Making Patient-Controlled Analgesia Safer for Patients

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ABSTRACT

The Pennsylvania Patient Safety Authority has received approximately 4,500 event reports associated with patient-controlled analgesic (PCA) pumps (June 2004 through May 2010). PCA infusion pumps allow patients to self-administer doses of pain-relieving medication as needed, rather than having to summon a caregiver. The most significant risk when using these pumps is overmedication leading to opioid-induced respiratory depression. This article assesses this and other risks associated with PCA therapy reported to the Authority. It reviews ways to prevent adverse events. (Pa Patient Saf Advis 2011 Sep;8[3]:94-9.)

Patient-controlled analgesic (PCA) infusion pumps allow patients to self-administer opioid analgesics within the limits prescribed by a physician or other licensed professional. PCA therapy is used for postoperative, obstetric, terminally ill, and trauma patients. PCA pumps deliver solutions intravenously, subcutaneously, or epidurally and allow patient activation by means of a pendant button on a cord connected to the pump or a button directly on the pump. Accidental overdoses by patients are prevented by lockout features on the pump and by the fact that heavily sedated patients will be too somnolent to self-administer more analgesics.

The programmable features of pumps allow the clinician to select the drug concentration, patient bolus dose, lockout interval between patient-controlled boluses, and a continuous (basal) rate. Drug concentration is typically specified in mg/mL, the patient-activated bolus dose is specified in mg, and lockout intervals between patient boluses are programmed in minutes. If a continuous rate is ordered, it would be in mg/hr or mcg/hr.

PCA pumps come in two main styles: larger pole-mounted pumps and smaller ambulatory-style pumps. Pole-mounted pumps are intended for bedside use, often in an inpatient setting; most offer limited ambulation time. They emphasize function for complex care, with larger display screens and easy-to-navigate menus that guide the clinician through the programming process. These pumps generally offer more computing power and therefore more comprehensive features, functions, and event logs, and typically can only deliver medications that are available in prefilled vials or syringes. Ambulatory-style pumps are intended to be carried by the patient to allow ambulation in inpatient, outpatient, and home care settings; they may also be clamped to an intravenous (IV) pole. They typically deliver fluid from small bags or cassettes and emphasize portability and simplicity of programming.

A dose error reduction system (DERS) is a critical element in detecting and preventing errors in prescribing and programming. Devices with this functionality are commonly referred to as "smart" pumps because they can compare programmed parameters (e.g., dose, concentration) against preset limits stored in a drug library; the limits are specific to each drug and clinical location. If a clinician tries to program a dose outside the limits, the device alerts the clinician and either requires the program to be changed to something within the limits (these are referred to as "hard" limits) or allows the clinician to continue with the programmed infusion after acknowledging the alert ("soft" limits).

OVERVIEW OF PCA INFUSION ERRORS

The first six years of Pennsylvania Patient Safety Authority data (June 2004 through May 2010) contain approximately 4,500 reports associated with a PCA pump. (In the initial search, "PCA" was used for *patient care assistant* in approximately 20% of the reports.) Many of the reports related to patient-controlled analgesia reflected confusion about the infusion order but did not identify a source of error. Other reports documented problems common to any infusion therapy: infiltration, tubing disconnection, medication leakage, and delay in therapy when a pump was unavailable. Delivering the wrong medication or the wrong amount are also reported for all infusion pumps, but the use of PCA pumps entails more hazards than use of other types of pumps. PCA pumps are used with potent opioids, so even small errors can lead to serious patient harm. For example, although it is counterintuitive, an erroneously programmed low drug concentration will cause a pump to deliver an excessive amount of the drug, causing an overdose.[1] Or, the concentration could be programmed as ordered but a vial or bag with a higher concentration could be selected and connected to the pump.

The U.S. Food and Drug Administration's (FDA) Manufacturer and User Device Experience (MAUDE) database reveals that reports of PCA-related device events are three times as likely to result in injury or death as reports of device events involving general-purpose infusion pumps. Authority analysts searched for all reports in the MAUDE database (as of January 31, 2011) for devices by both FDA product code and outcome (i.e., outcome = death *or* injury). Of 4,230 reports for product code MEA (PCA pumps), 826 (19.5%) resulted in injury or death. Of 48,961 reports for product code FRN (general-purpose pumps), 3,240 (6.6%) resulted in injury or death. This may be due to the exclusive use of high-risk analgesics in PCA pumps.

