Framework for Alarm Management Process Maturity

James Welch, Michael Rayo, Benjamin Kanter, Tandi Bagian, Katrina Jacobs, Hassan Shanawani, Rory Jaffe, Marlyn Conti, and Lynn Razzano

Editor's note: The AAMI Foundation's National Coalition for Alarm Management Safety developed this framework for medical device alarm management. This article is intended to guide stakeholders in developing sustainable solutions and to serve as a foundation for discussions with hospital executives, healthcare technology managers, patient safety officers, and risk managers. The framework is not intended to be prescriptive but rather a guide for continuous improvement efforts to reduce nonactionable alarms of all types originating from medical devices.

The purpose of medical device alarms is to "redirect attention from something that is less important to something that is more important."[1] Alarm signals (hereafter called alarms) are meant to warn clinicians of potentially hazardous events that should be addressed immediately. Unfortunately, high rates of false and nonactionable alarms have made it difficult for clinicians to effectively redirect attention to truly hazardous events.

Alarm fatigue occurs when clinicians are overwhelmed by alarms to the point that they become desensitized to hazardous events. Alarm fatigue continues to be a major patient safety challenge. Although organizations have mobilized to address this complex socio-

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technical problem, there have been only anecdotal and marginal improvements in reducing nuisance alarms.[2,3] ECRI Institute consistently and repeatedly reports alarm management–related issues as the number 1 or 2 patient safety hazard.[4] In 2011, the Association for the Advancement of Medical Instrumentation (AAMI) and the Food and Drug Administration (FDA) convened an alarm summit to address the challenge. The spirit of the summit was captured by Mary Logan, AAMI president and CEO: "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."[1] Soon after the alarm summit, the AAMI Foundation formed the AAMI Alarm Steering Committee, which formed the National Coalition for Alarm Management Safety in 2014.

The AAMI Foundation is working with a number of patient safety and professional organizations (i.e., The Joint Commission [TJC], ECRI Institute, American Association for Critical-Care Nurses, American Hospital Association, Department of Veterans Affairs, National Center for Patient Safety, American College of Clinical Engineering, Healthcare Technology Foundation, National Patient

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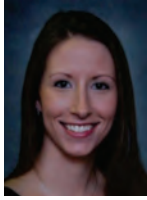
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Safety Foundation), researchers, and clinicians to make patient care environments safer through a more rational, evidence-based approach to alarm management. In June 2013, TJC announced National Patient Safety Goal (NPSG) 06.01.01, "Improve the safety of clinical alarm systems," which became an accreditation requirement on Jan. 1, 2014. The NPSG is being implemented in two phases. The first phase, which took effect on Jan. 1, 2014, focused on awareness of the patient safety risks associated with alarms, specifically making alarm safety a priority and identifying the most important alarm signals to manage. The second phase, effective Jan. 1, 2016, introduced requirements to reduce risks, including the development of policies, procedures, and internal education.[5]

Although the AAMI Foundation (**www.aami.org/thefoundation**) is disseminating tools and information for healthcare providers to meet the NPSG, the challenge facing hospital leadership goes beyond complying with the NPSG. It extends to developing a sustainable management program that addresses the patient safety issues posed by alarm fatigue.

The broad spectrum of medical devices with alarm capabilities is widely distributed throughout the environment of care. No one department represents all users. Alarm settings for one clinical area may be suboptimal for another. Multiple internal stakeholders, each with their own requirements, must be considered.

Alarm management is a component of a much larger initiative for hospitals to become high-reliability organizations (HROs) similar to commercial aviation, petrochemical plants, and nuclear power operators. For hospitals to achieve the status of HROs, leadership must be committed to achieving zero patient harm, a sustainable culture of patient safety must exist, and effective process improvement tools must be in place.[6] TJC has defined four stages of HRO maturity: beginning, develop-

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ing, advancing, and approaching. TJC also defines a fifth stage (arriving), but no hospital has achieved this goal. Major sociotechnical and cultural differences exist between hospitals and existing HRO models because of the unique relationships among healthcare providers, clinical support staff, and patients.[7] Organizational resilience (i.e., the ability to respond and adapt to adverse events and near misses) is a trait common to HROs. HRO principles are found in other maturity models, notably the Capability Maturity Model (CMM).

TJC does not specify how to achieve patient safety goals related to alarm management, neither does it endorse a specific process or model. This article provides a proposed framework for building an enduring solution to alarm management based on the CMM.

We have chosen the CMM because it provides a focused approach to technical challenges while maintaining the goals and principles of HRO for hospitals. The optimization of when alarm signals are generated is governed by how institutions determine, apply, manage, and measure the effectiveness of the alarm settings embedded in medical devices. These attributes of alarm settings are determined by institutional process and policies.

We look to this model to guide clinical stakeholders on their alarm management journey. Improving alarm safety cannot be an activity performed once and then assumed to be done. As new equipment, users, and environments are introduced in clinical care settings, the ability to reevaluate how alarms summon clinicians to the bedside needs to be part of a sustainable solution. This is an important and critical exercise, to be viewed as a path for continually improving the chances that alarms will appropriately signal human engagement.

By considering the state of the clinical organization in terms of capability maturity, we provide a consistent roadmap that organizations can use to chart their progress.

Elements of the CMM were specifically chosen so that increased capability would be a strong predictor for improved patient safety. Increased maturity requires safety experts, clinicians, clinical engineers, and vendors to be focused on the common goal of improving patient safety. This framework allows an organization to reevaluate process, technology, and training as new technologies, environments, or processes are introduced.

