



Safety issues with patient-controlled analgesia

Part I - How errors occur

Patient-controlled analgesia (PCA) has great potential to improve pain management, allowing patients to self-administer a more frequent but smaller dose of an analgesic when in pain. When used as intended, PCA actually reduces the risk of oversedation, which is an unintended consequence of the traditional nurse-controlled analgesia in larger, less frequent doses. However, it's clear from anecdotal reports in the literature and events reported to ISMP that errors happen frequently, sometimes with tragic consequences. The following factors have often contributed to PCA errors.

PCA by proxy. A crucial built-in safety feature with PCA that's often overlooked is that the device is intended to be activated by the *patient*. A sedated patient will not press the button to deliver more opiate, thus avoiding toxicity. More opiate is required to produce respiratory depression than to produce sedation. However, family members and health professionals have administered doses for the patient, by proxy, hoping to keep them comfortable. This well-intentioned effort has resulted in respiratory depression and even death. (This problem was a topic in the December 20, 2004, Joint Commission *Sentinel Event Alert*.) For example:

■ A postoperative patient asked her husband to press the button on her meperidine PCA if she moved or made any noise as she slept during the night. Sadly, he complied, and by morning, the patient suffered a respiratory arrest and could not be successfully resuscitated.

■ A nurse consistently woke her elderly patient, assessed his pain, and pressed the button on his morphine PCA, believing she was helping this "stoic" patient. Extreme oversedation resulted by morning, which eventually contributed to the patient's death.

Improper patient selection. Since an important safety feature with PCA is that the *patient* delivers each dose, candidates for PCA should have the mental alertness and cognitive, physical, and psychological ability to manage their own pain. However, the benefits and convenience of PCA have led providers to extend its use to less than ideal candidates such as infants, young children, and confused patients. This facilitates the dangerous practice of PCA by proxy. For example:

■ A previously alert elderly patient was prescribed morphine PCA postoperatively, but she became obtunded and confused, and unable to verbalize pain or press the button. To keep her comfortable, nurses delivered PCA doses when the patient exhibited restlessness. Within 48 hours, the patient experienced respiratory depression and seizures, resulting in hypoxic encephalopathy, and death 2 months later.

Oversedation has also occurred in less than ideal candidates at risk for respiratory depression due to comorbid conditions such as obesity, asthma, or sleep apnea, or use of concurrent drugs that potentiate opiates (e.g., benzodiazepines, barbiturates). PCA use in unsuitable patients may also result in undertreatment due their inability to clearly communicate pain.

Inadequate monitoring. Even at therapeutic doses, opiates can suppress respiration, and decrease heart rate and blood pressure. Accordingly, nurses typically monitor patients receiving opiates at distinct intervals. However, these activities may not alert caregivers to opiate toxicity. Patients may not be monitored frequently enough, especially during the first 24 hours and at night when nocturnal hypoxia can occur. The way that nurses assess

continued on page 2

pearls from patients



Excerpts from an eloquent letter that a patient sent a physician sheds light on our need to improve patient education about PCA.

I thought you'd be interested in the "pain pump" experience I had at your hospital. I hasten to add that ANY hospital could have been at fault for the same things.

During my pre-op visit, no explanation was given about a "pain pump." I went to surgery and then was returned to my room - -all pain free until gradually, the morphine wore off and my pain was real indeed. However, the effects of the anesthetic had not worn off and I was quite muddle-headed. The "just push this button" for pain relief made no sense to me and could not be properly assimilated by my muddled brain. For well more than 5 hours, I suffered while my husband stood by helpless. He wasn't allowed to push that button for me!

I clearly remember (funny what a muddled brain remembers) thinking that, if I'd had a gun, I'd have shot myself so extreme was my pain. IM injections finally began and, glad to say, I was out of the hospital in no time.

Please let anyone know that clear instructions about "pain pumps" AND the frequency that they can be given ought to be given to the patient at their pre-op appointment, as well as on the gurney awaiting the actual surgery. I'd bet that I'm not the first to be confused (and I am just 40 years old, not nearly elderly or slow thinking).

Additionally, a lighted monitor (4" large letters for the nearsighted please) indicating when the next dose is available should be mandatory.

Source: Personal communication to D. John Doyle, MD, PhD, FRCPC.

