HTM NEWS & VIEWS

The Complexity of Clinical Alarm Systems

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About the Author

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Healthcare technology management (HTM) is ideally suited to take a leadership role within healthcare organizations on the subject of clinical alarm systems, because technology issues are a major part of the overall alarm picture. In order to do so, they need to be an excellent knowledge source on the subject. If an HTM department is currently only marginally involved in clinical alarm systems, I strongly encourage it to use the information gained from this article to become part of the core team. Because the clinicians need to live with consequences of clinical alarms decisions on a daily basis, they should be the ultimate decision makers.

There has been a lot of attention given to the subject of clinical alarm systems since the 2011 Clinical Alarm Summit[1] was convened by AAMI, the U.S. Food & Drug Administration (FDA), The Joint Commission (TJC), the American College of Clinical Engineering (ACCE) and ECRI Institute. The AAMI Foundation's Healthcare Technology Safety Institute (HTSI) has spearheaded follow-up work on the issues raised by the summit, and has set up an online resource page at www.aami.org/htsi/alarms that is definitely the best and most complete collection of resources on the subject. If you are not familiar with this website, you need to be. If you haven't visited the site recently, you need to—additional resources and webinars are being added continually. Healthcare leadership's interest in alarm systems increased when TJC published a *National Patient Safety Goal*[2] paper on the subject.

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The purpose of this article is not to try and summarize all of the great work being disseminated on clinical alarms. Instead, the purpose is to sift through the blizzard of information on the topic and highlight those parts of the overall picture that others may have missed as they address clinical alarm systems. Hopefully, the selections will help clarify issues and/or stimulate important discussion, rather than simply adding to the blizzard.

What Is an Alarm?

To many clinicians, an alarm is anything that makes noise, interrupts their work, and demands attention. From the clinician's standpoint, this definition is not unreasonable because the constant noise from alarms often is a major pain point. Serious discussion about alarms with clinicians should lead to the realization that what some perceive as "alarms" needs to be sorted into many different buckets. Alarms come in many

varieties. When discussing clinical alarms, it is extremely important to introduce the correct terminology early so that everyone is using the same definition. The terms themselves can also help team members understand various strategies for managing clinical alarms.

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Vocabulary

The HTSI website includes a document titled *Alarm System Vocabulary*.[3] These definitions are important as one reads other alarm material and discusses the topic. Some published alarm material makes use of these definitions but others may use other terminology which may lead to ambiguity. These vocabulary definitions are excerpted from the (International Electrotechnical Commission (IEC) standard IEC 60601-1-8[4] on alarm systems in medical electrical equipment and medical electrical systems and are therefore understood by all medical device manufacturers. Key definitions from that report are reproduced in the box article on page 207. In keeping with the IEC style, when I use one of these defined terms, they are in ALL CAPS. This terminology can be clumsy initially until the team truly understands the definitions. My experience is that once understood, the terminology facilitates discussion.

I offer the following as a practice example: when an ALARM LIMIT is set and the limit is exceeded, the ALARM SYSTEM may not have declared an ALARM CONDITION; possibly because the ALARM SETTINGS specifies an ALARM CONDITION DELAY. Even after there is an ALARM CONDITION, the ALARM SYSTEM may have an ALARM SIGNAL GENERATION DELAY before generating an ALARM SIGNAL.

Two related terms commonly used in recent articles dealing with clinical alarms are “actionable” and “non-actionable.” That distinction is necessary because many TRUE POSITIVE PHYSIOLOGIC ALARM CONDITIONS are nonetheless “non-actionable” for clinicians. These non-actionable ALARM SIGNALS are considered “nuisance” alarms to clinicians; and increase the probability that clinicians may miss the actionable ALARM SIGNALS because of “alarm fatigue.” In the institutions that are leading the way dealing with clinical alarms, much of the effort has gone to changing ALARM SETTINGS, particularly ALARM LIMITS and ALARM CONDITION DELAY, in order to minimize non-actionable alarms. ALARM SIGNALS may or may not be audible; particularly for LOW PRIORITY ALARM CONDITIONS; if an ALARM CONDITION persists for defined period of time, the ALARM SYSTEM may ESCALATE the ALARM SIGNAL to be audible.

