Using Data to Drive Alarm System Improvement Efforts
The Johns Hopkins Hospital Experience

The key to reducing alarm signal noise is the collection and analysis of quantitative data to evaluate the applications of alarm system management in hospitals.
Acknowledgements:
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About the Healthcare Technology Safety Institute (HTSI)
Founded within the AAMI Foundation, the 501(c)(3) charitable arm of AAMI, the HTSI is a community of leaders throughout the healthcare system that are dedicated to one common vision, “No patient will be harmed by medical technology.”
HTSI’s mission is “To engage the entire healthcare community in multi-disciplinary safety initiatives that strengthen the development, management, and use of medical technology for improved patient outcomes.” HTSI engages the healthcare community in research, education, consensus, and partnerships related to the challenges facing healthcare technology industries, regulatory and accrediting bodies, clinicians, caregivers, and patients.

ALARM CONDITION
State of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists
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.

ALARM SIGNAL
Type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

From IEC 60601-1-8:2006, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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Introduction
Starting in 2006, the Johns Hopkins Hospital has taken on several major initiatives to reduce hazardous situations related to alarm systems. By relying on data to establish baseline alarm priority levels and then iteratively evaluating the effectiveness of improvement efforts, a multidisciplinary team has helped to cut noise in hospital units, made clinicians more attentive to the alarm signals that do sound, and optimized both technology and workflow at every step in the process.

The Alarm System Challenge
“We in healthcare have created the perfect storm with all of these monitoring devices,” says Maria Cvach, RN, assistant director of nursing, clinical standards, who has been heading up the alarm system improvement efforts at Hopkins since 2006. “In hospitals today, we have too many alarming devices. The alarm default settings are not set to actionable levels, and the alarm limits are set too tight. Monitor alarm systems are very sensitive and unlikely to miss a true event; however, this results in too many false positives. We have moved to large clinical units with unclear alarm system accountability; private rooms with doors closed that make it hard to hear alarm signals; and duplicate alarm conditions which desensitize staff.”

While the hospital staff recognized the effects of excessive noise on the units, it took a few adverse patient events to focus attention on the problem. Once they launched the alarm system improvement effort, they finally had the data to demonstrate how severe the problem of alarm fatigue really was.

Since then, their alarm system efforts have been informed by data at every step of the way, according to Cvach. The number of alarm conditions they recorded initially was astounding. In one 12-day alarm system analysis, there were 58,764 alarm conditions, or 350 alarm conditions per bed per day. Their pediatric intensive care unit (PICU) experienced 20,158 auditory alarm signals in 8 days for 17 beds. While the number of false or clinically insignificant alarm conditions is known to be high, the Hospital does not know the exact false alarm condition rate because the data extracted is numerical rather than from actual waveforms. In the case of 157 apnea alarm conditions, 90% were thought to be false.

Cvach says that the all-time noisiest units were their ICUs. Before improvement efforts, the average number of alarm conditions per bed per day in one ICU unit

At a Glance
Subject: Johns Hopkins Hospital
Location: Baltimore, MD
Size: The Johns Hopkins Hospital is a 1,051-bed teaching hospital located in Baltimore, MD.

What was intended to be a short-term task force has now become a full-fledged hospital committee that in many ways is still only beginning its work. Its members know how difficult the alarm systems problems can be, and that resolving those problems will require a continuous, hospital-wide, multi-pronged effort.
was 771. “They had all of their monitor parameters set tight and everything was on,” she says. “They thought they were working in everyone’s best interest, but we have shown that frequent alarming causes desensitization due to a “cry wolf” effect,” says Cvach.

Felix Guzman, RN, works in one of the noisiest units. He says that the noisy environment made it difficult for the nurses to function. “We even had central monitors back-to-back, so you couldn’t identify where the noise was coming from,” he says. Judy Ascenzi, RN, a pediatric nurse, says that they discovered that most nurses don’t know all of the ways that the alarm system can be customized to individual patients. Both Guzman and Ascenzi are now on the alarms committee, along with representatives of most of the hospital’s monitored units.

