FIRST
Do No Harm

In this Issue:

Massachusetts General Hospital Case Study: Physiological Alarm Monitoring

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SPECIAL ARTICLE

Did you hear an alarm?

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EVENT DESCRIPTION:

At Massachusetts General Hospital, our aim is to deliver the very best health care in a safe and compassionate environment, guided by the needs of our patients and their families. Despite our efforts and commitment to safety, a most tragic and unfortunate incident occurred at our hospital and our hope is that our story and lessons learned will be of benefit to our colleagues in patient safety. This event prompted an immediate and vigorous internal review, exposed vulnerable gaps in our physiologic monitoring process, and generated instant attention by the press.

This event involved an 89-year-old male patient found unresponsive and apneic lying in his hospital bed. The patient was being continuously monitored by his bedside cardiac monitor. His bedside monitor did not announce/alarm for a lethal arrhythmia - the lethal arrhythmia alarms and the bedside cardiac monitor alarm audio/volume were found to be off. The alarms were known to be functioning at the time of the patient's admission two days earlier. (See Alarm Guide, *Table 1)*

His past medical history included a Coronary Artery Bypass Graft, and a history of hypertension, and atrial fibrillation. The patient was admitted for an abdominal surgical procedure, which included the creation of a temporary colostomy. In the Operating Room, the patient developed complete heart block, which was treated with Epinephrine, Atropine, and the placement of a temporary pacing wire. Postoperatively, the patient was extubated and transferred to the Post Anesthesia Care Unit (PACU), where he remained alert, oriented and hemodynamically stable. The pacing wire was removed in the PACU, and the patient was transferred to the Coronary Intensive Care Unit (CICU) for continued monitoring and observation.

After more than 24 hours (Postoperative day 2 = POD # 2) in the CICU, his condition remained stable, with his heart rate 59-74 beats/minute in atrial fibrillation (his baseline rhythm preoperatively). It was deemed appropriate by the surgical team and medical attending to transfer him to a post op surgical floor (during the evening). Cardiology and electrophysiology consultants recommended the insertion of a permanent pacemaker, which was scheduled to be placed on POD # 5--three days later.

The patient had been up and out of bed with physical therapy during POD # 3. On POD # 4 he was progressing well, ambulating in the hall with nursing assistance, and had visited with his family within an hour of this event. His ostomy was reported to be functioning and his diet was advanced. He was well-appearing but oliguric and he was given a fluid bolus and salt-poor

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TABLE 1

Arrhythmia Alarm Guide:
3 Levels of Arrhythmia Alarm Level notification:

Crisis Alarm: audible sounds as three beeps high pitch, loudest sound
- Annunciated for Asystole
- Ventricular fibrillation/Ventricular tachycardia
- Vent Bradycardia and Sinus Pause

Warning Alarm: audible sounds as two beep lower pitch sound
- Vent tachycardia for >2
  (VT>2 = occurs when a run of ventricular beats is detected within a duration of less than six beats but longer than two beats and heart rate is greater than 100 beats per minute.)
- Tachycardia
- Bradycardia

Advisory Alarm: audible sounds as single monotone sound
- Accelerated Ventricular rhythm
- R on T phenomena

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albumin to increase urine output with good response.

At approximately 10:15 am on POD # 4, the patient was found pulseless and apneic in his hospital bed and a Code Blue was called. It was apparent he had vomited as vomitus was seen on his gown. The code team, consisting of medical and surgical residents, the surgical on-call attending, nurses and the clinical nurse supervisor, made every effort to resuscitate the patient, however, despite all measures, the resuscitation efforts were unsuccessful.

Immediately following the code, nursing staff and code team members discovered, after reviewing the central monitoring station that the lethal arrhythmia alarms had inadvertently been turned off on this patient.

EVENT INVESTIGATION – PROCESS AND RESULTS:

The MGH Center for Quality and Safety (CQS) was immediately notified and a thorough investigation began. On the day of the event, a biomedical engineer was consulted to interrogate the bedside cardiac and central monitors for information. On the same day as the event, nursing and biomedical engineering staff obtained logs from the central monitor.

