"We want more than information. We want wisdom."

— Matthew B. Weinger, M.D., Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, biomedical informatics, and medical education at Vanderbilt University School of Medicine

Challenge	Priority Action	Accountability
Determining which alarm conditions require action	Identify which alarm conditions are actionable and suppress alarm conditions or alarm signals that do not require action.*	Responsible organizations***
	Determine which alarm conditions are clinically important.*	Researchers
Understanding the connections between "alarm fatigue" and patient outcomes	Clearly define the patient outcome variables and environmental variables that would be improved by solving the "alarm fatigue" problem, so that others can use the same variables for quality improvement (QI) projects and research design.*	Researchers
Understanding the connections between remote distributed alarm systems and "alarm fatigue"	Research remote surveillance and how it impacts "alarm fatigue."*	Researchers
Identifying "False positive alarm conditions" and clinically insignificant true positive alarm conditions	Identify acceptable alarm condition delays or alarm signal generation delays, so that presented auditory alarm signals represent a true causing event that requires a response.*	Researchers
Delivering the right alarm condition with the right alarm signals to the right operator(s)	Determine the best ways of delivering alarm signals to the appropriate operator*	Responsible organizations***
Customizing alarm limits to individual patients	Develop a one-step way to tailor alarm limits around a patient's baseline parameters. Look closely at trending patient parameters, not just parameter values at the time of an alarm condition.*	Manufacturers

** Short-term (one- to two-year) time horizon*
*** Long-term (three- to five-year) time horizon*
****See Vocabulary Appendix for definition*
*****Frank Block says: We discussed at the AAMI Alarms Committee that this technology not only exists, but it has been incorporated in most ICU Monitors for the last decade. In other words, the clinicians who asked for this feature almost certainly have that feature today...but people don't know the features of their own monitors! (And they don't know how the alarms work, or how the alarms are supposed to work, etc.)*

Understanding the Issues: Looking for Trusted Sentinels and Advisors

Managing alarm systems is a complex endeavor that comes down to a straightforward tenet: Focus on the relationship between people and technology—and keep it simple.

Clinicians are looking for alarm systems to serve as trusted sentinels and advisors, asserted Wiklund of Wiklund Research & Design. Borrowing from *The Trusted Advisor*, a book about management consulting (Maister, Green, & Galford, 2001), he said that a trusted advisor:

- Speaks the truth
- Earns trust
- Gives advice effectively
- Builds a relationship

In a trusting relationship, people are willing to ask for advice, follow the advisor's recommendations, and experience less stress. For medical alarm systems to serve as trusted advisors, they should:

- Reliably detect a true event requiring clinical intervention
- Reliably draw attention
- Clearly state the problem and potential consequences
- Clearly communicate the corrective action (with words, pictures, and/or animations)

User-friendly alarm signals:

- Use familiar language
- Use simple graphics that emphasize important elements
- Animate corrective actions when a "working example" will help
- Make voice prompts available as an option (for homecare devices)

Wiklund showed sample alarm system displays that provide confusing alerts, generic information without advice, and wise counsel—specific information and necessary action accompanied by simple graphics or animations that guide operator actions, as shown in Figure 2. "For any particular device, there might be dozens of things clinicians need to do," he said. "Research shows that it helps to give them a working example."

To provide this kind of wisdom, any medical device with an alarm system must:

- Be "smart" enough to know what it is doing at any time
- Incorporate a capable display
- Incorporate a capable speaker
- Enable users to perform the necessary interventions with relative ease

From Confusion ...

... to Information ...

... to Wisdom.

Figure 2. Alarm System Displays
Source: Michael Wiklund, "Medical Device Alarm Systems Can Serve as Trusted Advisors." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 4, 2011.

A "Holistic Solution" for Managing People, Processes, and Technology

Addressing these issues requires a holistic solution, said Tim Gee, principal of Medical Connectivity Consulting. "You have to have the right monitor for the right task with optimum configuration," he said. "You have to execute on all three levels."

That means questioning device use issues, such as default alarm presets including alarm limits, standing orders for monitoring, and the suitability of monitoring for individual patient needs. It also means understanding the organizational workflow for responding to alarm signals, which varies across units; considering accountability for responding to alarm conditions and reporting during shift changes; and integrating rapid response and code teams into alarm condition response protocols.

Optimum configuration is more than a matter of default alarm presets settings, but also about ensuring that alarm signals are received wherever clinicians are. That could require extending alarm signals to central nursing stations or using remote speakers for alarm signal presentation, remote lights and message panels, technicians responsible for monitoring alarm signals, or directing alarm conditions directly to the responsible caregiver.

Handheld workflow automation technology can support alarm system management, Gee said, by:

- Conveying alarm signals directly to responsible caregivers
- Using closed loop tracking to ensure that alarm conditions are received, responded to, and resolved
- Escalating alarm signals to ensure timely responses
- Providing the clinical context for an alarm signal
- Supporting all devices connected to a patient
- Using location data to customize alarm signal delivery

In the future, Gee envisions that technology will provide more and better solutions to alarm system management challenges. For example, technology will improve conventional alarm systems by reducing nuisance alarm conditions and providing more clinical context for alarm conditions. It will also provide decision support systems to identify and eliminate duplicate alarm conditions. As well as combine physiological, therapeutic, alarm condition, and location data to generate additional knowledge of patients' changing conditions.

Technology alone won't solve the alarm system management problem, however. Appropriate nursing/clinical policies and procedures—and leadership from information technology (IT), biomedical, clinical engineering, and clinical professionals—will be needed to support safe and effective alarm systems in hospitals, Gee said.

Furthermore, while there is considerable research and best practices to guide alarm system management initiatives, more research is needed, according to Marjorie Funk, professor at the Yale University School of Nursing. "We still do not know which interventions will reduce false or non-actionable alarm [conditions], because they have not been rigorously tested. And we do not know the best way to increase the specificity of alarm [conditions] without an unacceptable loss of sensitivity."

Future research must focus on the entire spectrum of alarm system challenges, from selecting the appropriate alarm settings for a patient to signal acquisition to presentation of the alarm signal. And research is needed on the effect of alarm systems on patient outcomes and, possibly, on staff.

"With any study, we need to consider patient outcomes, to be sure that patients are not being harmed by the decrease in the number of alarm [conditions]," Funk said.

Funk offered specific recommendations for research design and outcomes, which are included in the Research Appendix as part of the research agenda that emerged from the summit.

Clarion Theme 3: Innovate to improve alarm system integration

"I like to say I treat patients, but I treat data. Without data, I make bad decisions."

— James M. Blum, M.D., assistant professor, director of clinical care research, acting director of the Cardiovascular Center ICU at the University of Michigan Department of Anesthesiology

Challenge	Priority Action	Accountability
Evaluating and addressing multiple parameters simultaneously	Integrate the cause of alarm conditions using sensor fusion from multiple data inputs and signals.*	Manufacturers Researchers
	Provide clinicians with multi-parameter analysis that supports decision making.*	Manufacturers Researchers
Exchanging and synthesizing data from proprietary alarm systems and different medical equipment	Provide open accessibility to data via open architectures.*	Manufacturers and Standards Setting Organization
Determining the source of an alarm condition—and whether an alarm condition is indicating a "false positive" alarm condition	Provide the clinical context for alarm conditions.	Manufacturers
Lacking clarity about who is responsible for integrating alarm conditions	Clarify who "owns" integrating alarm conditions in responsible organizations.	Responsible organizations**
	Share best practices of IEC 80001, *Application of risk management for IT-networks*. **Long-term (three- to five-year) horizon* ***See Vocabulary Appendix for definition*	Manufacturers

Understanding the Issues: Struggling to Connect the Dots and Make Sense of Data

Summit presenters and participants expanded the vision of a holistic solution to medical alarm system challenges by calling for improved integration of alarm systems—and other healthcare data systems.

In fact, one summit presenter offered a point of view about the problem that contrasted with most other comments: "The problem is not that we have too many alarm [signals]," said James M. Blum, assistant professor, director of clinical care research, and acting director of the Cardiovascular Center ICU at the University of Michigan Department of Anesthesiology. "We do not have enough alarm [signals] with priority and meaning that target specific provider types. In defining the problem, I would say the problem is integration." Why does this problem exist? Blum cited several issues:

- No penalty for high sensitivity of sensors with low specificity of alarm conditions
- Minimal data supporting bad outcomes
- Unappreciated need for different alarm signals for different providers or operators
- Lack of data integration

Clinicians rely on data to make patient care decisions. "I like to say I treat patients, but I treat data," he said. "Without data, I make bad decisions."