The First Step: Accessing Data

In 2006, Cvach and Andrew Currie, Hopkin’s director of clinical engineering, headed up a quality-based safety effort in conjunction with a CUSP team, which stands for “comprehensive unit-based safety program” (see sidebar on page 6). They put together a small task force that began analyzing alarm systems using a quality improvement rapid cycle change approach.

“Our first challenge was learning how to analyze alarm system data,” Cvach says. “It took us two years to figure out how to extract the right data.”

Currie was instrumental in helping to retrieve and interpret the alarm system data they needed. Luckily, he already had some experience with interpreting data feeds from bedside monitors. “Before the alarms effort began, a small group in our ICU did a tele-ICU evaluation project,” he says. They put in a real-time surveillance system to integrate data feeds at the bedside from multiple medical devices by combining a homegrown system and components from the Cardiopulmonary Corporation. “We were suddenly seeing unfiltered data from our GE monitors and we saw an unbelievable number of alarms,” he says. By observing the alarm condition patterns, they identified that many of the conditions were clearly false—for example, apnea alarm signals coming from patients on ventilators. Experience with this system drew their attention to the high volume and the inaccuracy of alarm conditions coming from their monitors.

Adam Sapirstein, MD, a patient safety expert and physician in the ICU, was involved in the pilot project. “It could have been one full-time person’s sole job to just respond to all of those alarms,” he says. To him, the patient safety implications of so many false alarm conditions were clear.

At the same time, Cvach and the CUSP team were focusing on the number of alarm conditions the nurses were encountering in their unit, which she says were “astronomical.” She worked with Currie to access the data, and a valuable partnership was formed.

“You need quantitative data to evaluate

**RECOMMENDATIONS**

**Document Baseline Alarm Conditions. At Johns Hopkins, the conditions were:**

- 58,764 alarm conditions, or 350 alarm conditions per bed, per day in 12 days
- 20,158 auditory alarm signals in 8 days for 17 beds in the PICU
- 157 apnea alarms, 90% were thought to be false
- 771 alarm conditions per bed, per day on average in one ICU

**Recognize the Contributing Conditions. At Johns Hopkins, the conditions were:**

- Alarm parameters were not set to actionable levels
- Alarm thresholds were set too tight resulting in too many false positives
- Staff working in large clinical units did not have clear accountability to respond to alarm conditions
- Patient rooms with closed doors made it difficult for staff to hear alarm signals
- Too many duplicate alarm conditions desensitized staff to alarm signals
- Lengthy time-lags between installation of devices and staff training on those devices did not allow for staff to become accustomed to the auditory alarm signals of new equipment.
the applications of alarm system management in hospitals,” says Currie. “Our initial efforts to generate data were very basic.” The GE monitors they used had a pager system that ran off of a local area network, he says, and a server listened to messages from the monitors and kept a log when it sent messages to pagers. “I began looking at that log and tracking the changes that our alarm group instituted to measure the success of our efforts,” he says.

Getting at the right data also took some work. When Cvach gets alarm data download from the clinical engineering group, she cuts the data down from 29 fields to 6, including such key data as the bed number, why the alarm signal sounded, and how long it sounded. Plus, the sheer number of parameters monitored is huge. “Every physiological monitor on every patient generates lots of data,” she says. “For example, we had to fine-tune 315 separate parameters for the monitor default parameters.”

“Once we saw a download, we began to understand how many alarms were occurring on the units,” says Cvach. They decided to use the average number of patient alarm conditions per bed per day as the key metric that would guide their efforts. That metric has proved useful and is still used today to evaluate improvement efforts. Whenever alarm system changes are implemented, they first record baseline alarm condition data and then measure changes to that key metric as the improvement efforts moved forward. Using that monitor data, Cvach was able to identify that a huge portion of the alarm conditions were low priority, inactionable “nuisance” alarms. “And even many of the true alarms were not clinically significant,” she says.

