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Nearly all say that they can distinguish an urgent or critical alarm from the others most of the time because of a distinct difference in tone, sound or rhythm. Many memorize the sounds to know the differences and say that over time, staff members can learn the different tones. However, some respondents say that after a prolonged period of time, the tones can begin to blend together. In addition, one respondent reports that some device alarms sound identical, for example, patient beds and infusion pumps, making it even more difficult to distinguish which device is alarming.

In addition to auditory alarms, all respondents report that most of their devices have visual alarms. Visual alarms include blinking and/or colored lights, and monitors with pictures or text. Nearly all respondents find visual alarms helpful. Some respondents describe a visual “red” (critical) alarm that flashes along with the room call light at the central monitor, which helps to quickly locate the alarm and the patient room. However, no one thought that voice alarms on devices would be helpful. Respondents believed that voice alarms would add to the noise and confusion on the nursing unit and thought it would be even easier to tune out voice alarms than standard alarms. Also, they believed voice alarms may upset patients and their families.

Alarm activation thresholds are another critical concern involving medical device alarms. Half of the respondents say volume and parameter threshold settings are adjusted based on a patient’s clinical status and clinical judgment. Others say that default parameter settings are adjusted depending on the type of nursing unit, such as the cardiac intensive care unit. Six of nine respondents say parameters are adjusted by unit nurses or other clinical staff. The remaining respondents have their biomedical engineering department make the parameter adjustments. When discussing silencing these alarms, seven respondents say they are able to temporarily silence alarms for purposes of troubleshooting for a period of 30 seconds to three minutes. After this time frame, the alarm usually resets and turns back on. The majority of respondents say that serious alarms, such as those for lethal heart rhythms, cannot be permanently disabled. And, according to nearly all respondents, once a patient is discharged from the device, the alarm settings revert back to their default settings.
Reducing alarm-related mishaps requires the utilization of risk management methods by hospitals, as well as by manufacturers. An ideal situation would be one in which hospitals and manufacturers would develop solutions together. The FDA is taking the first step by intensifying its pre-market review of medical devices.

Respondents have several ideas about alarm modifications that may improve the safety and effectiveness of medical device alarms. One suggestion is increasing the use of “smart alarms.” An example of this is an IV pump occlusion alarm that self-corrects when the occlusion is the result of a patient who temporarily bends an arm with the IV or rolls on the tubing. Another suggestion is linking the apnea and oxygen saturation monitor alarms because apnea monitors are very sensitive and alarm even when oxygen saturations values are within set parameters. Also, many oxygen saturation alarms do not distinguish between values that are high or low. For example, the alarms for values of 89 percent and 30 percent are the same sound, so different sounds would be more helpful.

Another suggestion is providing an escalating alarm or two different tones on cardiac monitors specifically for detecting bradycardia (slow heart rate) in infants. Having two distinct tones for bradycardia and tachycardia (rapid heart rate), particularly for infants in neonatal intensive care units, would help clinicians identify problems faster.

Several respondents say that when multiple alarms are sounding at once, it would be beneficial if the device could indicate the nature of the problem so the clinician could determine the type of response required. Examples of this include having different tones for a “leads-off patient” alarm versus an alarm for a critical patient issue, or an alarm that specifically indicates a high heart rate versus a low heart rate for an individual patient.

Respondents’ suggestions also included designing better technology to improve the safety and effectiveness of device alarms. These include providing clinicians with the ability to receive a text message about a device that is alarming on a smartphone, designing noise-canceling technology for unit hallways, providing portable monitoring through use of a pad or tablet, and improving algorithms in individual-patient monitor software that are more accurate and can help eliminate false alarms. In the event that an alarm is disabled, some suggest having a question appear on a monitor screen asking, “Do you want this alarm to remain off?”

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Reducing Alarm-related Hazards in Patient Devices

“Fresh from surgery, the patient was wheeled into the intensive care unit and immediately hooked up to a cardiac monitor that would alert nurses to a crisis. Sometime during the following days, though, the cables running from her chest to the machine slipped loose. The monitor repeatedly sounded an alarm — a low-pitched beep. But on that January night two years ago, the nurses at St. Elizabeth’s Medical Center in Brighton didn’t hear the alarm, they later said. They didn’t discover the patient had stopped breathing until it was too late [Ref. 3].” Such incidents are unfortunate, but preventable. There have been numerous Class I (high risk of harm) recalls related to cables affecting the alarms. A cable, which transmits an alarm from the ventilator to the nurses’ station, was recalled because an electrical shortage unexpectedly shut down the alarm system [Ref. 4]. Among other alarm-related recalls were: ventilators/oxymeters giving false positives/negatives, medical devices disabled by patients and delayed alarm and inherent failures in the alarm software or hardware.
Reducing alarm-related mishaps requires the utilization of risk management methods by hospitals, as well as by manufacturers. An ideal situation would be one in which hospitals and manufacturers would develop solutions together. The FDA is taking the first step by intensifying its pre-market review of medical devices. The Joint Commission, the national organization that accredits hospitals, is planning to survey hospitals and nursing homes and evaluate these devices.

**FDA Preventive Actions**

The following summary illustrates how the FDA plans to mitigate alarm-related hazards [Ref. 2]. It wants to provide additional training on alarm standards and alarm safety to its reviewers, who are responsible for scrutinizing 4,000 applications a year from manufacturers seeking permission to sell their medical devices, including heart and oxygen monitors. Alarms on monitors and medication pumps, ventilators and beds already blare endlessly in hospitals, and one of the FDA's top device officials indicated that he wants to prevent new products that do not serve an important function from needlessly adding to the cacophony.

Dr. William Maisel, deputy director and chief scientist at the Center for Devices and Radiological Health, said, “Reviewers are poring over new applications with increased awareness” about whether alarms provide information that is important to patient care and measure what a company claims they measure. “We certainly recognize our important role in addressing the alarm issue,” he said.

Maisel, a cardiologist who previously worked at Beth Israel Deaconess Medical Center in Boston, said that the FDA is particularly focused on “new alarms trying to measure new things,” such as alarms that monitor various physiological functions at once.

Manufacturers of these devices claim that considering several parameters together allows them to better predict when a patient is in trouble. Many monitors measure just one function, such as heart rate and rhythm.

The FDA is also considering more comprehensive measures, such as issuing guidance documents that would communicate to the industry a “significant changing expectation” regarding the use of alarms. Maisel said the “FDA could do everything right, but if the health care community is not doing its job, that won’t be enough.” Many of the patient safety lapses with ventilators are “not a malfunction of the alarm, but the use of the alarm.”

Alarm systems are in place to assist health care providers. Numerous design innovations and implementation strategies should be used to improve patient safety, while recognizing the inherent challenges in the care of sick patients, especially in critical care units. Although these devices can be life saving, it is the diligent care of the healthcare professional that provides the best warning, something at which an alarm is often not good enough.

**References:**