

A Roundtable Discussion

Alarm Safety: A Collaborative Effort

Mary K. Logan, Moderator

Roundtable Participants



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When an 89-year-old man died in his bed at Massachusetts General Hospital and the alarms that should have sounded didn't, the incident set off a different kind of alarm throughout the hospital, in Boston, and in state regulatory agencies. The tragic situation also provided a learning experience for Mass General and the larger medical community.¹ In that spirit, AAMI recently gathered a group of experts to discuss a number of alarm safety questions. What kinds of alarms are necessary, and how many alarms are too many? How can technology help solve this problem rather than compound it?

Mary Logan *What are some common problems seen with alarm systems for medical devices?*

Linda Talley I'm responsible for looking at how nurses interact with technology. The literature tells us, and our own experience at Children's National Medical Center indicates, that we're dealing with anywhere from an 85% to 99% false positive rate on alarms. We are inundated with information and alarms, most of which are meaningless to us.

Nurses become desensitized to the huge number of alarms they're confronted with in their daily work and, as a result, critical or clinically significant events can be missed. We had a serious patient event many years ago that related to the timeliness of our response to a monitor. In our post-event review, we learned that it wasn't an equipment failure. Rather, it was a human factors failure. That really

prompted us as an organization to try to wrap our hands around the whole issue of alarm fatigue. We just completed a study funded by one of our alarm manufacturing vendors on the issue of alarm fatigue.² We were aiming to partner with this vendor to increase the specificity and positive predictive value of the information the monitors give us.

Steve Wilcox But I see two other problems with alarm systems. Besides the false alarms, the second problem is the lack of integration between devices. All these independently developed alarm systems don't talk to each other or integrate in any way. So even if the false alarm problem was eliminated, there would still be this cacophony because of that lack of integration. The third problem is that the signals themselves are poorly designed so they're not natural sounds. They're difficult to learn and identify, and they go out of their way to be annoying. I think it's an artifact of the way they're designed.

Tobey Clark IEC standards for alarm systems^{3,4} aim to prescribe a way to standardize alarms in terms of priority and parameters so people can learn and understand alarm signals, and better recognize the higher versus lower priority alarms. The American College of Clinical Engineering's Healthcare Technology Foundation published a white paper about clinical alarms and one of their recommendations was for clinical alarm standards.⁵

Wilcox Of course these standards have made things a little more rational. But they haven't addressed the problems of integration or false alarms.

Talley Our experience, and our discussions over a three-year period with a vendor we were working with, indicates that device manufacturers are challenged as well by a consumer base that has asked them, over the past 10 years, to throw it all at us. We ask them to give us everything they can with these "magic machines" and we'll deal at the front line with how we are going to discriminate between the massive amounts of noise we're confronted with.

So I think they are very anxious to partner with us to figure out how to strike that balance. The machines we put in the hands of clinicians present serious challenges. The level of decision support is increasingly sophisticated and complex for any one clinician to manage. In many of our intensive care units (ICUs), we have additional personnel doing the decision support, trying to counteract the massive amounts of noise the technology produces.

In our study we recorded tens of thousands of alarms in a 30-day period, which translated to approximately 900 per day. In one of our critical care units, a total of 39,000 alarms were recorded in a 30-day period which equaled 1300 alarms per day, or one alarm sounding every 66 seconds. In another critical care unit, we observed approximately 600 alarms per patient per day.

In direct response to the sentinel event we had here at Children's National several years ago, we decided every patient in every unit was going to be on a monitor. So we became even more acutely aware then of the dilemma of having very little science to drive how we monitor alarm limits.

We felt bound, from an ethical perspective, to do no harm and monitor patients to the fullest degree possible. But we find ourselves now in this conundrum where we encounter an abundance of information that is of very little value. So we have duplicative measures on all of our units in terms of humans with an eye on patients, as well as trying to filter through what the alarms are telling us.

Jim Welch A study published in *Anesthesiology*⁶ focused on a general care setting, Dartmouth Hitchcock Medical Center, where my company worked directly with the end users. Rather than study how many alarms were occurring, we asked, "How many alarms are tolerable from a human factors standpoint to avoid alarm fatigue?" The nurses told us two to four alarms per patient per day.