PCA continued

patients may also be at the root of the problem. Patients with induced respiratory depression or oversedation can easily be stimulated to a higher level of consciousness and an increased respiratory rate. Thus, if nurses disturb patients in order to make the assessment, the observed level of consciousness and respiratory rate may not be helpful in detecting toxicity. Once the stimulus is removed, patients fall back into an oversedated state. There's also too much reliance on pulse oximetry readings, which can offer a false sense of security since oxygen saturation is usually maintained even at low respiratory rates, especially if supplemental oxygen is in place. For example:

■ An elderly patient on morphine PCA was found with a respiratory rate of 4 and an oxygen saturation of 96%. The patient's daughter, who had been advised not to press the button, was afraid the medication would wear off during the night. So she woke her mother frequently and encouraged her to push the button. Despite frequent monitoring during the night, the respiratory depression was not noticed until the next morning, in part due to reliance on high pulse oximetry readings. Fortunately, the patient responded quickly to naloxone.

Inadequate patient education. Most patients who are suitable candidates for PCA can be taught how to use the device successfully. But patients who have been taught to use the device during the immediate postoperative period have often been too groggy to fully understand its use, and have reported poor pain control during the first 12 hours after surgery. See *pearls from patients* for an example. Even alert, appropriate patients have misunderstood the directions for use, believing that they must press the button every 6 minutes or so, even when sleepy and comfortable.

Drug product mix-ups. Name similarities have also led to mix-ups between morphine and hydromorphone, or the mistaken belief that hydromorphone (**DILAUDID**) is the generic name for morphine (1.5 mg

of hydromorphone is equivalent to about 10 mg of morphine). Morphine is available in prefilled syringes in two concentrations, but the packaging may not help distinguish them, leading to errors. For example:

■ A nurse inadvertently selected a 5 mg/mL instead of the prescribed 1 mg/mL concentration of morphine from an automated dispensing cabinet to change the syringe of a PCA pump, causing a respiratory arrest in a young patient. Luckily, the patient was successfully treated with naloxone.

Since opiates are typically unit stock, these errors are rarely detected and, most often, have led to significant overdoses; less often, they have led to undertreatment of pain or to an allergic response to the medication.

Practice-related problems. Misprogramming of the PCA pump is, by far, the most frequent practice-related issue. While pump design issues are a common cause of programming errors (described in the section below), some errors have been linked to mental slips or mix-ups. For example:

■ A hydromorphone concentration was accidentally set at "2.0" mg/mL, not 0.2 mg/mL (undertreatment)

■ A hydromorphone basal rate was set at 0.5 mg/hr, not 0.05 mg/hr (oversedation).


■ A pump was programmed to deliver 5 mL (50 mg) of meperidine with each demand dose instead of 5 mg (oversedation).


■ A pump was programmed to deliver a loading dose (38 mcg of fentanyl) for each demand dose (oversedation).

■ A morphine PCA pump was set to deliver 10 mg every 2 minutes, not 2 mg every 10 minutes (oversedation).

Device design flaws. Programming a PCA pump requires multiple steps, but its design is often far from intuitive. In fact, two Abbott pumps (Lifecare PCA II and APM Infuser) have been under close scrutiny for years because of frequent programming errors, many which have led to deaths. For example:

safetywires

 **Weighty differences.** Weight-based heparin protocols are dependent upon an accurate weight! We know of a patient with deep vein thrombosis (DVT) who purposely understated her weight by 20 pounds because she didn't want her husband to know her actual weight. Her actual weight was obtained once she reached her room, but not in the emergency department (ED). While a twenty-pound difference may not cause a problem, larger discrepancies could. We've received reports of up to 100-pound differences between a stated weight and an actual weight! With the input of pharmacists and prescribers, explore clinical situations where weight differences would require a change in dosage, and establish parameters for when pharmacists and prescribers should be notified. This issue could justify the use of stretchers with built-in scales in the ED to get accurate weights prior to any weight-based dosage calculations.

 **Got air bubbles?** After hanging an insulin drip (2 units/hour) on a 9-year-old patient, a nurse attempted to remove air bubbles from the IV tubing and pump chamber to promote proper flow. She disconnected the tubing from the patient and increased the pump rate to 200 mL/hour. When the air bubbles were removed, she reconnected the tubing and restarted the infusion. However, she forgot to reset the infusion rate to 2 units/hour. The child received about 50 units of insulin before the error was detected. Luckily, the patient was treated with dextrose injection and sustained no permanent harm. When attempting to remove air bubbles, disconnect the tubing from the patient, remove the entire infusion set from the pump, and establish gravity flow while using the flow-control clamp so that the pump settings are not changed. By increasing the flow rate on the pump, you add a step that must be undone, which could be forgotten.

continued on page 3

PCA continued

■ A 19-year-old mother died hours after a routine cesarean section when a nurse accidentally misprogrammed an Abbott Lifecare PCA Plus II Infusion pump. Unknown to the nurse, the pump default for morphine was set at 0.1 mg/mL, not the standard 1 mg/mL which resulted in a 10-fold overdose. Because the nurse was unaware of this default setting, at first, she thought the pump had malfunctioned.