CMM

The CMM was developed between 1987 and 1997 at Carnegie Mellon University by the Software Engineering Institute (SEI).[8] At the time, the Department of Defense was facing challenges with the reliability and schedule predictability of mission-critical software development. It discovered that the maturity of the organization to conduct change management under a disciplined framework was what enabled success. SEI further recognized that the change management process could be modeled as a series of maturity steps. As the organization transitioned to higher stages, greater quality and predictability was achieved. The CMM Index (CMMI) was created to generalize the CMM process. CMMI has been broadly adopted by the U.S. military and by international manufacturing, software, and services corporations with well-vetted audit tools. Organizations are certified at various stages by independent certification authorities. Figure 1 shows the five levels of CMMI.

Central to the success of CMMI is the order in which maturity levels are achieved. Early maturity levels build the foundation for organizational learning, allowing core competencies in alarm management to be further developed. Organizations that adopt CMMI first assess the level of their current process, then plan initiatives to mature to higher levels. The timing to transition from one level to the next is determined by the complexity of the organizational challenge and the scope of the project.

Clinical Alarm CMM

Figure 2 builds on Figure 1 by including TJC maturity stages for an HRO. Organizations can establish their current level through self-assessment, then progress through a
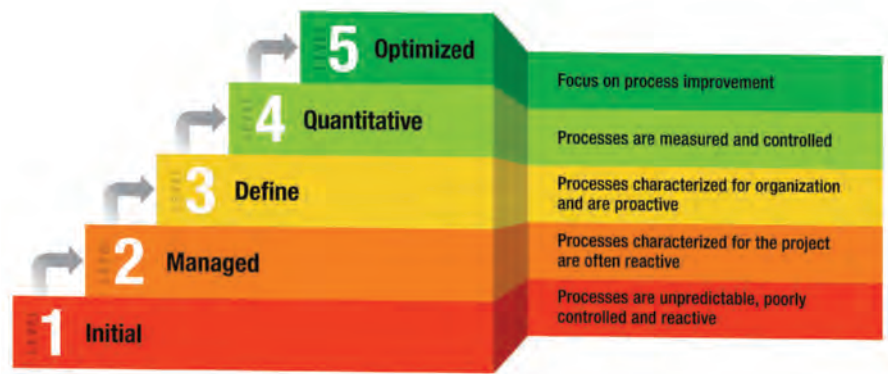

Figure 1. Characteristics of the five levels of the Capability Maturity Model Index

logical sequence as organizational skills and new processes develop. As the organization matures, the culture of patient safety is both enhanced and sustained.

The maturity levels are defined by the capability of the organization to systematically address alarm safety hazards that contribute to avoidable events. Each level defines activities that promote organizational learning rather than specific technical results, which is a core principle of high-reliability science. During level 2, learning starts at the executive level, where policies are developed, expectations are set, and resources are provided. This sends a powerful message to the entire organization that the norm of alarm fatigue is unacceptable and departments are empowered to find solutions. The learning continues in level 3 during the completion of the pilot project, where evidence-based metrics are created. The transition between levels is an iterative process consistent with continuous quality improvement. Learning from activities at various levels may result in revisiting decisions made in earlier levels. For example, many hospitals have a policy that does not allow nurses in non–intensive care unit (ICU) settings to change alarms without obtaining an order from the physician

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Figure 2. Clinical Alarm Capability Maturity Model

provider. The current policy comes from governance (level 2). Results from a pilot on a general care floor may cause leadership to revisit this policy in order to achieve higher levels of capability performance.

The model does not involve a timeline. The first two levels are focused on aligning leadership. Objective and repeatable evidence that false and nonactionable alarm signals have been reduced is developed in levels 3 and 4. Level 5 is achieved when the institution has eliminated avoidable adverse events that were caused by medical device alarms or that could have been detected by the appropriate use of medical device alarm systems.

Each stage is broken down into more specific activities, including a summary of goals, examples of successful practices, and/or a list of the most prominent activities. These goals and lists are not meant to be prescriptive but rather to assist the organization in mapping its journey to eliminating alarm fatigue in all clinical areas and thereby improving patient safety.

Level 1: Unmanaged Process

Level 1 is present when processes are in an unmanaged state and ad hoc solutions to alarm management are attempted. An organization is at level 1 when it:
- Lacks organizational structure to address alarm management issues.
- Lacks formalized practices that effectively guide alarm setting and response behavior.
- Lacks data to support change management.
- Approaches alarm management in an ad hoc and nonrepeatable process.
- Has a high volume of nonactionable alarms for unknown reasons.

Organizations at level 1 demonstrate ad hoc approaches to alarm management. Reducing alarm fatigue often lacks evidence-based data. Changes in alarm settings are difficult to measure because they are pervasive and because capturing objective data is labor intensive. Clinical staff do not know how, or do not feel empowered, to make meaningful changes regarding alarm management. These organizations lack a communication structure for clinicians to provide feedback to clinical/biomedical engineers and information technology staff. Due to the lack of evidence-based data, changes often are made based on opinion. As a result, improvements are difficult to quantify and sustain. This stage often is identified as putting out rather than preventing fires.

