

Medication errors involving patient-controlled analgesia

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Patient-controlled analgesia (PCA) is a method of pain relief in which a complex electronic infusion device (i.e., a pump) connected to a timing mechanism allows the patient to self-administer analgesic drugs, usually intravenously.¹⁻⁴ The PCA prescription order, initiated by a licensed prescriber and filled after a pharmacist's review, dictates the variables to be programmed into the PCA device and includes the analgesic drug, the bolus dosage (if any), the lockout interval, dosage limits, and the basal (background) infusion rate.² While PCA enables the patient to self-administer a dose of an analgesic when needed, each step in the PCA process may have some effect on safety.

Numerous reports describing PCA risks and benefits have been presented over more than three decades. Findings have suggested improved pain management, better utilization of nursing resources, increased patient satisfaction, and improved pulmonary function; results for length of stay in the hospital have been mixed.^{3,5-7} However, unfavorable outcomes and other adverse

Purpose. The magnitude, frequency, and nature of nonharmful and harmful medication errors associated with patient-controlled analgesia (PCA) were studied.

Methods. A retrospective analysis of Medmarx, a national voluntary medication error-reporting database, was conducted for the period from July 1, 2000, to June 30, 2005, to identify all PCA-related medication errors. Quantitative analysis of the records included the severity of each error, type of error, phase in the medication-use process, principal cause, contributing factors, actions taken, and drug and staff involved. A qualitative analysis was also performed.

Results. Over the five-year review period, 919,241 medication errors records from 801 facilities were submitted to Medmarx. Of these, 9,571 (1%) were associated with PCA. There were 624 records of PCA associated with harm, corresponding to 6.5% of the patients. Errors were reported across all phases of the medication-use process, but the majority occurred during drug administration. Over one third (38%) involved an improper dosage or quantity, while 17.4% involved an omission and 17.3% an unauthorized or wrong drug. Overwhelm-

ingly, human factors were the main cause of PCA errors. Equipment issues (19.5%) and similar drug names and product packaging (11.6%) were also implicated. Distractions (37.8%) and inexperienced staff (26.3%) were the leading contributing factors. Harmful errors required more institutional resources than nonharmful medication errors to manage. Prescribers often issued incomplete, duplicative, or contradictory orders or failed to adjust dosages for comorbid conditions. Dispensing errors were often associated with misfills from the automated dispensing cabinet, compounding of a wrong strength, or lack of drug product availability. Administration errors involved the wrong drug, amount, or concentration, often because the PCA device was misprogrammed.

Conclusion. Events during all phases of the medication-use process contributed to PCA-related medication errors, many of which harmed patients.

Index terms: Dispensing; Dosage; Drug administration; Errors, medication; Patient controlled analgesia; Physicians

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effects have also been associated with PCA. A meta-analysis of more than 30 randomized control trials

evaluating the safety and efficacy of PCA with opioids published between 1982 and 1999 identified bradypnea,

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hypoxia, nausea, vomiting, sedation, pruritus, and urinary retention as adverse effects.⁷ Death has been associated with PCA.³ Some adverse effects result from the opioids themselves, while others are attributable to poor patient selection or to human error during ordering, dispensing, or administering. Faulty PCA equipment design has been implicated in some cases.^{2,4,7-10}

A full understanding of the impact of PCA on patient safety has yet to be achieved. However, since 1998 institutions such as the Institute of Medicine (IOM) have successfully highlighted the magnitude of and issues surrounding all medication errors and have accelerated efforts to prevent them.¹¹ IOM has called for improved error-reporting systems, further research into factors that threaten patient safety, and improved safety of the medication-use process.

Successful error-reporting systems are nonpunitive, confidential, independent, timely, responsive, and system oriented and are based on expert analysis.¹² One example of a successful reporting system is Medmarx, established in 1998 by the United States Pharmacopeia (USP). Medmarx is an Internet-accessible, voluntary medication error-reporting program available to institutions by subscription. Since the inception of this program, more than 880 hospitals and health systems have contributed more than 1.3 million medication error records. Within Medmarx, a record is defined as an actual or a potential error event. Enrolled facilities collect medication error data at the local institutional level and designate a Medmarx-trained staff coordinator to review and enter data into the program's structured and free-text fields. Such a system allows for a macro-level examination of medication errors and for the sharing of information about such errors in hope of preventing them in the future.

The purpose of this study was to analyze the Medmarx database

to characterize the magnitude, frequency, and nature of nonharmful and harmful PCA errors.