Cvach, Sapirstein, Currie, and the alarms task force eventually joined forces to tackle the alarm system problem on several fronts. Their goal: to eliminate as many nuisance alarm conditions as possible and quiet the cacophony of alarm signals coming from monitors, infusion pumps, ventilators, bed exit systems, and the myriad other devices that beep or buzz and combine to make hospitals anything but the quiet, healing environments they were intended to be.

**Focus on Alarm Settings**

The original task force started out by conducting mini-experiments to address alarm system problems, says Cvach. A first project was to implement safety checks on alarm settings. “A charge nurse would come in and ask the clinician, ‘Did you set your alarms properly?’,” she says.

This effort heightened the focus on default alarm settings, so the group began experimenting with adjusting default alarm settings and the effects of those adjustments on safety, noise levels, and that key metric of number of alarm conditions per bed per day.

“Our approach with alarm management is that less is more,” says Currie. Clinicians get desensitized from all the noise, so we are trying to institute as much control as possible, enable only actionable alarm conditions, and set aside alarm

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**RECOMMENDATIONS**

**Take the First Steps:**

- Understand the problem and state your goals, e.g., “To eliminate 30% of alarm conditions throughout the hospital.”
- Share your goals with hospital staff, including clinicians, administration, clinical engineers and biomed technicians, and other key staff.
- Recognize the problem as institutional wide.
- Recognize the resolution of the problem as long-term and on-going.
- Get the support of your administration to achieve your goals.
- Engage a multi-disciplinary team to study and address the problems. Include nursing staff, clinical engineers, biomed technicians, patient safety officers, device vendors, and others.
- Conduct analysis of the problem - access the right data and know how to extract it – identify key data such as (but not limited to) bed number, purpose, and timeframe/length of alarm condition.
- Conduct a Fault Tree Analysis to understand the failures to respond to critical physiologic alarm conditions in a timely manner.
- Identify a key metric, e.g., average number of alarm conditions per bed per day.

**Food for Thought**

Do you know your hospital’s true false alarm rate?
conditions that aren’t actionable. Patients and staff need a quiet environment. We are trying to reserve the noise for the most important events.”

The group found that reliable data on appropriate alarm settings is scarce. So, the task force launched an alarm setting effort, led by Sapirstein and Cvach, to revise default alarm settings unit by unit, in all monitored units, to actionable levels. This monitor alarm task force is also charged with standardizing practices throughout the hospital and developing cardiac and physiological alarm system policy.

To reduce the alarm signal burden, Sapirstein and Cvach worked with the nurse and physician leaders from each unit to make “very modest” changes to the default alarm settings to about 300 alarm system parameters and limits, Cvach says. They 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.

“Going unit by unit was very helpful,” says Sapirstein. “Hopkins exists as a multi-cellular organism; settings that may be good in one unit may not necessarily work in another. A ‘one size fits all’ directive would have been met by protest.” He says that explaining the alarm system problem and their proposed approach to the unit leadership got them on board. “Plus, we had the data to show results” he adds. “Showing a 30% reduction in alarm conditions by making simple, safe changes led to great buy-in.”

Once again, the key to the effort was data. They provided the data to the unit managers and worked with them to develop a plan for improvement, focusing on the key metric of the average number of alarm conditions per patient per day. Sapirstein and Cvach acted as facilitators, guiding the clinical units in the process. “Alarm-by-alarm, we showed them what the alarm condition is, its priority, and our suggestions,” he says. Most often, their suggestions were adopted. “In rare occasions, units wanted to keep their alarm settings to increase their vigilance; we let them, even though they probably didn’t benefit from them.”

“Ultimately, the clinical managers made the decisions,” says Cvach. “Our role was to highlight the problem and help them develop possible solutions.”

To do this, they started with their baseline alarm data and sorted through it, parameter by parameter, to customize the default alarm settings to the unit. “We typically had a 20-page document in each unit listing parameters and would sort through them one at a time,” says Cvach. “We would ask, ‘When this alarm goes off, what do you do?’ If their answer was that they do nothing, we would most often turn off the sound and move it to a visual message.”

