Early action advisable to prepare for new alarm safety standards

Walk into any patient care unit—whether preoperative, intraoperative, or postoperative—and you will hear numerous alarm signals. Some are signaling a medical necessity, but many are false alarm noises that do not require action.

Health care workers can hear several hundred alarm signals per patient per day, which may cause alarm fatigue. Overwhelmed or desensitized by the constant barrage, care givers may take unsafe actions, such as turning down the devices, shutting them off, or ignoring them.

Patient safety advocates have warned of alarm fatigue for years, and it’s a growing concern as hospitals invest in more complex devices with a growing number of features and sensors.

In June, the Joint Commission approved a new National Patient Safety Goal on clinical alarm safety (NPSG.06.01.01). The effective date is January 2014.

The goal consists of 4 elements of performance to be phased in over 2 years—2 start in 2014 (Phase I), and 2 start in 2015 (Phase II).

The Joint Commission says it plans to publish the Phase I and II requirements at the same time to provide the field with complete information about the ultimate requirements of NPSG.06.01.01.

Phase II requirements may be enhanced before they are implemented in 2015. These changes could arise from hospitals’ experience with Phase I requirements as well as newly emerging evidence about best practices. If any changes to the Phase II requirements are made, accredited hospitals will be notified.

The new goal will appear in the 2013 Update 2 to the Comprehensive Accreditation Manual for hospital and critical access hospital programs.

Phase I begins in 2014

The first 2 elements of performance (EP) require the following:

EP 1. As of July 1, 2014, hospital leaders establish alarm safety as an organizational priority.

EP 2. During 2014, hospitals identify the most important alarms to manage based on the following:

- input from medical staff and clinical departments
- risk to patients if the alarm is not answered or malfunctions
- whether alarms are needed or unnecessarily contribute to alarm noise and fatigue
- potential for harm based on incident history
- review of best practices and guidelines.

Form a multidisciplinary committee

Before July 1, hospitals will want to form a multidisciplinary committee to review the literature and decide which alarm signals or alarm systems are most important to manage, says John R. Rosing, MHA, FACHE, vice president and principal, Patton Healthcare Consulting, Milwaukee, Wisconsin.

It is important that hospitals do this early, so the prioritization of alarms is estab-
Resources for alarm management

Association for the Advancement of Medical Instrumentation (AAMI)
The AAMI website contains useful information on safely managing alarm systems with links to activities the AAMI Healthcare Technology Safety Institute is engaged in to promote safe alarm system management, including:
- survey of hospital practices in setting alarm parameters, followed by a study of alarm parameters
- library of literature on best practices on alarm system management
- webinars on safe alarm management
- summary of the Clinical Alarms Summit hosted by AAMI in 2011.
http://www.aami.org/htsi/alarms/

ECRI Institute
ECRI Institute offers information such as articles, policies, and webinars on safely managing alarm systems on its website. The website also includes:
- Health Devices Top 10 Health Technology Hazards, which lists alarm hazards as the number 1 issue for 2012 and 2013
- Health Devices Achievement Award winners, which includes the Johns Hopkins Hospital Comprehensive Alarm Management Initiative
- Pennsylvania Patient Safety Authority alarms resources. (https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx)

Joint Commission
The Joint Commission published a Sentinel Event Alert on medical device alarm safety in April 2013. The alert contains suggestions for assessing and managing risks associated with alarms and complements the expectations of the new safety goal. (http://www.jointcommission.org/sea_issue_50/)
Other Joint Commission resources include:
- 2 Take 5 podcasts (http://www.jointcommission.org/podcast.aspx?CategoryId=13&F_All=y)
- replay of an alarm safety webinar held in May. (http://www.jointcommission.org/alarm_safety_webinar/)

Published before July 1, says Rosing. The committee should keep detailed minutes of its meetings, including a directive from leadership stating that alarm safety is an organizational priority. This documentation will be needed to demonstrate compliance when the Joint Commission does its survey, he says.

“T believe the committee should be organizational and not departmental,” advises Mary Logan, JD, CAE, president of the Association for the Advancement of Medical Instrumentation (AAMI). “If you try to approach the alarm problem as an OR issue, a PACU [postanesthesia care unit] issue, an ICU [intensive care unit] issue, or something else, the problem isn’t going to be solved,” says Logan. The committee needs to involve nursing leadership, quality and patient safety leadership, physician leadership, clinical engineering, and information technology, she says.

“A senior administrator, such as a chief nursing officer or a chief medical officer, has to lead this effort,” says Robert Maliff, MBA, director, applied solutions group, at ECRI Institute. “You need someone who is really going to believe in this and push this and secure the resources, or things will fall through the cracks,” he says.

Every member of this multidisciplinary team has a distinct role, says Maliff. For example, physicians are vital because they are ultimately responsible for patient care, and they can help establish alarm parameters. Nurses are crucial because they are ultimately responsible for responding to all alarms. Clinical engineering staff are important because they will be responsible for changing the alarm defaults. Both AAMI and ECRI Institute are engaged in activities to promote safe alarm system management and support the National Patient Safety Goal (see box on p 18).

Tailor strategies
According to the Joint Commission, it is important for each hospital and each department to understand its own situation and to develop a systematic, coordinated ap-
proach to alarm management. Standardization contributes to safe alarm management, but solutions may have to be customized for specific clinical units and patients.

Each care unit has a unique set of circumstances dictating how alarm signals are heard and responded to, says Rikin Shah, senior associate, applied solutions group, ECRI Institute. Thus, alarm response strategies should be tailored to each unit.

