

Patient-Controlled Analgesia: Making It Safer for Patients

A continuing education program for pharmacists and nurses

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Learning Objectives

After studying this monograph, the reader should be able to:

- Identify common safety issues related to use of patient-controlled analgesia (PCA).
- Design appropriate patient selection criteria for PCA use.
- Develop standard PCA prescribing and monitoring practices.
- Communicate the need for an interdisciplinary approach to prevent patient harm.
- Use a standardized process to evaluate the safety of PCA products or devices.

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Patient-Controlled Analgesia: Making It Safer for Patients

Safety Issues Associated with Patient-Controlled Analgesia

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The benefits of patient-controlled analgesia (PCA) are well known. Prior to the adoption of PCA, pain was alleviated by administering frequent, intermittent bolus doses of narcotic analgesics, and patients often complained about the number of injections required. Occasionally oral tablets were administered, but their effectiveness was questionable due to decreased absorption. In addition, pain management teams did not exist and pain control was not considered as high a priority as it is today. Patients could only ask a nurse for pain medication, and sometimes there would be significant delays in administration while the order was checked and the medication was obtained and prepared.

PCA is an effective method for administering opiates to patients for pain relief, and gives patients a sense of control over their pain. However, based on the information submitted to the United States Pharmacopeia–ISMP Medication Errors Reporting Program (USP-ISMP MERP), it is clear that there are problems associated with PCA. These problems will be examined in detail in this review. Please note that you can report medication errors to USP-ISMP MERP by calling 1-800-FAIL-SAFE or online at www.ismp.org.

PCA by Proxy

PCA is intended to be patient-controlled analgesia. Probably the most tragic error or event associated with PCA involves what is referred to as PCA by proxy, where someone other than the patient presses the button to inject a dose of pain medication into the patient. A very important safety feature of PCA is that patients who are oversedated from having received too much opiate will not be able to press the button to obtain additional doses of the drug. This safety feature is overridden if someone else pushes the button for them.

Family members may believe that they are helping the patient remain pain-free by pushing the button for them. When other individuals push the PCA button, they may seriously misjudge the patient's level of sedation, resulting in extreme oversedation, respiratory depression, and potential respiratory arrest.

When other individuals push the PCA button, they may seriously misjudge the patient's level of sedation, resulting in extreme oversedation and respiratory depression.

Like many medication errors, the exact incidence of PCA by proxy is unknown. The difficulty in determining an overall frequency of the problem is that the numerator and denominator are not known because the exact number of PCA prescriptions is not available. However, it is clear that this practice has led to fatal incidents.

ISMP has investigated several error reports involving PCA, including one involving an otherwise healthy teenage girl who died when her PCA button was pushed continuously by her mother. As a result of incidents such as this, there has been a call for action regarding PCA by proxy. At a minimum, there should be hazard warnings on the PCA equipment to caution family members and even health care practitioners about the dangers of PCA by proxy. Family members and medical staff should also be provided with education and training on proper PCA use.

PCA by proxy may be legitimately used by nurses in certain situations, but it is probably more appropriate to call this practice nurse-assisted analgesic dosing. Nurse-assisted analgesic dosing can be used safely when the healthcare professionals involved are authorized, properly educated on pain assessment and opioid toxicity, and required to follow a protocol.

Unauthorized PCA by proxy involving a spouse, family member, or friend is far more likely to result in patient harm. Other

by proxy situations may be more controversial, such as when parents control the administration of the drug by pushing the button for their child. Many children can be taught to use PCA, and although healthcare organizations may elect to have an age limit for this method of pain management, each case should be evaluated individually. Hospitals should develop policies and procedures to address family and nurse administration of PCA.

Patient Selection

Another significant problem is improper patient selection. The obvious benefits of PCA have led providers to extend its use to less than ideal candidates, such as infants, young children, and confused elderly patients. When less than ideal candidates are selected, the incidence of PCA by proxy may increase. Patients must be cognitively, physically, and psychologically capable of understanding the concepts of PCA and handling the procedure necessary to obtain pain relief. This frequently may rule out the use of PCA in many pediatric and confused elderly patients. Less than ideal candidates also include those at risk for respiratory depression due to comorbid conditions such as obesity, asthma, or sleep apnea, or use of concurrent drugs that potentiate opiates.

Patient Monitoring

Inadequate patient assessment and monitoring of patients using PCA also is a source of potential errors. Unfortunately, standard methods for assessing level of consciousness do not take into consideration that overly sedated patients can be aroused and respond to questions. Even though these patients can be aroused for a brief period of time and may in fact be able to speak, they immediately fall back into a state of oversedation when the stimulus is removed. In addition, an overly sedated patient's respiratory rate may improve with stimulation but quickly decreases when the stimulation is removed.