Methods

USP performed a free-text search of all Medmarx records submitted between July 1, 2000, and June 30, 2005, using key PCA-related search terms (e.g., "PCA," "patient controlled") from the error-description field (a free-text, narrative field that may contain up to 3000 characters). Wild-card searches (both incorporating mixed-case lettering and ignoring case and spacing) allowed for maximum inclusivity. Since the study used anonymous data voluntarily submitted to Medmarx, it was exempt from full human-subject review. All the textual error descriptions were read to determine the context of the use of "PCA." USP staff (three nurses, two pharmacists, and one analyst) participated in reading each unique record. These personnel identified 99 records in which "PCA" was felt to imply something other than patient-controlled analgesia. The investigators then rereviewed these 99 records to determine if they should be excluded. All remaining records were divided into one-year groups; a year was defined as July 1 through June 30.

Quantitative analysis of the records included the severity of each error (classified according to the National Coordinating Council for Medication Error Reporting and Prevention [NCCMERP] index for categorizing medication errors), the type of error, the node (the phase of the medication-use process where the error originated), the principal cause, the contributing factors, the actions taken following the error, the level of care rendered as a result of the error, the drugs involved in the error, the physical location of the error, the staff involved in the initial error, and (when known) the sex and age of the patient involved. Facility characteristics evaluated included

bed capacity and the owner or operator classification.

To examine the causes of the errors, a derivative of NCCMERP's taxonomy and the cause-of-error selection list from Medmarx was used. The NCCMERP taxonomy has been endorsed by more than 25 constituent organizations and has been used in error-reporting research by more than 400 organizations. Causes were classified as communication issues; drug name confusion; storage, packaging, and labeling matters; human factors; system errors; contraindications; equipment related; or reconciliation related or were reverted to one of the default values in Medmarx (computerized prescriber order entry, wrong diluent, drug shortage, and nonformulary drug).

To examine the level of care rendered as a result of the errors, Medmarx's 19-item selection list was reduced to eight groups of related items. The selections were further examined through a cross-tabulation analysis of nonharmful and harmful errors. Product information was explored by generic name and intended route of administration. Staff members identified as having made the error were examined by general groupings, namely anesthesia providers, prescribing personnel, dispensing personnel, administering personnel, and other. The physical location of an error was reported as perioperative, maternity, critical care, pharmacy, nursing unit, or other. Patient demographics were explored through a cross-tabulation analysis that examined patients' ages (grouped by decade) and error severity.

A qualitative review of each PCA error's description by the USP staff was performed to obtain an in-depth understanding of the details surrounding each error. To develop themes from the data, the records were grouped by medication-use node and then sorted by error severity and type.

Results

Quantitative analysis. Between July 1, 2000, and June 30, 2005, Medmarx processed 919,241 medication error records from 801 facilities (Table 1). Of these records, 9,571 (1%) were associated with PCA; these records came from 491 facilities (61.3%). Sixty-seven records in which “PCA” indicated something other than patient-controlled analgesia were excluded from the study. Even though there were annual increases in the number of records processed and the number of facilities reporting, the proportion of facilities reporting PCA errors remained flat at about 50%. The facilities that submitted records were mostly nongovernment, nonprofit hospitals and general community hospitals (Table 2).

Error severity. There were 624 records of PCA errors associated with harm (NCCMERP categories E through I), corresponding to 6.5% of the patients (Table 3). Of the 624 errors, 19 (3%) were sentinel events (categories G through I), including 2 errors (reviewed in the qualitative analysis section) that could have caused or contributed to a patient’s death. Harmful errors were most frequent between July 1, 2000, and June 30, 2001, the year when the fewest records were received.

Patient demographics. More than 4200 PCA error records identified the sex of the patient; 59.6% of the records involved females and 40.4% involved males. Errors were reported

for all age decades (Table 4). More than half of the 5404 records identifying patient age concerned patients between 40 and 69 years. Percentages of errors peaked at an older age group for harmful errors than for nonharmful errors.

Types of errors. In a review of records by year that identified at least one type of error, 88–100% of records included at least one selection from the multiselection error list. The leading type of error among all records was improper dosage or quantity ($n = 3377$ [38%]), indicating that a wrong amount of drug was involved (Table 5). For the five-year period studied, two other leading error types had nearly equal frequencies, omission errors (17.4%) and unauthorized or wrong drug errors (17.3%); there was some minor variation in the rank order of these errors over the period. Prescribing errors were fourth most frequent (10.2%). Together, these four types of errors represented 7369 (82.9%) of all errors.

A cross-tabulation analysis of the types of errors explored their association with the medication-use process (Table 6). A total of 682 errors (61.9%) were associated with prescribing, indicating that the medication order was the source of the error. Approximately one third ($n = 516$) of the omission errors originated during the transcribing phase. About a quarter ($n = 255$) of the dispensing errors involved an improper dosage or quantity. A

majority of all errors (4807 [54.9%]) were associated with administration. Almost half ($n = 2374$) of these errors involved an improper dosage or quantity. Nearly one third of the errors in the monitoring phase were errors of omission (30.8%) or improper dosage or quantity (30.3%).

