



Safety issues with patient-controlled analgesia (PCA)

Part II - Practical error-reduction strategies

Patient-controlled analgesia (PCA) has considerable potential to improve pain management, yet errors happen frequently, sometimes with tragic consequences. In Part I (January 2005 issue), we described factors that contribute to PCA errors. Part II presents a checklist of strategies related to practice, systems, products, and pumps that nurses can employ to reduce the risks associated with this patient-centered technology.

When selecting a PCA pump for purchase

- Perform a failure mode and effects analysis (FMEA) using the actual PCA pump under evaluation. Examples of questions to explore:
 1. Can the pump be programmed easily to deliver the desired concentrations?
 2. Is the pump operation intuitive for the clinician and patient?
 3. Does the pump provide visual and/or auditory feedback to patients when the activation button is pressed?
 4. What are the default settings for the opioid concentrations in use?
 5. Does the pump employ *smart* technology to alert users to unsafe doses or programming errors?
 6. Do the drugs names, units of delivery, and strengths appear in a logical sequence?
- Limit PCA pumps to a single model throughout the organization to promote proficiency with programming.

Before distributing new PCA pumps to clinical units

- Verify that all pump default settings are set up as expected (zero if possible, or the highest concentration available for the opioid).
- Attach programming instructions to each pump for user reference.
- Place a warning label on the PCA activation button that states "FOR PATIENT USE ONLY."
- Teach nurses to program PCA pumps, and verify their ability to enter a PCA prescription. Ensure that training occurs close to the introduction of new pumps. Offer practice sessions to maintain proficiency.
- Run simulations in which staff purposely write incomplete orders; select an inappropriate drug or dose; misprogram a pump; ignore double checks; forget critical monitoring points; and miss obvious signs of toxicity so that clinicians can identify these at-risk behaviors.

Before initiating PCA

- Perform a FMEA on the PCA process to identify and reduce areas of risk (visit www.ismp.org/d/FMEAofPCA.pdf for an example).
- Establish patient selection criteria for PCA, requiring an appropriate level of consciousness and cognitive ability to self-manage pain. Infants, young children, and confused patients are unsuitable candidates.
- Educate patients about the proper use of PCA before initiation. Begin during the preoperative testing visit, if possible, so patients are not too groggy to understand. Warn patients, family members, and visitors that no one except the patient should press the PCA button to deliver a dose.
- Design standard order sets that follow the pump's programming sequence

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Message in our mailbox



Inverse relationships.

In part I (January 2005) of *Safety issues with patient-controlled analgesia (PCA)*, we

described several errors due to misprogrammed opioid concentrations. For example, we reported a fatal 10-fold *overdose* in which the pump was set at a *lower* concentration (0.1 mg/mL) of morphine than actually loaded in the pump (1 mg/mL). We also described a 10-fold *underdose* in which the pump was set at a *higher* concentration (2 mg/mL) of hydromorphone than actually loaded in the pump (0.2 mg/mL). Numerous readers contacted us to see if we had mixed up these errors, suggesting that setting the pump at a *higher* concentration than the actual drug would result in an *overdose*, and setting the concentration at a *lower* concentration than the actual drug would result in an *underdose*. However, our descriptions of the errors are correct.

Although counterintuitive, concentration and volume have an *inverse* relationship. *More* concentrated drugs require *less* volume to deliver a specified dose; *less* concentrated drugs require *more* volume to deliver a specified dose. With PCA, the concentration must be programmed into the device so the pump can calculate the volume needed to deliver the prescribed dose. If the programmed concentration is *lower* than the actual concentration, the pump will deliver an *overdose*. If the programmed concentration is *higher* than the actual concentration, the pump will deliver an *underdose*.