A proper assessment is first performed by observation without stimulation, so that quality or depth of respirations as well as respiratory rate can be evaluated. Pain management teams should develop a standard sedation scale that is used throughout the organization for monitoring and documenting the level of patient sedation.

There are risk factors that can predict the potential for respiratory depression in patients using PCA, such as obesity, asthma, sleep apnea, and use of drugs that may potentiate opiates. The use of pulse oximetry as a monitoring tool is becoming more prevalent and the use of capnography is gaining favor as well. Capnography measures the end tidal volume of carbon dioxide, which is a more reliable indicator of respiratory depression

and has previously been employed in limited areas such as critical care units.

Patient Education

The lack of effective patient education is a factor in many errors with PCA. Patient teaching is often non-existent or inadequate. Patients who are candidates for post-surgical use of PCA should be trained prior to admission for their surgery. However, many patients only learn about PCA when they awaken from anesthesia and a nurse in the post-anesthesia care unit is explaining it to them for the first time. As part of the pre-admission process, patients and their families must be taught the relationship between pain, pushing the button, and adequate pain relief. They should understand the benefits of PCA and how it works. They also should be shown that the pain control button differs in appearance from the nurse call button.

Unfortunately, some patients and/or their families misunderstand instructions and believe that they must push the PCA button as often as possible. In one report submitted to ISMP, a patient's husband thought that his wife must push the PCA button every 6 minutes. Of course, what was really meant was that if the pain persisted, she could push the PCA button every 6 minutes.

Nomenclature

Drug name mix-ups have contributed to medication errors with PCA. It is not uncommon for practitioners to confuse hydromorphone and morphine. ISMP and ISMP Canada have investigated many error reports where these two drugs have been confused with each other—in at least one case, the mix-up resulted in the death of a patient.

Recommendations for preventing these errors include using auxiliary warning labels to alert staff that there is a potential for confusion and storing the drugs separate from each other and using tall man (upper case) letters to distinguish HYDRomorphone from morphine. Using bar coding technology also can help reduce the potential for drug mix-ups.

Drug Shortages

Drug shortages can also cause problems because they often result in non-standard drugs and concentrations being used in place of those that are well known to staff members. For example, during a period of time in which fentanyl was unavailable in the marketplace, many organizations switched to Sufentanil. Sufentanil is much more potent than fentanyl and errors were made by programming infusion pumps based on fentanyl dosing, which resulted in the patient receiving too much drug.

Practice-Related Problems

Inadvertent misprogramming of infusion pumps also can result in over- or under-dosing (see figure 1). Errors occur when clinicians choose the wrong pre-programmed drug or concentration; for example, they may select a 0.01 mg bolus versus a 0.1 mg bolus, or select 1 mg/mL as the concentration when it is the 5 mg/mL product they are using. Or they may select the wrong lockout settings or dose limits. The terms milliliter and milligram also have been confused; for this reason, ISMP promotes expressing milliliter as mL with an upper case “L.”

FIGURE 1. HUMAN FACTORS/DESIGN FLAWS WITH PCA.

- 10-fold rate-setting errors (10 vs 1.0 vs 0.1 mg)
- mL vs mg confusion
- Difficulty in standardizing pumps (multiple types used by same organization)
- Insufficient hazard warnings on equipment to prevent PCA by proxy and device-specific errors
- Battery failures
- Prefilled syringe labels not readable once in pump
- PCA cord confused with patient call bell
- Drug security issues with manipulation of plunger and ability to open door without key

Other errors that have occurred include the PCA dose being confused with the basal rate or dose and frequency being mistaken for one another. Error reports have been received stating that the basal rate was inadvertently continued during surgery when it was intended to be stopped until after the surgical procedure. In some cases, the loading dose was programmed where the basal dose should have been entered. Other reports identify calculation errors and keying errors made when entering the prescription order into the infusion pump. The failure to document key patient information, such as drug allergies and opiate antagonist misuse, also has been identified as a factor contributing to medication errors with PCA.

To prevent these problems, independent double checks of the rate, concentration and dose settings as well as identification of the correct infusion line are recommended when PCA is initiated or if a rate change requires a change in programming of the infusion pump. Infusion pumps that have barcode technology and contain drug libraries with maximum established administration rates can help trap programming errors. Protocols and standard order sets and the development of a reference sheet with programming tips and maximum dose information also are helpful. The purchase of prefilled syringes containing the drugs used for PCA can help to reduce the number of dispensing errors as well.