Causes of errors. In a review of the percentage of records by year that identified at least one cause of errors, 85.7–100% of the records included at least one selection from the multiselection list. Each year a majority of PCA error records reported human factors as the leading causes of errors ($n = 6669$ [69.8%]). The second most frequent cause was faulty equipment ($n = 1860$ [19.5%]), followed by communication issues ($n = 1563$ [16.4%]); systems ($n = 1216$ [12.7%]); storage, labeling, and packaging ($n = 1106$ [11.6%]); documentation ($n = 1022$ [10.7%]); and name confusion ($n = 112$ [1.2%]).

Contributing factors. A contributing factor influences the occurrence of an error but does not directly cause it. About one PCA error record in three (37.6%) identified at least one contributing factor (Table 7). Two of the leading contributing factors were distraction ($n = 713$ [37.8%]) and workload increase ($n = 371$ [19.7%]). A distraction is any interruption in the medication-use process.

Six contributing factors were related to characteristics of the staff: inexperienced staff, shift changes, agency or temporary staff, insuffi-

Table 1.
Total Medmarx Records, Records Involving Patient-Controlled Analgesia (PCA), and Reporting Facilities by Year^a

Item	2000	2001	2002	2003	2004	Total
Total no. Medmarx records	62,643	149,016	223,463	246,689	237,430	919,241
No. (%) PCA records	695 (1.1)	1,780 (1.2)	2,442 (1.1)	2,497 (1.0)	2,157 (0.9)	9,571 (1.0)
Total no. facilities	282	440	551	617	618	801
No. (%) facilities reporting PCA errors	133 (47.2)	249 (56.6)	299 (54.3)	314 (50.9)	311 (50.3)	491 (61.3)

^aYears begin July 1 and end June 30.

cient staff, cross-covering staff, and floating staff. Collectively, staff-related issues accounted for 1100 (44.8%) of the errors for which contributing factors were identified. Inexperience was the most important staff-related contributing factor.

Even though patient transfer (patient movement from one clinical

area to another) was not available to error reporters as a selection option in 2000 or 2001, by 2004 it was the fourth most frequent contributing factor, accounting for 42 (8.8%) of the errors in this category.

Actions taken. Slightly less than half (45.9%) of the PCA error records identified at least one action taken as

a direct result of the error. Reporters most often specified that the action consisted of informing the staff who made the error (Table 8). Additional education and training followed an error 25.8% of the time. Actions taken were consistent in each of the years analyzed. “Informed patient’s physician” was frequently specified in the last two study years.

Level of care. An increased level of patient care is applicable only to errors that reach the patient (errors in categories C through I). Depending on the year, additional care was necessary as a direct result of the PCA error for 49.5–72.4% of the errors. Among the 458 harmful errors, the most common responses were changing the drug therapy regimen, including changing the analgesic drug or administering oxygen ($n = 286$ [62.5%]), and observation ($n = 228$ [49.8%]). In 26.9% of the cases ($n = 123$), antidotes or antagonists were needed. Other outcomes included increased length of stay ($n = 54$ [10.0%]), performance of a diagnostic test ($n = 27$ [4.8%]), a life-sustaining intervention [$n = 18$

Table 2.
Characteristics of Facilities

Characteristic	No. (%)
Facility type	
General community hospital	372 (75.8)
University hospital	38 (7.7)
Critical-access hospital	17 (3.5)
Specialty hospital	6 (1.2)
Outpatient pharmacy	3 (0.6)
Long-term care facility	1 (0.2)
Ambulatory care or outpatient clinic	1 (0.2)
Not reported	54 (11.0)
Facility ownership	
Nongovernment, nonprofit	317 (64.6)
Government	
Nonfederal	70 (14.3)
Federal	43 (8.8)
Investor owned (for profit)	7 (1.4)
Not reported	54 (11.0)

Table 3.
Severity of Errors in Patient-Controlled Analgesia by Year^a

Error-Severity Category ^b	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
A	50 (7.2)	134 (7.5)	262 (10.7)	354 (14.2)	225 (10.4)	1025 (10.7)
B	130 (18.7)	527 (29.6)	669 (27.4)	624 (25.0)	508 (23.6)	2458 (25.7)
C	347 (49.9)	839 (47.1)	1085 (44.4)	1104 (44.2)	1037 (48.1)	4412 (46.1)
D	100 (14.4)	171 (9.6)	252 (10.3)	272 (10.9)	257 (11.9)	1052 (11.0)
E	61 (8.8)	101 (5.7)	160 (6.6)	135 (5.4)	110 (5.1)	567 (5.9)
F	7 (1.0)	6 (0.3)	10 (0.4)	4 (0.2)	11 (0.5)	38 (0.4)
G	0	0	0	0	0	0
H	0	2 (0.1)	4 (0.2)	4 (0.2)	7 (0.3)	17 (0.2)
I	0	0	0	0	2 (0.1)	2 (<0.1)
Total no. errors	695	1780	2442	2497	2157	9571
No. (%) harmful errors	68 (9.8)	109 (6.1)	174 (7.1)	143 (5.7)	130 (6.0)	624 (6.5)

^aYears begin July 1 and end June 30.

