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Death by PCA

Commentary by **Rodney W. Hicks, PhD, RN, FNP**

The Case

A healthy 21-year-old pregnant woman delivered a healthy baby via Cesarean section after an uncomplicated pregnancy. Two hours after delivery, the post-anesthesia care unit (PACU) nurse removed the patient's epidural catheter (placed prior to Cesarean section) and implemented an order for a morphine patient-controlled analgesia (PCA) with a 2-mg bolus, 6-minute lockout, and a 4-hour limit of 30 mg. Two concentrations of morphine are normally available for PCA use, 1 mg/mL and 5 mg/mL. The nurse used a 5 mg/mL morphine cassette because a 1 mg/mL cassette was not available. Upon admission to the ward 3 hours after delivery, the ward nurse reviewed the history settings on the PCA pump and confirmed the pump settings were consistent with the order. However, she did not read the label on the cassette, open the pump, or assess the volume being infused.

Four hours after delivery, the patient complained of itching after breastfeeding her infant. The nurse administered 25 mg Benadryl intravenously followed by a second 25-mg dose of Benadryl 45 minutes later. Six hours after delivery the patient was alert, oriented, and awake. Later in the evening the patient was found asleep and snoring. Her vitals were within normal range and the nurse noted that 20 mg of morphine had been infused. Thirty minutes later the patient had no detectable pulse or respirations. Despite resuscitation efforts, she was pronounced dead 7.5 hours after initiation of the PCA.

Autopsy revealed a toxic concentration of morphine. The available evidence is consistent with a concentration programming error where morphine 1 mg/mL was entered in the infusion pump instead of 5 mg/mL.

The Commentary

by **Rodney W. Hicks, PhD, RN, FNP**

This case highlights many of the persistent complexities that clinicians face when dealing with patient-controlled analgesia (PCA). Like many iatrogenic errors, active and latent decisions (1) led to a tragic patient outcome. As early as 2003, mortality from PCA use was thought to be a low likelihood event, ranging between 1:33,000 to 1:338,800 cases.(2) A more recent analysis from 500 hospitals found that 6.5% of PCA errors resulted in harm, as compared with 1.5% of general medication errors.(3) Despite advances in patient safety awareness, such events are far too common and are not limited to the United States health care system.(2,4) The true incidence and burden of PCA errors remains unknown.

Opioids are the most commonly used class of medications for postoperative pain management.(5,6) For more than four decades and now in almost every developed country, PCA remains an effective means for postoperative pain management. PCA differs from nurse-controlled analgesia, which usually involves intermittent, intramuscular injections of analgesic agents. In the latter, patients depend on nursing staff to administer medication. Favorable attributes of PCA use include rapid onset of analgesia, avoidance of first-pass hepatic effect, decreased surgical complication rates, shortened stays, and lower risk of litigation.(3,4)

PCA errors are a subset of medication errors and can be categorized (and should be reported) using common medication error frameworks that describe severity (patient outcome), type of error, cause of error, contributing factors, and product involvement. Although PCA errors can originate in each phase of the medication use process (Table 1), it is the point of drug administration that is often implicated, such as excessive doses (7) (as evident in this case) or the use of the wrong opioid product.(3) Even with recent use of human factors engineering approaches to designing safer user interfaces (8), the majority of errors still originate with individuals making mistakes rather than being equipment related.(3,4)

In the current case, at least three opportunities to detect the error were missed. First, there was failure in the independent double check during the device set up. Independent double checks rank high among the many recommendations that have been suggested as a means to reduce errors (7,9), although this practice has been recently scrutinized and the evidence is insufficient to either support or refute its true value.(10) Contributing to the failed double check was the fact that the routinely stocked dose of morphine (1 mg/mL) was replaced with a higher dose (5 mg/mL). Thus, confirmation bias (9) likely occurred with the post-anesthesia care unit (PACU) nurses. Confirmation bias is a selective type of thinking whereby one tends to read or hear what they expect. In this case, the staff likely saw only the name of the product and then assumed the "routine dose" and, as a result, overlooked the dose variation. Validation of dose and product accuracy, however, could be accomplished through a bedside barcode medication administration (BCMA) process, which is clearly superior to and more reliable than independent double checks.(11)

The second missed opportunity deals with the patient's persistent pruritus. This symptom should have provoked the clinical staff to further assess the patient and the infusion. Opioids have a number of adverse effects, including pruritus, bradypnea, hypoxia, nausea, vomiting, sedation, urinary retention, and death.(6) Compounding the oversight, diphenhydramine, a sedating antihistamine, was administered twice—which should have been another red flag. The final opportunity to identify the opioid overdose before the patient was permanently harmed pertains to the presence of snoring respiration—a finding that suggests deeper sedation. Sedation generally precedes respiratory depression.

Missing from the case at hand is any discussion on the use of pulse oximetry, capnography, or other proven monitoring technology. In the not-too-distant past, the addition of either device required supplemental equipment. Newer PCA pumps (e.g., smart pumps) can supplement clinicians' activities by integrating capnography within the pump and temporarily suspend infusions when physiological parameters are breached.(5,12) Newer technologies offer drug error reduction systems, drug libraries (11), and programmable features.(11,13) For this case, capnography alarms would have alerted staff to a deteriorating clinical condition ahead of apnea.