Opioids commonly used in PCA therapy, such as morphine, HYDROmorphone, and fentaNYL, are considered to be high-alert medications.[2] Approximately one of four events reported to the Authority involved high-alert medications. Of those reports, 44% involved pain management medications often used for PCA, including morphine, HYDROmorphone, meperidine, and fentaNYL.[3] In addition, Authority data indicates that 21% of look-alike name errors involved opioids and included name confusion among morphine, HYDROmorphone (Dilaudid), and meperidine (Demerol).[4]

During a recent six-month period (December 2009 through May 2010), approximately 70% of the PCA therapy related reports to the Authority were attributable to errors associated with pump use (e.g., misprogrammed doses and concentrations, installation of the wrong drug or concentration). Naloxone (Narcan) was administered to reverse an opioid overload in more than 10% of these reports. Misprogramming of the PCA pump is by far the most frequently reported practice-related issue surrounding PCA therapy.[5] The following examples from Authority reports illustrate some of the ways PCA errors may occur, including misinterpreting orders, pump misprogramming (e.g., concentration, bolus dose, lock-out interval), and running the wrong drug or concentration:

> *PCA was ordered for morphine 1 mg dose, 8 minute lock-out with 10 mg hourly limit. PCA morphine concentration comes as 1 mg/ml standard. PCA [pump] was programed as morphine 1 mg dose, 8 minute lock-out with 10 mg hourly limit with a 0.25 mg/ml concentration. At the set concentration, the PCA [pump] delivered 4 ml for 1 mg dose when it should have delivered 1 ml for 1 mg dose, therefore giving 4 times the ordered dosage each time.*

> *I went to verify orders for this patient and noticed that the patient's HYDROmorphone PCA, patient administered dose, was increased from 0.25 mg to 2.5 mg. I called the nurse to check if she knew the rationale for such a large dosage increase. She thought this seemed inappropriate and spoke with the physicians who were rounding at the time. The physician had intended to order 0.25 mg rather than 2.5 mg. The order was corrected.*

> *Patient received from the PACU [postanesthesia care unit]. PCA documented as started by this RN [registered nurse]. Upon receiving the patient, the PCA was set as a 5 ml dose [0.2 mg/mL HYDROmorphone] with 10 minute lockout time; however, it was ordered as 1 ml dose with 5 minute lockout. Nurse practitioner was notified.*

> *PCA was discontinued and it was found to have incorrect medication given. The patient was ordered HYDROmorphone PCA, but morphine was infusing. The pharmacy was notified.*

> *We discovered the incorrect PCA settings during rounds. The HYDROmorphone syringe was the correct concentration. The settings for the PCA were ordered in ml–1 ml/6 min/0 basal/10 ml hourly limit–but the pump was set in mg–1 mg/6 min/0 basal/10 mg hourly limit. The patient was a little sleepy but easily arousable, with an O_2 saturation of 95% and adequate respirations. Upon questioning, the RN caring for the patient stated that the prior PCA pump was malfunctioning. She got another PCA pump and reprogrammed it but did not have another RN verify that she did reprogram the replacement pump properly.*

Authority reports also illustrate several reasons why physiologic monitoring may be desirable during PCA. Respiratory depression is likely to occur when one or more medications (e.g., other central nervous system depressants or other opioids by other routes of administration) are intentionally or inadvertently given to a patient who is also receiving an opioid via a PCA pump. Reports also reveal programming errors that were not detected despite a double check by another nurse or during two shifts. Two reports illustrate how monitoring helped alert clinicians in time to resuscitate patients with naloxone.

> *A code was called for patient who was not breathing. Patient was found being assisted with her respirations with bag-valve-mask ventilation by respiratory therapy techs. She was unresponsive and not breathing adequately. She was given large amounts of sedation throughout the day. From 0800 to 1600, the patient had received 200 mcg IV fentaNYL via PCA pump; she also received, at 1200, 30 mg of po oxycodone SR (sustained release). Then at 1700 she received 5 mg Dilaudid IV push. At 1800, a code was called for respiratory arrest, and the patient required transfer to ICU after for monitoring. She had been reversed and recovered with the use of IV Narcan.*

A patient was admitted after an automobile accident. The patient went to OR. An order for Dilaudid 1 mg IV every 4 hours as needed for pain and oxycodone 12 mg PO BID x 6 doses was made at 1700 post-operatively. The patient was agitated and had pinpoint pupils. An order to d/c [discontinue] the PCA was made at 1900 and it was to be started the next am. At 2000, Narcan 0.5 mg IV was to be given and repeated as needed to reverse narcotic effects as per order written in the chart. After Narcan was given, the patient was much more oriented and alert.

