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ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Worth repeating...

Recent PCA by proxy event suggests reassessment of practices that may have fallen by the wayside

Patient-controlled analgesia (PCA) allows patients to manage their own pain by self-administering more frequent but smaller doses of an opioid. This mode of pain control requires several safety strategies including careful patient selection, and patient, family, and staff education to avoid PCA by proxy—a term used to describe conditions under which someone other than the patient administers one or more doses of an opioid to the patient using the PCA device. A key safety feature of PCA is that the device is intended for patient use; a sedated patient will not press the PCA button to deliver more opioid.

ISMP first began publishing events associated with PCA by proxy in early 1996 to warn healthcare practitioners that well-intentioned family members and healthcare workers had been administering doses of analgesia to sleeping, sedated, or incapacitated patients, hoping to keep them comfortable but resulting in oversedation, respiratory depression, and even death. It's been more than a decade since we last published an article about a fatal event in which it was certain that PCA by proxy played a key role. However, a recent event reported to ISMP serves as a reminder that we must ensure that healthcare practitioners remain ever-vigilant to the risks of PCA by proxy. No one should allow critical prevention and safety steps to fall by the wayside, in particular: patient, family, and staff education about the dangers of PCA by proxy; proper selection of patients for PCA use; visual reminders to avoid activation of doses by anyone other than the patient; and appropriate patient monitoring.

Recent event

PCA had been prescribed and initiated for an elderly postoperative patient who had just undergone an above-the-knee amputation. When the patient returned to the inpatient care unit after surgery, she became confused and agitated and began hallucinating. She was started on haloperidol to treat her delirium and agitation, and hospital-employed, unlicensed "safety companions" were assigned to stay with her around-the-clock. One of the safety companions at the patient's bedside activated PCA doses for the patient by pressing the button 7 times during his 4-hour shift, which was discovered during the hand-off between this safety companion and an oncoming safety companion. The safety companion who administered the PCA doses understood that the patient could receive a dose every 6 minutes, but he felt that the patient was unable to press the button to activate a dose for herself and instead delivered a dose about every 30 minutes for the patient. He did not know that only the patient should deliver a PCA dose. Fortunately, the patient experienced little respiratory depression and was not permanently harmed.

During analysis of this event, the hospital determined there were several basic causative factors:

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NANALERT

NAN Alert about syringe leakage. An alert was distributed last month through the National Alert Network (NAN) asking clinical and technical healthcare staff to look for fluid leakage during the syringe-filling process. The alert was distributed by ISMP, the American Society of Health-System Pharmacists (ASHP), and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The alert was issued after the ISMP National Medication Errors Reporting Program (ISMP MERP) received reports of medication leaking beyond the syringe plunger onto surfaces exposed to air. The leaks happened most frequently when the plunger and barrel were not vertically aligned while filling the syringe. Leakage has occurred with both hazardous and nonhazardous drugs. The reports included syringes of various sizes and were manufactured by BD. However, BD has determined the 10 mL syringe is most affected and a correction is underway. ISMP recommends discarding syringes with fluid that has leaked past the black stopper on the plunger, as contents may be potentially contaminated or pose a risk to workers. Additional precautions to avoid contamination of work surfaces and exposure to personnel are required if leaking syringes contain hazardous drugs. The alert, which provides additional information and recommendations, is available at: www.ismp.org/sc?id=2811.

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- There was a lack of physician leadership to clearly define and appropriately enforce patient selection criteria for PCA, which would have excluded a confused and hallucinating patient, and other patients who were not suitable and safe candidates for PCA
- PCA policies did not clearly specify who can and cannot activate a dose
- A warning label no longer appeared on the PCA cord to indicate that only patients can activate the button
- There was limited staff awareness about the dangers and prohibition of PCA by proxy

The analysis team also found that the PCA policies did not clearly define and require specific patient monitoring that could quickly identify patients with respiratory depression.

This recent event is almost identical to an event we described in our May 29, 2002, acute care newsletter (www.ismp.org/sc?id=2807) in which nurses delivered PCA doses to an elderly postoperative patient who was confused and agitated. But in the 2002 event, the PCA by proxy led to seizures, cardiopulmonary arrest, hypoxic encephalopathy, and death of the patient.