^bBased on the National Coordinating Council for Medication Error Reporting and Prevention index for categorizing medication errors (www.nccmerp.org). Category A events are circumstances or events that have the capacity to cause error. Category B errors are errors that occurred but did not reach the patient. Category C errors reached the patient but did not harm the patient. Category D errors either required monitoring to confirm that they resulted in no harm or required intervention to preclude harm. Category E errors may have contributed to or resulted in temporary harm and required intervention. Category F errors may have contributed to or resulted in temporary harm and required initial or prolonged hospitalization. Category G errors may have contributed to or resulted in permanent harm. Category H errors required intervention to sustain life. Category I errors may have contributed to or resulted in the patient’s death.

(3.3%)], and interruption of care ($n = 7$ [1.5%]). Most frequently, no additional care was rendered in cases of nonharmful errors.

Drugs involved. Between 75.3% and 95.6% of the error records identified at least one drug by generic

name; morphine was named most frequently ($n = 4495$ [49.2%]) (Table 9). Hydromorphone and meperidine were also frequently associated with the errors. The records also pointed to use of the opioid-receptor antagonist naloxone following the error,

which is internally consistent with the patient outcome findings.

Staff involved. Nurses were involved in nearly three fourths of the errors ($n = 6008$ [73.0%]) (Table 10). Dispensing personnel were the group involved second most frequently ($n = 1150$ [14.0%]).

Locations. Most errors ($n = 6263$ [71.3%]) originated on nursing units, followed by pharmacy locations ($n = 995$ [11.3%]) and the perioperative area (Table 11). Within the perioperative area, the postanesthesia care unit was the locus of the most errors ($n = 510$ [83%]).

Qualitative analysis. The qualitative review of each PCA error's description showed that a majority of the errors ($n = 4687$ [54.8%]) occurred during the administration phase, followed by transcribing ($n = 1631$ [19.1%]), prescribing ($n = 1012$ [11.8%]), dispensing ($n = 1001$ [11.7%]), and monitoring ($n = 215$ [2.5%]).

Prescribing. Prescribing errors comprised issues such as incomplete

Table 4.
Errors in Patient-Controlled Analgesia by Patient Age and Error Harmfulness

Age (yr) ^a	No. (%) Errors		
	Nonharmful ^b	Harmful ^b	Total
<10	34 (0.7)	3 (0.5)	37 (0.7)
10–19	179 (3.7)	25 (4.5)	204 (3.8)
20–29	476 (9.8)	43 (7.7)	519 (9.6)
30–39	728 (15.0)	69 (12.3)	797 (14.7)
40–49	912 (18.8)	102 (18.2)	1014 (18.8)
50–59	844 (17.4)	115 (20.5)	959 (17.7)
60–69	761 (15.7)	97 (17.3)	858 (15.9)
70–79	606 (12.5)	76 (13.5)	682 (12.6)
80–89	279 (5.8)	29 (5.2)	308 (5.7)
>89	24 (0.5)	2 (0.4)	26 (0.5)
Total no. errors	4843	561	5404

^aAge information was available for error categories C through I only.

^bNonharmful errors include National Coordinating Council for Medication Error Reporting and Prevention category A–D errors, and harmful errors include category E–I errors.