Judy Ascenzi, the pediatric nurse, headed up the parameter right-sizing effort for the pediatric units. In those units, they would develop customized profiles for five different patient types, grouped by age and size, which meant wading through a 100-page document of parameters for every unit. Ascenzi says that the cooperation of the monitor vendor in fine-tuning the settings was essential in this effort. “During this process, we set up five different age groups with their own defaults. The more we pushed the vendors, the more we got. The vendor was at the table, and let us learn what we needed to know.”

They began by making modest default alarm settings changes to focus on actionable alarm conditions, differentiating between visual and auditory alarm signals and adjusting parameter limits. Their goal was to reserve auditory alarm signals for actionable, high-priority alarm conditions. They made the changes incrementally, monitored the data as the changes were implemented, and finally compared the pre- and post-change data.

On six units, they achieved reductions in the average number of alarm signals per bed per day ranging from 24% to 74%. With weekly meetings, it took Cvach and Sapirstein about ten months to work through the process with all of the monitored units.

The CUSP Program

The Hopkins alarm improvement effort was launched under the Comprehensive Unit Safety Program (CUSP), a five-step program designed to change a unit’s workplace culture—and in so doing bring about significant safety improvements—by empowering staff to assume responsibility for safety in their environment. This goal is achieved by providing employees education, awareness, access to organizational resources and a toolkit of interventions. Its five steps include:

1. Train staff in the science of safety
2. Engage staff to identify defects
3. Senior executive partnership/safety rounds
4. Continue to learn from deficits
5. Implement tools for improvement.
Parallel Efforts

Right-sizing the parameter settings led to questions of risk, workflow and technology, so those were also areas of focus as each clinical unit’s alarm signals were being evaluated.

Specific questions that Cvach and Sapirstein would ask clinicians on each unit included, “If an alarm condition occurs, how do you hear the alarm signal?” They were trying to decide the time it takes an alarm condition to roll to a backup clinician is correct.

They would also ask, “What is the risk if a device creates an alarm condition?” Each alarm condition was analyzed in terms of its clinical significance and rated by priority and risk. For example, an extracorporeal membrane oxygenation (ECMO) machine would be rated very high priority but very low risk, because a caregiver is constantly in the room with the device. On the other hand, a ventilator would be rated high priority plus high risk, in need of a secondary, backup notification system. To date, they have evaluated priority and risk for cardiac monitors and ventilators across the hospital, and plan to do so for other devices.

Other early efforts included testing new equipment; assessing alarm system management alternatives like using a monitor watch group; developing new policies; creating and assessing training efforts; and considering new alarm technologies.

The concept of using a monitor watch—a centralized unit where trained operators watch monitor waveforms 24x7 and rapidly alert caregivers to problems—was thoroughly evaluated. The committee recommended that such a system be adopted, but it was never rolled out hospi-

Focus on Alarm Parameters:
• Implement safety checks on alarm settings
• Revise default alarm parameters in each unit to actionable levels – recognize that settings may vary from one unit to another
• Implement revisions/changes incrementally
• Prioritize and differentiate between actionable alarm signals in each unit e.g., visual vs. auditory (recognize that settings may not be the same from one unit to another)
• Define alarm condition types e.g., false, true, nuisance, inactionable, etc. and assure that definitions are understood by unit staff
• Gather quantitative baseline data to evaluate alarm conditions
• Examine logs from the network that track alarm messages from devices in order to capture the quantitative data
• Observe alarm condition patterns and distinguish between alarm conditions
• Compare pre- and post-data to measure changes

Ask the Right Questions and Gather the Right Data:
• Where are the alarm conditions coming from?
  What is the bed number?
• Who is the patient?
• Why alarm signals are sounding - what is the cause?
• How long are alarm signals sounding?
• How many alarm signals are occurring in units?
• When an alarm signal goes off, what do you do?
• When an alarm goes off, how do you hear it?
• What is the average number of patient alarm conditions per bed, per day?
• What is the workflow of a clinical unit e.g., backup notification, nurses per unit, assignments, etc.?
• What is the clinical significance of an alarm condition? - Determine high/low priority alarm conditions along with high/low risk alarm conditions.