Equipment Problems

Equipment-related errors can occur with PCA. Infusion lines have been connected or reconnected incorrectly. Using two different PCA pumps in the same institution has resulted in errors due to equipment mix-ups. Occasionally clinicians have even failed to remember to push the start button to begin the infusion after it is set up. Patients also have confused the nurse call button with the button on the infusion pump that is pressed to administer a dose of analgesia. This mistake results in failure to administer a dose when patients thought they were requesting one or administering an unintended dose when they thought they were calling for a nurse. Other problems that can contribute to errors include battery failures and syringe positioning that prevents the drug name on the label from being visible once it is inserted.

Prescribing

The prescription for PCA can itself be a source of errors. Mistakes have been made when converting the dose from the oral to the intravenous form of hydromorphone. Verbal orders for PCA and poor handwriting have led to misinterpretation. Occasionally PCA has been ordered for a patient who still had an active order for another opiate that was being given orally or intravenously, and that order was not discontinued, resulting in additional opiates being administered.

Staff Education

Staff education is crucial to the success and safety of PCA. Unfortunately, physician and staff credentialing for PCA is uncommon. Staff education must cover several key areas, including interpreting the prescription order, proper entry of the information into the infusion delivery device, educating the patient and family members, and effective patient monitoring and documentation.

Educational Tools

After reviewing input received from several experts, The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published on their website a sentinel event alert regarding PCA. The information presented may be helpful to organizations in the development of policies and procedures. The alert can be found in the sentinel event section of JCAHO's website (www.jointcommission.org); click on the December 20, 2004 issue. On ISMP's website, practitioners can find a patient safety video produced by the Food and Drug Administration (FDA) that addresses safety issues with PCA. To view the video, go to www.ismp.org/Tools/fdvideos.asp, and click on the link for August 2002. ■

Developing Quality Indicators for Patient-Controlled Analgesia

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Patient safety is an area of significant concern with patient-controlled analgesia (PCA) because serious errors have occurred when PCA has been employed. According to an analysis of national error data from the MEDMARX database, opiates represent one of the four drug categories that cause more than 60% of serious adverse events in the United States (the others are anticoagulants, insulin, and antibiotics).*

However, safe practices can be developed for PCA, and quality indicators established to monitor these practices. It is important to understand that evaluating quality is difficult unless one can measure a baseline prior to the implementation of the identified safety practices. This article will address how to create a successful quality improvement initiative and measure results.

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Involving Stakeholders

Key stakeholders must be involved at the start of any effort to improve safety and quality. Members of the Pittsburgh Regional Health Initiative (PRHI) have discovered that the most important person linked to the success of patient safety initiatives is the physician. The Pittsburgh group has concluded that success is not possible without a physician champion who feels passionately about the initiative and is willing to tackle any barrier in the organization to achieve successful

* An analysis of regional and national MEDMARX data was performed in July 2004 by Robert Weber and the University of Pittsburgh School of Pharmacy Data Coordinating Center as part of the Pennsylvania Regional Health Initiative (PRHI).

implementation. Other key elements are support from the chief executive officer, simplification of processes, and staff management of the program 24 hours a day, 7 days a week. The PRHI also has identified several common roadblocks to implementing a patient safety initiative and effectively measuring the resulting improvement in quality. If staff believe that they are not empowered to actually effect change, it can be difficult to get a patient safety initiative off the ground. In addition, some clinicians have inertia of previous practice—defined as the attitude “that is how we have always done it”—which also can quickly derail an initiative. It is important to determine whether these potential barriers are present at the start, so that they can be taken into account during the planning stages.

Using Reporting Systems

Medication error reporting programs can be a valuable part of the quality improvement process, as long as the data obtained is converted into learning. In order to improve safety, the healthcare culture must be changed, medication error reporting programs put into place, the data analyzed, and evidence-based interventions implemented. Only then a quality improvement process can be put in place to measure change from a baseline.

The PRHI has collected data on serious medication errors resulting in harm and requiring additional patient treatment. Opiates were one of the most common drug classes involved, and nearly 50% of the errors involving opiates were related to PCA.* This data demonstrates that while PCA provides significant benefits, it is associated with significant risks. The first step of the quality improvement process is to find a process to improve, and there is certainly enough data to show that PCA is in need of attention.

Developing Quality Indicators

Once problematic processes have been identified, the next steps are to quantify the problems associated with those processes and then develop quality indicators for them. Simple and clear quality improvement indicators provide rich data that can be used extensively within an organization to improve the quality of care. Developing those indicators can seem like a daunting task, but in reality it is not difficult.