A Systems Approach

Organizations should take a true systems approach to alarms. Many individual devices generate ALARM SIGNALs. Some of those devices are bound together in systems of

similar devices (e.g., patient monitors on a nursing unit). There may be several device systems on a nursing unit, but the overall alarm environment on the nursing unit may also include ALARM SIGNALS from other sources. An overall systems approach takes into account issues such as human factors and the clinicians' need to deal with ALARM SIGNALS generated from multiple sources within their environment.

A Farewell to Alarms

For an "off the beaten path" look at clinical alarms with some very interesting perspectives, I suggest that readers be aware of a book in development by Frank Block, a retired anesthesiologist and cochair of the AAMI Medical Device Alarms Committee, titled, *A Farewell to Alarms*.[5]

> *"The title is, of course, a word play on Hemingway's "A Farewell to Arms." And, in fact, our English word "alarms" comes from the Old English "alarum," "to arms." While certainly ALL the alarms will not be going away, 1) it seems likely that we will make good headway in eliminating many of the false alarms and the clinically insignificant alarms, and 2) it seems likely that targeted delivery of the alarm signals to a designated caregiver will replace the broadcast alarms of today. On these bases it is to be hoped that "alarms" as we know them today— the countless blaring alarms which are mostly false alarms—will indeed disappear."*

Other Kinds of Alarms

Readers should be aware that clinical alarms don't all originate from traditional medical devices, even though most of the alarms discussion has been about physiologic monitors and a little bit on other medical devices. Don't forget nurse call signals, urgent lab test results, major radiology image results, dialysis machines, or fetal monitors. Some might question if urgent lab/radiology reporting results are really alarms, but I would argue that they meet the definition for an HIGH PRIORITY ALARM CONDITION. Some alarm reporting systems currently on the market have realized this need and have incorporated a means for managing these urgent messages in a similar manner to HIGH PRIORITY physiologic alarms. As ALARM SYSTEMS get more sophisticated, they will be able to utilize the information from multiple parameters, from multiple medical devices, to determine if an ALARM SIGNAL is needed.

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Technical Alarms

I have been involved in situations where a TECHNICAL ALARM CONDITION (e.g. "Low Battery" and "Leads Off") was ignored by clinicians because of alarm fatigue, which prevented the device from recognizing that a serious adverse clinical event was happening. As organizations tackle the job of reducing alarms, they need to come up with ways of preventing these common TECHNICAL ALARM conditions. In the case of physiologic monitors, strategies such as routine battery change protocols or purchasing quality ECG electrodes combined with adequate skin preparation has been demonstrated to greatly reduce the volume of TECHNICAL ALARMS.

The Importance of Middleware

In order for all the disparate alarm sources from different manufacturers to function as a DISTRIBUTED ALARM SYSTEM, some sort of middleware is generally needed. To learn more about what middleware is and why it is almost essential for an overall DISTRIBUTED ALARM SYSTEM, I suggest listening to an AAMI/HTSI webinar on the topic.[6] Particularly if a healthcare organization desires an INTELLIGENT ALARM SYSTEM that incorporates information from several medical devices and wants to direct the ALARM SIGNALS directly to the user—minimizing loud noises at the bedside—middleware may be the only choice at this time.

The middleware market is undergoing a transition[7]. Look for systems that are listed by

the FDA as a Medical Device Data System (MDDS). That indicates that the manufacturer has designed the system to have closed loop "handshaking" between the alarming medical device and the annunciating device to make sure that the message got through. Look for systems that are versatile enough to work with many different medical devices and communication systems. Look for systems that participate in the Integrated Health Enterprise (IHE) Patient Care Domain (PCD) Alarm Communication Management (ACM)[8] protocol. Beware of devices that are strictly one-way communication where the medical device sends out an alarm signal to the annunciating device, but has no idea if the message got through or not.

The AAMI Medical Device Alarm Committee recognizes that in order to encourage the development of INTELLIGENT ALARM SYSTEMs, it needs to provide guidance to manufacturers, regulators and users. The committee has commenced work on a Technical Information Report (TIR66) titled *Guidance for the Creation of Evidence to Demonstrate Reasonable Assurance of the Safety and Efficacy of Alarm System Algorithms*, with the following justification:

"Numerous studies have shown that the majority of ALARM CONDITIONS in the ICU are clinically irrelevant. There have been a number of attempts to develop improved ALARM SYSTEMS to increase clinical sensitivity and specificity. However, there is no established method for evaluating the performance of such improvements or of "intelligent alarm systems".