Physiological monitors are a key source of excellent data on individual patients—but both

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the data and the alarm systems fall short when it comes to delivering meaningful information. The monitors indicate a patient's current status, but do a poor job providing trending or predictive information. "I have no idea what the patient status was," Blum said. "I have no idea where I'm going. I have no idea whether I'm going to Europe, Asia, Africa, or Antarctica."

In addition, central station monitors and monitoring alarm signals are "not at all useful," because they do not provide information needed to make plans, he said. Integrating other sources of patient data with physiological monitors and alarm systems would help clinicians to better understand patient conditions and make sense of alarm signals. These sources include:

- Electronic medical records (EMRs) (also called documentation, flowsheets, labs, or billing) would provide wide accessibility to the context of a patient's history. However, EMRs "frequently suffer from garbage in/garbage out" syndrome, so they would need to be tailored to be useful as a clinical decision-making tool.
- Lab data from multiple sources, which is "frequently useful, occasionally critical, and often overlooked," would provide additional clues to appropriate responses to alarm signals.
- Combined data from different hospital units, including the operating room, ICU, and floor, would provide trending data about patient conditions.
- Data from other systems, such as computerized physician order entry (CPOE) systems, would provide information about patient medications, another data point to consider in making sense of alarm signals.

Figure 3 shows a systems integration model that connects all of these data systems.

Shifting Paradigms—and Moving Toward Multiparameters

There is an upside to summit participants' calls for eliminating nuisance alarm signals, turning alarm systems into trusted sentinels and advisors, and integrating alarm systems: Manufacturers are listening.

"Industry can help," said David Barash, chief medical officer, patient care solutions, GE Healthcare. "But we need to shift some paradigms. In hearing the discussion, some of the things we are talking about are really useful. We can't be isolated. We shouldn't and we can't do it on our own."

Barash provided a historical context of industry's role in developing and improving alarm systems on multiple fronts:

Accuracy
- ECG and other algorithms
- Multiparameters

Relevance
- User-configurable alarm settings
- Adjustable alarm limits

Assurance
- Guard alarm limits
- Locking alarm limits
- Smart alarm systems
- Smart technical alarm conditions
- Auditory and visual alarm signals
- Minimum volume lockout on auditory alarm signals

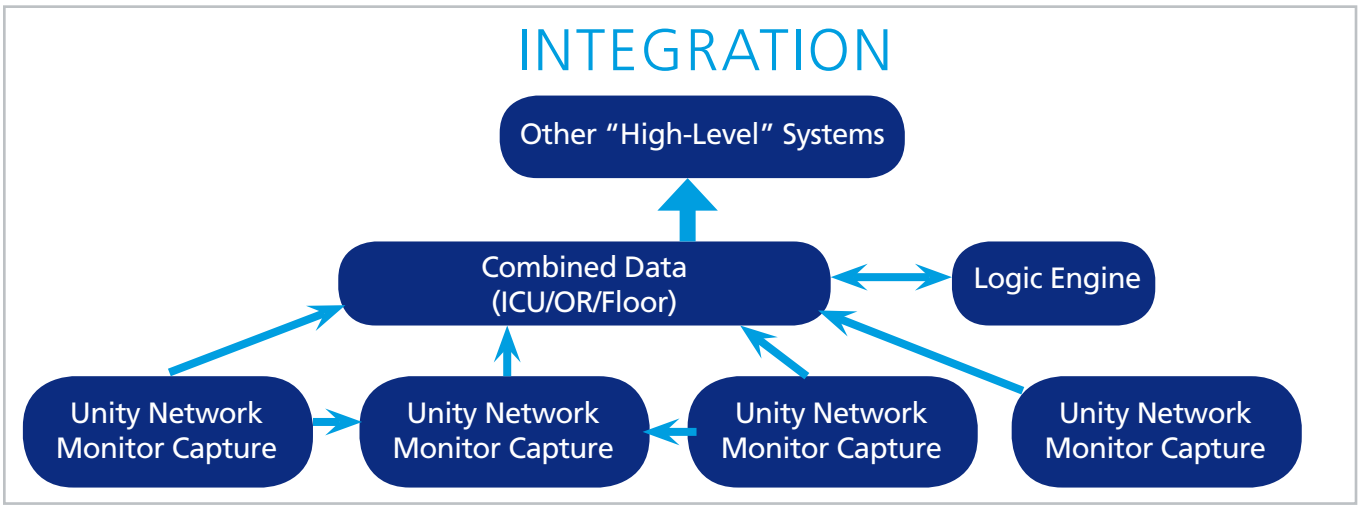

Figure 3. A Systems Integration Model
Source: James W. Blum, "Defining the Alarm Problem." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 4, 2011.

Workflow

- Alarm condition escalation and remote alarm signals
- Bedside alarm conditions at the central station and other locations
- Bedside alarm conditions at the operator's personal device (e.g., tablet, smart phone)

"We've done a lot to attack this problem with technology," he said. "But, 'there is such a mismatch of technology and what we are trying to achieve,'" he said, quoting Theresa Gallivan, associate chief nurse at Massachusetts General Hospital, in a *Boston Globe* article.

Industry will need to broaden its role in solving alarm system challenges not just with new technology, but also with process change tools, systems integration, and collaborative research. Benchmarking the practices of other industries that have traveled this path before is a good place to start, Barash said. "The airline industry was about where we are now in the 1980s," he said. Both aircraft and medical alarm systems are complex systems with conflicting constituency requirements that need to be harmonized.

The airline industry's numerous system and process problems with aircraft maintenance parallel the current problems with clinical alarm systems, as shown in Figure 4. Boeing addressed these problems by breaking the system down into subdomains and using a process change tool—a computerized "fault model"—to collect data (multiple parameters) about symptoms, diagnose real faults (root causes), correlate the faults with flight crew observations (alerts), and inform maintenance crews of required repair actions. In essence, this process change tool supports knowledge management for complex systems, which makes it a good fit for managing medical alarm systems.

In the future, medical devices with alarm systems will be able to provide predictive information about patients' conditions, using the same kinds of predictive algorithms and imaging data that are used for weather forecasting, Barash said.

That's beginning to happen already, according to Michael O'Reilly, executive vice president and chief medical officer at Masimo Corporation and professor of anesthesiology and perioperative care at the University of California Irvine. Masimo markets physiological monitoring systems that integrate multiple parameters into a single display, known as a Halo Index, which provides global trending and assessments to quantify changes in patient status. The systems also feature Adaptive Threshold Alarms™ that issue audible alarm signals only when there is a significant change on patient conditions, thus reducing non-actionable alarm conditions.

Still, summit participants pointed out that many responsible organizations do not yet have this technology. "We don't buy technology every year," one participant said. "That kind of technology doesn't exist in my world."

Honeywell

• *Prior to latest generation solutions, aviation maintenance systems suffered from:*	• *Current clinical alarms* suffer from:
• Poor correlation between pilot observations and required mechanic actions	• Poor correlation between actual clinical need and actions prompted by generated alarm
• Human usage scenarios not adequately addressed	• Human usage scenarios not adequately addressed
• False, misleading and ambiguous nuisance messages	• False, misleading and ambiguous nuisance messages
• Lack of built-in test consistency among subsystems	• No validation or confirmation based on other parameters measurements
• Optional equipment not covered by maintenance system	• Optional equipment not covered by maintenance system
• Slow turnaround of software rule updates did not keep up with aircraft design changes	• Software revisions may not be maintaining pace with complexity of clinical environmental requirements
• Poor visibility into effects caused by software rule updates	• Unintended consequences of providing more parameters than can be managed by the clinician or the system itself

Figure 4. Similarities in the Challenges of Managing Complex Systems: Airline Maintenance and Clinical Alarms

Source: David Barash. "Industry can help. But we need to shift some paradigms …" Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 5, 2011.

