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ISMP Medication Error Report Analysis

Tragedy in the Postanesthesia Care Unit

Mix-ups between Risperidone and Ropinirole

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.
Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.
Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

TRAGEDY IN THE POSTANESTHESIA CARE UNIT

In April 2012, after receiving a dose of intravenous (IV) fentanyl in the postanesthesia care unit (PACU) at an outpatient ambulatory surgery center, a 17-year-old girl died following an uncomplicated tonsillectomy. The case made headline news recently when a civil lawsuit filed by the teen's parents was resolved. Although it is too late to reverse the tragic outcome of this case, we call upon all hospitals and outpatient surgery centers to learn from the event and take action to prevent a similar tragedy in your facility.

Following surgery, the teen arrived in the PACU where a nurse anesthetist administered a dose of fentanyl by slow IV push to the patient to help manage pain. The drug led to respiratory depression and eventual respiratory arrest. The patient had no pulse and was breathless 25 minutes after receiving the fentanyl. Resuscitation efforts were initiated, and the patient was transferred from the ambulatory surgery center to a hospital emergency department. Tragically, as a result of oxygen deprivation, the patient suffered profound, irreversible brain injury and died.

After investigating the causes of this adverse event, the ambulatory surgery center staff identified several reasons why the PACU staff failed to notice the patient's declining respiratory status.

Inadequate Monitoring

After receiving the IV fentanyl, the teen was not observed or assessed for 25 minutes. The attention of the teen's PACU nurse was temporarily diverted to tend to a patient who had developed postoperative complications. An initial set of vital signs had been taken upon the patient's arrival in the PACU, but no further assessment of the patient occurred until she was found in cardiac arrest 25 minutes later.

Muted Alarms

The alarms on the monitoring equipment used to alert health care professionals to changes in the patient's cardiac and respiratory status were muted. In fact, all the alarms associated with monitoring equipment in the PACU were muted, most likely due to alarm fatigue. The purpose of a medical device alarm is to warn caregivers of potential problems with patients who may require immediate action. The cacophony of sounds from alarms that echo through a hospital or PACU, however, can be overwhelming.[1]

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The sheer number of alarms—up to 700 per patient per day[2]—along with a high rate of false or clinically insignificant alarms, can quickly desensitize staff and cause alarm fatigue, leading to missed alarms, ignored alarms, delayed responses to alarms, muted or low volume alarm settings, or adjustments to alarm limits outside a safe range.[1,2] Alarm fatigue has been described by those who experience it as follows[3]:

- When a nurse or other caregiver is overwhelmed with hundreds of alarm signals per patient per day
- When a patient can't rest with the multitude of alarm signals going off
- When a true life-threatening event is lost in the noise because of the multitude of devices with competing alarm signals, all trying to capture attention, without clarity about what action is needed

Additionally, in a PACU where nurses are rarely far from the patient's bedside, staff may have a mistaken belief that the risk associated with muting alarms is not significant.

Obstructed View of the Patient

A curtain had been drawn around the patient, obstructing the nurses' view and preventing them from maintaining an ongoing visual assessment of the patient.

Patients in the PACU are particularly vulnerable to adverse events and are more likely to encounter medical difficulties as they emerge from anesthesia versus later in their recovery.[4] In the operating room, an entire team of practitioners is directly caring for the patient and monitoring the patient's response. Once the patient moves into the PACU, highly trained PACU nurses are available to provide care, but they may be caring for more than one patient. Although PACU nurses may be experts in interpreting and responding to events during the brief but intense period immediately following a procedure requiring anesthesia, staffing patterns that do not support necessary monitoring, alarms that are inaudible, and a blocked line of sight for observing patients invite untoward clinical events. While airway obstruction may be the most common untoward event in the PACU, inadequate ventilation and oversedation from residual anesthesia-related medications and pain medications administered in the PACU are a close corollary.[4]

Unexpected patient emergencies can quickly arise in the PACU and result in the diversion of staff attention, so all hospitals and ambulatory surgery centers must recognize the likelihood of these events and their effects on patient care and consider the following recommendations to reduce the risks in the PACU (or a similar unit such as the emergency department).

Maintain a Direct Line of Sight to Patients

Although patient privacy is an important concern during the postoperative experience,[5] a direct line of sight to PACU patients is vital to allow staff to observe all patients at all times.[4] Privacy curtains should be used judiciously, and a PACU staff member who is assigned only to one patient may need to remain behind the curtain with that patient if close observation is required. In the ambulatory surgery center where this event occurred, it is now prohibited to draw curtains that would restrict the view of patients, according to the news.

