

The Joint Commission

Journal on Quality and Patient Safety

Improvement from
Front Office to Front Line

August 2010
Volume 36 Number 8

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Risk and Event Assessment

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Patient-controlled analgesia (PCA), available by the intravenous (IV) route since the early 1980s,¹ has revolutionized the management of postoperative pain in adults and children in the institutional health care setting. Yet despite the technologic advances in design, resulting in the development of “smart” pumps to help deliver analgesia more safely to the patient, PCA continues to be involved in a significant proportion of the medication errors ascribed to IV drug administration, many of which have harmed patients.^{2,3}

Several studies have used large databases in an attempt to identify the events during the medication-use process that contributed to PCA-related medication errors. In a retrospective analysis for a five-year review period,³ for 919,241 medication-error records from 801 facilities that were submitted to MED-MARX, a national voluntary medication error-reporting database in the United States, 9,571 (1%) were associated with PCA—624 (6.5%) of which resulted in patient harm. Errors were reported across all phases of the medication-use process, but the majority occurred during drug administration. In another large retrospective review, 7.9% (430) of the 5,377 errors attributed to PCA were associated with patient harm.⁴ The most common errors were wrong dose (38.9%), wrong drug (18.4%), omitted drug (17.6%), prescription error (9.2%), wrong administration technique (4.8%), and extra doses administered (4.7%).⁴ When PCA pumps were involved, as compared to all other routes of medication administration, the risk of patient harm was increased more than 3.5-fold.⁴ In the Food and Drug Administration Manufacturer and User Facility Device (MAUDE) voluntary database, in 2004 PCA pumps were associated with 106 adverse events, 22 of which led to death.⁵ As with all voluntary registries, a substantial degree of underreporting exists, so the true error rates are likely much higher than the reported values.^{6,7}

Failure Mode and Effects Analysis (FMEA), a systematic, proactive risk-analysis process used to identify and assess the effects of potential failure points that occur within a particular process or practice (Table 1, page 360), can be used to reduce

Article-at-a-Glance

Background: Despite the technologic advances in design, resulting in the development of “smart” pumps to help deliver analgesia more safely, patient-controlled analgesia (PCA) is still involved in a significant proportion of the medication errors ascribed to intravenous (IV) drug administration, many of which have harmed patients. In 2003, Failure Mode and Effects Analysis (FMEA) was used to assess the PCA process at a 695-bed teaching and research tertiary hospital.

Identifying and Addressing Failure Modes: For the three processes with hazard scores > 8—patient selection, prescribing, and medication administration—the potential cause(s) were identified, allowing the process to be redesigned to eliminate the potential cause(s).

Results: In January 2003 to May 2003, before the FMEA process began, there were 11 PCA errors (extrapolated to 26 for the entire 2003 calendar year). In 2004, when most of the corrective actions were taken, there were 22 reported PCA errors. In October 2007, a new online occurrence-reporting program was implemented, making reporting much easier. From October 2007 through September 2008, there were only 8 reported PCA errors, representing a 69% reduction from baseline. No serious adverse events were associated with any of these PCA errors.

Discussion: Despite the reduction in PCA errors since the FMEA was conducted, misprogramming of drug concentration remains a common PCA error. Solutions include safety software for IV infusion pumps, an integral bar-code reader for detecting concentration errors, and interoperability of the software with other hospital information systems. One lesson learned was that an FMEA can lead to resolution of problems beyond the scope of original intent—in this case, the development of a new system for identifying all broken equipment.

PCA errors⁸ and other patient safety risks in health care.^{9–16} This article describes how a multidisciplinary team in a mid-western medical center used FMEA to analyze the PCA process.

Conducting the FMEA

At Advocate Christ Medical Center (Oak Lawn, Illinois), a 695-bed teaching and research tertiary hospital with a Level I trauma designation, a multidisciplinary team was formed in September 2003 for analysis of the high risks inherent in PCA. The team, composed of representatives from nursing, pharmacy, medicine, performance improvement, risk management, clinical engineering, information systems, and equipment processing and distribution, was co-led by an advanced practice nurse [J.M.] and a pharmacy director. This was the first FMEA to address PCA at this institution.