Lead User Profile: Massachusetts General Hospital

Developing robust alarm systems through systems engineering will "take a village," according to Julian Goldman, director of the CIMIT/MGH (Center for Integration of Medicine & Innovative Technology/ Massachusetts General Hospital) Program on Medical Device Interoperability. He offered his thoughts on the importance of multiparameter "smart" alarm conditions, interoperable systems, and the elements necessary to develop them.

"Single-signal analysis is not sufficient to create clinically meaningful alarm [conditions]," he said. He offered the example of the problem of patient-controlled analgesia systems: patients can call to request more analgesia, but cannot call for help when over-medicated. Comprehensive monitoring is not typically used in these situations due to high false positive/nuisance alarm condition rate.

However, there remains a need to reduce or terminate infusions and call caregivers when monitoring technology suggests the presenter of opioid-induced respiratory depression. "By integrating SpO2, respiratory rate, and pulse rate, we can separate nuisance alarm [conditions] from true alarm [conditions]," he says. "We can also implement multiple trend analysis to increase sensitivity. The great challenge is understanding context, and contextual awareness requires data from several devices and systems."

He offered the following suggestions:

- Alarm settings must be easily personalizable at the point of care, and must be "smarter"
- A device/network data log is required to obtain a complete data set to optimize systems and alarm systems
- Manufacturers alone cannot personalize alarm settings; the clinical community must be empowered to participate.
- An open "app platform" is needed to efficiently develop clinical decision support and alarm system apps.
- The community can contribute to solutions: clinicians and engineers can develop, share, and assess proposed algorithms, while others can evaluate, validate, and sell such systems.

A Tool for Interoperability in Alarm System Management

A supplement to the Integrating the Healthcare Enterprise (IHE) Patient Care Device Technical Framework now in the works could help to answer the call for improved interoperability in alarm systems.

IHE Technical Frameworks are a resource for users, developers, and implementers of healthcare imaging and information systems. They define specific implementations of established standards to achieve effective systems integration, facilitate appropriate sharing of medical information, and support optimal patient care. They are expanded annually, after a period of public review, and maintained regularly by the IHE Technical Committees.

The IHE Patient Care Device Technical Framework Supplement on Alarm Communication Management, released for trial implementation in July 2011, extends the Device Enterprise Communication profile of the IHE Patient Care Devices domain. It further specifies the communication of alarm condition data describing physiological and technical states and events significant to patient care from patient care devices to distributed alarm systems.

The intent of this supplement is to give a uniform way of representing common alarm conditions in HL7 (Health Level Seven International) messages to facilitate interoperability of systems from different vendors.

www.ihe.net/Technical_Framework/upload/IHE_PCD_Suppl_Alarm_Communication_Management_ACM_TI_Rev1-2_2011-07-01.pdf

IEC 80001: A Tool for Risk Management

Safely integrating alarm systems and other healthcare technology systems raise more than technical considerations, but also risk management concerns. The International Electrotechnical Commission (IEC) 80001 standard, *Application of risk management for IT-networks incorporating medical devices,* defines the requirements of a process for addressing problems that might emerge when medical devices, such as alarm systems, are connected to a network.

The 2010 standard addresses roles and responsibilities for risk management and a robust process for managing risk throughout the entire life cycle of a network incorporating medical devices. The standard focuses on the key properties of safety, effectiveness, and security in preventing patient harm.

A 2011 AAMI handbook, *Getting Started with IEC 80001: Essential Information for Healthcare Providers Managing Medical IT-Networks*, offers practical guidance for applying the risk management standard successfully, beginning with a pilot project.

Both the IEC standard and the AAMI handbook are available on AAMI's website: **www.aami.org/publications**

Clarion Theme 4: Reconcile challenges and differences in use environments

"Competency isn't a destination, it's a continuum and a continuous process."

— Laurie Groesbeck, manager of nursing services at Complete Infusion Services, LLC, and director-at-large on the Infusion Nurses Society board of directors

Challenge	Priority Action	Accountability
Strengthening core competencies in alarm system use and response	Standardize training content and formalize the training process in a hands-on, interactive, simulated environment where there is no possibility of harm to patients.	Responsible organizations** and manufacturers
	Protect time for alarm system orientation and training.*	Responsible organizations**
Reducing unnecessary alarm system malfunctions	Change single-use sensors more frequently (e.g., ECG electrodes) (except in pediatrics). Place ECG electrodes properly, with good skin preparation that adheres to instructions for use and best practice (which calls for soap and water).*	Responsible organizations**

**Short-term (one- to two-year) time horizon*
***See Vocabulary Appendix for definition*

Understanding the Issues: A "Perfect Storm" of Challenging Conditions

Alarm system challenges are so commonplace that healthcare professionals have a shared vocabulary for describing them. The "cry wolf" phenomenon occurs when repeated high-priority alarm signals so frequently prove false that, when a true high-priority alarm signals, an immediate response is delayed. "Alarm desensitization" happens when so many low-priority alarm signals present in patient care settings that clinicians tend to respond only to high-priority alarm signals.

Adverse patient outcomes have resulted from these challenging conditions in use environments, according to Maria Cvach, assistant director of nursing, clinical standards, at The Johns Hopkins Hospital. She listed a "perfect storm" of impediments to effective responses to alarm signals, which span technology, facility, and human constraints:

- Too many devices with alarm systems
- Alarm limits not set to actionable levels
- Alarm limits set too tight
- Monitor alarm systems very sensitive and unlikely to miss a true sustained event—but this results in too many false positive alarm conditions
- Large units with unclear accountability for response
- Private rooms with doors closed
- Duplicate alarm conditions, which desensitize staff
- Single parameter monitor analysis
- Unit culture

Kathryn Pelczarski, director, applied solutions group, ECRI Institute, took aim at the "culture conundrum" that prevents healthcare organizations from addressing alarm system challenges. "The real question is, why does this perfect storm continue?" she asked. Complacency,

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blame, denial, and defeatism signal a culture in trouble, with no foundation for improvement.

Many of the impediments—and the opportunities—to improve alarm system management are in a hospital's control, Pelczarski said. A culture that makes improving alarm system management possible requires a demonstration by leadership that patient safety is a core value. An opportunity culture demands beliefs, attitudes, behavior, and ownership of the monitoring system as a tool in patient care, and an understanding that effective and efficient alarm system management is essential to patient safety. It requires education and ongoing reinforcement.

"Atlas solutions," in which one group of stakeholders, such as clinical engineers or nurses, takes on alarm system management challenges, "are doomed to failure, she said. "Band-aid solutions are likely to introduce new failures." Instead, Pelczarski recommended a multidisciplinary, systematic approach to alarm system management and cited six characteristics of successful improvement efforts:

Opportunity: A Multidisciplinary Approach

- Input from key stakeholders
- Understanding the problems
- Harnessing the strength of collaboration
- Securing resources
- Gaining buy-in
- Shared ownership

Effective alarm system management also requires strategies tailored to the complexities of particular use environments, as shown in Figure 5. Systematically addressing these complexities involves thorough analysis and planning that encompasses the culture, infrastructure, practices, and technology. Healthcare organizations need to proactively identify and address potential failures and patient safety vulnerabilities.

Training and Competency Requirements for Alarm System Management

Two infusion nursing practitioners and educators balanced the institutional perspective on alarm system management with a professional perspective focused on nurses. Kathy Puglise, vice president of patient care services and founder of Home Choice Partners and president-elect of the Infusion Nurses Society (INS), and

Figure 5. Implementable Strategies Tailored to Unique Context

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Source: Maria Cvach and Kathryn Pelczarski. "Environmental Challenges, Impediments, and Opportunities." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 4, 2011.

Laurie Groesbeck, manager of nursing services at Complete Infusion Services, LLC, and director-at-large on the INS board of directors, asserted that improving nurses' core competencies is an essential component of organizational efforts to address alarm system challenges.

"We've got to make changes to perfect our systems," Puglise said. "We need topline leadership and staff buy-in. We need organizational approaches that include nurses—and get patients involved as well. Training and education make a huge difference."

Moreover, Puglise and Groesbeck broadened the focus on alarm system challenges to home care. "Home infusion therapy can contribute to alarm fatigue," Groesbeck said. "When a patient has an alarm ringing at 3 a.m., alarm fatigue is real for the patient and the nurse. We need to teach nurses, patients, and lay people how to use infusion devices and deal with alarm [conditions]."