Alarm signals occur from many medical and nonmedical devices. Manufacturers typically set default alarm values at the time of installation based on generalized risk assessments as part of their FDA clearance. These settings often are adopted by hospitals without consideration of other alarming devices in the environment of care. As a result, alarm sensitivity typically is set high. One study in an ICU setting reported that only 8% of the 2,942 alarms that occurred

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over the 298 hours of the study required a clinical intervention.[9] This makes the overall system vulnerable to a host of issues. The high rate of clinically nonactionable alarms predicts that the rate of response to all alarms will be approximately 8%, which is unacceptably low. The cacophony of alarm sounds results in a rise in environmental noise, which causes true alarms to go unnoticed. These sounds also can cause annoyance to both patients and staff. The high volume of noise impairs the healing process and leads to poor patient satisfaction scores. This state of chaos begs for a thoughtful approach that is integrated into existing workflows and clinical practice. Improving this condition requires policy and procedural changes, staff education, and leadership oversight. Otherwise, changes will either be unsustainable or new potentially harmful patient conditions may be created.

Organizations at this stage may be seen responding to single events, having different levels of response across nursing units, and using little oversight or consistency in protocols and procedures. TJC expects hospitals to take a coordinated and systemic approach to improving alarm management by developing policies and procedures to comply with the NPSG for clinical alarms. Reactive responses may address an immediate need but are likely to be insufficient to meet TJC NPSG requirements.

Level 2: Managed Process

Level 2 is evident when the organization has established an executive sponsor with an empowered committee that is devoted to improving alarm management and willing to test changes (pilot)t in a controlled manner. An organization is at level 2 when:

- An executive reporting to the CEO has been identified.
- An executive-level mission statement has been developed and communicated to the organization.
- A multidisciplinary team has been established with defined roles and responsibilities.
- A pilot project has been identified with defined scope.
- An environmental assessment of alarm sources has been completed.

- The pilot is well structured with defined inputs, outputs, and goals.
- Sufficient resources are provided to staff the effort.

An effective alarm management program requires engagement and commitment at all levels of the organization, starting with executive leadership. TJC recognized the importance of executive governance for alarm management with the requirement to "establish alarms (management) as an organizational priority." The executive sponsor plays an important leadership role, especially as the organization matures to higher levels. Mastering alarm management will require motivating stakeholders and managing change as the organization acquires new skills. The differences in environment of care among hospital settings require a generalized guidance that empowers working committees to address alarm solutions for specific areas. Drafting a basic charter early allows the organization to mature faster.

The environment of care for the pilot must include an inventory of all devices that generate alarm signals, how these devices are configured, and the prioritization of alarms in the context of which alarms require a timely response in order to avoid patient harm.

A one-size-fits-all approach to alarm settings for an entire hospital is not likely to work. Further, policies identifying the clinical staff who can change alarms may vary among hospital care areas. Alarm fatigue must take into account the patient population being served. Alarm settings for an ICU may not be appropriate for the recovering patient on a general care floor. For example, a low SpO_2 alarm of 90% saturation is appropriate in the operating room, where the anesthetist is carefully controlling patient oxygenation. The anesthesiologist can change alarm settings based on the patient's condition. However, in the general care surgical units, where nurses are not allowed to change alarms, a low SpO_2 alarm setting of 90% will create alarm fatigue because many patients, especially those with sleep disorders, naturally desaturate for short periods of time. These short

Hospital Alarm Charter: One Example

(Hospital name) is committed to providing a safe and healing environment for our patients and caregivers. We depend on medical devices to notify caregivers of an unsafe or undesirable condition. The Clinical Alarm Safety Committee, reporting to the (executive sponsor) will engage clinical, administrative, and technical stakeholders in developing procedures that optimize alarm behavior for each care area to ensure the highest level of patient safety.

desaturations should be noted for further indications of physiologic condition, but they are not urgently harmful events unless they persist for long periods of time. To filter these nonactionable alarms, many hospitals are migrating to a low SpO_2 alarm of 85% with an alarm delay.

The goal should be to standardize monitoring practices across similar clinical environments to ensure consistency of practice. (Note: Patient harm due to alarm fatigue can be caused by any medical device. We use monitoring devices in this article as an example, but the principles generally can

Optimizing alarm configurations for patient populations requires a multidisciplinary team. The organization, team membership, and authority of the team requires executive sponsorship; otherwise, recommendations may not be enforceable.

be applied to all alarming sources in the environment of care.) In particular, when a patient transfers from one care unit to another, alarm settings should be reviewed in the context of that individual's course of care. Optimizing alarm configurations for patient populations requires a multidisciplinary team. The organization, team membership, and authority of the team requires executive sponsorship; otherwise, recommendations may not be enforceable. A committee reporting directly to an executive staff sponsor ensures a coordinated and systematic process by which clinical alarm management systems are developed and deployed throughout the hospital.

The primary task of the team in level 2 is to identify a pilot clinical area and a plan for addressing alarm fatigue. Pilot projects are effective because the scope of the problem becomes constrained to a specific environment of care, allowing change management to be localized and controlled by the team. For the purpose of this article we define a *true alarm* as an alarm that requires an immediate response to reverse a deteriorating patient condition that could result in patient harm, a *false alarm* as an alarm caused by signal artifact, and a *nonactionable*

alarm as a true alarm that does not require an immediate intervention to avoid patient harm. *Nuisance alarms* are the combination of false and nonactionable alarms. The goal of level 2 is to develop a plan to reduce nuisance alarms without sacrificing the annunciation of true positive alarm events. The multidisciplinary team will require input from all user areas, then prioritize which areas will receive the greatest benefit from a reduction in nuisance alarms. The chosen pilot requires strong local nursing leadership and a willingness to champion change management. The primary purpose of the pilot area is to develop alarm-reduction strategies and process. The staff and leadership must agree that the current status quo is unacceptable and agree to explore opportunities to reduce nonactionable alarm events. The team must identify alarms that contribute the most to alarm fatigue. This can be done by surveying the bedside staff and encouraging open dialogue during the pilot. Vendors should be engaged to determine what data can be extracted from the medical devices generating the most alarms.