RECOMMENDATIONS

Food for Thought

Getting to the right data requires time and effort on the part of the clinical engineering and the clinical staff. Do you have buy-in from the hospital staff to extract and analyze alarm system data and to modify alarm system parameters?
tal-wide due to prohibitive expense and lack of data that such watches are more effective than less costly approaches. Currently, only the progressive cardiology care unit (CCU) and surgical intensive care unit (SICU) use a unit-based monitor watch.

Various other technologies have been evaluated and adopted to varying degrees to ensure that caregivers receive notification of alarm conditions. Hallway waveform displays with continuous split screens that show caregivers all of their patients on one monitor are in use, as well as monitors that allow caregivers to view one patient’s data from another patient’s room. In addition, wireless notification devices (pagers) have been implemented in some units that allow closed-loop communications and escalation of alarm conditions to backup caregivers. “For high-priority alarm conditions, redundancy is important. Our units need multiple ways to assure alarm signal audibility,” says Cvach.

No one technology works in every unit across the hospital, and few of the technologies are perfect, says Cvach. “Monitor watchers appear to be beneficial, but we found no well-defined studies or metrics that demonstrate that,” she says. “Split screen monitors are useful for fully monitored units and where patient-to-nurse ratios are 2:1.” The other technology shortcomings include:

- Waveform screens in hallways can increase noise in hallways and don’t address lower priority alarm conditions.
- With mobile wireless devices, caregivers need a waveform to provide clinical context for the alarm condition.
- View on alarm/Auto-view on alarm condition, where one patient’s data can be viewed from another patient’s room, increases noise at the bedside. Plus, the split screen can be confusing, and this technology does not address the lower-priority alarm conditions.

Lower-tech equipment has also received scrutiny for its contribution to alarm system problems. When Cvach noted a large number of system warning alarm conditions related to electrode leads, she decided to conduct a 24-hour electrode change pilot in two units. The electrodes were changed daily by the clinical staff who were assigned to perform this task at a specific time of day.

**Great Progress**

The original alarms task force that was intended to meet only for a short time is still going strong 6 years later and has evolved into the hospital-wide Alarms Management Committee, which includes about 25 people and meets monthly. It has been deemed so important that in early 2012, it became a medical board subcommittee.

Its achievements have been impressive. For example, the number of alarm signals

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**RECOMMENDATIONS**

**Work with Clinical Units:**
- Share the goal with clinical unit managers
- Share the data with the unit managers, sort through the data with them
- Work with unit managers in developing a plan for improvement focusing on key metrics of the average number of alarm conditions per patient per day
- Highlight the problem and work with unit managers in making decisions throughout the process
- Create new training programs on alarm systems for staff and assess these programs regularly for effectiveness

**Take Other Important Steps:**
- Test new equipment to make sure that alarm settings are set according to hospital needs – technologies are not perfect
- Realize that no one technology works in every unit across the hospital – consider more than one alarm signal notification technology
- Assess alarm system management alternatives, e.g., user-based monitor watch group
- Develop alarm system management policies
- Consider new alarm signal technologies, e.g., wireless notification devices/pagers, split screen monitors
- Change electrode leads regularly
- Conduct small tests of change
per bed per day on the noisiest unit, an ICU, have been cut in half. And more importantly, the nurses are benefiting from the changes.

“Now, when something generates alarm signals, it’s more likely to be a true alarm condition,” says Felix Guzman, a nurse on the intermediate care unit. “We are paying more attention to the alarms that do sound. If we don’t adhere to the alarm system policies, we learn by being inundated with alarm signals.” Plus, he says, they have seen fewer patient safety incidents after resetting the parameters. “People are more aware and will respond to alarm signals more quickly.”

“We have learned how to measure alarm data, and how to develop policies for when to put a patient on or off monitoring. We have learned what we didn’t know,” says Judy Ascenzi, the pediatric nurse. “And nurses are noticing a difference in sound levels. When we initiated disposable patient leads, we noticed a huge improvement.”