Table 5.
Types of Errors Associated with Patient-Controlled Analgesia by Year^a

Error Type	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
Improper dosage or quantity	254 (39.4)	561 (34.7)	815 (37.9)	893 (38.3)	854 (39.6)	3377 (38.0)
Omission	111 (17.2)	266 (16.5)	421 (19.6)	378 (16.2)	372 (17.2)	1548 (17.4)
Unauthorized or wrong drug	126 (19.5)	395 (24.4)	323 (15.0)	363 (15.6)	333 (15.4)	1540 (17.3)
Prescribing error	41 (6.4)	143 (8.8)	241 (11.2)	261 (11.2)	218 (10.1)	904 (10.2)
Drug prepared incorrectly	40 (6.2)	70 (4.3)	75 (3.5)	132 (5.7)	117 (5.4)	434 (4.9)
Extra dose	32 (5.0)	71 (4.4)	86 (4.0)	104 (4.5)	111 (5.1)	404 (4.5)
Wrong administration technique	36 (5.6)	74 (4.6)	100 (4.7)	98 (4.2)	108 (5.0)	416 (4.7)
Wrong time	18 (2.8)	51 (3.2)	89 (4.1)	95 (4.1)	85 (3.9)	338 (3.8)
Wrong dosage form	18 (2.8)	25 (1.5)	27 (1.3)	13 (1.3)	43 (2.0)	126 (1.4)
Wrong patient	10 (1.6)	33 (2.0)	68 (3.2)	56 (2.4)	39 (1.8)	206 (2.3)
Expired product ^b	0	0	3 (0.1)	20 (0.9)	27 (1.3)	50 (0.6)
Deteriorated product ^b	0	1 (0.1)	6 (0.3)	16 (0.7)	18 (0.8)	41 (0.5)
Wrong route	5 (0.8)	9 (0.6)	13 (0.6)	12 (0.5)	18 (0.8)	57 (0.6)
Mislabeled ^c	0	0	0	0	12 (0.6)	12 (0.1)
Total no. errors	691	1699	2267	2441	2355	9453
Total no. records	645	1617	2149	2329	2157	8897

^aYears begin July 1 and end June 30.

^bThis error type was added as a selection option in calendar year 2002.

^cThis error type was added as a selection option in calendar year 2004.

orders, duplicate orders, contradictory orders, and failure to adjust the order on the basis of laboratory test values. In one case, the prescriber failed to order the four-hour maximum-dose limit. Because of the oversight, the patient developed respiratory impairment, necessitating transfer to the intensive care unit (ICU). In another case, a patient was receiving morphine sulfate via PCA and had inadequate pain control, despite receiving 54 mg. The prescriber changed the product to hydromorphone but failed to perform dosage conversions. As a result, the patient received 36 mg before being found unresponsive. The patient was treated with two doses of naloxone and was mechanically ventilated in the ICU.

A surgical patient with underlying comorbidities of hypertension, renal impairment, and obesity received intraoperative fentanyl and two doses of hydromorphone in the postanesthesia care unit. The prescriber did not adjust the PCA for the renal impairment or the comor-

bid conditions. On the patient care unit, the patient received 12 mg of morphine sulfate over an eight-hour period and was found unresponsive. The patient had to be transferred to the ICU for respiratory support. The patient's history of sleep apnea was thought to have contributed to the episode.

Another patient was prescribed morphine sulfate by PCA. The case report described that family members also participated via PCA by proxy (people other than the patient activating the PCA system). Respiratory suppression resulted, necessitating intubation and transfer to the ICU. It was determined that the patient lacked the judgment to use PCA appropriately and that the family's PCA by proxy contributed to the event.

Excessive meperidine was implicated in one of the fatal cases involving a postoperative patient with multiple comorbidities being cared for by a surgical resident. Contributing to the event were the resident's inexperience and the continuation

of multiple central-nervous-system medications in the surgical ICU.

Dispensing. Dispensing errors were associated with misfills of automated dispensing devices (having either the wrong concentration of a commercially available product or the wrong product in the machine's pocket), not having the product available when needed, and compounding the wrong strength. Dispensing errors generally did not result in harm. However, one harmful compounding error resulted from the lack of standard concentrations. In this case, a patient had terminal cancer, the pain of which was managed with morphine sulfate 20 mg every 30 minutes. The patient fell and sustained a fracture, resulting in a hospital admission accompanied by inadequate pain control. It was necessary to increase the morphine sulfate dosage to 26 mg every 30 minutes. As a result of the dosage increase, the infusion provided by hospice was completed earlier than expected, and a pharmacist had to resupply the morphine. The pharmacist changed the solu-

Table 6. Types of Errors Associated with Patient-Controlled Analgesia by Node in Medication-Use Process

Error Type	No. (%) Errors					Total
	Prescribing	Transcribing	Dispensing	Administering	Monitoring	
Improper dosage or quantity	204 (6.5)	254 (8.1)	255 (8.1)	2374 (75.4)	60 (1.9)	3147
Omission	62 (4.0)	516 (33.4)	173 (11.2)	731 (47.4)	61 (4.0)	1543
Unauthorized or wrong drug	60 (4.2)	477 (33.6)	226 (15.9)	643 (45.3)	14 (1.0)	1420
Prescribing error	682 (88.5)	52 (6.7)	13 (1.7)	18 (2.3)	6 (0.8)	771
Wrong administration technique	10 (2.4)	17 (4.1)	21 (5.0)	351 (84.4)	17 (4.1)	416
Extra dose	13 (3.5)	90 (24.1)	43 (11.5)	214 (57.2)	14 (3.7)	374
Drug prepared incorrectly	12 (3.6)	46 (13.6)	116 (34.3)	163 (48.2)	1 (0.3)	338
Wrong time	24 (7.5)	53 (16.5)	121 (37.6)	113 (35.1)	11 (3.4)	322
Wrong patient	8 (4.7)	69 (40.1)	28 (16.3)	66 (38.4)	1 (0.6)	172
Wrong dosage form	14 (11.0)	12 (9.4)	24 (18.9)	76 (59.8)	1 (0.8)	127
Wrong route	11 (22.4)	7 (14.3)	4 (8.2)	23 (46.9)	4 (8.2)	49
Expired product ^a	0	5 (12.8)	6 (15.4)	22 (56.4)	6 (15.4)	39
Deteriorated product ^a	0	1 (4.5)	8 (36.4)	11 (50.0)	2 (9.1)	22
Mislabeled ^b	1 (11.1)	1 (11.1)	5 (55.6)	2 (22.2)	0	9
Total no. errors	1101	1600	1043	4807	198	8749