The Infusion Nurses Society offers education, training, and assessments of core competencies of knowledge, skills, and safe practices. "Competency isn't a destination, it's a continuum and a continuous process," Groesbeck said. "It always will be in healthcare, especially if we're after best practices."

Organizations need to set their own core competencies for nurses, based on their use environments. "Improving nursing competency

through a multidisciplinary approach will decrease the number of alarm [conditions] and improve patient safety," Puglise said. Pre-certification and mentoring programs, and support for education and training from vendors of devices with alarm systems, can support nurses in improving their core competencies.

Lead User Profile: The Johns Hopkins Hospital

The Johns Hopkins Hospital could be the poster child for alarm system management. Beginning in 2006, the hospital has taken on several major initiatives that underscore the opportunities for healthcare organizations committed to improving patient safety by reducing hazardous situations related to alarm systems:

- A monitor alarm task force is charged with standardizing practices throughout the hospital and developing cardiac and physiological alarm system policy
- An unusual physician-led alarm management committee is responsible for revising alarm limits to actionable levels throughout the hospital, on a unit-by-unit basis, and developing criteria for placement on and discontinuation of physiological monitors on patients
- Piloting of innovations in alarm system design management at two new clinical buildings, an initiative undertaken with ECRI Institute

The Johns Hopkins initiatives have been informed by data at every step of the way, according to Maria Cvach, assistant director of nursing, clinical standards, at The Johns Hopkins Hospital. She shared a sample assessment of a 12-day alarm system analysis, which found a grand total of 58,764 alarm conditions, or 350 alarm conditions per patient per day.

"The system warnings," or technical alarm conditions—2,227 in that 12-day period—"really concerned us," she said. Those "technical warnings" of alarm system lapses or failures essentially meant that patients were not being monitored. The hospital's simple solution to these warnings, piloted in July 2011, resonated with summit participants. "Changing [ECG lead] electrodes daily really made a difference for us," Cvach said. "Total alarm [conditions] fell by about 48 percent. Getting back to basics really helped us."

Johns Hopkins also used a fault tree analysis to parse the specific challenges of responding to high priority alarm signals and developing specific solutions to overcome them.

To reduce the alarm signal burden, the alarm system management committee made "very modest" changes to the default alarm presets to about 200 alarm system parameters and limits, Cvach said. The committee prioritized actionable alarm signals by making them auditory alarm signals, and subordinated lower-priority, "advisory" alarm conditions by presenting them with visual alarm signals without auditory alarm signals.

Now, the leadership teams for alarm system management are working on multiple approaches for getting "true and reliable information" to clinicians on every unit, including those in two new clinical towers that will open in 2012. Approaches to alarm system management and alarm signal presentation may vary from unit to unit, Cvach said. Those approaches include monitor watches, split screens, hallway physiological monitors with waveform screens for high-priority alarm signals, wireless mobile devices, and utilizing alarm condition delays and alarm signal generation delays and escalation protocols.

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Lead User Profile: Boston Medical Center

Engineers at Boston Medical Center (BMC) came up with an innovative way to take alarm system management training to the floor: they developed a self-contained portable telemetry training unit.

The 508-bed academic medical center covers more than one million square feet of clinical space spread across several buildings and several blocks in Boston. Training the clinical staff on telemetry alarm settings in this distributed environment proved challenging. "The volume of staff we must train is high, and written materials are not always effective," says James Piepenbrink, director of the facility's clinical engineering department. "The classroom environment is also difficult, and there were logistical and scheduling problems with providing everyone access to our Simulation Center."

To solve the problem, he and his team developed a portable, self-contained telemetry system to educate staff about changes in telemetry alarm systems and portable monitor alarm systems. They used a portable cart to integrate a telemetry server, receiver cabinet, patient monitor, central station, network switch, antenna system, display, keyboard, mouse, and simulators.

They have used the cart with vendor and nurse educators to train nurses on system changes; demonstrate changes to default alarm presets; and even demonstrate alarm system changes to hospital committees.

"Managing change is effective when we can take the change to the user and show them what the change means," says Piepenbrink. "It works well showing the cause and effect of events in a timely and comprehensive way."

Several projects are ahead on the alarm systems front for BMC, including:

- Opening a new, consolidated simulation center in early 2012
- Integrating middleware data on alarm conditions into the simulation center to use on situational awareness
- Using enterprise data accessed from middleware to help create refined alarm system knowledge and drive change and education
- Creating dashboards for alarm system data to place knowledge in the hands of those who use devices

Lead User Profile: VA Boston Healthcare System

A partnership between clinical engineering and nursing leadership at the VA Boston Healthcare System has resulted in an effort to combat hospital noise and false (non-actionable) alarm signals in a nursing unit. Rebecca Schultz, a nurse manager in the progressive care unit, teamed up with Elena Simoncini, a clinical engineering intern, to study the issue and implement improvements.

They offered this quote from Florence Nightingale as their motivating belief: "Unnecessary noise is the most cruel abuse of care which can be inflicted on either the sick or the well."

They conducted a preliminary nursing survey which found that almost 82 percent of nurses felt the unit was extremely noisy; nearly 73 percent wanted more training on monitors and alarm settings; and nearly 91 percent felt that if they were a patient, they would not be able to heal in the current environment.

The study team measured actual noise levels by placing noise meters at key points in the unit and measuring average decibel levels over time. They demonstrated that noise from alarm signals contributed significantly to noise levels, finding that the average alarm signal measures at 54 decibels. They measured average nighttime noise levels at 50 decibels near the unit's central station, at 52 decibels at the end of the hallways, and at 51 decibels in a patient room. Noise at levels as low as 40 decibels or as high as 70 decibels can keep us awake.

To combat the problem, clinical engineering worked to analyze and optimize the current alarm settings and developed training materials including manuals and easy, step-by-step overviews of alarm system practices. "An alarm [signal] that means nothing is noise" was a key training message, along with methods users could follow to reduce false positive or clinically insignificant alarm signals from alarm conditions. They rolled out the training with an awareness campaign for nurses dubbed SOUND (silence over unnecessary noise and distractions).

Once initial alarm retraining is complete, they plan to re-evaluate noise levels; schedule refresher trainings; and spread the SOUND program to other wards and units throughout the hospital.

Clarion Theme 5: Strengthen medical electrical equipment standards and contracting language to promote success in all intended use environments

"It takes a long time for standards to get implemented in the marketplace."
— David Osborn, senior manager for international standards and regulations, Philips Healthcare

Challenge	Priority Action	Accountability
Contradictions between general and particular medical electrical equipment standards	Customize standards to particular use environments.*	AAMI and responsible organizations ***
Inconsistent naming of alarm conditions	Standardize terminology of alarm conditions.*	AAMI
Inability to integrate alarm condition data from different alarm systems	Develop medical electrical equipment standards and contracting language for data output and exchange of data, with a defined clearance pathway, to improve connectivity of medical equipment from different manufacturers.*	AAMI, ACCE, IHE-PCD; MD-FIRE, and similar organizations
Inadequate user participation in standards development	Increase user participation in standards development.**	AAMI, ACCE
Lack of user understanding of implications of "alarms off" or other alarm signal inactivation states	Improve indicators of "alarms off" and improve user understanding of the state of medical electrical equipment when alarm signals are inactive.*	Manufacturers
Lack of guidance on optimizing alarm limits and other default alarm settings	Develop a guidance document or toolkit of methodology to help responsible organizations learn how to optimize default alarm settings, with a standardized method to determine which alarm limits are too broad and too narrow.**	AAMI, ACCE, ECRI

** Long-term (three- to five-year) time horizon*
*** Short-term (one- to two-year) time horizon*
****See Vocabulary Appendix for definition*

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Understanding the Issues: Medical Device Alarm System-related Standards

The development of standards typically lags behind innovation. Standards for medical devices with alarm systems are no different. The standards landscape parallels the challenges and opportunities identified in alarm system management, systems integration, and use environments.

Until recently, there were no healthcare standards for alarm system functionality, according to David Osborn, senior manager for international standards for Philips Healthcare. In the 1980s, anesthesiology and respiratory device committees began work to craft three sets of standards:

- EN (European Standard) 475:1995, *Medical devices—electrically-generated alarm signals*
- ISO 9703-1:1992, *Alarm signals for anaesthesia and respiratory care—Part 1—Specification for visual alarm signals*
- ISO 9703:1994, *Alarm signals for anaesthesia and respiratory care—Part 2—Specification for auditory alarm signals*
- ASTM F1473:1993, *Standard specification for alarm signals in medical equipment used in anesthesia and respiratory care*

"These standards were narrow in scope—they were only about flashing lights and beeping sounds," Osborn said. For this reason, they were not widely used.