Several organizations have publically shared experiences with comprehensive safety initiatives surrounding PCA use.(5,7,11,12,14) Facilities in Pittsburgh have reported that PCA safety has been significantly enhanced by the low cost intervention of standardizing the PCA prescribing and administering processes across the community. An understanding of, and investment in, the medication use process offers the best protection to avert similar errors. Patient safety begins with a multidisciplinary team of clinicians and organizational leaders committed to practicing safe medication use and embracing strategies that will reduce the burden of medication errors (Table 2). Of particular promise are the technology advances in electronic order entry, appropriately stocked medication dispensing cabinets intricately linked to the pharmacy information system, fully deployed bedside BCMA with a smart pump, and capnography with corresponding pulse oximetry capable of wireless monitoring. Ultimately, having a trained staff and appropriately integrated technology will become the new organizational norm.

Take-Home Points

- PCA is widely used and is generally an effective method of postoperative pain management.
- While deaths from PCAs are rare, they can occur and this heightens the importance of developing safe processes surrounding PCA use.

- Safe PCA use is highly dependent on a team comprised of clinicians, administrators, biomedical engineers, and quality improvement personnel.
- Organizations that employ PCAs must adopt and integrate technology—such as bedside barcoding and monitoring with capnography and oximetry—in order to facilitate safe medication use.

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Tables

Table 1. The Medication Use Process.(15)

Step in Medication Use Process	Defined
Procuring and Storage	The formal action of how organizations obtain and store products
Prescribing	The action of a legitimate prescriber to issue a medication order
Transcribing	Anything that involves or is related to the act of transcribing an order by someone other than the prescriber for order processing
Dispensing	Begins with a pharmacist's assessment of a medication order and continues to the point of releasing the product for use by another health care professional
Administering	The action during which the medication product and the patient intersect
Monitoring	Involves evaluating the patient's physical, emotional, or psychological response to the medication and the recording such findings

Table 2. Roles in the medication use process (MUP) that promote safe use of PCA.

POINT IN MUP	RESPONSIBLE PARTY (PARTIES)	SAFETY SOLUTIONS OF MOST PROMISING BENEFITS
Procuring	Chief executive officer Chief operating officer Chief nursing officer Chief medical officer Chief information officer	<ul style="list-style-type: none"> ● Evaluate and purchase <i>smart</i> PCA pumps with proven safety features including: <ul style="list-style-type: none"> ○ Dose error reduction systems (DERS) ○ Capnography ○ Wireless capabilities ○ Barcode scanning ● Integrate order entry systems, pharmacy management systems, barcode verification systems, and electronic medication administration records.(5,13,14)
	Pharmacy and therapeutics committee (P&T)	<ul style="list-style-type: none"> ● Standardize and limit the concentrations for PCA agents available in the organization.(14) ● Standardize smart pump drug libraries (11) throughout the organization and community. ● Include review of medication errors as part of P&T function.

	Purchasing	<ul style="list-style-type: none"> ● Ensure sufficient supply chain to avoid product shortages. ● Obtain products with manufacturer's barcode and minimize "in house" barcoding.
Storing	Pharmacy	<ul style="list-style-type: none"> ● Store products to avoid errors from sound-alike/look-alike drug packaging. ● Store only one strength of a product in a dispensing cabinet. All other strengths should come directly from pharmacy.
Prescribing	Prescribing	<ul style="list-style-type: none"> ● Standardize order entry process (7), not only for the organization but the entire community (including competitors). ● Ensure appropriate patient selection prior to procedure.(5,14) ● Prescribe non-sedating antihistamines (for pruritus) and non-sedating antiemetics.(16)
Transcribing	Chief executive officer Chief operating officer Chief nursing officer Chief medical officer Chief information officer Clinical staff	<ul style="list-style-type: none"> ● Adopt electronic order entry systems that eliminate the need for manual order processing.(13)
Dispensing	Pharmacy	<ul style="list-style-type: none"> ● Deploy real-time pharmacy alerts for antidote medications retrieved from dispensing devices. ● If non-standard product strengths are used, centralize and dispense from main pharmacy with appropriate alert over-wraps. ● Participate with other clinicians in annual competency reevaluation of the PCA process. ● Participate with wireless monitoring activities of all infusion devices. ● Develop policies and procedures that review automated dispensing device overrides and variances.(3) ● Ensure appropriate labels that are simple to distinguish from other products and easily understood.
Administering	Licensed clinicians (includes physicians, nurses, therapists)	<ul style="list-style-type: none"> ● Ensure adequate pre-procedural education to patient and family.(7) ● Perform independent double checks of the order, product, and PCA pump settings.(7) Require both clinicians to be readily identifiable through documentation.(9) ● Ensure medication administration records

		<p>documentation includes pump settings.</p> <ul style="list-style-type: none"> ● Embrace BCMA principles. ● Recognize the heightened patient risk for the first 24 hours of initiation. ● Participate on P&T committees. ● Include PCA process as part of annual evaluation of clinical competencies. ● Assess and record vital signs (including depth of respiration), pain, and sedation. ● Record oxygen saturation levels and capnography values at every assessment. ● Ensure avoidance of "PCA by Proxy" (PCA doses triggered by family members or other loved ones). ● Review annual competency by staff.
Monitoring	Biomedical department Quality improvement department	<ul style="list-style-type: none"> ● Establish policy and procedures for reviewing "pump logs."^(1,4)
	Clinical staff	<ul style="list-style-type: none"> ● Perform ongoing assessments of all patients receiving PCA therapy. ● Record oxygenation and capnography values at every assessment.
	Chief executive officer Chief operating officer Chief nursing officer Chief medical officer Chief information officer Clinical staff	<ul style="list-style-type: none"> ● Encourage open investigation and reporting of near miss errors and actual errors. Report externally to Patient Safety Organizations (PSOs).