Take, for example, a patient who is supposed to receive 1 mg of morphine with each demand dose. If a nurse programs the concentration as 0.1 mg/mL, the pump calculates that 10 mL of

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- for drug selection, doses, and lockout periods. Include required patient monitoring and precautions such as avoiding concomitant analgesics, and how and when to administer oxygen and naloxone (**NARCAN**).
- ❑ Design standard flowsheets to document PCA doses and patient monitoring (visit www.ismp.org/d/PCAFloWSheet.pdf for an example). Include prompts to document vital signs, pulse oximetry or capnography (measurement of respiratory CO₂) if used, pain and sedation scales, the drug and concentration, and cumulative doses over time.
 - ❑ Develop monitoring requirements for PCA patients. Identify risk factors that could increase respiratory depression (e.g., obesity, low body weight, concomitant medications that potentiate opioids, preexisting conditions such as asthma and sleep apnea) and determine special monitoring required for these patients (e.g., capnography, apnea alarms at night).
 - ❑ Designate the infrequent situations where critical care patients may be suitable for nurse-controlled PCA, and the level of enhanced monitoring (e.g., capnography, separate flowsheet for more frequent documentation) that would be required for these patients.
 - ❑ Educate nurses to recognize the signs and symptoms of opioid toxicity and withdrawal, the need to assess patients using minimal verbal or tactile stimulation, and the ability to distinguish between oversedation and other pulmonary, neurologic, or cardiovascular complications.
 - ❑ Work with pharmacy to create and update charts or cards that contain relevant information about the PCA opioids used in your facility, including the differences between HYDROmorphone (**DILAUDID**) and morphine.
 - ❑ Provide ongoing education to clinicians about PCA errors that have occurred within the organization, as well as those that have been published in the literature, to build awareness.
 - ❑ Require initial and annual competency assessments for all professionals who prescribe, dispense, and administer PCA.

When accepting/transcribing/verifying PCA orders


- ❑ Check patient allergies, which should be visible on order forms/screens.
- ❑ Require the use of standard PCA order sets (all sections completed) and limit verbal orders to dose changes only.
- ❑ Accept PCA orders with opioid doses expressed in mg or mcg, not volume (mL). *Exception: some epidural PCAs (e.g., HYDROmorphone/bupivacaine) may be prescribed by volume (mL).*
- ❑ Ensure that the PCA prescriber has undergone a privileging process to verify proficiency. (An updated list of privileged prescribers would help.)
- ❑ Verify the PCA order with a pharmacist if meperidine (**DEMEROL**) is prescribed (meperidine should only be used if patients are allergic to other PCA drugs), or if fentanyl is prescribed by anyone except anesthesia staff, pain management teams, or critical care prescribers.
- ❑ Use tall man lettering when transcribing HYDROmorphone PCA orders onto the MAR to help avoid confusion with morphine.
- ❑ When evaluating the safety of PCA doses, consider other medications that the patient has received (e.g., analgesics taken at home, intraoperative medications), other medications prescribed (e.g., antihistamines, nighttime sedatives), and the maximum potential dose over 24 hours.

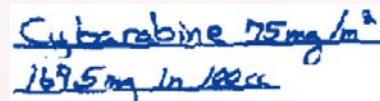
When receiving or selecting PCA medications

- ❑ Establish one standard concentration for each PCA opioid.
- ❑ Stock only standard concentrations of morphine and HYDROmorphone

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safetywire

 **An error of precision.** The order below illustrates what can happen when healthcare professionals pay attention to exact dosing without considering how the order appears when communicated. The physician, wishing to be precise, wrote the dose as 169.5 mg of cytarabine, a chemotherapeutic agent. But the decimal point was poorly visible, making the dose look like 1,695 mg. Luckily, the physician included the desired mg/m² dose along with the calculated dose.



Cytarabine 75mg/m²
169.5mg in 100cc

Were it not for that, plus a required double-check of all chemotherapy doses, this error could easily have reached the patient. In fact, it would have been hard to uncover an error in this case because cytarabine has a published dose range of less than 50 mg/m² to more than 3 g/m², depending on the diagnosis. So a dose of 1,695 mg could have been well within the boundaries. Typically, adult chemotherapy doses over 10 mg can be rounded safely to the next whole number. If a chemotherapy dose cannot be rounded, prescribers should make sure that the decimal point is obvious. Also, consider eliminating lines on order copies and preprinted order forms so that decimal points, when needed, are clearly visible.

Message in our mailbox continued

solution must be administered to deliver each 1 mg dose. But if the *actual* concentration of morphine in the pump is 1 mg/mL, the pump will still deliver 10 mL of the solution, since the concentration was set at 0.1 mg/mL. Thus, the pump would deliver 10 mg (10 mL) of morphine – a 10-fold overdose, not the intended 1 mg dose. For more on this complex issue, visit: www.ismp.org/d/SpecialFollowUp.pdf.