Provide Staffing to Ensure Proper Monitoring

Review current staffing patterns and monitoring practices in the PACU to ensure patients are adequately observed and cared for during the immediate postanesthesia period, particularly when IV opioid analgesics are administered. Guidelines from applicable professional associations and national and state regulatory agencies should serve as a resource to ensure that staffing and monitoring practices comply with current standards of care. For example, the American Society of Anesthesiologists (ASA) Standards for PostAnesthesia Care note that a quantitative method of assessing oxygenation such as pulse oximetry should be used during the initial phase of recovery from anesthetics[6] and that physiologic monitoring such as cardiac monitoring has become a de facto standard.[4] The ASA also suggests that, during the initial 15 minutes in the PACU, one nurse should be caring exclusively for that patient.[4] The American Society of PeriAnesthesia Nurses (ASPAN)—the professional association to which the ASA defers for issues of nursing care—has promulgated a standard requiring a 1:1 nurse-patient ratio from the time the patient is first admitted to the PACU until explicit critical elements are met and the patient is hemodynamically stable.[5,7]

Because of the cumulative effects of opioids given near the end of a surgical procedure and then again in the PACU, which may contribute to respiratory depression, the surgical center where the adverse event happened now requires one-on-one nursing care for patients who have received opioids in the PACU. Because patient emergencies can quickly arise in the PACU and require unexpected staff attention, the facility also established a charge nurse position in the

PACU to monitor the patient flow and staffing and to redeploy resources as needed.

Manage Alarm Hazards

According to the ECRI Institute—a leading organization that evaluates medical technology—alarm hazards are once again number one on its list of the *Top 10 Health Technology Hazards for 2013*.[1] The potential for alarm-related harm exists every day in every health care facility. Given the ubiquitous nature of medical alarms, ECRI suggests that the potential for alarm-related events may always warrant inclusion on a list of the most pressing technology hazards.[1] Nonetheless, health care facilities must do more to improve the manner in which alarms are managed. Awareness of the problem is not at issue—the absence of meaningful action is.

Driving this point home, The Joint Commission (TJC) has been evaluating a proposed 2014 National Patient Safety Goal (NPSG) related to alarm management,[8] which would require accredited organizations to:

- Establish alarm safety as a priority.
- Prepare an annual inventory of device alarms and identify default settings.
- Identify the most important alarms to manage.
- Establish policies for managing important alarms, including clear guidelines regarding when alarms can be disabled, when alarm parameters can be changed, who has the authority to make these decisions, how to monitor and respond to alarms, and when to check alarms for accuracy.
- Educate staff about alarm policies and procedures.

The public comment period for the proposed NPSG has ended. However, TJC recently published a *Sentinel Event Alert* describing the extent of alarm-related events reported to TJC along with recommendations for improvement.[9]

The ambulatory surgery center where the event happened no longer allows muted alarms with monitoring equipment in the PACU. While ISMP concurs with this action, the scope of alarm hazards is larger than just muted alarms and broader than can be addressed with a few bullet points in this article. Therefore, ISMP strongly encourages health care organizations to utilize external resources that are more appropriate to guide the assessment and improvement of alarm hazards. Two great resources are the upcoming TJC *Sentinel Event Alert*[9] as well as an in-depth resource that describes priority issues and consensus recommendations from a 2011 medical device alarms summit convened in October 2011 by the Association for the Advancement of Medical Instrumentation (AAMI), the US Food and Drug Administration (FDA), the American College of Clinical Engineers (ACCE), TJC, and ECRI Institute.[3] The report, *A Siren Call to Action*, identifies and prioritizes a range of issues with medical alarms and priority actions for addressing them, including, among others, the following[3]:

- Conduct clinical testing and analyze alarm data to optimize alarm limits and delays for self-correcting alarm conditions that will reduce clinically non-actionable alarms.
- Test the acoustics on clinical floors; environmental noise impacts patient and staff well-being and patient safety.
- Change single-use sensors frequently to reduce nuisance alarm conditions, except in pediatric units (eg, change ECG leads every 24 hours).

The *Sentinel Event Alert* and the summit report make it clear that clinical leadership support and interdisciplinary efforts are an absolute requirement to make headway with this challenging problem.

MIX-UPS BETWEEN RISPERIDONE AND ROPINIROLE

We received a report of a mix-up between risperidone (*Risperdal*) and ropinirole (*Requip*). A patient experienced nausea and an unexpected sedative effect after taking what was thought to be 6 mg (2 x 3 mg tablets) of risperidone. The patient noticed that the tablets looked different than tablets from previous prescriptions for the same medication, so he brought the medication back to the pharmacy. It was discovered that ropinirole 3 mg tablets had been dispensed in error. Both products are from the same manufacturer and in the same shaped bottle with similar label printing.

The US Food and Drug Administration (FDA) warned the public about this name pair last year after ISMP and FDA received more than 200 reports of medication errors, some of which involved patients who required hospitalization. Risperidone is an antipsychotic agent whereas ropinirole is a dopamine agonist used to treat Parkinson's disease and restless legs syndrome.

The causes of confusion contributing to these errors included similar names; illegible handwritten prescriptions; similar product strengths, dosage forms, and dosing intervals; storage locations next to each other; and product names appearing together in computer listings. Similarities also contribute to container

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