Recommendations

ISMP urges all healthcare facilities that provide PCA for patients to reassess their current safeguards around this mode of pain management to ensure adequate prohibition of PCA by proxy and patient monitoring to quickly detect and correct signs of opioid toxicity. Perhaps over the years, the initial steps taken to prevent tragedies associated with PCA by proxy may no longer be rigorously applied.

Consider implementing the following recommendations so that pain management with PCA can be safely utilized within your organization.

Patient selection criteria

Assess current policies and *practices* regarding the proper selection of patients for PCA use. Stringent patient selection criteria for PCA may be included in protocols and order sets to support candidates who have the mental alertness and cognitive, physical, and psychological ability to manage their own pain, but the criteria may no longer be followed or enforced. The benefits of PCA, along with a lack of current reports of harm from PCA by proxy, may have led providers over the years to extend its use to less than ideal candidates who require practitioner-initiated PCA doses, including infants, young children, confused or incapacitated patients, or other inappropriate candidates such as patients on additional drugs that potentiate the effect of opioids or contribute to respiratory depression. Since an important safety feature with PCA is that the patient delivers each dose, proper patient selection is critical. (Also, The Joint Commission requires adherence to established patient selection criteria for PCA therapy, and the Centers for Medicare & Medicaid Services [CMS] *Conditions of Participation* require a documented assessment of the capacity of the patient to successfully administer any self-administered medications.)

Patient monitoring

Review current policies and *practices* related to patient monitoring during PCA use to determine their effectiveness in identifying and acting upon respiratory insufficiency to avoid patient harm. The Anesthesia Patient Safety Foundation (APSF) suggests continuous monitoring using pulse oximetry as well as capnography to detect unrecognized hypoventilation and carbon dioxide retention (www.apsf.org/newsletters/html/2011/fall/pdf/fall_2011.pdf). APSF recommends the use of pulse oximetry to detect hypoven-

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SAFETY wires

Crash cart drug mix-up. During a neonatal code, a physician asked for **EPINEPH**rine, but a nurse inadvertently prepared a prefilled emergency syringe of infant 4.2% sodium bicarbonate injection. Three doses of the wrong medication were given. The outcome of the neonate that coded is unknown at this time. The error was discovered post-code when the empty packages were recognized as incorrect.

Although it's clear that the sodium bicarbonate carton's label must not have been properly confirmed, part of the problem may have been related to the way the crash cart trays were prepared with a packing slip placed inside the tray that covered the **EPINEPH**rine carton labels (**Figure 1**). Also, the sodium bicarbonate syringe labels may have been oriented upside down in comparison to the nurse's point of view. During a neonatal code, since doses are so small, more than one dose of medication might come from the same syringe, which can compound a selection error. The report we received did not specify if this was the case or if different prefilled syringes were used.

Holding mock codes is helpful in identifying potential problems like this. Nurses, pharmacists, and others would also become more familiar with available items in code carts, how they are stored, and

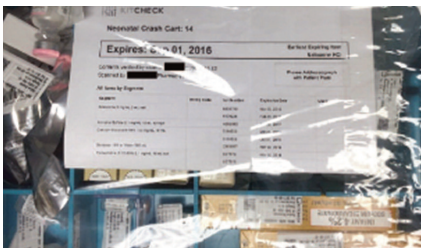

Figure 1. The packing slip inside the crash cart tray covered the **EPINEPH**rine carton labels, which led to erroneous preparation of sodium bicarbonate syringes.

what they look like. This is especially important in hospitals that may treat neonatal, pediatric, and adult populations with different code carts containing different concentrations of medications. During an actual code, any packing slips should be immediately removed from trays so they don't interfere with content visibility. Items in trays must be properly oriented for

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tilation when supplemental oxygen is not being used. For patients receiving supplemental oxygen, monitoring ventilation with capnography is necessary to provide an additional measure of safety. Because oversedation has occurred in patients with certain comorbid conditions such as pre-existing respiratory disease, obesity, and sleep apnea, or when using concurrent drugs that potentiate opioids, an effective screening process is also necessary to identify these risk factors and, if PCA is still used, to employ extra safeguards including capnography. Also be sure that any alarms in use (e.g., pulse oximetry, capnography, apnea alarms) are audible and responded to appropriately and in a timely manner—an unheard alarm or lack of response due to alarm fatigue can be deadly.