After a pilot area is identified, the committee creates a pilot plan with clinical staff. The pilot project is an opportunity to develop repeatable processes and actions that are transferable to other clinical areas. Each task force member plays an essential role in identifying the metrics and outcomes for success. Clinical team members define the metrics for acceptable nuisance alarm reductions. Technical members identify limitations inherent in the existing medical devices and a mechanism to extract alarm data from the devices. Administrative members provide the necessary resources to empower and support the team to translate the findings into new or modified hospital policies.

Determining which alarms are essential and which can be disabled can be a controversial discussion. One can argue that all alarms are important and should remain active. However, not all alarms are time sensitive, requiring immediate or even urgent corrective action to avoid patient harm. An alarm signal can be physiologic or technical; it can be audible, visible, or both. The technical alarms are primarily used as workflow aides (e.g., low battery) and often

alarm at the same level of priority as life-threatening alarms (e.g., ventricular fibrillation). Changing alarm priorities can reduce overall alarm occurrence substantially. After agreement on prioritization is achieved, a risk assessment should be conducted. A failure modes and effect analysis of reported incidents may help to identify the most important actionable alarms. Improved training and procedures may allow some alarms to be disabled, moved to a lower priority, or only visually annunciated.

The completion of the pilot yields a set of metrics that allow the team to make informed decisions on changes to alarm settings. The emerging measure of alarm behavior is the number of alarms per patient (room) per day. This allows the team to assess the overall alarm burden experienced by the nursing staff and allows comparisons among nursing units with different nurse-to-patient ratios. Alarm signals from individual medical devices can use the same metric, and the sum of all alarms becomes a measure of alarm fatigue. The team analyzes the reports and compares alarm distribution against the risk management assessment. Those alarms with low incidents and low risk scores become candidates for disablement or lower priority configuration. Alarm patterns may also support policy changes such as who has the authority to set or modify alarm parameter settings. The hospital executive clinical leadership is made aware of the findings with recommendations for changes. Once agreed upon, the changes are implemented, users are trained, and the process is repeated. The next cycle of data analysis confirms quantitative improvements in alarm performance. Each iteration is compared against end-user experience to confirm the changes have not compromised patient safety. The full engagement of clinical staff is important to this process. The team must be vigilant that true and actionable clinical events are not lost with each cycle of changes. Eliminating alarm fatigue is not a well-defined end point. Staff surveys will inform the team when alarm incidents are at the appropriate levels for the environment of care.

In cases where remote alarm systems are available, additional filtering, routing, and

escalation strategies can be implemented. These systems allow routing of alarms directly to clinical personnel. Escalation schemes inherent in these systems allow alarms to be annunciated to additional clinical individuals if the alarm condition persists. These systems can only be effective if nuisance alarms are addressed. If properly implemented, these systems can reduce environmental noise and may reduce the dependency on monitoring technicians.

Level 3: Define Process
Level 3 is evident when the organization has completed a local pilot with objective evidence that alarms are appropriately controlled and the improvement is sustainable. An organization is in level 3 when:
- Objective data from a local pilot study demonstrates measurable improvements in alarm management through reduction of false and nonactionable alarms.
- A repeatable and sustainable system to collect and analyze alarm performance metrics is established.

Aspect	Description	Potential Measures
Sensory	Ability to detect and identify a harmful event among the cacophony of other alarms and background sounds in the environment	Volume (decibel level) relative to environment, tonal characteristics (e.g., variation in pitch, frequency, roughness), direct measurement of person's ability to discriminate among sounds
Information	Ability to unambiguously convey clinically actionable alarm events	Positive predictive value, area under receiver operating curve, discriminability between signal and noise, number of events or urgencies signified by a single sound (i.e., group alarms)
Attention	Ability to redirect attention to respond to an actionable event	Time required to redirect caregiver attention and correct an alarm condition and/or clinical event
Workload	Sensitivity to current workload and ability to support task prioritization	A measure of task reprioritization to respond to an alarm, percent of attention/time to fully understand alarm
Advisory	Ability to assess the severity of the alarm, integrate additional information (e.g., with electronic health record) and deliver the appropriate intervention	Proportion of correct clinical interventions, usability of the user interface/experience

Table 1. Descriptions and measures for cognitive aspects of human-alarm interactions[10]

- The methodology is refined so that it is generalizable to other environments of care.

When choosing and performing local pilots, selecting specific and objective measures in the observed alarms is important. Pilots do not necessarily need to be performed in patient care areas. Simulation laboratories are a good venue to test and refine alarms before deployment in patient care areas. In other cases, data capture and offline analytics can be performed to predict alarm behavior.

Regardless of the method of testing, measures that give an adequate picture of alarm performance in the pilot setting should be chosen. The cognitive aspects of human-alarm interactions (Table 1) should be considered, even if some are not ultimately represented in the final list of pilot measures. Otherwise, the pilot risks missing key indicators of the true performance of the intervention. For example, if false alarms are found to decrease, but in reality the alarms could not be heard over the background noise of the unit, subsequent expansions of the pilot into organizationwide implementation may fail.