The easiest way to get things underway is to obtain consensus opinions from hospital staff. The Pharmacy and Therapeutics Committee or the Pain Management Committee can identify the practices that should be implemented in the organization and their appropriate quality indicators. The key is to remain focused and to realize that not every indicator has to be

measured. For example, if the group identifies six safe practices for PCA, then decide how many of those should be studied. I recommend that organizations just starting out with quality improvement choose two or three to study for one year, focus on making improvements around those indicators, and then move on to some of the others on the list.

As part of the PRHI, it was useful to bring clinicians together to discuss the best medical evidence and form a consensus opinion on the safe practices for PCA. Having consensus on the safe practices and the indicators selected helped prevent or defuse disagreements that arose when quality improvement results begin to appear. Members of the PRHI group asked themselves “How do we create the safest patient environment with PCA?” and “What practices should be implemented?” They then developed 26 safe practices for PCA, which eventually were honed down to ten.

A few of the safe practices recommended by members of the PRHI were:

- 1) Preprinted order forms (were being used for new PCA orders, but not after dose changes, which resulted in dosage errors)
- 2) Independent checks
- 3) Standard parameters for monitoring
- 4) Standard concentration
- 5) Removing meperidine from the formulary

Measuring Outcomes

When measuring outcomes, you must first decide whether to measure a process outcome or a clinical outcome. Process outcomes measure the efficiency of a system, how well the system is functioning, or compliance with a process, so they are merely indicators of how well the system is working. It is easier to measure a process outcome, but the data may not be as valuable. A clinical outcome measures the results of patient treatment. An example of a process outcome is compliance with using a preprinted order form for PCA. An example of a clinical outcome is the following statement: “Patients will report a pain scale of less than (a number defined by your organization), concomitant with an acceptable sedation level evaluation.”

An important question to ask when developing an outcome measurement strategy may be “What is the most crucial indicator or clinical outcome in PCA?” One of the most crucial outcomes to avoid in patient care is the adverse drug event. Therefore, an extremely useful indicator is measuring the incidence of adverse drug events associated with PCA. Once you identify the indicators that you wish to follow, you must develop a method for monitoring them.

An important question to ask when developing an outcome measurement strategy may be “What is the most crucial indicator or clinical outcome in PCA?”

The creation of a table that displays the indicator, the data source, how the indicator will be measured, and how often it will be measured is a good way to track your progress. A sample is provided in figure 1. Understanding the data and being able to articulate results can help promote the understanding that a practice improves quality of care. For example, evidence that a percentage of a healthcare organization’s errors result from dose changes can help explain to staff why it is important to use preprinted order forms when doses are changed, as opposed to using them only at the initiation of PCA therapy. Showing in reports to staff that the number of adverse drug events with PCA decreased because of the implementation of safe practices also will help them understand the value of quality improvement efforts.

FIGURE 1. SAMPLE QI TABLE.

Quality Indicators & Data Management			
	Data Source	Measurement Scale	Measurement Frequency
ADEs to PCA	Naloxone usage report, reported ADEs	Review by pain experts, pain team	Weekly
Order form for dosage changes	Standing PCA order form, pharmacy orders for dosage changes	Pharmacist/ technician review of orders	Weekly

Tools and Resources

The PRHI has created a PCA toolkit that has been very useful in implementation of quality improvement efforts (see figure 2). The toolkit contains several different aids that assist end users in knowing how to use PCA safely. Some of the items included are a pocket pain card, IV guidelines, computer-generated order forms, posters, and PCA therapy guidelines. The toolkit also provides the opportunity for another quality indicator—whether staff understand and know how to use these resources. Another aid to consider developing is a formal pharmacy competency assessment tool for PCA.

FIGURE 2. PCA TOOLKIT AND IMPLEMENTATION OVERVIEW.