Both the first and second editions of IEC 60601-1 medical equipment standards were silent on alarm systems. Some particular device standards had some requirements—but there was no consistency between standards.

In 1998, IEC and ISO formed a large, multidisciplinary Joint Working Group to develop a standard with a wider scope that would address not just alarm signals, but alarm systems, alarm conditions, and alarm limits on all nonimplantable, active medical devices.

The resulting standard—IEC 60601-1-8 (General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems), is a collateral standard to the second edition of IEC 60601-1 (Medical electrical equipment), which has been termed the "bible" of electromedical equipment safety and the parent standard of over 60 particular device standards (Sidebottom, Rudolph, Schmidt, & Eisner, 2006). Published in 2003, IEC 60601-1-8 took on a wider set of challenges, including:

- Inventing a vocabulary to discuss the problem (the word "alarm" is used only as an adjective, as in alarm system, alarm signal, alarm condition, and alarm limit, not as a noun)
- Prioritizing alarm signals by urgency of action (high-, medium-, and low-priority)
- Harmonizing alarm signal inactivation states and their indication
- Making alarm signals consistent with use of color and rhythm to indicate priority
- Restricting certain configuration properties to responsible organizations that should not be available to ordinary operators
- Offering large rationale and guidance sections
- Permitting (smart) intelligent alarm systems and distributed alarm systems

IEC 60601-1-8 has had mixed success, primarily because "it takes a long time for these standards to get implemented in the marketplace," Osborn said. Many devices with alarm systems in hospitals, which may have life spans exceeding 10 years, were produced before the standards were released. Until the most recent update of IEC 60601-1 in 2005, the alarm system standard was considered optional. And the standard has been criticized for not going far enough, particularly regarding distributed alarm systems, he said.

IEC and ISO are revisiting alarm system standards now, according to Oliver Christ, CEO, Protosystem AG, who is active in these international standards efforts. A Joint Working Group of the two standards-setting organizations plan to release a new technical report on alarm system integration, using the lens of safety, effectiveness, and data and system security of IEC 80001-1 (highlighted on page 28). A draft technical report, which will include an analysis of the results of this AAMI/FDA summit, is planned for release in the spring of 2012.

EXPERT PERSPECTIVE: "IF I RAN THE ALARMS"

Frank Block, M.D.
Co-Chair, AAMI Alarms Standards Committee

"Am I really going to turn off all the alarms on each bedside device, even if I could, and rely solely on my new, intelligent, integrated alarm system? Or will I just have double the number of alarms? Who validates the alarm as a true or false alarm? Who should respond to each alarm? How does the alarm get to the person who should respond to it? Can anyone possibly keep up with 100 different alarms?"

"Alarms—and alarm standards—need to be designed as a system, and not as a 'box,'" asserted Frank Block, retired anesthesiologist and member of the IEC-ISO Joint Working Group that developed IEC 60601-1-8, *General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.

Block poked holes in the standards development process and product—and identified opportunities for improving the standards and their impact. First, he listed drawbacks of IEC 60601-1-8 from a clinician's vantage point:

- Limited clinician participation and input
- Limited application of knowledge on the design of medical alarm systems in other, well studied fields, such as manufacturing processes, nuclear power plants, aviation and air traffic control, railroads, and submarines
- No specificity on acceptable response times for "immediate" response to high-priority alarm signals or "prompt" response to medium-priority alarm signals
- Attention to priority and urgency of alarm signals and responses, but little or no attention to whether devices should sound present alarm signals
- Attention to lights and sounds, but no attention to whether a human being will see or hear the signals and be able to address the problem
- No specificity about staffing levels required to address the alarm conditions that caused the alarm signals
- No information about how to create or use intelligent or integrated or unified or distributed alarm systems, which are mentioned in the standards
- Lack of clarity on "false alarms," and no information on the percentage of false (negative or positive) alarm conditions that is acceptable
- No guidance on how any clinician can keep up with the more than 100 different alarm conditions in a typical ICU that can be configured, turned on or off, or manipulated

Block's litany of the limitations of the standard is sobering. The opportunities to create more rational alarm systems circle back to the same kinds of solutions that other summit presenters recommended:

- Focus on improving patient outcomes
- Make sure that the alarm conditions for which clinicians can intervene and improve the outcome are identified and addressed
- Obtain the greatest caregiver response to true alarm conditions
- Design a study to determine where to set alarm limits

"What matters is if you have enough competent caregivers to identify and correct the problem in a timely fashion," Block concluded. "A well designed alarm system could be one tool among many to help us achieve that goal."

Clarion Theme 6: Clarify regulatory requirements

"What is the right balance between minimizing device false negative [alarm conditions] and minimizing device false positives, which can adversely impact environmental and human factors? What data is needed to establish that changes in this balance are not adversely affecting the [alarm] system in ways that matter to the patient? Perhaps the effort to answer these questions could be under the scope of standards."

— Felipe Aguel, branch chief in the Cardiac and Electrophysiology and Monitoring Branch, Division of Cardiovascular Devices, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Challenge	Priority Action	Accountability
Industry concerns about making changes to alarm systems because they might not be cleared or approved Industry confusion about FDA requirements for "valid evidence" of alarm system safety and effectiveness	Clarify requirements for "valid evidence" of alarm system safety and effectiveness (e.g., published, peer-reviewed data vs. unpublished, controlled experiments) sufficient to gain FDA clearance.*	FDA Possibly AAMI (standards)
Secondary (remote notification) alarm systems used for notification	Eliminate the disconnect between secondary (remote) alarm systems regulated as secondary but used as primary notification systems.* **Long-term (three- to five-year) time horizon*	FDA Possibly AAMI (standards)

Understanding the Issues: Tensions Between Innovation and Regulation

Summit participants called attention to the perennial tension between the desire to innovate and the hesitancy to innovate, due to concerns about FDA clearance or approval requirements. This tension is particularly challenging when it comes to alarm systems. Industry representatives cited uncertainty about what qualifies as "valid evidence" of safety and effectiveness to gain FDA clearance for new or modified alarm systems.

"Regulatory challenges are really scientific challenges," said the FDA's Felipe Aguel, branch chief in the Cardiac and Electrophysiology and Monitoring Branch, Division of Cardiovascular Devices, Center for Devices and Radiological Health. "The case should be made based on valid scientific evidence and data," as well as reliance on consensus standards and algorithms to quantify false negative and false positive alarm condition rates.

The FDA considers the balance between the patient-centric goal of helping healthcare professionals act on clinically relevant events in a timely manner and mitigating environmental and human factors that could result in no action or untimely action. "Remember that the goal is to ensure [that alarm systems indicate] clinically relevant events and reduce missed clinical events," Aguel said. "What is the right balance between minimizing device false negative [alarm conditions] and minimizing device false positives, which can adversely impact environmental and human factors? What data is needed to establish that changes in this balance are not

adversely affecting the [alarm] system in ways that matter to the patient? Perhaps the effort to answer these questions could be under the scope of standards."

Aguel also encouraged summit participants to review a summary of a 2011 MedSun Small Sample Survey on alarm fatigue, which is available at fda.gov/cdrh/medsun.

Shawn Forrest, biomedical engineer lead reviewer in the Cardiac and Electrophysiology and Monitoring Branch, Division of Cardiovascular Devices, Center for Devices and Radiological Health, reviewed the FDA requirements and guidance for remote, or secondary, alarm system notifications. Secondary alarm signals are intended to supplement, not replace, primary notifications, typically from bedside monitors or central stations. The FDA expects that monitoring systems that provide secondary notifications should be implemented based on this intended use—although some secondary alarm systems are being used as primary notifications.

"Real innovation comes from the front lines, and even if the Health Technology Safety Institute did nothing else, discerning, listening to, and sharing front line successes will be a huge help to the healthcare community. Healthcare systems yearn to know what others are doing successfully to solve issues, and the success stories help industry in their R&D."