Explicitly tying measures to these aspects ensures a more robust study of the effects of interventions being tested and follows an important principle of the science of alarm response: Alarms are not perceived individually in a vacuum but in the context of the current environment and their own past performance.[11] Correct clinical response to alarms often requires the integration of other data such as those found in the patient electronic health record. If using measures that are directly tied to one or more aspects described above is impractical, proxy measures can be used as long as it's understood that they are proxies and are analyzed as such. Examples of proxy measures are shown in Table 2.

Many medical devices capture alarm data, and vendors of these devices provide mechanisms for extracting these data. In general, using data gathered from alarm databases and self-report surveys can be effective if it is not feasible to use one or more robust measures. If multiple proxy measures are used together, or used with one or more robust measures, they can give powerful insights on current issues in the organization and the effectiveness of a particular intervention. For example, a systematic reduction in the overall occurrence of alarms, along with an improvement in the number of alarms that require clinical intervention, is likely to improve the measure of positive predictive value (PPV). An increase in PPV translates to a decrease in nuisance alarms and an improvement in workflow.

The most important outcome of level 3 maturity is the development of a pilot testing process that is repeatable and evidence based. Making improvement in one area without a repeatable process will make it difficult to transfer the learning experience to other clinical areas. Important elements to consider to ensure that pilot testing processes are robust and can be transferred to other clinical areas include:

- Primary goal of reducing false and nonactionable alarms, with secondary goals described.
- Concise description of the alarm problem, including rationale for why specific events require either audible or visual annunciation and what aspects of the interaction (Table 1) are affected. Priority can be determined by a combination of internal incident report review, current alarm data

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Measure	Robust Measurement	Proxy Measurement
Positive predictive value	Direct observation of false and unnecessary alarms requiring chart access, retrospective annotation of alarms using waveform values and chart review	Number of alarms per patient per day (gathered from medical device generated database), proportion of alarms resulting in corrective action and/or escalation of care
Time to understand alarm	Direct observation, time study (data will be numeric)	Self-report in survey (data will be categorical: low/medium/high)
Discriminability	Controlled study measuring proportion of alarms that are discriminable and identifiable	Self-report survey of overall alarm landscape in their setting

Table 2. Potential proxy measures

MEASURING ALARM EFFECTIVENESS
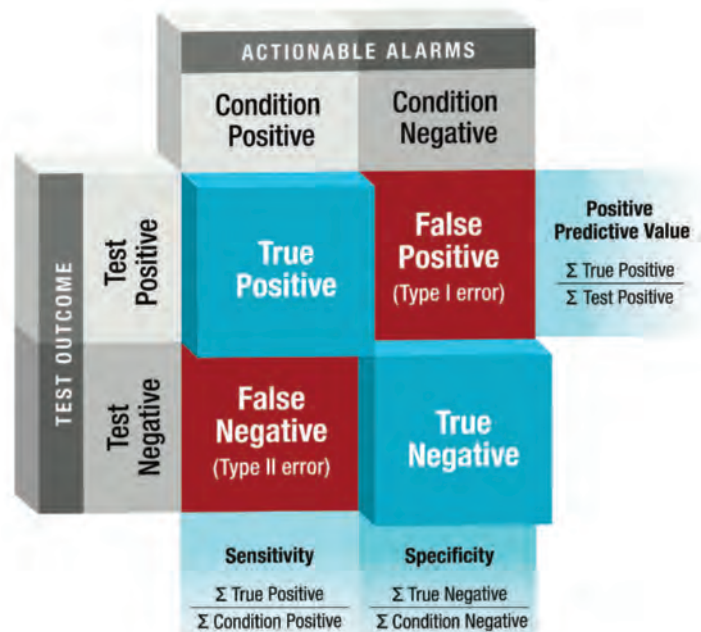
Sensitivity
A measure of the device's capability to detect a true, clinically-actionable event

Specificity
A measure of the device's capability to reject non-actionable events

Positive Predictive Value
A measure of the diagnostic capability to identify an actionable event

ACTIONABLE ALARMS

	Condition Positive	Condition Negative
Test Positive	True Positive	False Positive (Type I error)
Test Negative	False Negative (Type II error)	True Negative

TEST OUTCOME

Positive Predictive Value
$$\frac{\Sigma \text{ True Positive}}{\Sigma \text{ Test Positive}}$$

Sensitivity
$$\frac{\Sigma \text{ True Positive}}{\Sigma \text{ Condition Positive}}$$

Specificity
$$\frac{\Sigma \text{ True Negative}}{\Sigma \text{ Condition Negative}}$$

Figure 3. Relationship between sensitivity, specificity, and positive predictive value

extracted from the medical devices, and alarm literature review.

- Description of current response to targeted alarms (i.e., Are critical events being ignored? Is the response to alarms within a clinically appropriate range for the events being signified?).
- Selection of evidence-based measures to track the pilot's progress.
- Discovery of multiple possible solutions to the problem, including the introduction of new technologies, escalation paths, alarm policies, or training.
- Documentation of typical and unique aspects of pilot setting, including an inventory of all devices with alarms in the care area, their current alarm configurations, and their flexibility to changes in configuration.