Components of Successful PCA Safety Initiatives

Staff and Patient Education

Written materials

- Pocket pain card
- Regional PCA safety guidelines
- Patient education leaflet

Verbal education

- 1:1 education with new residents and pain nurse specialist
- Pharmacy staff inservices
- Pain resource nurse monthly teaching

Electronic access

- Intranet pain card
- Intranet policies
- Online adverse event reporting
- IV guidelines
- Electronic MAR charting screen

End-User Tools/Processes

- Preprinted PCA order form
- Nursing medication administration record (MAR) form
- PCA pendant warning for patient safety
- Standard PCA drug concentrations
- Pharmacist rewrite of orders if not on preprinted form
- New PCA pump evaluation for health system

Summary

In conclusion, developing quality indicators is not hard—it just requires common sense. The following are a few key points to keep in mind when developing quality indicators for PCA: focus on a few specific indicators; utilize experts within the organization to develop, promote, and track them; create a measurement process that makes sense and is clear to all involved; and consider creating and using tool kits to assist staff members with implementation. ■

Failure Mode and Effects Analysis in Reducing Errors with Patient-Controlled Analgesia

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The process of Failure Mode Effects Analysis (FMEA) provides an excellent opportunity to uncover both the safeguards and risks inherent in the use of patient-controlled analgesia (PCA). PCA technology has rapidly progressed over the years, giving clinicians the impression that it is now safer than ever, even for pediatric patients. By participating in FMEA, practitioners become keenly aware of the potential failures in their PCA processes. FMEA also offers a clear method for identifying and selecting strategies to reduce the modes of failure.

Many healthcare organizations have chosen to perform FMEA for PCA due to the publication of a Sentinel Event Alert by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Many hospitals were surprised by the degree of risk involved after reading the alert and performing their own FMEA, especially those that had never experienced a serious adverse event with PCA.

FMEA is a time-consuming process, sometimes taking several months to a year. However, because of its proactive nature, FMEA may be easier to perform than a Root Cause Analysis (RCA) because there is no “pressure” to find the cause of an event that has already caused harm to a patient.

FMEA Steps

The steps in the FMEA process are as follows:

- 1) Select a high-risk process and assemble a team
- 2) Diagram the process
- 3) Brainstorm potential failure modes and determine their effect
- 4) Prioritize failure modes
- 5) Identify root causes of failure modes
- 6) Redesign the process
- 7) Analyze and test the new process
- 8) Implement and monitor the new process

Step 1. Select a high-risk process and assemble a team. PCA is an ideal candidate for FMEA due to the high-risk nature of the medications used. Ideally, the FMEA team will include a diverse mix of practitioners to offer varying perspectives on the process and reduce the placing of blame for potential problems identified on any one particular professional group. For example, a team may consist of individuals from the following areas:

- Pharmacy
- Nursing
- Performance improvement
- Risk management
- Medicine
- Biomedical/clinical engineering
- Equipment processing and distribution

Step 2. Diagram the process. This may be the most challenging step of a FMEA. Many times what seems like a process of just a few steps actually looks quite complicated once it is documented in a flowchart. Only after all the steps are laid out can the brainstorming stage begin. Without a detailed diagram, potential failure modes could be overlooked and the opportunity to prevent a failure could be lost. The team should also include any subprocesses in the flowchart.

Step 3. Brainstorm potential failure modes and determine their effect. For each step in a process, ask team members to think of ways that step could fail, causing the PCA process to reach an undesired outcome or next step (these are the failure modes). For each failure mode, determine the effect that failure would have on the process and patient.

Step 4. Prioritize failure modes. The prioritization step can be made easier by computing a hazard score for each failure mode. Those with highest scores should be considered first priority for analysis and action. Hazard scores are typically computed by multiplying a severity score by a probability score. Specific numbers assigned to each score vary by hospital, but many facilities use the VA National Center for Patient Safety scoring criteria.

Step 5. Identify root causes of failure modes. The main question to ask and continue asking is “why?” Only by getting to the real root cause(s) of a failure mode can appropriate actions be taken to reduce the severity and probability.

Step 6. Redesign the process. Develop actions to reduce failure modes by redesigning the process or parts of the process.

Step 7. Analyze and test the new process. This can be accomplished by piloting the new design first. Then begin a facility-wide rollout of the redesigned process.

Step 8. Implement and monitor the new process. Choose measurement indicators to test and analyze the new process. Choose direct and balancing measures to track effectiveness of actions.

Before the patient ever comes in contact with a drug delivered by a PCA device, they must first be determined an appropriate candidate.

Selected Examples

To illustrate FMEA, several processes from an actual FMEA of PCA are described below.

Process: Patient Selection

Before the patient ever comes in contact with a drug delivered by a PCA device, they must first be determined an appropriate candidate. Failures in this process can be stopped before the patient can even be put at risk. PCA requires the cooperation and understanding of the patient—they must have the physical ability to use the device, the cognitive ability to sense their level of pain and correctly use the device, and the ability to understand the directions presented to them. Patient characteristics that may preclude someone from being an ideal candidate, and thus elevate the risk of harm from using PCA, are if they are confused, have limited dexterity to operate the pump, have comorbidities that increase the risk of harm from opioids, or if their primary language is not English.