IDENTIFYING AND ADDRESSING FAILURE MODES

In November 2003, the team identified failure points associated with PCA therapy (Table 2, right) and created a flowchart to diagram the PCA process step by step. Each step became its own process, consisting of numerous subprocesses. For example, a subprocess of the process *patient selection* was the assessment of a patient's competence to operate the PCA device. As each process was carefully dissected, potential failure modes were identified and scored on the basis of probability of occurrence and severity of effects. A hazard score was defined as the product of the probability and the severity (probability × severity) of a potential failure mode (Table 3, page 361). The FMEA team focused its efforts on failure modes with hazard scores > 8.

Failure modes were prioritized in terms of the order in which they were to be addressed. The potential cause(s) of each failure mode were then identified, allowing the process to then be redesigned to eliminate the potential cause(s). Action plans to eliminate potential cause(s) were developed with input from all team members. To ensure that action plans were effective, measurement indicators were developed and data were collected during an agreed-on period of time. When it was determined that the action plans were effective, this new process was incorporated through education and revisions of policies and procedures. Data collection continued until the new process was firmly established.

Three processes had hazard scores > 8—patient selection, prescribing, and medication administration (Table 4, page 361). Pharmacy was not identified as a critical potential failure

Table 1. Failure Mode and Effects Analysis (FMEA) Process

1. Select a high-risk process.
2. Diagram the process.
3. Outline potential failure modes and their effects.
4. Prioritize failure modes (in the order in which to “attack” them).
5. Identify the potential cause(s) of each failure mode.
6. Redesign the process to eliminate the potential cause(s).
7. Analyze and test the new process.
8. If beneficial, implement and monitor the redesigned process.

Table 2. Risk Factors Associated with Patient-Controlled Analgesia (PCA) Therapy*

- Improper patient selection
- Inadequate patient monitoring
- Practice-related problems (e.g., misprogramming the pump, transcription errors, calculation errors)
- Inadequate staff training
- Inadequate patient education
- Prescription errors (e.g., prescribing a drug to which the patient is allergic, misreading written orders, concurrently ordering IV and/or oral opioids)
- “PCA by proxy”
- Soundalike drugs, e.g., hydromorphone and morphine
- Device-design flaws

* Adapted from Institute for Safe Medication Practices: Safety issues with patient-controlled analgesia. Part I: How errors occur. *ISMP Medication Safety Alert!* Jul. 20, 2003. <http://www.ismp.org/newsletters/acutecare/articles/20030710.asp> (last accessed Jun. 28, 2010). IV, intravenous.

mode because processes associated with pharmacy were already well-organized at the institution. However, two actions to reduce failure modes with respect to pharmacy were identified:

1. Cessation of approval of orders that were not on the standard PCA order form
2. Cessation of allowing overrides for PCA in the automated medication-dispensing cabinet

Patient Selection. The team identified inaccurate patient assessment and practitioner-knowledge deficit as potential causes for inappropriate patient selection; actions to eliminate them are provided in Table 5 (page 362). Central to enhancing PCA safety are appropriate patient selection and early identification of at-risk patients.^{8,17} PCA is appropriate when the patient who requires parenteral analgesia is both cognitively and physically capable of activating the device by pressing the

Table 3. Failure Mode and Effects (FMEA) Severity and Probability Scoring of Potential Failure Modes*

Severity Score	
1	Minor patient outcome: no injury, nor increased length of stay, nor increased level of care
2	Moderate patient outcome: increased length of stay or increased level of care for 1 to 2 patients
3	Major patient outcome: permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) disablement, surgical intervention required, increased length of stay for 3 or more patients
4	Catastrophic patient outcome: death or major permanent loss of function (sensory, motor, physiologic, intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction or discharge to wrong family
Probability Score	
1	Remote: unlikely to occur (may happen sometime in 5–30 years)
2	Uncommon: possible to occur (may happen sometime in 2 to 5 years)
3	Occasional: probably will occur (may happen in 1 to 2 years)
4	Frequent: likely to occur immediately or within a short period (may happen several times in one year)