Ultimately, a pilot is most successful when it generates quantitative data that alarms have been reduced without compromising patient safety. A combination of quantitative and qualitative data often will give objective evidence of the impact of the pilot. Data extracted from medical devices can be used for a before/after comparison of alarm performance. Survey data from clinical users provide a qualitative measure of improvements in the clinical environment. Improvement in both qualitative and quantitative data is a clear indicator that nuisance alarms have been reduced. Several iterations of alarm configuration changes often are required before final settings are determined. Iteration also allows the team to refine and improve alarm metrics. The continuous improvement outcome is a process that can be extended to other patient care areas and new environments of care.

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Using PPV to Measure Alarm System Performance

The effectiveness of alarm performance can be expressed in the same way diagnostic tests are reported. Figure 3 shows the relationship among sensitivity, specificity, and PPV. Sensitivity and specificity are

traditional reporting measures of test performance. However, PPV best reflects the clinical utility of the alarm system, as it relates true actionable events to the total number of alarms. A high PPV represents low incidents of false and nonactionable alarms. The number of alarms per patient/bed per day provides an indication of the prevalence of alarms, as well as the nursing workload. For example, a medical device that generates 10 alarms per patient per day may be tolerable in an ICU environment where there is one-to-one nurse-to-patient ratio. However, in a general care area where nurses are assigned six patients, this same medical device would generate 60 alarms to the assigned nurse. Lowering the overall incidents of alarms without generating adverse events (i.e., maintaining high sensitivity without sacrificing specificity) improves PPV.

Alarm Performance Metrics

The goal in optimizing alarm settings is to pilot-test changes and their impact on patient safety in a deliberate manner that is transparent, is safe, and meets peer review expectations. Currently, no standardized metric measures alarm performance and no literature identifies when alarm fatigue occurs. Determining at what point nonactionable alarms are sufficiently reduced to facilitate the desired alarm response requires measures. Without objective evidence, the alarm management team will have difficulty determining baseline alarm performance or improvements. Further, translation of the pilot experience will be difficult.

Most medical device systems have digital outputs that report alarms, with varying degrees of fidelity. Those systems connected to a central server have a database or file that includes alarm data. Extracting data and developing reports are roles for the technical team members in collaboration with the medical device provider. Often, preconfigured reports and alarm analysis tools are available using third-party middleware systems. These reports aid the team in

determining which alarm types may be safely removed or reduced in quantity. Useful metrics from such systems include:

- Total rate of alarms.
- Rate and duration of alarms by alarm source.
- Rate and duration of alarms by event type (e.g., critical dysrhythmia, low oxygen saturation, technical alarms).
- Rate and duration of alarm by patient or room.

Alarm metrics allow the multidisciplinary team to make evidence-based recommendations for changes in standardized alarm settings. Changing alarm settings must be considered in the context of the impact on patient safety. The primary purpose of any alarm is a call to action. While many medical device alarms are true alarms, they do not necessarily require an immediate intervention to avoid harm. Often, nonactionable alarms can be reduced with no compromise to patient safety, simply through minor changes to alarm threshold settings. Some medical device systems also allow alarm delays for some or all parameters. Alarm delays allow improvement in alarm specificity without affecting a reasonable clinical response time. As smart alarms become available, these same measures can be applied to assess clinical utility.

Ideally, the recommended changes are compared against clinically actionable events. This can be a major challenge because the definition of clinically actionable events may vary among care areas and hospitals. Documenting actionable events for comparisons against device alarms requires a substantial resource investment. Therefore, an iterative approach of modest modifications with considerable clinical input is more manageable. For example, in non-ICU areas, adding a modest alarm delay of 15 to 30 seconds to the low SpO_2 alarm can substantially reduce the incidents of nonactionable alarms without compromising severe desaturation alarms.[12] The analytic results of the pilot along with the hospital alarm management policy provides objective evidence that the hospital

> **Often, nonactionable alarms can be reduced with no compromise to patient safety, simply through minor changes to alarm threshold settings.**

is addressing alarm fatigue and the program is sustainable, therefore meeting essential elements of the 2016 NPSG requirements from TJC.

Level 4: Evidence-Based Organization-Wide Management

Level 4 is evident when the organization has demonstrated the capability to expand pilot learning across the institution with consistent metrics reported routinely that indicate lasting improvements in alarm performance. An organization is in level 4 when:

- A repeatable alarm management process is established, including methods for:
  - Scaling alarm management solutions across the organization.
  - Disseminating, validating, and adopting new learning from pilots throughout the organization.
  - Developing unit-by-unit alarm reports that are reviewed by an alarms oversight committee or a hospitalwide alarm report.
  - Establishing continuous improvement methods with effective feedback to improve alarm management.
- Alarm performance metrics are established, reviewed, and refined based on organizational learning and best available evidence.
- Evidence is present that associated patient safety processes and outcomes are improving.
- Defined performance improvement interventions demonstrate nurse action on all actionable alarms and progressive decrease in nonactionable alarms.

An organization operating at level 4 alarm management is addressing the issues that come with scaling project-based pilots to enterprise-level programs. First, the team analyzes pilot findings. These steps include determining the success of the pilot compared with baseline data and determining what parts of the pilot system changes (e.g., policy changes, technology changes, training changes) should be implemented as-is or altered to account for differences between the pilot and other care settings. In addition, a level 4 organization will have established processes and capabilities for employee communication, training, and deployment. The primary purpose of the communication capability is to craft messages and use

Level 4 is evident when the organization has demonstrated the capability to expand pilot learning across the institution with consistent metrics reported routinely that indicate lasting improvements in alarm performance.

reliable communication channels to effectively reach a broader audience. The primary purpose of the training capability is to distill learning and knowledge obtained from pilots to create easily understood and consumable training programs. The primary purpose of the deployment capability is to coordinate all of the clinical and technology stakeholders necessary to build the final solution.

