The Joint Commission
Sentinel Event Alert

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Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or redesigning relevant processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

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Medical device alarm safety in hospitals

Many medical devices have alarm systems; among them are bedside physiologic monitors that include ECG (electrocardiogram) machines, pulse oximetry devices, and monitors of blood pressure and other parameters; bedside telemetry; central station monitors; infusion pumps; and ventilators. These alarm-equipped devices are essential to providing safe care to patients in many health care settings; clinicians depend on these devices for information they need to deliver appropriate care and to guide treatment decisions. However, these devices present a multitude of challenges and opportunities for health care organizations when their alarms create similar sounds, when their default settings are not changed, and when there is a failure to respond to their alarm signals.

The number of alarm signals per patient per day can reach several hundred depending on the unit within the hospital, translating to thousands of alarm signals on every unit and tens of thousands of alarm signals throughout the hospital every day. It is estimated that between 85 and 99 percent of alarm signals do not require clinical intervention, such as when alarm conditions are set too tight; default settings are not adjusted for the individual patient or for the patient population; ECG electrodes have dried out; or sensors are mispositioned.[1] As a result, clinicians become desensitized or immune to the sounds, and are overwhelmed by information – in short, they suffer from "alarm fatigue." In response to this constant barrage of noise, clinicians may turn down the volume of the alarm, turn it off, or adjust the alarm settings outside the limits that are safe and appropriate for the patient – all of which can have serious, often fatal, consequences.[2] One such example occurred in the summer of 2010. According to a *Boston Globe* article, a 60-year-old man died in the intensive care unit of a hospital – not from the injury he suffered to his head from a fallen tree branch – but from a system failure that resulted in delayed response to an alarm signal that indicated significant changes in his condition.[3] These changes – that set off alarms – included rapidly increasing heart rate and falling blood oxygen levels. Staff responded only after one hour, when a critical alarm condition signaled that the patient had stopped breathing – but the damage had been done. In addition to his head injury, the patient sustained irreversible brain damage from a lack of oxygen, and several days later he was removed from life support. This unanticipated death was the result of a significant problem that occurs every day, in many hospitals in the country – a failure to respond to appropriate alarm signals in a timely manner**.**

A frequent and persistent problem

The Joint Commission's Sentinel Event database* includes reports of 98 alarm-related events between January 2009 and June 2012. Of the 98 reported events, 80 resulted in death, 13 in permanent loss of function, and five in unexpected additional care or extended stay. Common injuries or deaths related to alarms included those from falls, delays in treatment, ventilator use and medication errors; all were traced back to alarm system issues. Alarm-related events are recognized as underreported and occur in all health care settings. Ninety-four of the reported events occurred in hospitals, with the majority of those events occurring in telemetry, intensive care,

* The reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.

general medicine, and emergency department areas. For the reported events, among the major contributing factors were:

- Absent or inadequate alarm system (30)
- Improper alarm settings (21)
- Alarm signals not audible in all areas (25)
- Alarm signals inappropriately turned off (36)

For every sentinel event, multiple contributing factors can be identified. In addition to the contributing factors reported to The Joint Commission's Sentinel Event database, other factors that contributed to alarm-related sentinel events include:

- Alarm fatigue – the most common contributing factor
- Alarm settings that are not customized to the individual patient or patient population
- Inadequate staff training on the proper use and functioning of the equipment (e.g., inconsistent team training, response, and interpretation of alarm signals)
- Inadequate staffing to support or respond to alarm signals
- Alarm conditions and settings that are not integrated with other medical devices
- Equipment malfunctions and failures

Since 2007, ECRI Institute has reported on the dangers related to alarm systems. In its annually published "Top 10 Health Technology Hazards" list, clinical alarm conditions consistently appear as the first or second most critical hazard, reflecting both the frequency and serious consequences of alarm-related problems.[4] "We've reported the problem for many years and sought ways to bring the issue to larger prominence," says James P. Keller, M.S., vice president of health technology evaluation and safety, ECRI Institute.

In addition, the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database reveals that 566 alarm-related patient deaths were reported between January 2005 and June 2010, a figure that is considered by industry experts to underrepresent the actual number of incidents.