Patient is on a PCA and I also gave Percocet in the morning for pain. No other narcotics should have been given with the morphine PCA.

Dilaudid PCA programmed incorrectly by RN: drug concentration entered as 0.1 mg/ml instead of the actual 1 mg/ml. As a result of this error, the patient received more drug than intended over an 8-hour period before the error was detected. This error was not detected as part of the double-checks performed at initial pump setup or change of shift. Patient became symptomatic and required Narcan and supplemental oxygen. The patient did not require transfer to a higher level of care.

The patient had a PCA morphine infusing, 0.2 mg patient bolus was ordered and 2 mg patient bolus was being infused. Pharmacy was called to double check concentration and physician assistant was notified of error. Error went through two shift changes.

[A patient with a] known history of sleep apnea on PCA morphine developed respiratory arrest. [The patient was] initially on 2 mcg basal, up to 2.5 mcg when unable to achieve pain control. The patient was then sleeping, and was easy to arouse for 6 hours. Alarm sounded, O_2 saturation low; staff rechecked patient and found her unarouseable; respiratory code called. PCA was stopped; Narcan was given twice with return to 97% saturation.

Patient on PCA post total knee arthroplasty. Noted to have snoring respirations, low pulse oximetry, somnolent. Given Narcan 0.2 mg IVP, more alert, responds to questions, pulse ox returned to 97%.

FACTORS THAT CONTRIBUTE TO ERRORS WITH PCA THERAPY

Improper Patient Selection

An important safety feature with demand PCA (PCA therapy without a basal rate) is that the patient delivers each dose. For this reason, candidates for PCA should have the mental alertness and cognitive ability to manage their pain and communicate their pain level to their caregiver. However, the benefits of PCA have led some healthcare providers to extend its use to less-than-ideal candidates (e.g., young children, confused elderly patients). Oversedation also has occurred in less-than-ideal candidates who are at risk for respiratory depression because of comorbid conditions such as obesity, asthma, or sleep apnea or use of concurrent drugs that potentiate opioids. However, even when these factors are identified and considered, patients respond to opioids in different ways, and what is a safe dose for most patients can cause dangerous reactions in a small percentage of the population.[6]

Prescription Errors

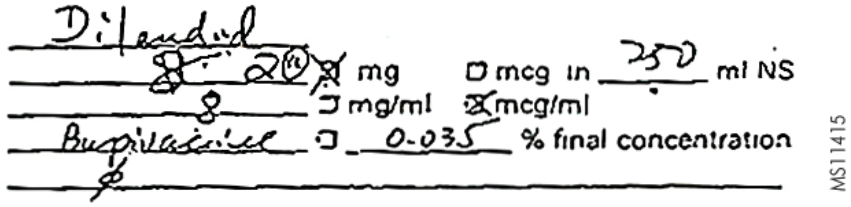
The PCA order itself can be a source of error. Prescribers have made mistakes in converting oral opioid doses to the IV route; most problematic is HYDROmorphone, which has an oral to IV conversion range of 3:1 to 5:1.[7] Errors in selecting an opioid that is not appropriate for the patient, such as prescribing meperidine for individuals with renal impairment, have also been made. Occasionally, one opioid has been prescribed, but the dose has been for a different opioid.[6]

Even with correct PCA orders, clinicians have been known to miscommunicate orders, sometimes leading to serious errors. Concurrent orders for other opioids while PCA is in use have resulted in opioid toxicity. Problems also have occurred when patients are started on PCA therapy but have a documented allergy to the ordered medication. One example includes an order that was given for a "stat" dose of morphine, but the patient had a documented allergy to this drug. Fortunately, a pharmacist caught the error and contacted the physician, but not before the nurse used the override function to remove morphine from the automated dispensing cabinet and administered the drug to the patient.[6]

Errors have occurred even with the use of facility-defined PCA order forms. In one case reported to the Institute for Safe Medication Practices (ISMP), a 70-year-old patient received a tenfold overdose of HYDROmorphone. A physician prescribed PCA using HYDROmorphone 2 mg in 250 mL of normal saline 0.9% injection, creating a concentration of 8 mcg/mL. While writing the order on a preprinted form, he mistakenly entered the 8 mcg/mL concentration on the wrong line. He quickly recognized the mistake, scribbled over the erroneous entry, and wrote the correct value of 2 mg in 250 mL. He then initialed and circled the change.[6] (See Figure.)

