

A photograph of a hospital room. In the foreground, a bed is covered with a white sheet. To the left, a medical monitor is mounted on a stand, displaying green waveforms on its screen. The background shows a white wall with a door handle and a metal stand with a hook.

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Cause for Alarm

Biomedics are at the forefront of an initiative to educate professionals and consumers about the importance of proper management of clinical alarms

By Rich Smith

Any time a bedside monitor; ventilator; infusion pump; or other medical device beeps, chimes, buzzes, clangs, pulses, artificially verbalizes, or even outright ululates to call attention to out-of-kilter parameters or machine malfunctions, clinical staff are expected to respond immediately.

Usually, they do. Sometimes, they do not—and for reasons that biomedics need to be concerned about. “In a critical-care environment, not responding promptly to a device alarm could prove fatal to patients,” says Tobey Clark, MSCE, CCE, director of instrumentation and technical services for the University of Vermont in Burlington. “In 2001, hospitals around the country reported 189 deaths and serious injuries in which alarms were in some way involved. In 2004, that number had risen to 449, according to the US Food and Drug Administration’s [FDA] Maude database.”

Close heed to device alarms is not always paid because they have been known to trip when nothing is wrong with the patient. In some institutions, these false alarms occur so often that clinicians become desensitized to the clarion’s call—if, that is, they have not first thrown up their arms in frustration and switched off the untrustworthy noisemaker, says Clark. Other times, alarms go ignored simply because they are inaudible: Either the alarm volume is set too low to be heard, or the clinician is too far away to notice it sounding. Then, there are occasions when clinicians cannot quickly respond to an alarm because they are not sure which machine is finally issuing the aural alert.

Disquieting Finding

The deficiencies of clinical-alarm management have long been a matter of concern for Clark—enough so that a year ago, he took on a leadership role in a biomedical engineering-led effort to help hospitals in the United States do something about the problem. He is the codirector of the Clinical Alarms Management Project sponsored by the American College of Clinical Engineering’s Healthcare Technology Foundation (AHTF).

The focus of the Clinical Alarms Management Project is bedside devices: chiefly, ventilators, monitoring systems, and infusion pumps. Many of the insights Clark possesses with regard to the situation come from a survey the AHTF has been conducting for the past several months. The questionnaire is accessible online until early 2006 at the AHTF’s Web site and those of approximately 10 professional societies. Thus far, nearly 700 completed survey forms have been returned, most of those coming from care providers.

“Forty-three percent of respondents are nurses in intensive-care units,” Clark says.

Among the disquieting preliminary findings of the still-in-progress survey: Many clinicians have developed an over-reliance on alarms. That is, rather than make the effort to

routinely check patient parameters and stay on top of potentially life-threatening changes, they leave it to the machines to alert them when something is awry. The risk there, says Clark, is that an alarm may be broken and unable to sound. As such, a clinician depending on the alarm to signal trouble would be unwittingly placing the patient in grave jeopardy.

A goal of the survey is to help the AHTF get a reliable handle on the extent to which the management of clinical alarms is a problem in hospitals so that equipment manufacturers can take appropriate corrective action, says AHTF President Mark David, PE, CCE, director of the biomedical engineering department at Texas Children’s Hospital in Houston. According to David, manufacturers are eager to learn what, if anything, the survey results can tell them about user experiences with clinical alarms.

“Industry has shared with me that they’ve been trying for the last 50 years to come up with an ideal alarm, but have no clue as to whether they’ve been successful in doing so,” David says, adding that the FDA, too, would love to acquire such knowledge to know how to better evaluate the safety and efficacy of these critically important products.

After the survey period ends, Clark and others involved in the Clinical Alarms Management Project will sit down to write a white paper on the causes of and possible cures for problems arising from unheard, ignored, and over-relied-upon alerting systems. Hoping to make the white paper available during the first quarter of 2006, Clark says it will offer clinical alarms guidelines and best-practices information “that can be adopted by equipment manufacturers, standards organizations, caregivers, and clinical engineers.”

Patient Education

The Clinical Alarms Management Project is but one of four initiatives—or modules—currently sponsored by the AHTF, a tax-exempt 501(c)3 corporation.

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technologies more understandable to the general public and to provide that information through a single, readily accessible source," says AHTF Board Member Marv Shepherd, PE, president of Devteq Consulting in Walnut Creek, Calif. "Although educational information is available from many of the companies that manufacture these technologies, and also from public entities, it has historically been difficult to dig out. Sometimes, the information available is pretty [sparse]. Other times—actually, most times—it's written in ways that only engineers can comprehend. We're hoping the public will come to see the AHTF as a valuable resource for clear, complete information about equipment and safety issues that they are likely to encounter during a stay in the hospital."

The first of the four education modules is already completed. It addresses safety issues that arise when patients attempt to bring their own medical devices into a hospital.

"I've had my own medical devices brought into the hospital, but I understand why the hospital won't let them bring in devices from home—an ambulatory infusion pump, for instance," says Shepherd. "What we want to help them appreciate is that the hospital takes the position it does because it may not fully understand the safe operating procedures for that particular piece of equipment, let alone be able to maintain it. Conversely, we also want hospitals to understand why patients would want in the first place to bring such equipment with them from home. We're seeking to bridge the knowledge gap on both sides of the issue."

A second module is planned to discuss general safety issues in the home-care environment (use of oxygen in particular), while a third will evaluate the safety of various bedside devices, Shepherd divulges. "In general, AHTF chooses the modules to be written and sets forth what their content will be, but then relies on paid expert authors to do the actual writing."

Something the AHTF did not plan on is that it has more good module ideas worthy of development than it has actual budget dollars and manpower. "At present, we have a modest budget of just \$15,000 for our educational modules," says Shepherd, to which David adds, "We need people to step forward and help out."

Noble Ambition

The AHTF's emphasis on the education of health care consumers is necessary to maintain tax-exempt status. However, Shepherd is convinced that the educational materials targeted to the public will also be found useful by biomed. Moreover, there is room in the organization's charter for public-service projects of a decidedly technical nature—for example, the AHTF has on the drawing board a program that will bestow recognition on clinical engineering best-practices.

That is in keeping with David's reason for founding the AHTF 3 years ago as an entity to promote safer and more efficient delivery of health care via technology management. "There was no place we in clinical biomedical engineering could go to for the focused resource support and funding needed to advance our ideas about how to do a better job

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