The biomedical engineer confirmed that the lethal arrhythmia alarm setting (a default setting) had been turned off at the central station. In addition, the biomedical engineer discovered that the bedside monitor audible volume alarm had also been turned off. Immediately, all cardiac monitors on this surgical unit were checked for active functionality of lethal alarm settings and audibility of alarm volumes. The monitor arrhythmia default settings were set to either full alarms (which includes alarming for all abnormal rhythms), or lethal arrhythmia alarm notifications (which audibly sounds only for lethal arrhythmias). At this time, biomedical engineering staff completely disabled the ability to suspend all alarms (default setting "off"). For reference the lethal arrhythmia alarm audibly sounds as a crisis alarm, which annunciates as a high pitched three beeps, which is the loudest sounding alarm signal.

Biomedical engineering's initial review of the central monitor log demonstrated that two alarm notifications sounded for this patient before and during this event. The first audible alarm was a lower level sounding (2 beep warning) alarm that signaled for low oxygen saturation and had signaled before the event. This was followed by an audible alarm annunciating for bradycardia that rang for a prolonged period of time prior to the code. This bradycardia alarm has the same sounding 2 beep warning audible alarm that had been sounding for the low oxygen saturation alarm. Staff were unaware of and did not respond to these lower level alarms.

The CQS convened an emergency leadership meeting, which included nursing, administration, and biomedical engineering leadership staff to discuss the event. They reviewed the findings that were known at this point and identified who would lead the investigation. A second meeting was held that afternoon to assess the status of the investigation. Biomedical engineering had begun a unit to unit evaluation of alarm default settings and alarm audibility for the over 1100 monitoring devices within our facility. CQS staff interviewed, debriefed and offered support for the team involved in the event. All nurses interviewed denied hearing the two beep warning alarm signal or announcement of the alarm situation on the visible alarm display units. Nursing leadership and the Employee Assistance Program staff were also on hand to lend their support during this time of crisis.

A Critical Alert email message was sent to the nursing leadership of all patient care units requesting that they verify that all bedside alarms were activated with audible volume and lethal arrhythmia default settings on. They were also asked to verify that the default alarm setting "off" option was disabled.

Subsequently, all cardiac monitors in the institution were reviewed by our biomedical engineering department. All monitors were confirmed to have only two arrhythmia alarm default settings: Full and Lethal. Biomedical engineering also performed a unit by unit review of the audibility of alarm volume within hallways with our distributed speaker systems. They also reviewed the functionality of our hallway visible alarm display devices known as Alarm Display Units (ADU's) on each floor. The audibility of volume annunciation for all bedside monitors alarms was checked, and the default settings were reset to the lowest limit of no less than 10% with a standard default setting of 50% of the full alarm volume. Biomedical engineering developed a quality control review and audit process of default settings for future central monitoring installation or any systems upgrades.

The event was immediately reported to the Department of Public Health. A further corrective action plan included the

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assignment of nurses to continuously observe central monitors on each unit and a hospital-wide educational program was commenced on physiologic monitoring and alarm settings. We improved our clinical settings with installation of additional alarm display units (ADU's), and an increase in the number of alarm speakers on select patient units.

Coincidentally, during our investigation, the Centers for Medicaid and Medicare Services (CMS) arrived for an unannounced post Joint Commission verification survey. CMS thoroughly reviewed this sentinel event, approved our initial actions and strongly encouraged us to immediately implement our corrective action plan.

This critical event brought to light the complexity of MGH monitoring systems. We presently have two different central monitoring systems, with seven unique monitor models and multiple software versions. We identified we have a large number of patients on physiologic monitors without consistent standards for monitoring practices across the spectrum of clinical areas. The event also raised our awareness about the impact of alarm fatigue/desensitization related to multiple devices, equipment and noise levels within clinical settings. We concur with a recent study: "When alarm frequency is high, nurses are at risk for becoming desensitized to the alarms that are intended to protect their patients. Cardiac monitor algorithms are intentionally set for high sensitivity at the expense of specificity."[1]