Even with these exclusionary criteria, PCA may still be prescribed for inappropriate patients. The FMEA team found some of the root causes (reasons why) to be inaccurate patient assessment, patient competency bias, and practitioner knowledge deficit. Practitioners may overestimate a patient’s physical or cognitive ability and prescribe PCA believing that they are appropriate for the device. They also may determine patient competency to use a PCA pump without an objective measurement tool, which brings their own bias into the decision. In addition, practitioners may not fully understand the patient selection criteria, intention, and operation of PCA. Pharmacists in particular may lack this knowledge, making it difficult for them to review an order for safety if they cannot determine which patients should and should not be prescribed PCA.

To address these potential failures, the FMEA team initiated a major education campaign for all practitioners, especially pharmacists. This involved developing educational materials and presentations as well as a competency exam. In addition, interpreters were used more consistently for non-English speaking patients.

Process: Prescribing

Many parameters must be selected or defined on a prescription order for PCA—such as drug, dosage, and mode—and any one of them could be a potential chance for a mistake. Some of the root causes behind failures identified by the FMEA team were practitioner knowledge deficits, incomplete or inaccurate pain assessments, lack of standardized concentrations, and the removal of meperidine (Demerol) from the formulary.

Areas where knowledge deficits existed included allergies, modes of drug delivery, and dangers of nonstandard drug concentrations. True allergies to morphine are rare, yet many patient charts have an allergy noted. Morphine is usually the primary drug for PCA—it is safer because the most clinical knowledge exists about its effects, and most practitioners are comfortable prescribing or administering it. If the practitioner does not know enough about allergies to make further inquiries about the morphine notation, a secondary drug such as hydromorphone (Dilaudid) or fentanyl is usually chosen instead, which places the patient at a greater risk for harm.

Lack of knowledge about the mode of PCA drug delivery can also cause problems. Most PCA devices offer a continuous or basal rate feature in addition to the patient-activated dose. Without specialized knowledge about basal or continuous rates (and a detailed pain treatment history), the ordering of a basal rate can be error prone and place the patient at a greater risk for opioid toxicity. Basal rates should not be ordered unless the patient is truly opioid-tolerant, i.e. has a diagnosis of sickle cell, cancer, or pancreatitis. Many surgical patients are opioid-naïve and should not receive a basal rate on PCA, which increases the risk of serious side effects.

Lack of familiarity with nonstandard concentrations was identified as another potential root cause of prescribing and administration errors. Sometimes, for a reason such as fluid restriction, a more concentrated form of a drug may be requested. These nonstandard concentrations are a set up for failures unless every single clinician that may change the order, adjust the pump, or prepare and dispense the drug is knowledgeable about them.

Incomplete or inaccurate pain assessments were identified as another source of errors. A complete pain assessment is more than a numerical rating on a scale. A thorough pain history as well as assessment of the present episode is necessary to determine appropriate PCA parameters.

An interesting finding of this FMEA was the unintended consequence of the removal of meperidine (Demerol) from the formulary. While standardization is a good thing to prevent errors, the narrowing of choices created a different potential root cause. Without the option to order meperidine for PCA, the only options were hydromorphone (Dilaudid) and fentanyl. Nurses identified a large knowledge deficit with hydromorphone and fentanyl administration, and thus a subsequent lack of comfort with their use. Nevertheless, leaving meperidine on the formulary for PCA use would have left open the potential for greater patient harm, as it can be a problem when used in elderly patients with decreased renal function.

To address these root causes, the organization standardized PCA ordering and PCA drug concentrations. They also required that pharmacy review all PCA orders before initiation of therapy (thereby prohibiting overrides from automated dispensing cabinets), and embarked on a major educational campaign. Although the changes were not popular with nurses initially, they have been accepted over time.

The standardized PCA order form included monitoring parameters, treatment of side effects, selection of drug (morphine, hydromorphone, and fentanyl) and mode of device action. Drug selections were also standardized for the concentration of each IV opioid. At first, the standardized order form was not consistently used among all prescribers. This prompted a policy change where PCA orders were accepted only on the standard form, which facilitated organization-wide acceptance and use.

Educational methods included a website, pocket reference cards (see figure 1), pharmacy newsletters, lectures, and competency exams. The website provided easy access for all staff to topics such as clinical skills, drug and pump information, and how to order PCA, which was helpful for new residents. The PCA pocket cards were tri-fold, yellow cards with information on opioid characteristics and recommended doses. The organization's pharmacy newsletters ran informative articles about PCA guidelines. In addition, lectures and competency testing were offered for pharmacy and nursing staff.