Even for Adam Sapirstein, the doctor who spearheaded the alarm setting effort, the changes were surprising. “In my own unit, on the day we implemented the alarm changes, I asked, ‘Why is it so eerily quiet?’ I had forgotten that we had just adjusted the alarm defaults!”

He says that in terms of patient safety, the results are impressive. “We have gone unit by unit to assure ourselves that the data are solid. We have also checked back with clinicians to see if new parameters resulted in missing clinical events. The results are telling: Since instituting the setting changes, we have never had one event fall through the cracks.”

Still a Long Way to Go

And yet, for as far as the team at Hopkins has come in improving clinical alarm system safety, they all recognize that there’s still a long way to go.

Fundamental change is needed, says Andrew Currie. “Everyone is scared. They are used to noise, because it means something. When things are quiet, something is wrong. In our simulation center, clinicians have actually asked for noise levels to be present during code blue simulations exercises because it is more realistic and makes them more comfortable.”

“In reality, we’ve been simply rearranging the deck chairs for a number of years,” says Currie. “After we make a change, things start migrating back up; we need to be able to sustain the improvements. While we

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<th>MPCU Daily Electrode Change</th>
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Table 4. Comparison of alarms for Medical Progressive Care and Cardiology Care Units pre/post daily electrode change pilot.
have seen some sustained improvements, going from 500 to 200 auditory alarm signals per patient per day, that is still way too many. Alarm signals are still at a level where they overwhelm people. The bottom line is that single parameter alarm conditions are simplistic and subject to artifact. Despite our best efforts to get alarm conditions where you want them, we still get way too many alarm conditions.”

Everyone agrees that multi-parameter “smart” alarm conditions are badly needed. They are trialing different systems that capture data and use a rules engine customized by clinicians to integrate that data, alarming only when necessary. “These technologies still aren’t where they need to be,” says Sapirstein. The Armstrong Institute, a safety initiative within Hopkins, is working with Lockheed Martin to do simulation testing of alarm systems so they don’t have to be tested on live patients.

Cvach reports that their focus has shifted away from rescue alarm conditions and toward developing better predictive systems. “Originally, our goal was to silence as many alarm signals and get as many people off monitors as possible,” she says. “Now, our goal is to develop better predictive multi-parameter monitors that can flag declining states before they become emergencies.”

The goal is to use negative trends in vital signs to generate predictive alarm conditions. “We are looking for a good system that will allow us to pull in multiple parameters and help us identify patients in distress before they progress to the point of generating rescue alarms, which are either false or too late to help the patient,” says Cvach.

So far, no end is in sight for the alarm management committee. The good news: “In the end, people are recognizing this as a serious problem and are embracing the changes,” says Sapirstein.

Food for Thought

To move toward predictive alarms and away from rescue alarms, the focus needs to be on trends, not numbers. To do this, you will need a remote waveform and integrated, multi-parameter monitoring system. Is your hospital looking at this as a potential patient safety solution?

Construction of a new clinical building has given the Johns Hopkins team the opportunity to evaluate and implement cutting-edge alarm system technologies that they hope will address many of their alarm system challenges—without creating entirely new ones.
FINAL RECOMMENDATIONS

• Sustain the improvements – Don’t migrate back to where you started
• Make your alarms team a permanent part of the hospital-wide management team
• Meet on a regular basis
• Measure alarm signal noise in units before and after making changes and conduct follow-up and regular assessments of alarm signal noise

Work Toward:
• Waveforms that can be sent to notification devices with alarm text messages
• Multi-parameter alarm condition algorithms to reduce frequent false positive alarm conditions
• Alarm system logic algorithm that increases the urgency of the alarm condition based on the number of times the alarm condition has occurred
• The capability to access visual message alarm signals in patient alarm history
• Timely physiologic monitor upgrades to match technology improvements in freestanding devices
• Better understanding of all of the default settings and the impact of each.

Contact Information:
AAMI Foundation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203
Phone: (703) 525-4890
Fax: (703) 276-0793
Email: slombardi@aami.org
www.aami.org/foundation

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