Recommendations and potential strategies for improvement

While this Alert highlights the important safety issues and approaches to improving safety surrounding alarm-equipped medical devices, The Joint Commission is exploring other options to address this problem, including the possible development of a National Patient Safety Goal. The solutions and attention to this serious patient safety issue require leadership and a multidisciplinary approach. The Joint Commission offers the following recommendations to health care organizations to reduce patient harm related to alarm systems. The first five correspond to recommendations made by both the Association for the Advancement of Medical Instrumentation (AAMI) and ECRI Institute. *Note: For details, see the AAMI and ECRI Institute websites.*

1. Leadership ensures that there is a process for safe alarm management and response in high-risk areas (as identified by the organization).
2. Prepare an inventory of alarm-equipped medical devices used in high-risk areas and for high-risk clinical conditions, and identify the default alarm settings and the limits appropriate for each care area.
3. Establish guidelines for alarm settings on alarm-equipped medical devices used in high-risk areas and for high-risk clinical conditions; include identification of situations when alarm signals are not clinically necessary.
4. Establish guidelines for tailoring alarm settings and limits for individual patients. The guidelines should address situations when limits can be modified to minimize alarm signals and the extent to which alarms can be modified to minimize alarm signals.
5. Inspect, check, and maintain alarm-equipped devices to provide for accurate and appropriate alarm settings, proper operation, and detectability. Base the frequency of these activities on criteria such as manufacturers' recommendations, risk levels, and current experience.

Additional strategies include:

Training and education

6. Provide all members of the clinical care team (as defined by the organization) with training on the organization's process for safe alarm management and response in high-risk areas (as identified by the organization), and on the safe use of the alarmed medical devices on which they rely. Also provide ongoing training on new alarmed medical devices and updates to alarmed medical devices, and ensure that new members of the clinical care team receive training on the alarmed medical devices on which they rely.

Equipment and physical environment

7. To help reduce nuisance alarm signals, change single-use sensors (for example, ECG leads) according to manufacturer's recommendations, unless contraindicated.
8. Assess whether the acoustics in patient care areas allow critical alarm signals to be audible.

Leadership and organizational planning

9. Re-establish priorities for the adoption of alarm technology; the priority-setting process should drive technology adoption rather than allowing technology to drive the process.
10. Establish a cross-disciplinary team that includes representation from clinicians, clinical engineering, information technology, and risk management, to address alarm safety and the potential impact of alarm fatigue in all patient care areas.
    - Establish a process for continual improvement and constant optimizing of alarm system policies and configurations.
    - Review trends and patterns in alarm-related events to identify opportunities for improving alarm use.
    - Implement an alarm system management policy, including the periodic review of alarm coverage processes and systems, and the development of realistic, implementable strategies to address vulnerabilities.
11. Share information about alarm-related incidents, prevention strategies, and lessons learned with appropriate organizations, such as AAMI, ECRI Institute, the FDA, and The Joint Commission.

Related Joint Commission requirements

In addressing their performance with respect to alarm safety, organizations should reference the following relevant standards:

- Environment of Care: EC.02.04.01 elements of performance (EPs) 2 and 3; EC.02.04.03 EPs 2 and 3; EC.04.01.01
- Provision of Care, Treatment, and Services: PC.02.01.11; PC.02.01.19 EPs 1 and 2
- Performance Improvement: PI.02.01.01 EPs 12, 13, 14
- Leadership: LD.03.06.01 EP 3; LD.04.04.05 EP 13
- Human Resources: HR.01.06.01

References

[1] Association for the Advancement of Medical Instrumentation: Alarms Pose Challenges to Healthcare Facilities, *Horizons*, Spring 2011
[2] Association for the Advancement of Medical Instrumentation: Why Clinical Alarms Are a "Top Ten" Hazard, *Horizons*, Spring 2011
[3] Kowalczyk L: 'Alarm fatigue' a factor in 2d death: UMass hospital cited for violations, *Boston Globe*, September 21, 2011
[4] ECRI Institute: *2013 Top 10 Health Technology Hazards*, November 2012

Resources

- *"A Siren Call to Action: Priority Issues from the Medical Device Alarms Summit*," Association for the Advancement of Medical Instrumentation
- *"Horizons: Improving Medical Alarm Systems*," Spring 2011, Association for the Advancement of Medical Instrumentation
- "Sound the Alarm: Managing Physiologic Monitoring Systems," *Joint Commission Perspectives on Patient Safety*, December 2011;6-8, 11
- ECRI Institute Alarms Safety Resource site
- Association for the Advancement of Medical Instrumentation (AAMI) Alarms Systems site

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