Patient Safety Advisory

Veterans Health Administration Warning System
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Item: **Alarms on bedside physiological monitors**

Specific Incidents: NCPS has received multiple reports of close calls and adverse events leading to patient deaths associated with patients on monitoring systems where the alarms were turned off or where the alarm was inaudible. One VAMC reported that after the central station monitoring system failed on the midnight shift in an intensive care unit (ICU), a patient connected to a bedside monitor went into asystole and the alarm from the bedside monitor was unable to be heard outside the room. At a second VAMC, a patient went into respiratory arrest in the post anesthesia recovery unit (PACU). The alarm had been inaudible a few feet from the bedside. The patient was found cyanotic and unresponsive and was able to be resuscitated.

General Information: In the first incident, after checking the audible alarm volume in the ICU, staff found that all of the bedside monitors were set to the minimal alarm volume and were inaudible outside of the room. In the second incident**,** the default audible alarm volumes on all the PACU monitors were set to almost the lowest possible setting, which was well below the factory default settings, in order to reduce the noise in the unit. In both situations, changes to the alarm volumes were made without the knowledge or approval of the unit managers.

Clinical alarm management has been the focus of considerable attention, including a Joint Commission National Patient Safety Goal in 2004 (see Attachment 1a) and an article in the American Journal of Critical Care in 2008. Inappropriate alarm settings and failure to respond to alarms are among the most common issues resulting in patient harm associated with medical devices. Alarm hazards are at the top of the ECRI Institute's Top Ten Health Technology Hazards reported in a guidance article published in November 2008. Consideration for not disturbing the sleep of patients in the vicinity is not sufficient rationale to set the audible limits low. Although the ICU incident involved a patient care unit with a central station monitor connected to the bedside monitors, the same concerns exist if there is no central station monitor. Managing the bedside clinical alarms settings is independent of the equipment vendor and model. More effective patient outcomes can be achieved when systems are set to send out only actionable alarms.

Recommendations: The following recommendations are a compilation from many sources. Clinicians/users should complete the following recommendations or implement other measures to achieve an equivalent or increased level of safety.

1. Nurse Managers should periodically convey the importance of correct alarm settings, audible volume settings and alarm response to their staff.

2. Nurse Managers on monitoring units should ensure that their staff know how to set physiologically reasonable alarm limits for specific patients. This will provide protection for the patient but minimize clinically unimportant heart rate alarms or other minor or transient changes from triggering unwanted alarms. Limits that are too narrow result in excessive, non-relevant alarms. Limits that are too wide result in missing actionable alarms. Clinically pertinent alarm settings are particularly important in managing arrhythmia alarms.

3. Nurse Managers on monitoring units should ensure that default bedside and central station alarm volume settings are set at appropriate minimum levels and are periodically verified. They should also assure that their staff is aware that, for patient safety, the alarm volumes cannot be set below these minimally acceptable volume levels or disabled.

4. Facilities should use the initial alarm configuration checklist from the manufacturer and use it to assign audio and visual alarms based on the severity of the alarm. The checklist should be referenced when systems updates/upgrades and Preventive Maintenance Inspections and repairs are accomplished. The agreed to checklist should be signed off by the Biomedical Engineering professional and the Nurse Manager of the unit.

5. Users experiencing excessive false alarms should identify and address what is causing the majority of the false alarms. By far, the greatest opportunity for improvement is at the sensor-patient interface. ECG electrodes need to be applied correctly, with good skin prep, adhesion and attention to strain relief for the electrode wires. The monitoring system cannot analyze noisy signals, usually identified as “artifact”. In addition, pulse oximetry measurements can be affected by nail polish, skin coloration, extraneous light and patient motion. When possible, users should set brief (15 – 30 second) alarm delays so that only sustained excursions beyond a clinically important threshold activate an alarm.

6. Consider adding alarm-specific investigation questions for incidents in which a clinical alarm was a possible factor so that all relevant pre-alarm device settings (alarm status, limits, volume, staff assigned) can be captured from the monitoring system and other relevant sources. These can also be used as Root Cause Triage questions during a Root Cause Analysis.