Educate patients and staff

Despite widespread awareness in the past about PCA by proxy, don't assume this is an old problem that has been resolved. Ensure that all patients, family members, and new staff who work in clinical units are educated about this potential knowledge gap. Patient education should not take place in the post-anesthesia care unit but rather before surgery while the patient is alert. If family members or clinical staff feel the patient is not receiving adequate pain relief with PCA, the patient's physician should be notified to determine if a different form of analgesia is needed for the patient.

Assess the need for warning signage

Assess whether warning signs are necessary on PCA cords to alert family members and remind staff that PCA doses should be administered only by patients. If used, be sure the warning is clear and understandable to patients, family members, and staff (e.g., **WARNING: BUTTON TO BE PRESSED ONLY BY THE PATIENT**).

For more information on PCA by proxy and other PCA risks, please see our July 10, 2003 (www.ismp.org/sc?id=2808), July 24, 2003 (www.ismp.org/sc?id=2809), and our May 30, 2013 (www.ismp.org/sc?id=2810) acute care newsletters.

Don't bring controlled substances to the bedside or procedural area before they are ordered or needed

Ongoing interaction with healthcare providers across the US suggests that a risk identified by ISMP during the analysis of a 2006 event[1] may be an ongoing problem that could cause patient harm—bringing a controlled substance (or any other medication or solution) into the patient's room, bedside, or procedural area before it is ordered or needed. This introduces the risk that the controlled substance might be mistaken as a different drug or solution packaged similarly. Practitioners who inadvertently administer the incorrect medication may not even know that the controlled substance has been brought to the immediate area. As you know, administering a controlled substance in error has led to significant patient harm.

In a 2010 journal article we published about the 2006 event, this practice played a major role in a mix-up between bags of epidural fenta**NYL** and bupivacaine and intravenous (IV) penicillin, which ultimately led to the death of a young mother in labor.[1] While several factors led to the decision to bring the epidural medication into the room before it was ordered or needed, the nurse's desire to have everything ready for anesthesia staff was the primary factor.

As in many instances before the event, the young patient's nurse brought the fenta**NYL** and bupivacaine bag into the room so that it would be available for anesthesia staff to initiate an early epidural. Before the event, anesthesia staff had expressed

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recognition during the code. It is also helpful for the person preparing the drugs during the code to be different from the person administering them. That gives an opportunity for the preparer to say, "Here's the **EPINEPH**rine 1 mg," then hand it off and have the person administering the medication read the label to confirm (e.g., "I have in my hand **EPINEPH**rine 1 mg."). It only takes a few seconds to confirm the correct drug is in hand. Including pharmacists on code teams to help participate in drug selection and prepare the necessary medications is also an important error-reduction strategy.

Strength confusion. A new oral cystic fibrosis treatment, **ORKAMBI** (lumacaftor and ivacaftor), is available in a 2-part blister pack, each containing two 200 mg/125 mg tablets (**Figure 1**), for a total of 4 tablets. Listing the strength for just 1 tablet on the 2-tablet blister can be confusing. In one hospital, the first time the

Figure 1. Confusing blister package label for new Orkambi tablets.

drug was prescribed, a pharmacy technician thought that 4 tablets were needed for a 400 mg/250 mg dose. Vertex Pharmaceuticals was contacted and confirmed that each tablet is 200 mg/125 mg, so each 2-tablet pack contains 400 mg/250 mg. We've seen this type of packaging confusion in the past with other drugs (**Figure 2**, page 4).

The danger is that clinicians, parents, and patients may see "200 mg/125 mg" and think the 2 tablets equal that dose, and then give all 4 tablets in the 2-part packages that are contained in cartons of the drug. The dose is typically 2 tablets every 12 hours, but patients with severe hepatic impairment or on certain medications should receive 1 tablet every 12 hours.