— Nat Sims, M.D., anesthesiologist and physician advisor in biomedical engineering at Massachusetts General Hospital and co-chair of AAMI's Infusion Device Standards Committee

The FDA's MAUDE reporting system provides insights into potential remote notification problems leading to unintended loss of monitoring:

- Network hardware failures
- Hardware conflicts
- Spontaneous system reboots
- Network traffic that precludes or delays delivery of alarm conditions
- Receivers lose connections or connect to the wrong network (and don't notify)
- Receiver batteries unexpectedly deplete

Forrest recommended these design considerations to ameliorate these problems:

- Validated network requirement specifications
- Acceptable latency
- Closed-loop communication systems
- Backup routing
- Receivers with reliable batteries that ensure constant connection to the correct network and that log alarm conditions and connections to assist troubleshooting
- End-to-end compatibility

Verification and validation of any alarm system should be based on the level of risk. "The risk of missing a critical [high priority] alarm [condition] should guide testing," Forrest said. Key aspects of this testing should be wireless and electromagnetic compatibility (EMC) validation, software validation, and adherence to alarm system-related standards. The FDA has issued draft guidance for radio-frequency wireless technology in medical devices and final guidance on software validation to support medical device review.

Recognized standards relating to all medical devices involving alarm systems include IEC 60601-1-8 Ed. 2:2006 and AAMI/ANSI HE75, *Human factors engineering—Design of medical devices*. Other recognized standards do apply to alarm systems for specific devices, such as ANSI/AAMI/IEC 60601-2-27:2011, *Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*. The FDA's draft guidance document on mobile medical applications may be relevant as well. Forrest cautioned that the Medical Device Data Systems (MDDS) initiative is not relevant to alarm systems used for active patient monitoring.*

**This means that active patient monitoring devices are not MDDS certified and therefore would be subject to FDA pre-market regulatory processes.*

Will Managing New Risks Drive Innovation?

Regulatory challenges notwithstanding, "you are going to get some opportunities for innovation," said Katie McDermott, an attorney and partner in the Washington, DC, law firm of Morgan, Lewis & Bockius LLP.

McDermott was one of several summit presenters who recalled the impact of the 1999 Institute of Medicine report, *To Err Is Human: Building a Safer Health System*, which spurred continuous improvement initiatives. Alarm system issues will drive innovation in products and practices as well, she said.

The pressure to innovate will come not primarily from malpractice litigation over adverse events—although that is a real concern—but from the omnibus healthcare reform law enacted in 2010, McDermott anticipates. "Under healthcare reform, if the patient dies from no alarm [signal, condition, or response], can you bill for that?"

That question will impact healthcare organizations, manufacturers, and clinicians alike. "Your concept of legal risk may change," she said. Beyond malpractice risks, there are risks associated with lack of transparency—failure to report adverse events. "In an era of transparency and accountability, being silent doesn't put you in the best face in the eyes of regulators. Go ask GlaxoSmithKline, which paid $700 million for not reporting [that the drug Advantia caused heart attacks and strokes]." The healthcare reform law will increase the need for reporting and data because that information will drive healthcare payments as well.

Manufacturers face product liability risks and, with healthcare organizations, fraud and abuse law risks if they do not provide adequate education and training for clinicians to use alarm systems. "Industry needs to be more involved in improving clinical outcomes and providing education and training for nurses," she said.

McDermott, like other summit presenters, believes that greater collaboration among stakeholders is essential for innovative solutions to manage all of these risks. "If there isn't innovation clinically, there are going to be lawsuits in the courtroom," she said. "Short- and long-term solutions will have to consider these issues."

"If there isn't innovation clinically, there are going to be lawsuits in the courtroom."

— Katie McDermott, partner, Morgan, Lewis & Bockius LLP

ALARMING CHALLENGES

Perspectives on Problem Reporting, Root Cause Analysis, Alerts, and Recalls

If knowledge is power, it is no wonder that alarm system challenges leave many stakeholders feeling powerless to come up with solutions.

ECRI Institute's James Keller, vice president, health technology evaluation and safety, summarized the areas in which inadequate information is problematic:

Limitations of Problem Reporting Data

- Underreporting—Some estimates suggest that the actual number of alarm [system]-related deaths is ten-fold higher or more than what problem data shows
- Very limited information for data analytics—MAUDE reports are not very helpful; data analysis requires reading through hundreds of reports
- Lack of information in actual reports—The typical language in a report, in paraphrased form, is "During use of the device, the alarm did not sound and the patient died."

Typical Root Cause Analysis Challenges

- Only basic device information is recorded and logged
- Multiple devices in use may not be time-synched
- Limited recording of alarm settings—and when this record is available, it does not include information about who adjusted alarm settings or when they did it
- Definition of manufacturers' event codes are not readily available or are proprietary

Complexity and Variety of Alerts and Recalls

- Device complexity and alert variety
  - o EMI (electromagnetic interference) may cause false asystole alarm conditions
  - o Audible backup alarm signals may fail during power loss
- Lack of clear guidance in many recall notices on how to correct the problem
- Regulatory requirements may delay implementation of the "fix"
- Many hospitals don't have an adequate process to catch recalls of their devices

"Some estimates suggest that the actual number of alarm [system]-related deaths is ten-fold higher or more than what problem data shows."

— James Keller, vice president, health technology evaluation and safety, ECRI Institute, and president-elect of the American College of Clinical Engineering

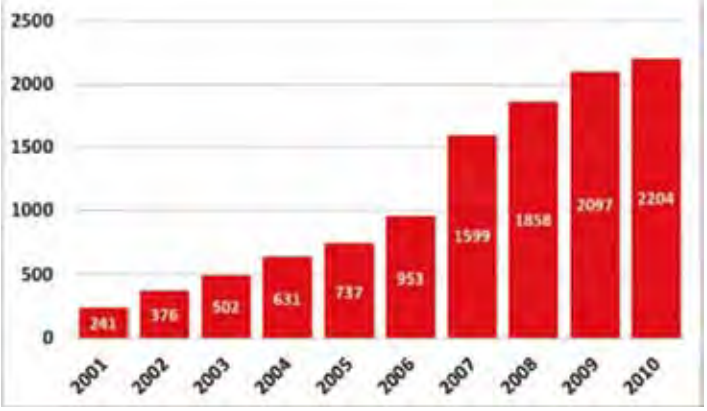

Figure 6. ECRI Institute data showing the growing number of Medical Device Safety Alerts

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Source: James Keller. "Perspectives on Problem Reporting, RCAs, and Alerts and Recalls." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 4, 2011.

Clarion Theme 7: Share illuminating practices with all stakeholders

"There is no source or standard that industry can go to find best practices. There are different practices even from one unit to the next even within hospitals."

— A participant at the Medical Device Alarms Summit

Challenge	Priority Action	Accountability
Insufficient awareness of and attention to issues with alarm systems	Make clinical leadership an essential element to success.* Form an interdisciplinary team responsible for continuous quality improvement in alarm system use.*	Responsible organizations**
Inadequate consideration and coordination of all facets of alarm system management	Develop, revise, and periodically review policies and procedures that integrate workflow, people, processes, protocols, and alarm system technology.*	Responsible organizations**
Limited information about front-line alarm system experiences in use environments	Create a forum for stakeholders to contribute, exchange, and study information about alarm system experiences. Validate alarm system information from front-line clinicians and caregivers.*	TBD Researchers
Limited information about the impact of alarm systems on patients	Focus on the patient impact of alarm systems.*	All stakeholders
Inadequate Information about managing and using alarm systems in different healthcare settings	Develop standards and management frameworks for different types of responsible organizations.* Develop guidance documents for setting up an alarm system for responsible organizations.* Develop clinical practice guidelines.*	AAMI (standards and guidance documents) HTSI (white paper); Nursing organizations (clinical practice guidelines)
Limited opportunities to benchmark best practices	Share findings, challenges, best practices, and lessons learned in an interdisciplinary way across disciplines and industries.* **Short-term (one- to two-year) time horizon* ***See Vocabulary Appendix for definition*	All stakeholders

Understanding the Issues: A Leadership Void and a Dearth of Information

The call for action on medical alarm system challenges seems to be sounding everywhere but in the ranks of clinical and administrative leadership in healthcare, according to many summit participants. Without leadership involvement, system-wide improvements are extraordinarily difficult.