* Adapted from VA National Center for Patient Safety: *HFMEA (Healthcare Failure Mode and Effect Analysis)*. <http://www4.va.gov/ncps/CogAids/HFMEA/index.html#page=page-9> (last accessed Jun. 28, 2010).

button.^{17,18} The patient must be able to understand the relationship between pain, pushing the PCA button, and pain relief.¹⁸ The practitioner must ensure that he or she does not overestimate the patient’s cognitive or physical abilities for using PCA therapy.

Patient types at risk—and therefore potentially inappropriate candidates for PCA—include pediatric patients, elderly patients, and patients with comorbid conditions such as obesity, obstructive pulmonary disease, end-stage renal disease, and sleep apnea.^{8,19,20} Sleep-apnea syndromes were special cases of the at-risk conditions that were identified. Many patients with these syndromes were also obese and hence at risk because of obesity hypoventilation syndrome. In addition, central and obstructive types of sleep apnea are worsened by opioid use. Opioids blunt the response to carbon dioxide, which provides the primary stimulus to breathe during sleep apnea episodes. Episodes—fatal and nonfatal—of respiratory depression in patients with sleep apnea undergoing PCA have been reported.²¹ Therefore, respiratory depression is a risk in patients in whom sleep apnea has not been diagnosed and/or is not suspected. In patients with known respiratory compromise, the use of continuous pulse oximetry (SpO₂) or capnography (which measures end-tidal carbon dioxide) where respiratory rate is also measured may be valuable monitoring adjuncts.²²

Patients who had not taken or who had seldom used opioids (“opioid-naïve”) were also identified as being at risk, particular-

Table 4. Hazard Scores for the Selected Potential Failure Modes

Potential Failure Mode	Severity	Probability	Hazard Score*
Patient Selection	3	3	9
Prescribing	3	4	12
Administration	3	4	12

* Hazard score = Severity × Probability score.

ly for sedation and respiratory depression. Non-English-speaking patients were at increased risk if interpreters were not used because complete patient understanding of PCA could not be ensured; such patients were identified as failure modes within this process.

Prescribing. For prescribing—the second process examined by the team—several failure modes were identified, including wrong analgesic selected, wrong mode of administration, wrong dosage prescribed, and having multiple drug concentrations available for PCA opioid analgesia. As shown in Table 6 (page 362), potential causes for prescribing errors included inaccurate patient assessment, knowledge deficit (physician, nurse, pharmacist), incomplete/inaccurate pain assessment, lack of standardized concentrations, and removal of meperidine from the formulary.

Although removal of meperidine from the hospital formula-

Table 5. Actions in Response to Identified Potential Causes of Failure Modes in the Patient-Controlled Analgesia (PCA) Process: Patient Selection

Potential Causes

- Inaccurate patient assessment
- Knowledge deficit (physician, nurse, pharmacist)

Actions Taken

- Education for physicians, nurses, and pharmacists
 - PCA pocket cards
 - Pharmacy newsletters
 - PCA competency
 - Lectures
- Increased use of interpreters
- Increased focus on patient competency assessment
- Web site

Table 6. Actions in Response to Identification of Potential Causes of Failure Modes in the Patient-Controlled Analgesia (PCA) Process: Prescribing*

Potential Causes

- Inaccurate patient assessment
- Knowledge deficit (physician, nurse, pharmacist)
- Incomplete/inaccurate pain assessment
- Lack of standardized drug concentrations
- Removal of meperidine from the formulary

Actions Taken

- Education for physicians, nurses, and pharmacists
- Written information on hydromorphone and fentanyl posted on all patient care units
- Standardized order form
 - PCA orders only accepted by pharmacy on standardized form
- Standardized concentration for all opioids
- No STAT orders allowed
 - Inclusion of IVP PRN order on standardized order form with discontinuation order 3 hours after order written
- No overrides from automated cabinets

