

Is the Warning Effective?

Clinical Alarms Remain an Area for Patient Safety Improvement

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Alarms warn of danger, alert care givers to critical medical information, or warn of adverse changes in a patient's condition. For many years, clinicians, safety professionals, and engineers have known that alarm effectiveness needs improvement. Early efforts at addressing alarm issues were undertaken by the Anesthesia Patient Safety Foundation, ECRI,¹ and in the American Society for Testing and Materials (ASTM) standards.

Alarm shortcomings fall into the categories of system design, system performance, care management, and environmental influences. False positives, missed critical alarms in some cases due to defeating alarms, and poor human factors interfaces are issues related to design. Lack of adaptation to different patient conditions or not including a systems design approach (e.g., standardized alarm visual and audible indicators) lead to performance shortcomings. Incidents related to improper alarm setup or poor response to alarms have been reported with causes sometimes linked to a lack of vigilance, training, or staff shortages. Environmental issues such as noise sources and poor facilities design complicate matters.

Shortly after publishing a *Sentinel Event Alert* in February 2002,² the Joint Commission (JCAHO) began scoring Patient Safety Goal 6 — *Improve the effectiveness of clinical alarm systems*. The goal covered both technical and care management areas. Goal 6 was dropped as a hospital Patient Safety Goal in 2004. This begs the question: "Has clinical alarm improvement been significant due to JCAHO implementing Goal 6?" A quick review of deaths and injuries reported to the *FDA MAUDE* database searching the Problem Description with the word criteria "alarm" shows an increase in reports from 189 in 2001 to 449 in 2004. Although some of the

increase can be traced to better reporting, a doubling of reports makes one question an improvement due to Goal 6 and shows the need for a continued focus on clinical alarms as a patient safety issue.

Today's alarm indicators go beyond the traditional audible and visual alerts at the bedside and nursing stations. New developments include alarm integration systems that combine alarms from various sources and intelligently manage and deliver messages to clinicians via pagers, nurse call systems, dashboards, tactile devices, or cell phones.³ As diagnostics move to the patient at the point-of-care, these alerts will not only include alarms from the physiological monitors, but will also include critical diagnostic results from the clinical laboratory, pathology, and imaging.

Much work has been done related to smart alarms, which use advanced signal processing of physiological data. Predictive alarms and statistical process control techniques have been applied to more intelligently warn of adverse conditions.⁴ Standards have been developed by ISO/IEC for audible and visual requirements for alarm priority and parameter characteristics.⁵ Care management advances have been instituted in many facilities in response to Goal 6. Best practices have been published in clinical journals. The Association of periOperative Registered Nurses has published on clinical alarms systems testing and has a home study program on the subject.⁶ Organizations such as the Veterans Administration are focusing on safety at the VA National Center for Patient Safety. Educational materials on the VA's website describe the VA's Healthcare Failure Mode and Effects Analysis being used to evaluate ICU alarms. Notices are published about such topics as the failure of medical alarm systems using paging technology to notify clinical staff. The Anesthesia Patient Safety Foundation lists clinical alarms as an initiative and had an October 2004 workshop on audible alarms. As part of their *Health Devices* subscription service, ECRI has published detailed guidance for healthcare facilities on the management of clinical alarms⁷ and routinely reports on serious patient incidents related to problems with clinical

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alarms. Despite improved clinical strategies, clinical alarm issues persist and must be improved.

In 2005, the American College of Clinical Engineering (ACCE) put forth an initiative to *improve patient safety by identifying issues and opportunities for enhancements in clinical alarm design, operation, response, communication, and appropriate actions to resolve alarm-related events.*

A task force has been formed to focus on clinical alarm management. Activities include audio conferences, literature and hazard reviews, and the design and implementation of a clinical alarms survey.

At the 2005 AAMI Annual Conference in Tampa, AAMI and ACCE co-sponsored a town meeting on clinical alarms. The discussion included the role of alarm standards, developing prioritization systems, the difficulty in training clinical staff on alarms, and defining "What is an alarm?" The assembly stressed that improving alarms requires a systems approach.