These ALARM SYSTEMS can use a multiparameter approach to adjudicate a single parameter ALARM CONDITION (e.g. use availability of valid pulse for suppression of false ECG asystole). MANUFACTURERS are hesitant to embark on the development of, and clearance for these algorithms based on prior experience or lack of clarity to the required levels of evidence.

An ALARM SYSTEM can also be used to provide interpretation of physiologic and clinical data ("Respiratory Distress/Depression", "Sepsis", "Pulmonary Embolus") for the OPERATOR. In these cases, it is also unclear what type of data and clinical studies are required.

Further, there is a need for consensus means to suitable evidence to alternative RISK CONTROL or test methods according to subclause 4.5 of IEC 60601-1.

This work is also needed to facilitate improvements to ensure clinically actionable alarms so a clear mental model of the ALARM SYSTEM can be delivered to the OPERATOR. A reduction in single signal sensitivity is expected to be present when such approaches are utilized."

Most middleware systems operate on a Medical-IT Network that is used for other purposes besides the middleware. A Medical-IT Network is any data network that includes at least one medical device. The risks involved in managing such a network and how to address them are specified in AAMI/IEC 80001[9] in order to provide overall system reliability. If not fully aware of this standard, there are many resources available about AAMI/IEC 80001 on the AAMI website. While not available at this time, readers should watch for the following document which is currently under development: *"AAMI/IEC TIR80001-2-5/Ed.1, Application of Risk Management for IT-Networks Incorporating Medical Devices—Part 2-5: Guidance on Distributed Alarm Systems."*

I recommend reading a recent HTSI Safety Innovations white paper[10] that gives the perspective of someone who specializes in military alarm systems, but has also spent the last few years working with the HTSI alarm team to study clinical alarms. This paper says that success for a clinical alarm management depends on "answer[ing] the question: "What does a health care worker need to know and when do they need to know it in order to make a good decision? Then, respond by doing the following: identifying which patient a nurse should be attending to now; and determining what actions a nurse must take at this time." The paper goes on to point out three major problems with medical device alarms: "1) The design of current alarm signal delivery is not focused on helping the nurses triage time across multiple patients; 2) Many medical devices are built by a number of different vendors and cannot relate or talk to each other; and 3) Nurses are mobile and medical devices are static." The solutions proposed for resolving these problems require work

from standards organizations, manufacturers and health care organizations. Even if the answers to these problems don't fully exist today, being aware of them is important.

Alarm Awareness Wish List

A recently published article[11] proposes an "Alarm Awareness Wish List of Nine Technological Solutions to Help Manage Alarm Fatigue and to Promote Better Alarm Management. Some of these solutions exist today, while others are suggested patient safety solutions to this issue." I recommend this article to both manufacturers and healthcare systems as they think about what should be their "future state" when it comes to alarms. This article comes from The Johns Hopkins Hospital, one of the healthcare systems that is advanced in its overall systems thinking about alarms; I also recommend a recent summary of The Johns Hopkins Hospital efforts as described in a recent HTSI alarm webinar[12].

Physiologic monitors are typically the medical devices that generate the largest number of non-actionable ALARM SIGNALS. Particularly with older generation physiologic monitors, many resultant ALARM CONDITONS involving cardiac arrhythmias that were at one time thought to be clinically significant and therefore actionable. Many of these cardiac arrhythmias are no longer considered to be actionable by the medical community.

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Default Alarm Presets

The manufacturer designs DEFAULT ALARM PRESETS (DAP) for physiologic monitors and other medical devices (manufacturer DAP). For physiologic monitors, the manufacturer usually allows users (sometimes with a password) to modify the manufacturer DAP to a customized "user DAP." The user DAP establish the baseline DEFAULT ALARM PRESETS every time the monitor is rebooted, powered up, or a new patient is admitted. Manufacturers have taken a variety of different approaches to designing their DAP and how much leeway is allowed to modify the manufacturer DAP. Manufacturers of medical devices are required to follow the (IEC) 60601-1-8 standard on alarm systems[4]. The AAMI Medical Device Alarms Committee is actively working with the IEC to update this standard to accommodate new insights on clinical alarms following the alarm summit.