I would encourage the community to agree to a common set of metrics and terminologies. Everybody knows what alarm fatigue is, but it needs to be defined. They took a different approach at Dartmouth by actually separating the alarm annunciation, or the sound of the alarm, because alarm fatigue is mostly an audio rather than a visual phenomena. They set alarms to a lower threshold for surveillance, that is, letting you know when a patient needs to be rescued versus letting you know when a patient crosses the threshold. That is a very different approach to the traditional conditional settings found in ICU settings. By adding a delay to it, they were able to achieve four alarms per patient per day. And because of that, they were able to actually improve patient safety methods as measured by escalation of care to the ICU and rapid response activations.

On the technical side, monitoring companies have followed this paradigm of alarms being activated by the crossing of a threshold. Those thresholds often have not been defined using an evidence-based, rationalized approach to alert a nurse or clinician to go to the bedside.

In a study out of Johns Hopkins,⁷ they found that by lowering an SpO₂ alarm from 90% to 88%, they were able to reduce the occurrence of alarms by more than 50%. A methodology to rationalize what's an appropriate alarm is needed. The whole topic of alarm fatigue really begs the question of why are we doing alarms? What's the primary purpose of them, and how do we create decision systems or filters so that nurses can focus on clinically actionable alarms?

Logan *What are the biggest obstacles to solving challenges related to alarms?*

Wilcox One is a strong bias toward false positives instead of false negatives. If an alarm signal fails to annunciate when there is

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a legitimate situation, the liability is obvious. On the other hand, when the alarm signal annunciates when there's not actually a problem, there is a logical liability because it's undermining the value of the alarm. However, I've never heard of anybody being sued for a false positive. So to avoid even the thought of a false negative, we're just inundated with false positives.

Welch There is a lack of research in this area. I've scoured the literature for publications on alarm recurrences, origins, and causes, and I'm only aware of a few published studies: the ones I've already mentioned and another in the *Journal of Emergency Medicine (JEM)*⁸

The *JEM* piece studied the occurrence of alarms and what were clinically actionable events. It was predominantly focused on electrocardiogram (ECG) alarms, which is, I think, the primary cause of most alarms, along with impedance respiration rate. In the emergency room, they found that less than 2% of all alarms require a physician to do something at bedside to reverse the condition.

So what we don't answer in the literature is, what's being monitored? What's the alarm mean? And what's the profile of that alarm? We conducted a study in 10 hospitals looking at SpO₂ alarm occurrences using our technology. We found that if you set your SpO₂ alarm at 90%, you will have a lot of true alarms. But those true alarms do not require a clinical intervention. By lowering the alarm level from 90% to 88% and putting a 15-sec-

ond audio delay on it, essentially a filter, we found that we could eliminate more than 80% of the alarms. So now we've got the alarms people care about, the ones where levels fall and stay below a threshold for a sustained amount of time, that would cause a clinician to rationally say, "I'm worried about that patient."

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Angela Andrew-Webb I can offer a home healthcare perspective on the alarm fatigue issue. In part, machines are going off because they are too sensitive. With the probes we use in the home setting, if the client moves a bit too much or even if their extremities are cold, we see a lot of false alarms. If ventilators are not set up properly, we can have water in the lines, which will give us false alarms also.

The payer source is our major obstacle to solving these problems. For instance, with ventilators, some of the home medical equipment (HME) companies are only compensated to give us two vent circuits a month. That means the circuits are only changed every two weeks. They need to be changed every week to function properly.

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Welch If we look at this from a systems perspective, think about links in a chain. If you don't have the correct or optimized sensor, then you don't have a high-performance sensor, and you're going to generate false data. False data leads to false alarms. If you're trying to use the same cable over and over and it's at the end of its life and its signal is becoming intermittent, you'll get false alarms.

So from a provider medical community, how do you optimize every link in that signal chain? Because the more you measure, the more alarms you're going to have. Once you have optimized the sensor, its placement, the skin prep, and you've got a good signal, now you can ask, what is a rational approach towards where I set the alarms? For example, the heart rate area—is it okay to set it at 140 versus 120? If you do that, you will get fewer alarms. The question is, at what point is the alarm threshold set beyond a reasonable level, such that you're causing harm? That evidence does not exist right now. And it's not a one-size-fits-all solution.