The architectural layout and the alarm coverage model play a huge role, says Shah. For example, most PACUs are open spaces with direct lines of communication between nurses and patients, so most alarm signals are both heard and seen across the unit. In ICUs, where patients are secluded in small private settings, a more robust plan for communication and alarm response is needed.

Alarm fatigue is not quite the same issue in the OR that it is in the ICU, says Rosing. In the OR, it is understood what alarm signals mean for a patient, and they are responded to quickly. But, Rosing says, OR leadership will still want to participate in committee discussions and decisions about alarms.

Rosing anticipates that surveyors will go into the OR and ask, “Have you been part of the discussion on alarm management and fatigue?” OR managers will want to be able to say “yes we have,” says Rosing, and they may want to continue with “we have decided to leave our alarm settings as they are.” That would reflect a deliberate decision made by OR leaders as opposed to not having been at the table at all, he says.

Prioritize alarms
The approved version of the safety goal is easier to comply with than the draft would have been, says Rosing. The annual inventory of alarms has been deleted, and the phasing of the safety goal into 2014 and 2015 rather than January 1, 2014, allows more time for implementation.

Even though the annual inventory has been deleted, he says, it will likely be necessary to create a master inventory list of all alarms or alarm systems so the committee will have something to work from as it prioritizes the alarms that are the most important.

It also may be useful to categorize this list by service, such as alarms serving the OR, PACU, ICU, medical-surgical units, telemetry units, and the emergency department.

“When identifying the highest priority alarms,” notes Logan, “you have to ask, ‘What are the actionable alarm signals and why? What are the nonactionable alarm signals and why? How can you assess who needs to hear them and why?’”

For example, says Logan, nurses and anesthesiologists have very specific re-

Top 10 Actions You Can Take Now:
10 things you can do now to improve alarm conditions in your health care organization

- Gain cross-disciplinary leadership support.
- Establish a cross-functional team with clinical leadership to address alarm fatigue across all environments of care.
- Re-establish priorities: Process should drive technology adoption rather than allowing technology to drive the process.
- Develop a continuous improvement process for constantly optimizing alarm system policies and configurations.
- Conduct clinical testing and analyze alarm data to implement optimized alarm limits and delays (both alarm condition and alarm signal generation delays) and to reduce clinically nonactionable alarm conditions.
- Test acoustics on clinical floors: Environmental noise impacts patient and staff well-being and patient safety.
- Implement an alarm system configuration policy based on clinical evidence.
- Change single-use sensors more frequently to reduce nuisance alarm conditions (except in pediatric units).
- Mandate alarm system management training for all clinical operators.
- Share experiences with AAMI, the FDA, TJC, ECRI Institute, and others with problem reporting systems so everyone can benefit from your efforts in a cross-disciplinary way.

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quirements for the alarm signals needed in the OR, which are different from the alarm signals nurses need in the PACU, surgical ICU, or cardiac ICU. “This is why everyone has to work together,” she says.

In 2011, AAMI and the Food and Drug Administration co-convened a Clinical Alarms Summit. It brought together clinicians, regulators, alarm system experts, industry, and others to discuss and set priorities for alarm management issues. The Joint Commission, ECRI Institute, and American College of Clinical Engineering also participated in the summit, which brought much greater national attention to the problems with alarm management and identified priorities for action.

A list of “Top 10 Actions You Can Take Now” to improve alarm conditions in health care organizations was developed from audience discussion at the summit (see box on p 19).

**Phase II begins in 2015**

In the last 2 elements of performance, the following steps are required as of January 1, 2016:

**EP 3.** Hospitals will establish policies and procedures for managing the alarms identified in EP 2.

At a minimum, these policies and procedures will address:
- clinically appropriate settings for alarm signals
- when alarm signals can be disabled
- when alarm parameters can be changed
- who in the organization has the authority to set alarm parameters, change alarm parameters, and set alarm parameters to “off”
- monitoring and responding to alarm signals
- checking individual alarm signals for accurate settings, proper operation, and detectability.

**EP 4.** Hospitals will educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

**Manage alarms**

Two of the key issues to be addressed by policies and procedures for alarm management are clinically appropriate settings for alarm signals and unnecessary alarm signals.

“To have clinically actionable alarm signals, which means eliminating nuisance alarm noise, you first need to look at what is happening in the context of your unit,” says Shah.

For example, how are system alarm sounds such as leads-off alarm signals being handled? Too many leads-off alarm signals could be a result of inadequate skin preps and lack of electrode replacement. Most hospitals probably already have a skin prep policy for leads and electrode replacement, and they could eliminate many of these system nuisance alarm sounds if they were following their policies, Shah says. He noted that ECRI Institute was part of an alarms management review at Johns Hopkins Hospital in Baltimore in which proper skin preps and electrode replacement eliminated close to half of the alarms on an acute care unit. AAMI’s “Top 10 Actions” list also includes changing leads.

Another policy that might already be in place is standardization of default volume settings on monitoring equipment or in central stations, says Shah.

“One of the things we recommend is attacking the ‘low-hanging fruit’ first,” says Maliff. “Start with the care areas with a lot of alarms and a lot of monitored patients. It is a tall task to tackle every single unit with physiologic monitors,” he says.

Health care delivery organizations need to set a timeline for what they are going
to get done by when, says Logan. Hospitals that think they can wait until the 4th quarter of 2015 to implement new alarm policies “are going to be in big trouble,” she says. “This is something that takes planning and takes time.”

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—Judith M. Mathias, MA, RN

References


http://www.jointcommission.org/joint_commission_announces_2014_npsg/