Healthcare systems need to have a process when they adopt a user DAP. To the extent possible based on patient population, the user DAP should be standardized within an institution so that as staff move between units, they know what ALARM SETTINGS they can expect when starting with a new patient. The HTM organization has a special role to play with user DAPs; if a device is returned from an external repair facility, or has certain major repairs done, the device will be restored to the manufacturer DAP. HTM must have an accurate list of all user DAPs and take responsibility for restoring the user DAP. The clinical community must understand that HTM is the custodian and keeper of all user DAPs, even though the clinical community is the decision maker.

Ventilator Alarms

While there is a big focus on physiologic monitor alarms, ventilator alarms also need a lot of attention. Here is a link to a recent seminar on the topic: www.aami.org/news/2014/021914_Ventilator_Technology_at_AAMI-FDA_Fall_Summit.html.

Overall Alarm Policy and Education

I strongly urge healthcare organizations to develop an overall alarm policy. I had the experience of leading the clinical team developing such a policy while I was the Director of Clinical Engineering at Christiana Care Health System (CCHS) in Delaware. Following is a list of topics I think should be addressed in such an overall policy:

- Who has the authority to:
  - Adjust ALARM SETTINGS for a specific patient including alarm volume?
  - Turn alarms "OFF" for a particular patient? Is it okay to for other staff to silence an alarm if they notify the responsible party immediately?
  - Suspend (turn OFF for a short time that will automatically revert to "ON") alarms for a particular patient?
  - Establish, change and maintain user DAPs?
- Who has responsibility and when should ALARM SETTINGS be checked for each patient?

ALARM SYSTEM VOCABULARY

Alarm Condition: State of the alarm system when it has determined that a potential or actual hazardous situation exists for which operator notification is required.

Alarm Condition Delay: Time from the occurrence of a triggering event either in the patient, for physiological alarm conditions, or in the equipment, for technical alarm conditions, to when the alarm system determines that an alarm condition exists.

Alarm Settings: Alarm system configuration, including but not limited to:
* alarm limits;
* the characteristics of any alarm signal inactivation state; and
* the values of variables or parameters that determine the function of the alarm system

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

Alarm Signal: A type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition.

Alarm Signal Generation Delay: The time from the onset of an alarm condition to the generation of its alarm signal(s).

Default Alarm Preset: An alarm preset that can be activated by the alarm system without operator action.
NOTE: manufacturer- or responsible organization-configured alarm presets are possible types of default alarm presets.

Distributed Alarm System: An alarm system that involves more than one item of equipment of a medical electrical system.
NOTE: the parts of a distributed alarm system can be widely separated in distance.

Escalation: The process by which an alarm system increases the priority of an alarm condition or increases the sense of urgency of an alarm signal.

False Negative Alarm Condition: Absence of an alarm condition when a valid triggering event has occurred in the patient, the equipment, or the alarm system.
NOTE: an alarm condition can be rejected or missed because of spurious information produced by the patient, the patient equipment interface, other equipment or the equipment itself.

False Positive Alarm Condition: Presence of an alarm condition when no valid triggering event has occurred in the patient, the equipment or the alarm system.
NOTE: a false positive alarm condition can be caused by spurious information produced by the patient, the patient-equipment interface, other equipment or the alarm system itself.

High Priority: Indicates that immediate operator response is required.
NOTE: Each priority is assigned through risk analysis.

Intelligent Alarm System: An alarm system that makes logical decisions based on monitored information without operator intervention.
EXAMPLE 1 an alarm system that changes priority based on the rate of change of a monitored variable.
EXAMPLE 2 an alarm system that suppresses an alarm condition when a related alarm condition of higher priority has recently generated an alarm signal.

Low Priority: Indicates that operator awareness is required.

Medium Priority: Indicates that that prompt operator response is required.

Physiological Alarm Condition: An alarm condition arising from a monitored patient-related variable
EXAMPLE 1 High exhaled anesthetic agent concentration
EXAMPLE 2 Low exhaled tidal volume
EXAMPLE 3 Low oxygen saturation measured by pulse oximetry
EXAMPLE 4 High arterial pressure
EXAMPLE 5 High heart rate

Technical Alarm Condition: An alarm condition arising from a monitored equipment-related or alarm system-related variable.
EXAMPLE 1 An electrical, mechanical, or other failure
EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.)
EXAMPLE 3 An algorithm that cannot classify or resolve the available data

Source: AAMI

- Who has the responsibility for responding to alarms?
- How much documentation about alarm settings and changes is required?
- What is the process for exceptions to the policy because of the needs of a particular patient?