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dissatisfaction if the drug or patient was not ready for an epidural upon their arrival on the unit. This dissatisfaction had placed considerable pressure on nurses to ensure that the patient and drug supplies were ready before anesthesia staff arrived. As a result, guidelines and a checklist to promote patient readiness had been established, which included retrieving the epidural medication for anesthesia personnel before their arrival on the unit. Yet, nurses found it difficult to anticipate the arrival time of anesthesia staff because they did not directly communicate with them—obstetricians notified anesthesia staff to request the epidural analgesia and did not always communicate this with the nursing staff. Thus, before receiving a signed order and often long before it was actually needed, nurses routinely brought the epidural analgesia into patients' rooms. This was obtained via override from an automated dispensing cabinet (ADC) before an order was verified by pharmacy. Tragically, in the case above, the nurse accidentally picked up the bag of epidural fenta**NYL** and bupivacaine and administered it IV instead of the intended penicillin, which was in a similarly sized plastic bag. The young mother reacted to the bupivacaine and quickly developed seizures, respiratory distress, and cardiovascular collapse. A healthy infant was delivered by emergency cesarean section, but the mother could not be saved.

Today, we continue to hear that nurses are bringing controlled substances into procedural areas or to the bedside before they are needed or ordered for basically the same reason—to be prepared for when the physician and/or anesthesia arrives to carry out the procedure or administer sedation or analgesia. Preparedness is important, but the risk of mixing up an intended medication with the unnecessarily available controlled substance is not a risk worth taking. Syringes, vials, and bags containing controlled substances can look very similar to other medications that are needed for administration before the procedure. There may also be drug diversion concerns associated with unsecured controlled substances left unattended at the bedside or in the procedural area, or carried in practitioners' pockets.

Any controlled substance needed for a procedure should be ordered and verified by pharmacy, if possible, and then brought to the bedside immediately before use. This way, the controlled substance will not be accessible until needed and can't be confused with other medications that are ordered for the patient. A time-out process before a procedure should include verification of the controlled substance as it is handed off to the physician who will be administering it, without setting the drug down. Another option is to require anesthesia staff or other physicians to obtain any medication they plan to administer to the patient before or during the procedure, once they arrive on the unit, or to bring the medications with them in a secure anesthesia bag. If the medications are in an ADC, furnish anesthesia staff and other key providers with individual access codes. If possible, segregate the medications used for this purpose from other drugs in the ADC. Barcode scanning is also highly recommended prior to any drug administration by any practitioner.

Reference

1) Smetzer J, Baker C, Byrne FD, Cohen MR. Shaping systems for better behavioral choices: lessons learned from a fatal medication error. *Jt Comm J Qual Patient Saf.* 2010;36(4):152-63.

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Thus, there is also a risk that patients with hepatic impairment could receive both tablets. Dosing is explained well in the package insert but not on the blister label. The barcode on the label includes the NDC, so the blister will scan as correct if both tablets are administered in error.

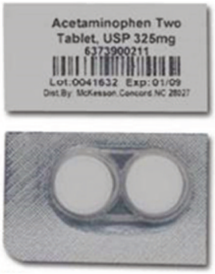

Figure 2. (2 photos) How much acetaminophen is in this package? There's 325 mg in each tablet. The label was later changed to 650 mg.

We have asked the US Food and Drug Administration (FDA) to look into this. A draft guidance from FDA, *Guidance for Industry Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (www.ismp.org/sc?id=1733), recommends labeling unit dose blisters as the amount (e.g., mg, g) per tablet/capsule. For Orkambi, the label should clearly state the strength as "each tablet contains 200 mg/125 mg (400 mg/ 250 mg total for 2 tablets)."

Special Announcement

ISMP webinar

Join us on **November 9, 2016**, for our next webinar, **Medication Reconciliation: Important Lessons Learned from an Emergency Department Pharmacist**. A review of medication reconciliation errors and their causes will be highlighted, followed by a description of the challenges with medication reconciliation faced by staff in the ED. Steps and recommendations for improvement will be outlined. To register, visit: www.ismp.org/sc?id=349.

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