The Joint Commission, which accredits more than 19,000 healthcare organizations and programs, might soon get their attention. In response to widespread alarm system challenges, The Joint Commission has proposed a National Patient Safety Goal for 2013 focused on alarm system management.

"We are hearing from our surveyors' observations in the field, our standards interpretation group, and our sentinel events group that alarm system mismanagement is really, really a problem," said Ana Pujols-McKee, chief medical officer, The Joint Commission. "They confirm the high frequency of concerns and the complexity of challenges for organizations. There is a proliferation of alarms—they beep when something is wrong and beep when something is right. Everybody is struggling."

Already, The Joint Commission is laying the groundwork to "refresh its role" in scrutinizing alarm system challenges. That role began with a 2003 National Patient Safety Goal to improve the effectiveness of clinical alarm systems.

The 2003 National Patient Safety Goal was retired in 2005, based on a high level of compliance in the field and the incorporation of the goal's measures into standards.

Now, environment of care rounds include a detailed and focused assessment on alarm systems. Observations from the field indicate the need to reduce the number of alarm signals by appropriately placing patients on telemetry monitoring and managing audibility by setting higher volume levels to the high priority alarm signals. McKee cited these opportunities for the field:

- Alarm conditions that go directly to the responsible caregiver (operator) via a mobile device
- Improving audibility by reducing overhead paging
- Closed-loop communication systems that can acknowledge receipt of alarm conditions and response of an operator
- Automatic escalation of alarm signals
- Multidisciplinary teams to conduct proactive risk assessments and review events
- Monitoring staff response to alarm signals to identify staffing, fatigue, and other issues on all shifts
- Industry standardization

McKee referenced a number of Joint Commission standards that are relevant to coordinating all facets of alarm system management, including:

Environment of Care (EC) standards

- EC.02.04.01: The hospital manages medical equipment risks
- EC.02.04.03: The hospital inspects, tests, and maintains medical equipment
- Provision of Care (PC) Standards
- PC.02.01.19: The hospital recognizes and responds to changes in a patient's condition

Element of Performance (EP) Standards

- EP 1: The hospital has a process for recognizing and responding as soon as a patient's condition appears to be worsening
- EP 2: The hospital develops written criteria describing early warning signs of a change or deterioration in a patient's condition and when to seek further assistance
- EP 3: Based on the hospital's early warning criteria, staff seek additional assistance when they have concerns about a patient's condition
- EP 4: The hospital informs the patient and family how to seek assistance when they have concerns about a patient's condition

Performance Improvement (PI) Standards

- PI.02.02.01 EP 12: When an organization identifies undesirable patterns, trends or variation in its performance related to safety or quality of care, it includes the adequacy of staffing, including nurse staffing, in its analysis of possible causes
  - Adequacy of staffing includes the number, skill mix, and competency of all staff
  - Consider workflow, competency assessment, credentialing, supervision, orientation, training, and education
- PI.02.01.01 EP 13: When analysis reveals a problem with adequacy of staffing, the leaders responsible for the organization-wide safety program are informed of the results and actions taken to resolve the problem

"Governance is a huge part of making sure you have the right implementation."

— Tim Gee, principal, Medical Device Consulting

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- PI.02.02.01 EP 14: At least once a year, the leaders responsible for the organization-wide safety program review a written report on the results of any analyses related to adequacy of staffing and any actions taken

Leadership (LD) Standards

- LD.04.04.05 EP 13: At least once a year, the organization provides governance with written reports on the following:
  - All results of the analyses related to the adequacy of staffing

Learning from Other Industries

Like healthcare, nuclear power is an industry where safety is intensely important. What can the healthcare community learn from this industry's experience with alarms? J.J. Persensky of the Idaho National Laboratory offered his perspective on alarm systems management in nuclear power applications with an eye to sharing information with the medical community.

There are currently 104 active nuclear power plants in the United States, and the large majority of those are more than 20 years old. Like the healthcare industry, there is a need for updated and improved alarm systems in nuclear power plants. Problems include:

- Overabundance of binary state alarm annunciator tiles, with a typical plant featuring over 1,000 individual alarm tiles.
- Ineffective filtering of alarms leads to nuisance alarms that can overload operators.
- Analog systems are reaching their service lifetimes; the shift to digital systems is slowed by utilities hesitant to explore new technologies that may require costly amendments to operating licenses.

"Like healthcare, the nuclear power industry would like to shift from labor-intensive control room technologies to technology-based solutions that decrease operator workload and potentially increase plant safety," says Persensky.

Persensky offered insight gained from recent research in alarms systems in the nuclear industry, which show that alarm processing can address alarm overload, associate cause/consequence alarms, reduce nuisance alarms, decrease response times, and improve user acceptance. He also said that further research is needed to:

Conventional nuclear power plant control room

Source: J.J. Persensky, "Alarm Systems Management in Nuclear Power Application." Presentation at the AAMI/FDA Medical Device Alarms Summit, Oct. 5, 2011.

- Go from a system in which operators have to filter relevant from less relevant alarms to a system that helps to filter alarms and aids operators in taking actions
- Create improved alarms to help the operator with alarm monitoring and response planning
- Transfer alarm systems knowledge across industries

"Advance alarm displays and intelligent alarm systems exist," Persensky says. He points to the aerospace, petrochemical, defense, transportation, and other process control industries with advanced control room technologies and improved alarm systems as possible models.

Where We Go From Here

"The absolute critical point of this summit is that we have to have tremendous clinical involvement in the standards work and in the design of alarm systems."
— Frank Block, M.D., Co-Chair of AAMI's Alarms Committee

One of the most significant benefits of the Medical Device Alarms Summit was the creation of a safe forum for cross-disciplinary discussion and consensus building on the priority actions needed to address alarm system challenges. We are more and more convinced that these tough challenges are "systems" issues that cannot be solved well by any single stakeholder group in the system.

Bringing industry, regulators, outside experts, patient safety officers, healthcare technology management professionals, and clinicians together in the same room helped everyone gain a better understanding of the multidisciplinary collaboration that characterizes innovative practices. AAMI will continue to work collaboratively with many stakeholders on the ambitious, action-oriented priority actions that came out of the summit.

"Any intelligent fool can make things bigger and more complex... It takes a touch of genius—and a lot of courage—to move in the opposite direction."
— Albert Einstein

The biggest challenge will be to keep the momentum going. The structure for sustained action is already in place. This year, AAMI created a Medical Device Alarms Committee to help tackle the issue of alarm system management with new standards, technical information reports, and guidance documents for industry and users. This committee met two days after the summit, and will meet again in February 2012.

AAMI expects to set up new working groups in the AAMI Foundation Healthcare Technology Safety Institute for non-standards work needed to make progress on the priority actions. This work will begin early in 2012. AAMI will provide quarterly updates on post-summit progress to summit participants and on the AAMI website.

Clinicians' continued involvement in the Medical Device Alarms Committee and working groups is crucial. We urge all stakeholders—manufacturers, healthcare institutions, professional organizations, and regulators—to find ways to ensure that clinicians are at the table.

Join the Medical Device Alarms Committee

The AAMI Medical Device Alarms Committee is looking for new members, particularly nurses, regulators, academia, and other non-industry interested parties. For more information, contact Jennifer Moyer at jmoyer@aami.org.

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Conclusion

"We are more likely to act ourselves into new ways of thinking than think ourselves into new ways of acting. "
— Mark Twain

The October 2011 summit that AAMI co-convened with the FDA, The Joint Commission, ECRI Institute and ACCE issued a "*siren call*" to action for improving medical alarm system safety. The seven clarion themes and priority issues resonate with urgency and inspired all of us to "act ourselves into new ways of thinking."

From a 30,000 foot perspective, the Summit:

- Coalesced all stakeholders around a common goal: No patient should be harmed from adverse alarm system events.
- Energized end users to dare to challenge the norm.
- Challenged (in a good way) the entire vendor community to get past certain historical problems and barriers and come to grips with the problem, and created a setting for industry to truly "hear" the needs of users
- Challenged the FDA to engage in being part of the solution and in supporting innovation
- Developed an important research agenda (see the Research Appendix)
- Gave health care organizations ideas on what they can start to work on now, without waiting for research or longer term solutions (see "Top 10" list)
- Proved once again that these complex technology-related safety issues require a holistic approach to "solutions" that can only happen when the entire healthcare community collaborates, because the issues are systems-based.