7. Nurse Managers on monitoring units with central stations should review their policies and, if necessary, develop and implement a Central Station Down procedure similar to the example in Attachment 1b.

8. Biomedical Engineering staff should ensure that their scheduled performance inspection procedures include validation of the alarm setting operations and verification of the audible alarm levels.

9. Patient Safety or Environment of Care (EOC) Rounds may be used effectively to conduct and document Clinical Alarm Assessments.

10. In situations where adequate audible and visual notifications are compromised by the physical layout of the unit, users should consider alarm enhancement or alarm consolidation systems. Monitor alarms can be displayed on remote monitors or LED displays throughout the care unit. Monitor alarms can also be linked to the Nurse Call System or communicated through pagers or mobile phones; however these can only be used as secondary systems for alerting staff. Users will need to consider how additional alarm events will impact the primary function of the Nurse Call system.

11. The Patient Safety Manager is requested to document implementation of this Patient Safety Advisory on the VHA Hazardous Recalls/Alerts website within 30 days of the issue date.

Addl. Information: ECRI cites typical examples of clinical alarms that have been found inappropriately set: pulse oximetry monitors with the low saturation alarms limits set too low, ECG heart rate high and low alarm limits not adjusted to meet the needs of individual patients, and ventilator high peak pressure alarms set too high**.**

Source: VA Medical Centers

Attachment: 1a. The Joint Commission 2004 National Patient Safety Goal on Clinical Alarms.
1b. Sample Central Station/Monitoring System Down Procedure.

References:

1. Top Ten Health Technology Hazards – Guidance Article: *Health Devices*, ECRI Institute. 2008; November.
2. Clinical Alarm Management: A Team Effort. Joan Brown and Pat Anglin-Regal. *Biomedical Instrumentation &Technology*: 2008; March/April.
3. A National Online Survey on the Effectiveness of Clinical Alarms. Denise Korniewicz, Tobey Clark, Yadin David. *American Journal of Critical Care*: 2008; January, 17, No. 1.
4. Impact of Clinical Alarms on Patient Safety, Clinical Alarms Task Force - ACCE Healthcare Technology Foundation. *Journal of Clinical Engineering*: 2007; January/March.
5. How to Make the Most of Failure Mode and Effect Analysis. Erik Stalhandske, Joseph DeRosier, Bryanne Patail and John Gosbee. *Biomedical Instrumentation &Technology*: 2003; March/April.

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Attachment 1a: The Joint Commission 2004 National Patient Safety Goal on Clinical Alarms

6	**Improve the effectiveness of clinical alarm systems.**
6a	Implement regular preventive maintenance and testing of alarm systems.
6b	Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.

Note: In 2005, clinical alarms were removed from the National Patient safety Goals for hospitals. However, **The Joint Commission incorporated clinical alarm safety into their Environment of Care standards.** Under standards EC.6.10 and EC.6.20 it is expected that health care organizations integrate clinical alarms into their medical equipment maintenance strategies. In addition, Management of Human Resources standard, HR.3.10, and Leadership standard, LD.5.40, require organizations to facilitate appropriate responses from caregivers to clinical alarms.

Attachment 1b: Sample Central Station/Monitoring System Down Procedure

NOTE: Specific steps will vary depending on the particular manufacturer and model of the equipment used.

Check each bedside monitor after the central station becomes inoperative

1. On the front of the bedside monitor, select “Alarms/Volume”.
2. Then go to “Volume Control”.
3. Set the **Alarm Tone Volume** to a mid-level value. The alarm **MUST** be audible at a distance of 20 feet outside the patient’s room.
4. Check that alarms are not Suspended (disabled for a temporary time period, typically several minutes).
5. Verify the appropriateness of the High and Low Heart Rate Alarm Limits for each patient.
6. Open the patient’s door, except for patients in Isolation.
7. The patient’s room lighting must be adequate to allow easy viewing of the patient.
8. The patient’s room blinds must be in a position to allow easy viewing of the patient.
9. Patient checks are to be done every 15 minutes until the Central Station is functional.