* IVP, intravenous push; PRN, as needed.

ry early in the FMEA process was a positive step in providing safer and more effective pain management for patients, it resulted in the increased use of hydromorphone. It was at this step of the process that the team discovered that the physicians, nurses, and pharmacists had less clinical knowledge of and experience with hydromorphone than meperidine. One specific intervention that we undertook was the use of standard PCA order sets (Table 6), which, as reported by Weber and colleagues,²³ decreased the number of adverse events attributed to PCA cases and increased compliance with the recommended dosage intervals.

Medication Administration. For medication administration—the final process that the team focused on—the identified failure modes included incorrect pump programming, lack of an independent double-check system, PCA by proxy (activation of the PCA pump by anyone other than the patient, including authorized and unauthorized individuals^{24,25}), and pump malfunctions that were not corrected or repaired. The consequences of incorrect pump programming and a lack of an independent double-check system—common errors—are illustrated in a hypothetical case study (Sidebar 1, page 363).

Potential causes of medication administration errors included knowledge deficit, lack of a policy and procedure for an independent double-check system, lack of family education and/or family disregard for the hospital’s policy prohibiting PCA by proxy, and old/broken devices recycled back into use (Table 7, page 363). The team recommended numerous actions, all of which were implemented, to eliminate these potential causes (Table 7).

One of the actions identified to address medication administration errors was use of new infusion pumps. The hospital was in the process of purchasing new PCA pumps during the FMEA process. A key factor in the hospital’s decision to purchase the brand and model that was chosen was the ease of use. The new pump offered integral bar-code readability, reducing the risk of wrong drug/concentration errors, as well as pharmacy-generated bar codes for in-house customized medications (for example, hydromorphone and fentanyl). A final confirmation screen indicating all programmed parameters on a single screen offered further protection against a wrong-dose error.

Results

In January 2003 to May 2003, before the FMEA process began, there were 11 PCA errors, which extrapolates to 26 for the entire 2003 calendar year. In 2004, during which time most of the new processes identified by FMEA were implemented, there were 22 reported PCA errors. During the first nine months of 2005, only 8 errors were reported (data were unavailable for the remaining three months). In October 2007, a new online occurrence-reporting program was implemented, making reporting much easier. From October 2007 through

Table 7. Actions in Response to Identification of Potential Causes of Failure Modes in the Patient-Controlled Analgesia (PCA) Process: Medication Administration

Potential Causes

- Knowledge deficit
- Lack of policy/procedure for double-check system
- Lack of family education/disregard for policy against “PCA by proxy”
- Old/broken devices recycled back into use

Actions Taken

- Education
- Purchase of new pumps with integral bar-code readability
- Revised pharmacy labels for hydromorphone and fentanyl with increased emphasis on concentration
- PCA pump class in every new-nurse orientation
- Policy change to include independent double-check on initiation of therapy and with all setting changes
- New tags designed for broken equipment to prevent recycling of broken pumps
- Patient/family PCA instruction sheet
- Safety sticker in multiple languages attached to PCA pendant

September 2008, there were only 8 reported PCA errors, representing a 69% reduction from baseline. The total number of hospital error reports (PCA and non-PCA) increased 150% from 2003 to 2009. However, there was a 19% decrease in the number of reported PCA errors during 2009 compared with 2003 (21 versus 26).

No serious adverse events were associated with any of these PCA errors. The most common errors were misprogramming of medication concentrations that could result in inadequate pain management. This is highlighted in follow-up data from 2009, when the total number of PCA errors in 2009 was 21, 17 of which were associated with wrong dose. Ten of these 17 errors were wrong hydromorphone concentration, underscoring the need for the independent double-check system, as well as demonstrating the utility of smart pumps (Sidebar 1).

Discussion

PCA continues to be associated with errors and was the focus of an FMEA process, the first with respect to PCA at our institution, beginning in 2003. The FMEA team identified patient selection, prescribing, and medication administration as the three PCA processes critical to address to enhance patient safety.