In addition to new processes and capabilities, the organization must curate a list of organizationwide alarm metrics. These metrics assess alarm performance across the organization, allowing for a more efficient selection, design, and implementation of new pilots. These metrics are most effective when they are empirically derived: from the pilots within the organization and from alarm management findings from other organizations. Metrics also can measure impact on the organization's process efficiency, resource management, or financial goals. Not all metrics will be applicable to all alarms or care settings, but as new metrics are found to be relevant in pilots, these metrics are added to the list along with the types of alarms and settings to which they are applicable. An example is reviewing the hospital policy for the use of telemetry. Many hospitals are reducing the use of traditional telemetry because many patients do not meet the American Heart Association (AHA) criteria. Literature suggests the expanded use of telemetry for patients not meeting the AHA criteria has proven not to be clinically or cost effective.[13,14]

The aforementioned level 4 requirements describe a healthy, enterprisewide alarm management process. However, the alarm management program also should be associated with improved clinical outcomes. These can include process outcomes, such as reduced false and nonactionable alarms or greater compliance with alarm management policies. They also include patient outcomes,

such as reduced patient harm associated with alarm technologies. Ideally, effective alarm systems will improve patient safety metrics. These elements frequently require a change in the culture of patient safety. Reinforcement by the executive team needs to be visible at every level of the organization. The relationship between alarm management and improved patient safety should be reinforced. The message needs to come from the top and communicated effectively throughout the organization.

The focus of level 5 organizations is directed toward improving patient safety as measured by outcomes. After false and nonactionable alarms are eliminated, the team can focus on metrics that improve key patient safety indicators consistent with high-reliability organizational science.

Level 5: Continuous Improvement/ Program Expansion

Level 5 is evident when the organization has demonstrated a sustainable culture of care where no patient is harmed as a result of inappropriate alarm settings. Level 5 is aspirational. It assumes that the organization also is a recognized HRO. An organization is in level 5 when it is committed to continuous process improvement in the following areas:

- The entire organization is engaged at all levels, from the C-suite to the bedside, in eliminating harm due to inadequate alarm management.
- The hospital system is engaged in anticipating alarm management vulnerabilities in the system and proactively engaged in solutions.
- The hospital actively identifies settings with strong performance and looks to replicate what is working throughout the organization.
- The organization actively identifies new challenges and looks for opportunities to improve alarm management methodologies and technologies.

Whereas the output of achieving level 4 is a sustainable and expandable process, the focus of level 5 organizations is directed toward improving patient safety as measured by outcomes. After false and nonactionable

alarms are eliminated, the team can focus on metrics that improve key patient safety indicators consistent with high-reliability organizational science. These improved alarm sets will allow earlier detection of potentially hazardous situations, allowing staff to respond before the patient safety system deteriorates to a severe state. Patient safety indicators should improve with an effective alarm management system, especially in environments where alarm fatigue is recognized. Examples of improved patient safety include:

- Reduction in failure-to-rescue events (defined by AHRQ as patient deaths caused by complications while in the hospital).
- Reduction in avoidable adverse events.
- Lower incidents in the escalation of care (e.g., transfer to ICU).
- Lower aggregate length of stay.
- Reduced activation of rapid-response system (RRS).

The reduction in RRS may seem counterintuitive. Initially RRS activations may increase as true-positive alarms are more frequently identified. As the organization matures, the deteriorating patient should be recognized earlier with appropriate intervention by the bedside staff. This scenario should lower RRS activations and potentially transform the process.

Of note, although events like those listed above will decline, level 5 cannot just be about "chasing zero" (i.e., the elimination of adverse events). Safety is sometimes maintained in subtle ways—a nuance that must be understood to mitigate the risk of unintended consequences. This is a core principle of a high-reliability hospital. For example, increased rigidity in processes or procedures around prescribing and discontinuing continuous electrocardiogram telemetry monitoring may strip physicians and nurses of their ability to jointly tailor their care plan to patients at a specific point in time. It is essential that the team understand why such practices exist and whether a more appropriate substitution technology can be used. By understanding how clinicians communicate with each other and use technology, usually via direct observation, the organization can create interventions that institute best prac-

tices without compromising local practices.

Level 5 organizations exhibit an open environment in which all members can identify the active creation of safety and report real and potential events, especially the incidence of adverse events. Reducing false and nonactionable alarms also has an important secondary effect: a quieter patient environment. Patient satisfaction scores should improve if patients feel they are in a safe and healing environment. After nuisance alarms are eliminated, clinical staff can focus more time on the quality of patient care. Technology becomes an aid rather than a burden.

Reaching level 5 for alarm management safety takes a commitment by the entire organization. Leadership starts at the executive level through the empowerment of the alarm safety committee and provision of necessary resources. As the organization addresses more clinical environments, momentum builds within the institution. Reports can be collated at the enterprise level for reporting to TJC inspectors.

A level 5 organization focuses on integrating caregivers with the data and equipment systems, so that patients receive the best possible care. This includes the entire life cycle of each new device, from the prepurchase analysis to the determination that it should be retired. A level 5 organization will continuously ask the following questions throughout the life cycle:

- What types of personnel roles would interact with the device, and in what ways?
- What are the unique aspects of the different environments to which the equipment is exposed, and how would the environment be controlled to ensure optimal operations are sustained?
- What concurrent tasks might be performed while this equipment is in use?
- Are the devices, including their alarms, still appropriate given potential changes in requirements or environmental changes while the device is being used?