^aThis error type was added as a selection option in calendar year 2002.

^bThis error type was added as a selection option in calendar year 2004.

tion to a less concentrated infusion, labeled the bag, and dispensed it to the floor. The nurse caring for the patient replaced the empty infusion container with the new one but did not note the change in concentration and continued the infusion with the existing PCA-pump settings. As a result of the less concentrated solution, pain relief was inadequate.

Administration. A number of administration errors involved an improper dosage or amount. The error descriptions frequently cited incorrect PCA-pump programming. For example, in one case the intended dosage of meperidine was 2 mg every 7 minutes; however, the nurse programmed the pump to deliver 20 mg every 17 minutes. In another

case, the intent was to deliver 0.5 mg of morphine sulfate every hour, but the pump was programmed to deliver 2 mg/hr. In yet another case, the PCA order was for meperidine 5 mg every 10 minutes, but the pump was programmed to deliver 5 mL every 10 minutes.

Several errors described a failure to match drug concentration with pump programming. For example, a patient was given a PCA order for morphine sulfate 1 mg/mL. The pump was correctly programmed for this; however, the nurse was using morphine sulfate 10 mg/mL. In a different case with slight variation, the nursing staff overrode the automated dispensing device and withdrew morphine sulfate 10 mg/mL. The

staff then programmed the pump as if the concentration were 1 mg/mL.

Several case reports described omission errors that originated in the administration phase and indicated that the original order was overlooked. In other cases, the drug was not given because the machine was not turned on or the tubing was not connected to the patient. One patient's PCA was interrupted for a blood transfusion and not resumed when the transfusion was complete.

A cluster of records identified errors due to an unauthorized or wrong drug originating during administration. Many of these errors were attributed to look-alike or sound-alike drugs (e.g., morphine-hydromorphone and meperidine-

Table 7.
Factors Contributing to Errors in Patient-Controlled Analgesia by Year^a

Contributing Factor	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
Distraction	66 (44.6)	133 (40.8)	152 (35.3)	170 (33.9)	192 (40.0)	713 (37.8)
Inexperienced staff	46 (31.1)	50 (15.3)	139 (32.3)	147 (29.3)	113 (23.5)	495 (26.3)
Workload increase	26 (17.6)	98 (30.1)	63 (14.7)	81 (16.2)	103 (21.5)	371 (19.7)
Shift change	10 (6.8)	33 (10.1)	40 (9.3)	57 (11.4)	38 (7.9)	178 (9.4)
Agency or temporary staff	12 (8.1)	24 (7.4)	50 (11.6)	19 (3.8)	19 (4.0)	124 (6.6)
Insufficient staff	18 (12.2)	18 (5.5)	29 (6.7)	20 (4.0)	19 (4.0)	104 (5.5)
Cross-covering staff	2 (1.4)	12 (3.7)	13 (3.0)	37 (7.4)	36 (7.5)	100 (5.3)
Floating staff	10 (6.8)	20 (6.1)	19 (4.4)	27 (5.4)	23 (4.8)	99 (5.3)
Patient transfer ^{b,c}	0	0	12 (2.8)	32 (6.4)	42 (8.8)	86 (4.6)
No 24-hour pharmacy	2 (1.4)	12 (3.7)	7 (1.6)	10 (2.0)	17 (3.5)	48 (2.5)
Alternative-hour staffing	1 (0.7)	8 (2.5)	10 (2.3)	8 (1.6)	9 (1.9)	36 (1.9)
No access to patient information	1 (0.7)	5 (1.5)	13 (3.0)	7 (1.4)	3 (0.6)	29 (1.5)
Poor lighting	2 (1.4)	5 (1.5)	8 (1.9)	4 (0.8)	7 (1.5)	26 (1.4)
Emergency other than emergency resuscitation	0	2 (0.6)	5 (1.2)	6 (1.2)	3 (0.6)	16 (0.8)
Computer system or network down	0	0	3 (0.7)	5 (1.0)	3 (0.6)	11 (0.6)
Imprint, identification failure ^b	0	0	0	1 (0.2)	8 (1.7)	9 (0.5)
Emergency resuscitation	0	1 (0.3)	0	2 (0.4)	3 (0.6)	6 (0.3)
Similar or identical patient names ^b	0	0	0	2 (0.4)	2 (0.4)	4 (0.2)
Order containing range of dosages ^b	0	0	0	0	1 (0.2)	1 (0.1)
Total no. errors	196	421	563	635	641	2456
Total no. records	148	326	430	501	480	1885

^aYears begin July 1 and end June 30. "None" was not available as a selection option.