Sidebar 1. Hypothetical Case Study: Incorrect Pump Programming and Lack of an Independent Double-Check System

A 68-year-old female patient, status-post colon resection with a history of diabetes mellitus and mild renal insufficiency, was started on patient-controlled analgesia (PCA) while in the postanesthesia care unit. Hydromorphone was chosen as the analgesic to be administered via PCA because unlike morphine, it does not have an active metabolite that is renally excreted, making it useful in elderly patients and patients with renal dysfunction.* The PCA dose setting was ordered as 0.3 mg every 8 minutes, with a lock-out or maximum set at 8 mg every 4 hours. The concentration for hydromorphone was 0.2 mg/mL. However, when the nurse programmed the pump, the concentration was incorrectly set at 0.3 mg/mL.

The patient stated that her pain level was at 3 on the 0–10 pain scale when the PCA was initiated. On assessment by the nurse two hours later, the patient’s pain level had increased to 7. The nurse contacted the surgeon and received orders for a one-time bolus dose of 0.5 mg—which decreased the patient’s pain to 3. However, several hours later, the patient’s pain had increased to 7. During shift report, the nurse voiced her concern to the oncoming nurse that the hydromorphone PCA was not controlling the patient’s pain and that possibly the medication should be changed to morphine. Before the oncoming nurse contacted the surgeon for new orders, she assessed the patient and checked the PCA pump settings. She noted that the hydromorphone concentration was misprogrammed at 0.3 mg/mL instead of 0.2 mg/mL, which meant that the patient was receiving only two-thirds the hydromorphone that was ordered. The nurse reprogrammed the pump at the correct concentration and had another nurse perform an independent verification to ensure that all settings were correct. She received an order for another one-time bolus dose to bring the patient’s pain level to 3. The patient’s pain level remained well controlled on the PCA, and the patient was converted to oral analgesics two days later.

* MD ConsultDrugs Database: *Hydromorphone*. (available to subscribers only; last accessed Feb. 26, 2009).

Numerous health care professionals, especially nurses, are involved in virtually every aspect of PCA, including drug administration, patient monitoring, establishment of PCA and IV infusion policies and procedures, patient/family education, and PCA quality assurance measures. Because PCA is still involved in a significant proportion of medication errors attributed to IV drug administration, nursing involvement in measures to improve PCA safety is imperative. As suggested by the FMEA team’s work and the implemented actions, as described in this article, assessment of patient selection criteria, early identification of at-risk patients, and patient-monitoring requirements (for both efficacy and tolerability) present oppor-

tunities for nurses to enhance PCA safety.

Despite the reduction in PCA errors that has occurred at our institution since the FMEA's completion in 2004, misprogramming of drug concentration remains one of the most common PCA errors. Solution to this common error includes safety software for IV infusion pumps, an integral bar-code reader for detecting concentration errors, and interoperability of the software with other hospital information systems. Although such a system is costly, ongoing gains in patient safety would make it cost-effective in the long term. Additional safety features available in the updated version of the pump include customizable drug libraries supporting hospital-therapy and medication best practices, stored protocols assigned to specific clinical care areas, and downloadable data providing actionable information for performance enhancements.

A unique lesson learned during the FMEA process was that positive changes, such as removal of meperidine from the hospital formulary, can lead to unexpected process problems—in this case, lack of familiarity with replacement opioids. Another lesson is that the FMEA process can also lead to resolution of problems beyond the scope of original intent—the development of a new system for identifying all broken equipment. The team also learned how interdisciplinary collaboration is imperative to ensuring a successful outcome of the FMEA process and, finally, how using FMEA can indeed result in a readily discernable enhancement of patient safety. ■

The author serves as a speaker for Hospira, Inc. (Lake Forest, IL). The author acknowledges the support of her FMEA co-chair Beverly Tuck, R.Ph., M.B.A., Pharmacy Director, and Leticia Losurdo, R.N., B.A., Performance Improvement Manager.

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