What's Next: AAMI Foundation's *Healthcare Technology Safety Institute*

Not one of the seven clarion themes has a single point of accountability for follow-up. These systems issues will require the whole healthcare community to continue to work together as a team. The AAMI Foundation's new Healthcare Technology Safety Institute is committed to sustaining the momentum from the summit with an action plan for addressing the priorities. Like the summit itself, the action agenda will require multidisciplinary, collaborative efforts. No single group can do it alone.

AAMI will stay in touch with the community that came together on October 5-6, 2011 and ask that all of you stay in touch as well. To volunteer your time on a working group or steering committee or to donate funds for on-going research and action, contact the AAMI Foundation at 703-525-4890 or visit the AAMI Foundation web site at http://www.aami.org/foundation/htsc/funding.html.

Tackling the priority issues will take all of us – and many more – committed individuals who are willing to "act ourselves into new ways of thinking." Together, we will celebrate success.

www.aami.org/alarms/materials.html

VOCABULARY APPENDIX

ALARM CONDITION
state of the alarm system when it has determined that a potential or actual hazardous situation exists for which operator notification is required

NOTE 1: An alarm condition can be invalid, i.e. a false positive alarm condition.

NOTE 2: An alarm condition can be missed, i.e. a false negative alarm condition.

[IEC 60601-1:2006+A1:2012, definition 3.1]

ALARM CONDITION DELAY
time from the occurrence of a triggering event either in the patient, for physiological alarm conditions, or in the equipment, for technical alarm conditions, to when the alarm system determines that an alarm condition exists

[IEC 60601-1:2006, definition 3.2]

ALARM LIMIT
threshold used by an alarm system to determine an alarm condition

[IEC 60601-1:2006, definition 3.3]

ALARM SETTINGS
alarm system configuration, including but not limited to:

- alarm limits;

- the characteristics of any alarm signal inactivation state; and

- the values of variables or parameters that determine the function of the alarm system

NOTE: Some algorithmically-determined alarm settings can require time to be determined or re-determined.

[IEC 60601-1:2006, definition 3.8]

ALARM SIGNAL
type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition

[IEC 60601-1:2006, definition 3.9]

ALARM SIGNAL GENERATION DELAY
time from the onset of an alarm condition to the generation of its alarm signal(s)

[IEC 60601-1:2006, definition 3.10]

ALARM SYSTEM
parts of medical electrical equipment or a medical electrical system that generate alarm conditions and, as appropriate, present alarm signals

[IEC 60601-1:2006+A1:2012, definition 3.11]

DEFAULT ALARM PRESET
alarm preset that can be activated by the alarm system without operator action

NOTE: manufacturer- or responsible organization-configured alarm presets are possible types of default alarm presets.

[IEC 60601-1:2006, definition 3.16]

DISTRIBUTED ALARM SYSTEM
alarm system that involves more than one item of equipment of a medical electrical system

NOTE: the parts of a distributed alarm system can be widely separated in distance.

[IEC 60601-1:2006, definition 3.17]

ESCALATION
process by which an alarm system increases the priority of an alarm condition or increases the sense of urgency of an alarm signal

[IEC 60601-1:2006, definition 3.18]

FALSE NEGATIVE ALARM CONDITION
absence of an alarm condition when a valid triggering event has occurred in the patient, the equipment or the alarm system

NOTE: an alarm condition can be rejected or missed because of spurious information produced by the patient, the patient-equipment interface, other equipment or the equipment itself.

[IEC 60601-1:2006, definition 3.20]

FALSE POSITIVE ALARM CONDITION
presence of an alarm condition when no valid triggering event has occurred in the patient, the equipment or the alarm system

NOTE: a false positive alarm condition can be caused by spurious information produced by the patient, the patient-equipment interface, other equipment or the alarm system itself.

[IEC 60601-1:2006, definition 3.21]

HIGH PRIORITY
indicating that immediate operator response is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.22]

INFORMATION SIGNAL
any signal that is not an alarm signal or a reminder signal

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

[IEC 60601-1:2006, definition 3.23]

INTELLIGENT ALARM SYSTEM
alarm system that makes logical decisions based on monitored information without operator intervention

EXAMPLE 1 an alarm system that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 an alarm system that suppresses an alarm condition when a related alarm condition of higher priority has recently generated an alarm signal.

[IEC 60601-1:2006, definition 3.24]

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LOW PRIORITY
indicating that operator awareness is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.27]

MEDIUM PRIORITY
indicating that prompt operator response is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.28]

OPERATOR
person handling the equipment

[IEC 60601-1:2005, definition 3.73]

PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

NOTE: A patient can be an operator.

[IEC 60601-1:2005+A1:2012, definition 3.76]

PHYSIOLOGICAL ALARM CONDITION
alarm condition arising from a monitored patient-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[IEC 60601-1-8:2006, definition 3.31]

RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of an medical electrical equipment or an medical electrical system

NOTE 1: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. For in home use applications, the patient, operator and responsible organization can be one and the same person.

NOTE 2: Education and training is included in "use."

[IEC 60601-1:2005, definition 3.101]

RISK
combination of the probability of occurrence of harm and the severity of that harm

[IEC 60601-1:2005, definition 3.102]

RISK ANALYSIS
systematic use of available information to identify hazards and to estimate risk

[IEC 60601-1:2005, definition 3.103]

RISK ASSESSMENT
overall process comprising a risk analysis and a risk evaluation

[IEC 60601-1:2005, definition 3.104]

RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk

[IEC 60601-1:2005, definition 3.107]

TECHNICAL ALARM CONDITION
alarm condition arising from a monitored equipment-related or alarm system-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[IEC 60601-1-8:2006, definition 3.36]

RESEARCH APPENDIX

Research Agenda

Summit presenters and participants identified a dozen research questions and needs that could improve alarm systems, management integration, and human interactions with alarm systems.

Alarm Systems for Monitoring and Other Medical Equipment

1. In a perfect world, every patient should be monitored. With today's alarm systems, however, healthy patients are unlikely to have true alarm conditions, and instead their monitoring devices add to the already huge number of false alarm conditions.

   As a temporary solution, conduct risk analyses of patient populations within acute care facilities to question who should not be monitored, rather than who should be monitored. If patients should be monitored, what should be monitored? Look at earlier indicators of patient deterioration, including:

   - Respiratory rates
   - Pulse rate/heart rate
   - Systolic blood pressure
   - Pulse oximetry

   ** This research item assumes that adequate research outcome already exist to support all four of these bulleted points.

2. Develop better techniques and measurements for monitoring respiratory rates.

3. Determine optimum settings for alarm limits that result in the greatest number of true alarm conditions to be addressed by caregivers.

4. Include in alarms system research not just patient monitoring alarm systems, but additional medical equipment that provides alarm signals in patient care systems (e.g. infusion pumps, bed rail alarm conditions, and nurse call systems).

Alarm Systems Management

5. Consolidate existing research on alarm systems management.

6. Determine whether alarm signals should be standardized to be distinctive for each organ system (e.g., cardiac, respiratory, oxygen), for each kind of device (e.g., monitor, ventilator, infusion pump), or for each manufacturing company.

7. Develop databases and algorithms for multiparameter (fusion) alarm conditions.

8. Research the different challenges of medical equipment alarm systems used in outpatient and home settings.

9. Research the optimal interval for changing sensors (acceptable risk when weighing cost of changing sensors versus improved sensitivity and specificity of alarm systems).

Human Factors

10. Study the human reliability of clinicians to respond to alarm signals.

11. Determine the number of alarm conditions that caregivers can reasonably be expected to respond to per hour. This research could lead to guidelines for the minimum staff required in a unit, based upon the number of hourly alarm conditions that need a response.

12. Examine the effect of alarm signals on staff turnover and performance.

13. Conduct sleep studies that look at the optimal volume of alarm signals relevant to ambient noise and time of day.

Research Design and Outcomes

14. Design trials appropriately—and with the appropriate team. Ensure that trials are designed to generate the highest level of evidence. Establish sound surrogate outcome measures at the front end.

15. Look at patient outcomes, not just approaches for decreasing the number of alarm conditions.

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The Joint Commission:

- Environment of Care (EC) Standards
- Provision of Care (PC) Standards
- Element of Performance (EP) Standards
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