In response to these findings, we launched a multidisciplinary Physiologic Monitoring Tiger Team with representation from Medicine, the Emergency Department and Intensive Care, which included physicians, nursing leadership, clinical nurse specialists, biomedical engineering quality personnel, clinical engineers, administrators and ancillary staff. The task of the Physiologic Monitoring Tiger Team was to focus on the development of clinical decision making tools for use when choosing to monitor a patient and the key components of education and communication regarding the use of these tools. In addition, the team oversaw the development of practice standards related to the transport of the monitored patient from the patient care unit to a testing site. Finally the team addressed alarm response. Education was geared towards technical competency through a branding campaign to support a culture of alarm awareness and responsiveness. Specifically the branding campaign included the theme **"Every Alarm Warrants Action."**

Our major outcomes from the Physiologic Monitoring Tiger Team included the development of standards for initial and daily assessment of ongoing need for electrocardiogram (ECG) and/or pulse oximetry monitoring based on patient specific 24 hour risk assessment *and recommend this assessment would be reviewed daily.*

We identified the following monitoring risk assessment categories:

High Risk: continuous monitoring;

Moderate Risk: continuous monitoring with supervised removal;

Low Risk: intermittent monitoring; and

No risk: monitoring not clinically indicated.

Based upon the risk assessment, medical and nursing staff will collaborate to determine the monitoring requirements, the patient clinical placement, and travel monitoring requirements. Alarm default settings were reviewed by the Tiger Team and decisions were made to adjust some default settings for less clinically relevant settings in an attempt to lower the number of nuisance alarm situations for the clinical practice setting.

REPORTING:

The CQS reported and discussed this case promptly with hospital leaders, consistent with our policy that immediate internal safety reporting is conducted, there is an open and honest discussion among disciplines, and the error is disclosed to patient and family. The surgeon and hospital administration informed the family that an error had occurred with their loved one and a full investigation was underway. CQS prepared the press releases and colleagues in safety improvement programs were consulted on the content of the releases keeping in mind that we would not disclose the identity of the patient or the identity of employees/staff. An internal review of our performance, was conducted using "Just Culture" methodology [2]. Our physician leaders in CQS reported this unfortunate and tragic patient event to the Board of Registration in Medicine's Quality and Patient Safety Division.

Our final root cause analysis findings were the following*:*

- *Arrhythmia default alarms setting were discovered off* (we were unable to determine when turned off or by whom).
- *The ability to turn "OFF" the lethal arrhythmia default setting was unknown prior to this event*. Staff held a false belief that the monitoring system would always alarm/signal for lethal arrhythmias.

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- The monitoring system on this unit had been installed just eight months previous to this event and staff had educational gaps related to the system's full functionality.
- *The message displayed on central and bedside monitor indicating that arrhythmia alarms were off went unrecognized by nursing staff.*
- *The patient's bedside monitor alarm volume had been silenced.*
- *Staff experienced alarm desensitization/ fatigue.*
- *The two beep "warning" alarm notification sounded for prolonged period of time and the visible alarm notification on alarm display units (3 ADU's on the unit) went unrecognized by the staff.*

LESSONS LEARNED:

Our CQS philosophy is that we investigate such events immediately and involve multi-disciplinary teams in the analysis and development of an action plan. Our leadership believes in transparency both internally and externally for the reporting of issues and system improvements. This critical sentinel event has improved many systems and promoted the development and adoption of specific monitoring standards for our patients. This investigation had also empowered our staff members to apply the tools necessary to optimize and individualize patient monitoring standards to improve the quality of patient care.

The issue of clinical alarm desensitization/fatigue is a serious concern for all of us in healthcare who are committed to provide care that is safe and of the highest quality. It is a challenge to health care facilities, clinicians and manufacturers, who will need to work together on how we will develop the smart technology necessary to support patient care. It is a challenge to our health care system and a call to action for the manufacturers of monitors to assure that the technology developed is safe, and will protect our patients from harm. In summary our mission at MGH is to deliver the very best health care in a safe, compassionate environment; to advance that care through innovative research and education; to improve the health and well-being of the diverse communities we serve; and to commit ourselves to creating clinical practice environments that keep our patients safe and protect them from harm.

References:

1. Creighton-Graham, K, Cvach, M. Monitor Alarm Fatigue: Standardizing Use of Physiological Monitors and Decreasing Nuisance Alarms. American Journal of Critical Care. 2010; 19:28-34.

2. David Marx. Just Culture. Outcome Engenuity website link http://justculture.org

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