^bThis contributing factor was not available as a selection option in all five study years.

^cPatient movement from one clinical area to another.

morphine). Many of these errors involved nurses retrieving the wrong product from an automated dispensing device.

Morphine PCA was implicated in a fatality that occurred when the patient's spouse participated in pain management by depressing the button on the PCA pump, even while the patient was sleeping. A total of 48 mg was administered during one eight-hour shift, which was within

the lockout amount ordered by the physician. During this shift, when a nurse questioned the spouse about the patient's snoring, the spouse answered that it was normal for the patient. At the change of shift, a nursing assistant found the patient apneic and unresponsive.

Discussion

The value of pain control includes improved patient satisfac-

tion, decreased complication rates, shortened stays following surgery, and potentially reduced exposure to litigation.^{8,13} Methods for controlling acute pain have advanced greatly over the past three decades, especially since anesthesiologists organized services for the management of acute pain.¹² However, pain control carries its own set of risks.

This study sought to add to knowledge regarding PCA-related

Table 8. Actions Taken in Response to Errors in Patient-Controlled Analgesia by Year^a

Action	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
Informed staff who made error	239 (69.1)	437 (63.5)	672 (63.3)	766 (64.1)	605 (55.0)	2719 (61.9)
Provided education and training	85 (24.6)	152 (22.1)	351 (33.1)	262 (21.9)	283 (25.7)	1133 (25.8)
Informed staff indirectly involved in error	76 (22.0)	149 (21.7)	234 (22.0)	263 (22.0)	219 (19.9)	941 (21.4)
Enhanced communication process	29 (8.4)	84 (12.2)	121 (11.4)	146 (12.2)	132 (12.0)	512 (11.7)
Informed patient's physician ^b	0	0	15 (1.4)	171 (14.3)	207 (18.8)	393 (9.0)
None	35 (10.1)	54 (7.8)	80 (7.5)	100 (8.4)	99 (9.0)	368 (8.4)
Informed patient or caregiver	0	28 (4.1)	53 (5.0)	65 (5.4)	48 (4.4)	194 (4.4)
Modified staffing practice or policy	8 (2.3)	6 (0.9)	23 (2.2)	19 (1.6)	16 (1.5)	72 (1.6)
Modified or obtained computer software	2 (0.6)	1 (0.1)	13 (1.2)	8 (0.7)	7 (0.6)	31 (0.7)
Modified environment	2 (0.6)	5 (0.7)	11 (1.0)	5 (0.4)	21 (1.9)	44 (1.0)
Changed policy or procedure	11 (3.2)	19 (2.8)	20 (1.9)	16 (1.3)	15 (1.4)	81 (1.8)
Instituted policy or procedure	5 (1.4)	10 (1.5)	5 (0.5)	7 (0.6)	5 (0.5)	32 (0.7)
Changed formulary ^b	0	1 (0.1)	4 (0.4)	1 (0.1)	5 (0.5)	11 (0.3)
Total no. errors	492	946	1602	1829	1662	6531
Total no. records	346	688	1062	1195	1100	4391

^aYears begin July 1 and end June 30.

^bThis action was not available as a selection option in all five study years.

Table 9. Drugs Most Frequently Associated with Errors in Patient-Controlled Analgesia by Year^a

Drug	No. (%) Records in Which Drug Identified					
	2000	2001	2002	2003	2004	Total
Morphine	273 (48.8)	750 (49.9)	1172 (50.4)	1222 (48.7)	1078 (48.3)	4495 (49.2)
Hydromorphone	100 (17.9)	284 (18.9)	468 (20.1)	551 (21.9)	565 (25.3)	1968 (21.6)
Meperidine	105 (18.8)	204 (13.5)	286 (12.3)	290 (11.5)	194 (8.7)	1079 (11.8)
Fentanyl	19 (3.4)	51 (3.4)	105 (4.5)	137 (5.5)	111 (5.0)	423 (4.6)
Naloxone	7 (1.3)	29 (1.9)	21 (0.9)	13 (0.5)	13 (0.6)	83 (0.9)
Total no. records	559	1502	2325	2511	2234	9131

^aYears begin July 1 and end June 30.

medication errors by using secondary data from nearly 500 hospitals and more than 9500 PCA error records from institutions that participated in the Medmarx medication error-reporting program over a five-year span. Slightly more than 60% of the Medmarx subscribers reported at least one PCA error, suggesting that PCA errors are common rather than isolated.