A major focus of the task force is to develop a survey on clinical alarm usage, issues, and priorities for solution. Pilot studies have been done in large medical centers to refine the survey content, allow review for statistical relevance, and assess distribution and scoring questions. The American Association for Critical-Care Nurses has participated in the development of the survey and has distributed the questionnaire to its membership. The survey is available online at the ACCE Healthcare Technology Foundation website (www.acce-htf.org). Interested parties are encouraged to complete the survey. Results will be published in 2006. ■

References

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JCAHO Connection

Questions on Preventive Maintenance and NPSG #6

(Editor's Note: AAMI and JCAHO are working together to provide AAMI members with more information about JCAHO initiatives and medical equipment standards. AAMI members can pose questions to JCAHO standards experts and obtain responses, which will be published in the Joint Commission Resources' Environment of Care News and in BI&T. AAMI members can pose their questions by e-mailing Steve Campbell at scampbell@aami.org. Questions will be answered by JCAHO's Standards Interpretation Group, the official interpreters of JCAHO standards language.

Q: *In some instances, we do not follow manufacturer recommendations for preventive maintenance intervals and procedures. What evidence or data is required to justify deviating from manufacturer specifications?*

A: Healthcare organizations should use manufacturer recommendations as a starting point for developing maintenance protocols. However, an organization is free to modify these protocols based on its actual experience with the equipment. Ongoing monitoring of failures, misuse, and performance data could justify modifications to maintenance protocols.

Whenever you depart from a manufacturer's maintenance recommendations, have available performance data that support this decision. These data could include historical records that identify issues related to reliability, failures, misuse, and so on. Data should also demonstrate periodic monitoring to ensure that the decision was correct.

Q: *A portion of our equipment maintenance is handled by outside contractors. Will these providers be evaluated by the Joint Commission surveyor? If so, what criteria will be used?*

A: The Joint Commission's standards on medical equipment risk are aimed at ensuring patient safety. Therefore, the surveyor will evaluate these Joint Commission standards from the patient's perspective, independent of any business relationships that may be in place regarding maintenance, testing, or inspec-

tion. In other words, the healthcare organization is responsible for ensuring outcomes, and the standards apply equally to in-house staff and contracted providers. To ensure compliance, healthcare organizations should establish performance expectations and monitor outcomes for all maintenance services.

Q: *Does the term telemedicine equipment include equipment used for remote diagnosis? Specifically, if I send an x-ray via telephone lines to a radiologist in another city, are the phone lines temporarily telemedicine equipment? Also, is a fax machine used to transmit lab results considered a telemedicine device? Although I can ensure the quality of the equipment at my hospital, I have no control over the equipment used in another facility.*

A: The Joint Commission does not inspect public utilities, so any phone lines or data lines used to transport data for diagnosis are not part of a Joint Commission review. However, if a healthcare organization identifies communication line reliability as an issue, the Joint Commission would expect the organization to develop alternative or backup communication methods. Similarly, a fax machine, which normally would not be considered clinical equipment, could in a telemedicine application merit heightened attention from those maintaining other clinical equipment. From a service perspective, the intent is to ensure that the equipment at either site is clinically appropriate and functioning properly. If either organization is to be a Joint Commission-accredited location, staff would have to select and maintain equipment accordingly. (For the Joint Commission's definition of telemedicine, see MS.4.120.)

Q: *Will the National Patient Safety Goal on reducing surgical fires be included in future Joint Commission surveys for hospitals? If so, what will be assessed?*

A: Strictly speaking, the surgical fires goal applies only to ambulatory and office-based surgery centers, not hospitals. However, hospitals remain subject to Joint Commission standards on fire safety—including fire safety in surgical suites—that are already in place (see EC.5.10 and EC.5.30). The recommendations in this safety goal are excellent means to ensure fire safety standards compliance for all types of healthcare organizations.