Other design flaws that have led to programming errors include pumps that do not require users to review all settings before the infusion starts, pumps that require users to program the dose in mL, not mg (making it easy to overlook the drug concentration and amount of drug the patient is actually receiving), and pumps that have hidden defaults. For example:

■ One patient died from an overdose of fentanyl delivered during a clinician bolus dose. The two nurses who initially programmed the pump likely set the concentration at 50 mcg/mL as prescribed, but the Deltec CADD-Prizm PCS Pain Control System pump (model 6101) defaulted to a prior setting, 1 mcg/mL, when the Enter key was not pressed within 20 seconds.

Siphoning (free flow) also has been reported after entry of air into the system due to a fractured glass syringe, or a broken cassette that detaches from a pump without anti-siphon tubing. Mechanical problems, such as short circuits, are rare, but insufficient batteries can lead to failures in drug delivery. Some devices also obstruct the view of labels on syringes or cassettes once they are in the pump, thus limiting ongoing verification of the drug.

Design flaws can also be related to the patient's use of the pump. The activation button may look like a call bell, so patients have inadvertently given themselves a dose of analgesic while attempting to call a nurse. Many pumps fail to provide visual or auditory feedback so patients can't tell whether the press of the button has been successful. As a result, some become frustrated and give up.

Inadequate clinician education.

Programming a PCA pump requires a number of steps. However, nurses may not always receive adequate training, or may not retain adequate proficiency if multiple types of PCA pumps are used or if PCA is encountered infrequently. For example:

■ A graduate nurse who rarely encountered PCA needed to change a morphine syringe. She tried to figure out how to do this intuitively, but she failed to install the plunger with the syringe. The patient's continued complaints of pain led to discovery of the error.

Additionally, prescribers may not undergo a credentialing process designed to verify proficiency with this form of pain management. Prescribing errors have resulted.

Prescribing errors. The PCA order itself can be a source of error. Physicians have made mistakes in converting oral hydromorphone to the IV route (with an oral to IV conversion range of 3:1 to 5:1), and when selecting or calculating an appropriate dose for a morbidly obese, opiate naïve, or elderly patient. Occasionally, one opiate has been prescribed but the accompanying dose has been appropriate for a different opiate. Even with correct PCA orders, clinicians have been known to mishear or misread verbal or written orders, sometimes leading to serious errors. Concurrent orders for other opiates (oral or parenteral) while PCA is in use has also resulted in opiate toxicity. For example:

■ Preoperatively prescribed hydromorphone PCA was accidentally continued postoperatively without an order. Since the patient was also receiving oral narcotics, he experienced respiratory depression, which required treatment with naloxone and admission to ICU.

In part II, to be published in our February 2005 issue, a checklist of practical error-reduction strategies for PCA will be provided to reduce the risks associated with this innovative technology.

► Special Announcements

► **ISMP teleconference.** On February 4, from 1:30-3:00 p.m. (EST), ISMP will be holding a teleconference, **Meeting the 2005 National Patient Safety Goals Challenge: Avoiding dangerous abbreviations and errors caused by look-alike drug names.** Robert Catalano, MD, MBA, and Timothy Lesar, PharmD, from Albany Medical Center, will discuss their successful, medical staff-driven effort to eliminate error-prone abbreviations with a group of NY hospitals. ISMP President, Michael Cohen, RPh, ScD, will explore the difficulties of complying with the Joint Commission's "minimum list" of dangerous abbreviations, as well as ways to avoid errors with look-alike drug names. CE credit will be available for nurses and pharmacists. Visit www.ismp.org/npsg for information.

► **ISMP Fellowship.** ISMP offers a 12-month fellowship program that educates a healthcare practitioner in medication error-prevention methods. Nurses with risk management, quality improvement, or patient safety experience may apply. The Fellowship offers a generous stipend and full benefits. Relocation to the Philadelphia area is required. Additional information and applications are available at: www.ismp.org/Pages/fellowship.html.

► **Free CE Credit.** One hour of continuing education (CE) credit is now available at www.ismp.org/nursingce for the July through December 2004 issues of **Nurse Advise-ERR™**. To obtain credit, nurses must answer questions posted on our website.

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