Wilcox The aircraft cockpit used to be like our situation in the ICU or the operating room (OR) today. Separate vendors made different devices that had alarms, and when multiple things started happening simultaneously, pilots were overwhelmed. But they had the advantage of a general contractor who could create a unified, integrated system that represents an alarm philosophy that is consistent.⁹

We're not in that situation because there's no comparable general contractor who can rationalize everything like in the aircraft industry. And there's no incentive for individual manufac-

turers. So the only way that could happen is for hospitals and medical facilities to demand it. There have been third-party attempts to come up with a unified system that you plug all your devices into. To my knowledge, none of them have gotten off the ground yet, but ultimately that's going to be one of the solutions.

The liability issue is a big one here. When you talk to vendors, purchasers, trustees, and so forth, they all come back behind the defense of the incredibly high cost of litigation.

John Hedley-Whyte These problems have been around for a long time. Many of the topics we're addressing here were also addressed in a 1992 publication I edited.¹⁰ The bottom line is that everyone is to blame for problems with alarm systems.

The use of technology to allow intelligent escalation of alarms up the management chain and alarm retrievability is essential. We need to tap into the literature from other disciplines on this topic, such as aeronautics.

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Welch One more obstacle is FDA clearance for any kind of rationalized improvement in alarms. Any company that moves forward with an intelligent or smart alarm solution will have to run the FDA gauntlet of getting clearance. The question to the industry is, is that worth the effort? There's almost a resistance in the area of alarms because it raises the specter of a prolonged clearance cycle for any new platform that's developed.

Talley The partnership between the clinician, vendor, and FDA needs to be strengthened so we can get the national attention we need to discuss how more is not necessarily better in the realm of alarms. That would lead us into a dialogue about interoperability and intelligence, and how we can use that to move ahead. There is a mistaken notion that the information glut puts us at an advantage; instead, we find ourselves at a disadvantage.

Hedley-Whyte Another barrier to examine is the Health Insurance Portability and Accountability Act (HIPAA) regulations about confidentiality of medical records. People are finally realizing that, if your survival depends on transmission of what your critical care state is, then HIPAA is a bad thing. David Pogue wrote in *Scientific American* recently¹¹ that the general population of the United States needs to be told that some regulations about confidentiality or medical care need revising, and Congress needs to revisit the whole issue.

Logan *What steps can and should healthcare facilities be taking to address the problems?*

Hedley-Whyte Solving this issue will require involvement from top hospital executives. These hospital executives are generally not aware of the problems we're discussing today. The need for intelligent, integrated alarm systems generally comes as a surprise to them.

Clark Individual hospital units typically follow specific policies for alarm parameters, which is appropriate. But at the institutional level, there isn't a clear awareness of the problem. Unfortunately, the reporting of alarm events in *The New York Times* or *Boston Globe* that are read by a trustee or hospital executive is a common impetus to develop an alarms improvement program.

Wilcox Facilities can use the likelihood of false alarms as one of the top criteria for acquiring devices. Right now, that criterion is pretty low on the list, if it's even considered at all when comparing devices. However, with the lack of good metrics or research that compares one

vendor to another in a lot of parameters, it is very difficult for healthcare organizations to make those decisions. Some organizations like ECRI are beginning to test various technologies relative to false or nuisance alarms.

Hedley-Whyte When I am asked to visit other medical institutions, I have found it rare that hospitals have appropriate alarm policies. To initiate rational alarm policy often takes a committee or a very powerful central administration. The development of rationalized policies and procedures should be based on local evidence and published literature.

Also, the move of so much medicine and surgery toward home care does require urgent rethinking of the alarm systems that should be deployed. Nobody on a ventilator, hemodialysis machine, or infusion pump at home should be left without a distributed alarm system. It is nonsense to think that a single alarm is sufficient. You need a system distributed to other rooms where other people are.