The pharmacist misinterpreted the circled initials as a zero and dispensed 20 mg of HYDROmorphone in 250 mL normal saline, yielding a concentration of 80 mcg/mL. The bag was labeled as "20 mg/250 mL NS," but the concentration on the order was entered as "8 mcg/mL." Before administration, two nurses checked the bag using the original order, but they only verified the labeled

Figure. Patient-Controlled Analgesic Order



Circled orders on patient-controlled analgesic order caused 2 mg to be interpreted as 20 mg, which is a concentration that is 10 times greater than intended.

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concentration, and the error was not noticed because the concentrations on the order form and on the mislabeled bag were the same. Later, the night nurse found the error while checking the bag against the original entire order.[6]

Drug Product Mix-Ups

Some opioids used for PCA have similar names and packaging, which has led to drug selection errors. Errors have occurred when prefilled vials of meperidine and morphine have been packaged in similar-looking boxes. Morphine is available in prefilled vials in two concentrations, but the packaging may not allow quick differentiation of the strengths.[6]

Pharmacy-applied labels may look similar on extemporaneously prepared syringes or bags. Since opioids are typically in unit stock, when a new order is written, the nurse sees the order and takes the medication out of the automated dispensing cabinet, frequently with no independent double check. These errors are rarely detected and can lead to significant overdoses.[6]

Name similarities also have led to inadvertent mix-ups between morphine and HYDROmorphone or the mistaken belief that HYDROmorphone is the generic name for morphine. Thirty-two percent of the opioid look-alike-name events reported to the Authority have involved these two drugs. Contributing factors include the fact that both drugs are available in prefilled syringes in concentrations of 1 mg/mL, 2 mg/mL, and 4 mg/mL. As the estimated relative potency of IV HYDROmorphone to morphine is 7.5:1, these mix-ups can easily be fatal.[7]

Patient harm has occurred with mix-ups between other pairs of opioids. In one report to ISMP, a pharmacist drew 50 mg of 10 mg/mL HYDROmorphone from a 5 mL ampule to prepare two epidural PCA orders for 500 mcg of 50 mcg/mL fentaNYL. As a result, two women received opioid overdoses while in labor, and they and their babies developed respiratory difficulties.[6]

PCA by Proxy

Patients may be harmed even if the pump's programming matches the medication order. The effects of opioids may be difficult for caregivers to anticipate: a dose that is sufficient for one patient may oversedate another. Reports also indicate that PCA pump patients have received dangerous and even lethal amounts of opioids when family members or clinicians activated the pump's delivery request button on the patient's behalf (i.e., PCA by proxy).

It is essential, therefore, that clinicians be aware that allowing anyone other than the patient to press the delivery request button is a clear contraindication of PCA therapy and has been strongly warned against by the Authority, ECRI Institute, ISMP, and the Joint Commission.[5,8-10]

RISK REDUCTION STRATEGIES

Reducing Error through Standardized Protocols

One way to minimize adverse events and medication errors with opioid PCA is through the use of standardized protocols.[1] Some facilities have adopted facility-wide protocols for programming PCA pumps. The protocols may include standardized drugs, concentrations, and dosing regimens for typical patient characteristics—for example, protocols labeled "Morphine Post-Op" for standard postoperative pain control or "Morphine, Opioid-Tolerant" for patients who require higher doses of drug to achieve adequate pain relief. Dosing protocols are implemented in the form of either a preprinted order sheet or a preset list in an order entry system.

Using standardized protocols reduces medication errors by limiting the number of choices a physician needs to make when prescribing (e.g., deciding between a 1 mg bolus with 5-minute lockout and a 2 mg bolus with 10-minute lockout) and by reducing transcription and programming errors related to hard-to-read orders. Hospitals can also use dosing protocols to standardize on one or a few concentrations of each drug, reducing the likelihood of medication errors due to selecting the wrong-drug concentration when obtaining a drug vial or entering the concentration into the pump. Many of the risk reduction strategies presented in the September 2010 *Pennsylvania Patient Safety Advisory* article "Adverse Events with HYDROmorphone: How Preventable Are They?" are also applicable.[7]