FIGURE 1. PCA POCKET CARD.

Patient Controlled Analgesia (PCA) for Adults

OPIOID	SIDE EFFECTS	ADVANTAGES	DISADVANTAGES	CAUTIONS/ CONTRAINDICATIONS
MORPHINE	Nausea Sedation Pruritis Reduced peristalsis Respiratory depression	Vast clinical experience Less expensive than other opioids	Slow onset: ~ 15 min. Histamine release Active metabolite (M6G) accumulates in renal patients & causes excessive sedation & other side effects	Allergy (use fentanyl) Renal dysfunction Hepatic dysfunction Asthma (histamine release)
HYDROMORPHONE (Dilaudid)	Nausea Sedation Pruritis Reduced peristalsis Respiratory depression	Faster onset than morphine Less sedation No active metabolites	More expensive than morphine Less clinical experience than morphine Higher potential for abuse	Allergy (use fentanyl) High doses can result in excitation with impaired renal dysfunction
FENTANYL (Sublimaze)	Nausea Sedation Pruritis Reduced peristalsis Respiratory depression	Rapid onset No active metabolites Less constipation compared to morphine	More expensive than morphine Less clinical experience than morphine Short duration of action	Allergy Rapid administration of drug can result in “Stiff Chest” making ventilation difficult

	LOADING DOSE	PCA DOSE	LOCKOUT INTERVAL	FOUR HOUR LIMIT
MORPHINE	0.04 MG/KG (RANGE: 1–3 MG)	0.02 MG/KG (RANGE: 0.5–2 MG)	RANGE: 6–10 MINUTES	0.3 MG/KG (MAXIMUM: 40 MG)
HYDROMORPHONE* (Dilaudid)	0.01 MG/KG (RANGE: 0.25–0.6 MG)	0.005 MG/KG (RANGE: 0.1–0.3 MG)	RANGE: 6–10 MINUTES	0.06 MG/KG (MAXIMUM: 8 MG)

CONTINUOUS INFUSION

ACUTE PAIN — 1/3 of average hourly use.

CHRONIC PAIN — 2/3 of average hourly use.

May be necessary in opioid-tolerant patient or patient with high utilization of PCA over an extended period of time (>12 hours).

* Not FDA-approved for PCA

Process: Administration

Another major PCA process is administration of the drug, which involves infusion pumps and the way nurses and patients work with them. By definition, PCA should only be used by the patient. One failure mode identified by the FMEA team was when the nurse pushes the button for the patient. Many argue that nurse-controlled analgesia is unsafe when using a PCA pump, since the device is not intended to be used in that way. The problem extends beyond nursing to family members who

perform PCA by proxy by pushing the button for their loved one. If a family has been educated on the dangers of PCA by proxy but the practice still continues, then PCA should be discontinued for that patient. To reduce failures related to PCA by proxy, a new patient and family PCA instruction sheet was created and distributed (see figure 2). In addition, a safety sticker with warnings about PCA by proxy was attached to each PCA pendant. Both were made available in multiple languages.

FIGURE 2. INSTRUCTION SHEET.

PATIENT-CONTROLLED ANALGESIA (PCA) INSTRUCTION SHEET

Key Points For Using Your PCA Pump Safely

- This pump allows you to administer your own pain medication.
- The pump has control settings which are programmed for the medication the doctor ordered.
- You will only receive medication when it is time. If you push the button several times, the pump will only dispense pain medication when appropriate.
- The pump will alarm when the syringe is empty, alerting the nursing staff to change the syringe.
- You cannot accidentally roll over on the button and give yourself medication.
- Only use the pain button for pain – not to help you sleep.
- The patient is the **ONLY** one that can push the button. It is **very** dangerous for family/friends to push the button for the patient.
- If your pain is not being relieved, let the nursing staff know so adjustments can be made.
- The goal of PCA is to keep the pain level below a “4” on the 0–10 scale (1–3 being mild pain).

Another source of problems was pump malfunctions. To help identify root causes and reduce these failures, the FMEA team decided to improve the communication between nursing units, equipment processing and distribution (EPD), and biomedical engineering. As a result, new tags were designed to attach to broken equipment that offered more space to document problems. The tags also helped EPD distinguish which pumps needed to be sent to biomedical engineering for repair. In the past, broken pumps were placed in a utility room without any indication of their malfunction, and were frequently cleaned and put back into circulation where they could be confused with working pumps.