Cartwright From a home healthcare perspective, it's part of our assessment to verify

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that an alarm can be heard in every area of a home. Desensitization to alarm sounds is also a problem in the home environment. Because there is not a clinical person there with the patient all the time, family members come up with their own interpretation as to what alarms mean because of what has happened in the past. Often, family members will actually turn off alarms because they've heard so many false ones.

Welch In fact, if you go through device incidents reports, you'll find that home apnea monitors are one of the most egregious examples of too many false or nuisance alarms, and an inability to relay the true alarms that somebody would do something

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about. Remote annunciation of alarms is essential because caregivers, especially ones outside ICU settings, are not at the bedside when these events occur.

However, if you don't solve the problems of nuisance alarms or alarm fatigue, moving those alarms to an already-busy clinician, home healthcare provider, or family member is just going to annoy them, and they're going to turn off alarms. So first solve the alarm fatigue problem, and then start thinking about how to get alarms to the right person to rescue that patient.

Logan *What should industry be doing to address these problems?*

Hedley-Whyte There are many barriers to what industry can do to solve these problems in the home environment. In Massachusetts, we've had political infighting to get sophisticated, distributed alarm systems deployed in the home. You have to battle insurance companies for reimbursement to wire another room, set up a local area network, and so forth.

Welch Until there's reimbursement for companies developing these body-worn sensors for home healthcare, you are not going to get venture capitalists or their companies to invest

because there's no profit in it. On the acute-care and the long-term care side, however, industry definitely can do more because that's where monitors are today. How we solve these problems is really the call to arms.

At a children's hospital, we analyzed what measurements are most often alarming. We found that respiration rate was the root cause of most of the alarms that were driving nurses, patients, and families crazy. So that gives us an attack point from a technology standpoint. What can we do about improving that particular parameter? How do we integrate all of the parameters? For instance, why not couple respiration rate with oxygenation in patients? There are some rational ways of approaching this. The question for industry is, will that provide a competitive advantage of one company versus the other?

Logan *AAMI has just established a new standards committee on alarms, because of the importance of the issues that need to be addressed from a standards perspective. What do you think is needed on the regulatory, accreditation, or standards fronts to deal with this issue?*

Hedley-Whyte The international standards-setting process in this area is not smooth at all. We've had international standards for about 40 years on alarm systems. There's currently a disagreement between two standards bodies on how to approach these systems, which needs to be resolved.

Logan The new AAMI standards committee is waiting to get started until they hear the needs and priorities from all perspectives at the alarms summit that AAMI is co-hosting this October 4-5 with ECRI Institute and ACCE. The committee is also waiting on a revision of an updated IEC foundational standard (60601-1-8), upon which our new work will build. If we can solve many of the challenges with alarms from what we learn at this year's summit, then hopefully this preferable non-regulatory route for improvements throughout the system will eliminate the need for any additional regulatory action.

Talley In 2002, the Joint Commission issued an alert on alarm safety. That was helpful; it established a call to action and gave us leverage to say we are all accountable. We're almost 10 years past their recommendation and we've made little to no real advance in solving this alarm safety problem. The Joint Commission has since established a standard aimed at appropriate alarm settings and audible alarms. It's a start; however, it does not effectively get us to where we need to be. Clinicians are still encountering alarm fatigue in the hospital setting.

Logan *What next steps are needed to solve these problems?*

Talley We must continue to seek research opportunities. Healthcare providers must represent the patient and the family interests. As we said earlier, vendors are looking at the bottom line. The providers are the ones who are most closely aligned with patient/family interests. And it is incumbent on us to keep the topic alive through research endeavors. The

more we can look at it from an evidence-based perspective, the more we can maintain the momentum we've begun here.

Welch This is an enormously important issue in healthcare because we're already seeing that, due to so many nuisance alarms occurring, hospitals are looking at not monitoring patients. Removing the technology because there are problems with it is a step backward. Therefore, at a stakeholder meeting, it's going to be extremely important to have the right participants representing the political, financial, insurance, and vendor spectrums. Everybody recognizes that this is a worthy problem to solve. Getting agreement and collaboration on a way forward is the only way this is going to be solved.

Andrew-Webb With home healthcare, we need to work more with vendors to make sure they're aware of issues we are having with alarms so we can present that to insurance companies and try to resolve these issues together. ■

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