When to Discontinue Cardiac Telemetry

At CCHS, we decided to structure the overall alarm policy to be general, with an appendix that included references to specific device types or parameters (e.g. fetal monitors, ventilators, or pulse oximetry) and included hyperlinks to departmental policies that addressed specific alarm issues (e.g. Respiratory Therapy or Hemodialysis departmental policies that mentioned alarms).

In addition to a policy, I suggest that healthcare organizations also consider an education program for their clinicians about alarms and their importance, and implement some sort of quality assurance checks for monitoring actual alarm practices.

CCHS also has taken a leadership role in defining procedures for determining when cardiac monitoring should be discontinued on telemetry patients as a means of reducing the sheer volume of alarms simply because fewer patients are being monitored. I recommend considering this approach as presented in one of the HTSI webinars.[13]

In addition to a policy, I suggest that healthcare organizations also consider an education program for their clinicians about alarms and their importance, and implement some sort of quality assurance checks for monitoring actual alarm practices.

Wrap up

Clinical Alarms is a rapidly evolving topic. As this article is going to press, I just attended the kick off meeting of the HTSI "National Coalition for Alarm Management Safety" where much more great information was presented. Watch for future material from this group. ■

References

1. **AAMI.** Clinical Alarms 2011 Summit. Available at www.aami.org/htsi/alarms/pdfs/2011_Alarms_Summit_publication.pdf. Accessed April 11, 2014.
2. **The Joint Commission.** National Patient Safety Goal. Available at www.jointcommission.org/assets/1/18/JCP0713_Announce_New_NSPG.pdf. Accessed April 11, 2014.
3. **AAMI.** Alarm system vocabulary. Available at www.aami.org/htsi/SI_Series/Alarm_System_Vocabulary.pdf. Accessed April 11, 2014.
4. **International Electrotechnical Commission**. IEC 60601-1-8, *Medical Electrical Equipment—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*. International Electrotechnical Commission; 2006. Geneva, Switzerland.
5. **Block F.** *A Farewell to Alarms* [not yet published]. Excerpts available at: http://bit.ly/1kBIJu8. Accessed April 11, 2014.
6. **AAMI.** Use of Middleware in Alarm Management: Ancillary Notification and Obtaining Alarm Data. Available at www.aami.org/meetings/webinars/htsi/resources/01282014_slides.pdf. Accessed April 11, 2014.
7. **Gee T.** HIMSS 2014 in Review. *Medical Connectivity*. March 3, 2014. Available at http://bit.ly/1ncNJm9. Accessed April 11, 2014.
8. **Integrating the Healthcare Enterprise** (IHE). PCD Alarm Communication Management. Available at wiki.ihe.net/index.php?title=PCD_Alarm_Communication_Management; Accessed April 11, 2014.
9. **ANSI/AAMI/IEC 80001-1:** Application of Risk Management for IT Networks Incorporating Medical Devices— Part 1: Roles, Responsibilities and Activities; 2010. Arlington, VA.
10. **Scott Allen J.** Healthcare Alarm Safety—What We Can Learn From Military Alarm Management Strategies. Available at www.aami.org/htsi/SI_Series/Lockheed_Martin_White_Paper.PDF. Accessed April 11, 2014.
11. **Cvach M.** Nine Technological Solutions to Manage Alarm Fatigue. *24x7*. March 2, 2014. Available at www.24x7mag.com/2014/03/nine-technological-solutions-manage-alarm-fatigue/. Accessed April 11, 2014.
12. **AAMI**. Best Practices for Alarm Management: Kaiser Permanente, Children's National Medical Center, and The Johns Hopkins Hospital. Available at www.aami.org/meetings/webinars/htsi/resources/03052014_slides.pdf. Accessed April 11, 2014.
13. **HTSI.** Healthcare Technology Safety Institute (HTSI) Free Webinar on Alarm Signal Standardization: Learning from the Christiana Care Experience. Available at www.aami.org/meetings/webinars/2013/031813_HTSI_Alarm_Signal_Standardization.html. Accessed April 11, 2014.