Safety issues with PCA *continued*

- on units. Require pharmacy to dispense meperidine PCA to ensure proper renal dosing and monitoring. (Meperidine can cause neurological harm from accumulation of its metabolite, normeperidine.)
- Use prefilled syringes/bags/cassettes when available commercially. Have pharmacy prepare all PCA products that are not commercially available.
- Separate the storage of HYDROMorphone and morphine PCA syringes/bags/cassettes in units to avoid mix-ups.
- Require a pharmacist to review all PCA orders *before* initiation.
- Ask pharmacy to use tall man lettering on labels and computer-generated MAR entries for HYDROMorphone to differentiate it from morphine.
- Ask pharmacy to affix prominent warning labels if dispensing an opioid in a nonstandard concentration. Store the drug separately on the unit.
- Ask pharmacy to alert clinicians to drug shortages with PCA opioids and to provide clear dosing instructions for alternative drugs dispensed.

When initiating and maintaining PCA

- Check patient allergies, which should be visible on the MAR.
- Ask patients and their families questions about PCA, and require patients to demonstrate pump activation, to ensure understanding.
- Connect PCA to a port close to the patient (to avoid dead space) and prominently label the infusion line to avoid mix-ups with other lines.
- Require two clinicians to independently double check the patient's identification, drug and concentration, PCA pump settings, and the line attachment before initial use, pump refill, or programming change. Bedside bar coding can verify the patient and drug/concentration, but pump settings may still require an independent check (unless *smart* pumps are used).
- Verify PCA settings each shift, immediately after receiving report.
- Avoid administering concomitant opioids (an alert should appear on the MAR), and administer anxiolytics with caution.
- Have oxygen and naloxone readily available.
- Avoid nurse-controlled PCA unless enhanced monitoring is in place.

When monitoring the effects of PCA

- Initiate enhanced monitoring if nurse-controlled PCA is employed.
- At a minimum, assess PCA patients every 4 hours. Monitor patients more frequently in the immediate period following initiation, and during the first 24 hours and at night, when hypoventilation and nocturnal hypoxia may occur.
- Keep standardized PCA flowsheets at the bedside to document PCA doses and patient monitoring.
- Use a standard sedation scale with variables such as response to verbal commands and activity (e.g., Ramsey, Riker, MAAS [see Table 2 at: www.sccm.org/pdf/Sedatives.pdf]), and a developmentally-appropriate, pain measurement scale to assess PCA patients.
- Assess patient's sedation level using minimal verbal/tactile stimulation.
- Do not rely on pulse oximetry readings alone to detect opioid toxicity. If capnography is not available for all PCA patients, reserve its use for those at risk for toxicity, and with nurse-controlled PCA.
- Reassess the appropriateness of PCA therapy at regular intervals.

Error awareness and reporting

- Monitor the use of naloxone to identify adverse events related to PCA.
- Report errors and problems with pump programming or assembly to your facility, FDA, and external error-reporting programs (ISMP, ECRI).
- Read current literature and manufacturer materials concerning PCA to stay abreast of hazards and to proactively address known problems.

Special Announcements

► **Mosby's Nursing PDQ for Medication Safety, prepared by ISMP.** This new pocket-sized, handy reference has quick facts about high-alert medications, look-alike drugs, high-risk procedures, assessing risk, error reduction, error reporting, medication administration, and more – ideal for any clinical setting. For more information, visit www.ismp.org/Pages/Books.htm.

► **Nurses needed for study.** LaSalle University is seeking participants in a study related to *never again* stories – patient-care events that, once experienced, you have vowed will *never again* happen during your watch. If you're a RN with a critical care background, and have experienced a *never again* story, contact Dr. Wolfe (215-951-1431 or wolf@lasalle.edu) if you'd like to participate.

► **Free video viewing.** FDA *Patient Safety News* is a free satellite broadcast series that features information on new drugs and medical devices, FDA safety notifications and product recalls, and ways to protect patients when using medications and other medical products. Each month, new "shows" are posted online for free viewing. You can request e-mail notification when a new program is released.

Highlights from 2004 include:

- Caution on ethyl chloride flammability
- Avoiding confusion with Broselow Tapes
- Preventing fatal tubing misconnections
- Avoiding oncologic drug errors
- Caution treating infants with Tamiflu.

Visit www.fda.gov/psn for details.

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Report medication errors to ISMP at 1-800-FAIL-SAF(E).