Monitoring during PCA

The primary concern with opioid oversedation is respiratory depression and even respiratory arrest. The usual approach to minimizing this risk is to have nursing periodically assess patients on PCA. In addition, pain scores are crucial, because

pain is recognized as the "fifth vital sign" and is the therapeutic monitoring parameter to determine dose adjustments (either increase or decrease). ISMP has noted that the common practice of assessing the patient while interacting with him or her is inadequate since an overly sedated patient can be aroused and respond to questions but will fall back into oversedation when the nurse leaves. Accordingly, ISMP recommends observing the patient unobtrusively and noting both respiratory rate and depth of respiration in the absence of any stimulus.[11]

Continuous monitoring is another tool to reduce the risk of oversedation. Pulse oximetry is ubiquitous, easy to use, and relatively inexpensive. A recent study using continuous pulse oximetry monitoring in an orthopedic unit (where patients frequently receive PCA therapy and are not typically connected to physiologic monitoring) concluded that it resulted in reduced need for rescues and intensive care unit transfers.[12] Pulse oximetry is also recommended for selected patients receiving epidural or spinal opioids.[13]

However, while useful, pulse oximetry does not measure ventilation. Since oxygen saturation is a lagging indicator of respiration, pulse oximetry may not indicate a problem early enough for effective intervention. Pulse oximetry is even more problematic for patients who are receiving supplemental oxygen, since they may be adequately oxygenated even with dangerously depressed ventilation. Capnography, or end-tidal carbon dioxide monitoring, allows clinicians to track several indicators, but for purposes of PCA it is primarily used as a reliable monitor for respiratory rate, including apneic episodes. The Anesthesia Patient Safety Foundation (APSF) advocates monitoring both oxygenation and ventilation in all patients receiving PCA.[14] However, APSF also recognizes that universal monitoring will not be implemented immediately and therefore suggests using available monitors for the highest risk patients on PCA—in particular those with obstructive sleep apnea—in the short-term.

At an October 2010 infusion device summit cosponsored by the Association for the Advancement of Medical Instrumentation and FDA, the Veterans Health Administration stated that PCA pumps with an *integrated* end tidal carbon dioxide monitor could have prevented 60% of adverse events identified in 69 root cause analyses related to PCA pumps.[15] In addition to alarming, an integrated monitor would halt further opioid delivery by deactivating the pump.

Special Precautions

Healthcare facilities may consider implementing special precautions when administering opioids to patients with PCA pumps, including the following:

1. Limit choices by minimizing the variety of medications and concentrations used for PCA.[6]
2. Restrict fentaNYL PCA administration to anesthesia or pain management team members only.[6]
3. When available use "smart" PCA pumps that can alert clinicians to potential programming errors.[6]
4. It is desirable to match the sequence of information that appears on PCA medication labels and order sets with the sequence of information that must be entered into the PCA pump.[6]
5. Drug names are less likely to be confused if tall man lettering is used (e.g., HYDROmorphone).[5]
6. Patients must be cognitively, physically, and psychologically capable of understanding the concepts of PCA.[10]
7. Clearly define a manual *independent* double-check process for clinicians to follow when verifying PCA medications, pump settings via a confirmation screen, the patient, and line attachments.[6]
8. If a patient is not responding to PCA doses, consider the possibility of an error, especially before administering a bolus dose. In particular, independently double-check the drug, concentration, pump setting, and line attachment.[6]
9. Ensure that oxygen and naloxone are readily available where opioids are administered.[2]
10. Educate patients about the proper use of PCA (e.g., during a preoperative testing visit) before initiation when patients are not too groggy to understand.[6]
11. Warn family members and visitors about the danger of PCA by proxy.[6]
12. When possible, continuously monitor patients at risk for respiratory depression (e.g., patients with comorbid conditions or who are receiving concurrent drugs that potentiate opioids).[13,14]

CONCLUSION

PCA therapy is an effective way to provide pain management. However, reports to the Authority illustrate the multiple ways that errors with PCA happen frequently, sometimes with tragic consequences. Although smart infusion pumps can help detect medication errors, and patient monitoring can detect the results of errors, clinicians should nevertheless question orders for drugs or doses that are illegible or appear unsafe, ensure that the correct concentration has been selected, request independent double checks of pump programming, use proper patient identification techniques, and periodically assess patient vital signs and level of sedation.

Error-reduction strategies for PCA therapy should include a balanced approach of practice-related, system-related, product-related, and device-related efforts. By embracing proven prevention strategies, healthcare facilities can help reduce the risks associated with this technology and improve patient safety.

NOTES

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