Pump misprogramming was also a major failure mode, e.g., wrong drug, wrong concentration, or wrong rate. Many of these mistakes could have been prevented with consistent use of independent double checks among nurses when programming. FMEA brought the importance of double-checks back to the forefront, and several other methods to reduce programming errors were employed. New technology to improve patient safety was explored (see figure 3), and new pumps were purchased that were very user friendly, with easy-to-read screens and step-by-step guidance through the programming process. They also offered integral bar code readability, which

provided a computerized double-check system for nurses to compare the drug with the programming.

FIGURE 3. ADDITIONAL NEW TECHNOLOGIES.

- Customizable drug libraries to support hospital therapy and medication best practices
- Stored protocols assigned to specific clinical care areas that will reduce programming steps
- Wireless network access allowing real-time monitoring of infusions
- CQI reports providing actionable information for performance enhancements
- Pharmacy-generated bar codes for customized medication

The pharmacy also revised the labels for Dilaudid and fentanyl, since the original presentation of the concentration was confusing to the nurses. These drugs are not a 1:1 concentration like morphine, and the original labels listed what was used to compound the final product but not the final concentration. The revised labels now show the final concentration, which matches what is to be programmed into the pump.

In addition, policy changes were implemented as proactive error reduction strategies, including prohibiting STAT orders for PCA. It was found that when PCA was ordered STAT, the normal, safe system of checks was rushed and potentially incomplete, making programming mistakes more likely. If pain medication is needed quickly, and waiting for PCA does not seem clinically warranted, staff is instructed to simply order a dose based upon the immediate need to hold until a PCA order can be safely reviewed, dispensed, and administered. Independent verification of PCA programming upon initiation of treatment is now required and orientation for all new nurses now includes training on PCA pumps.

Lessons Learned

The FMEA process is a valuable experience that can reduce errors. Collaboration among healthcare disciplines on the FMEA team can lead to the resolution of problems far beyond its original mission, and the team's interdisciplinary nature positions it well to help manage future challenges. One important lesson that can be learned through the FMEA examples provided is to beware of unintended consequences of change. Sometimes what is intended as a positive change can lead to unexpected process problems—for example, the unintended consequences of removing meperidine from formulary mentioned earlier. In addition to actions to reduce failure modes, procedures need to be put in place to detect and manage emerging problems. ■

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Self-Assessment Questions

To take the continuing education (CE) test, please go to the ISMP website (www.ismp.org/ce/default.asp) and complete the answer sheet and evaluation. A passing grade of 70% is required to qualify for CE credit. Upon successful completion of the test, you will be able to print your CE statement. If online access is not available, please mail the completed test along with your name, address, and contact information to: ISMP, Continuing Education, 1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006. You can contact ISMP directly at 215-947-7797.

1. Patient-controlled analgesia (PCA) contributes to at least 50% of all serious narcotic-related medication errors.

- a. True
- b. False

2. All of the following steps should be taken in developing quality indicators for PCA except:

- a. Define and quantify the problem
- b. Use expert consensus of best medical evidence
- c. Develop a standing order form for PCA
- d. Establish priorities—focus education and measurement process

3. The most important quality indicator in PCA therapy is compliance with using a standing order form.

- a. True
- b. False

4. When used as intended, PCA can actually reduce the risk of side effects, including the risk of oversedation. What actions help ensure patient safety with PCA?

- a. Instruct the patient and the family that only the patient may push the PCA button
- b. Monitor the patient closely when a basal rate is used
- c. Have pharmacy verify that the settings are appropriate for patient's age, weight, and opioid tolerance level
- d. All of the above

5. A true allergy to morphine is common.

- a. True
- b. False

6. PCA by proxy is safe provided it is the patient's spouse or parent that decides when to push the button to administer a dose of pain medication.

- a. True
- b. False

7. PCA is safe for all patients provided they can be trained to use the device properly.

- a. True
- b. False

8. Drug mix-ups are more common with which of the following:

- a. Morphine and meperidine
- b. Fentanyl and meperidine
- c. Morphine and hydromorphone
- d. None of the above

9. If a patient can be aroused, it is an indication that he or she is not experiencing oversedation.

- a. True
- b. False

10. Checking your own pump settings and dose calculations is more effective in reducing the potential for medication errors than having a second person check them.

- a. True
- b. False



DOSE DELIVERED

MORPHINE
5 mg/mL
HIGH DOSE

SELECT
DELIVERY MODE

PCA ONLY

PCA + CONT

CONTINUOUS

PREVIOUS

EXIT

ENT

1

2

4

7





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