The organization holds regular simulations to ensure that the answers to the above questions have not changed over time. These simulations do not have to be expensive. They can range from walking through paper printouts in conference rooms or on the units to high-fidelity, data-driven exercises conducted in simulation labs.

A level 5 organization is committed to continuously learning about itself, anticipating unexpected combinations of patient, environment, task, and caregiver. Having a system to use what was learned and improve the alarm management strategy is critical. Ideally, these lessons learned will be shared with others, both within and outside the specific facility, so that others won't need to learn these lessons themselves as they discover combinations that weren't anticipated or are rare/hard to detect. Communicating and learning from what worked well, and why it worked well, will become as important to safe patient care as communicating and learning from what went wrong in the care system.

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Discussion

In its 1999 report, the Institute of Medicine estimated that 99,000 deaths occur per year due to medical error.[15] That equates to one death per 350 hospital admissions, many of which could be detected through effective medical device alarm systems. By comparison, commercial aviation has a safety record of 1.6 deaths per one million flights. Alarm fatigue is not in the lexicon of commercial aviation because of the systematic application of high-reliability science in all aspects of the commercial aviation culture.

The Clinical Alarm Capability Maturity Model is consistent with the principles of TJC's initiative for an HRO. It uses the same principles for process improvement and targeted tools. The model is untested and therefore a work in progress. We used examples presented in AAMI Foundation patient safety seminars on alarm management and the *Clinical Alarm Management Compendium*[16] to capture best practices and identify commonalities. The reports were

consistent in that successful teams involved strong executive support, leadership, a multidisciplinary team, and data-driven decisions. These successful experiences included a pilot, which allowed team leadership to coalesce and processes to evolve. This common framework can provide a roadmap for organizations that is consistent with high-reliability principles.

Conclusion

The Clinical Alarm Maturity Model is an outcomes-based framework that helps guide organizations in implementing multidisciplinary teams to improve patient safety by eliminating nuisance alarms while meeting the TJC NPSG for clinical alarms. By optimizing the PPV for clinically meaningful and actionable alarms through an evidence-based iterative process, nuisance alarms will be reduced and patient safety will be enhanced. ∎

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References

1. **Association for the Advancement of Medical Instrumentation.** Clinical Alarms: 2011 Summit Convened by AAMI, FDA, TJC, ACCE, and ECRI Institute. Available at: http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/2011_Alarms_Summit_publication.pdf. Accessed March 15, 2016.

2. **AAMI Foundation.** National Coalition for Alarm Management Safety: Monthly Coalition Meetings. Available at: www.aami.org/thefoundation/content.spx?ItemNumber=2004&navItemNumber=2685. Accessed March 15, 2016.

3. **AAMI Foundation.** National Coalition for Alarm Management Safety: Patient Safety Seminars. Available at: www.aami.org/thefoundation/content.aspx?ItemNumber=3108&navItemNumber=671#sthash.a5mNboSX.dpuf. Accessed March 15, 2016.

4. **ECRI Institute.** Top 10 health technology hazards for 2014. *Health Devices.* 2013;42(11):354–80.

5. **The Joint Commission.** The Joint Commission Announces 2014 National Patient Safety Goal. Available at: www.jointcommission.org/assets/1/18/jcp0713_announce_new_nspg.pdf. Accessed March 15, 2016.

6. **Chassin MR, Loeb JM.** High-reliability health care: getting there from here. *Milbank Q.* 2013;91(3):459–90.

7. **Bagnara S, Parlangeli O, Tartaglia R.** Are hospitals becoming high reliability organizations? *Appl Ergon.* 2010;41(5):713–8.

8. **Paulk MC, Curtis B, Chrissis MB, Weber CV.** Capability Maturity Model for Software, version 1.1. Available at: www.sei.cmu.edu/reports/93tr024.pdf. Accessed March 15, 2016.

9. **Tsien CL, Fackler JC.** Poor prognosis for existing monitors in intensive care unit. *Crit Care Med.* 1997;25(4):614–9.

10. **Rayo MF, Moffatt-Bruce SD.** Alarm system management: evidence-based guidance encouraging direct measurement of informativeness to improve alarm response. *BMJ Qual Saf.* 2015;24(4):282–6.

11. **Bliss JP, Gilson RD, Deaton JE.** Human probability matching behaviour in response to alarms of varying reliability. *Ergonomics.* 1995;38(11):2300–12.

12. **Welch J.** An evidence-based approach to reduce nuisance alarms and alarm fatigue. *Biomed Instrum Technol.* 2011;spring(suppl):46–52.

13. **Dressler R, Dryer MM, Coletti C, et al.** Altering overuse of cardiac telemetry in non-intensive care unit settings by hardwiring the use of American Heart Association guidelines. *JAMA Intern Med.* 2014;174(11):1852–4.

14. **Benjamin EM, Klugman RA, Luckmann R, et al.** Impact of cardiac telemetry on patient safety and cost. *Am J Manag Care.* 2013;19(6):e225–32.

15. **Institute of Medicine.** *To Err Is Human: Building a Safer Health Care System.* Washington, DC: National Academy of Sciences; 1999.

16. **AAMI Foundation.** Clinical Alarm Management Compendium. Available at: http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Foundation/Reports/Alarm_Compendium_2015.pdf. Accessed March 15, 2016.