

*Is the Warning Effective?*

## Clinical Alarms Remain an Area for Patient Safety Improvement

Tobey Clark

**A**larms 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,<sup>1</sup> 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,<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> Standards have been developed by ISO/IEC for audible and visual requirements for alarm priority and parameter characteristics.<sup>5</sup> 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.<sup>6</sup> 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 *IHealth Devices* subscription service, ECRI has published detailed guidance for healthcare facilities on the management of clinical alarms<sup>7</sup> 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) Healthcare Technology Foundation 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](http://www.acce-htf.org)). Interested parties are encouraged to complete the survey. Results will be published in 2006. ■

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