The first priority for patient safety is to minimize harmful errors and the second is to minimize all errors. While PCA events accounted for

only 1% of the errors reported to Medmarx, such events were associated with 6.5% of harmful outcomes. Two deaths were attributed to PCA errors. By comparison, during the same period, only 1.5% of all other errors reported to Medmarx led to harm. This represents a fourfold higher relative risk of harm for PCA events. More resources are required to treat patients with harmful errors because affected patients often received additional care, such as closer observation, change in the treatment plan, use of antagonists, interruption

of care, diagnostic testing, and life-sustaining interventions.¹⁴ Harmed patients often had extended hospital stays, further stressing already highly strained staffs.¹⁵ From a public health perspective, the finding that a greater percentage of harmful events occurred in older patients is concerning because this age group has greater surgical needs and is growing. The increased risk of harm in elderly surgical patients is likely due to their frailty and comorbidities, making the need to minimize PCA errors ever more imperative.

Table 10.

Types of Staff Committing Errors in Patient-Controlled Analgesia by Year^a

Type of Staff	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
Anesthesia providers	4 (0.7)	10 (0.7)	13 (0.6)	12 (0.6)	6 (0.3)	45 (0.6)
Anesthesiologists	2 (0.3)	6 (0.4)	8 (0.4)	9 (0.4)	5 (0.3)	30 (0.4)
Nurse anesthetists	2 (0.3)	4 (0.3)	5 (0.2)	3 (0.1)	1 (0.1)	15 (0.2)
Prescribing personnel	45 (7.4)	149 (10.5)	264 (12.4)	272 (12.7)	220 (11.4)	950 (11.6)
Physicians	41 (6.8)	131 (9.3)	221 (10.4)	236 (11.0)	172 (8.9)	801 (9.7)
Interns	0	0	0	1 (0.1)	5 (0.3)	6 (0.1)
Residents	4 (0.7)	17 (1.2)	31 (1.5)	30 (1.4)	30 (1.6)	112 (1.4)
Physician assistants	0	1 (0.1)	8 (0.4)	2 (0.1)	10 (0.5)	21 (0.3)
Nurse practitioners	0	0	4 (0.2)	3 (0.1)	3 (0.2)	10 (0.1)
Dispensing personnel	83 (13.7)	204 (14.4)	298 (14.0)	278 (13.0)	287 (14.9)	1150 (14.0)
Pharmacists	69 (11.4)	171 (12.1)	236 (11.1)	208 (9.7)	224 (11.6)	908 (11.0)
Pharmacy technicians	14 (2.3)	33 (2.3)	50 (2.3)	51 (2.4)	52 (2.7)	200 (2.4)
Not specified	0	0	12 (0.6)	19 (0.9)	11 (0.6)	42 (0.5)
Administering personnel	468 (77.2)	1042 (73.7)	1532 (71.9)	1565 (73.1)	1401 (72.5)	6008 (73.0)
Registered nurses	424 (70.0)	949 (67.2)	1341 (62.9)	1380 (64.4)	1220 (63.1)	5314 (64.6)
Graduate nurses	1 (0.2)	0	2 (0.1)	4 (0.2)	4 (0.2)	11 (0.1)
Traveling nurses	1 (0.2)	5 (0.4)	9 (0.4)	5 (0.2)	8 (0.4)	28 (0.3)
LPNs ^b or LVNs ^c	15 (2.4)	48 (3.4)	72 (3.4)	59 (2.8)	36 (1.9)	230 (2.8)
Not specified	2 (0.3)	0	40 (1.9)	54 (2.5)	80 (4.1)	176 (2.1)
Nursing assistants	0	1 (0.1)	2 (0.1)	2 (0.1)	3 (0.2)	8 (0.1)
Unit clerks	25 (4.1)	39 (2.8)	57 (2.7)	52 (2.4)	43 (2.2)	216 (2.6)
Unlicensed assistants	0	0	9 (0.4)	9 (0.4)	7 (0.4)	25 (0.3)
Other	6 (1.0)	8 (0.6)	25 (1.1)	15 (0.7)	18 (0.9)	72 (0.9)
Patients or family members	4 (0.7)	7 (0.5)	22 (1.0)	14 (0.7)	14 (0.7)	61 (0.7)
Information technology staff	0	0	0	0	1 (0.1)	1 (<0.1)
Students	2 (0.3)	1 (0.1)	1	0	1 (0.1)	5 (0.1)
Materials management personnel	0	0	0	1 (<0.1)	1 (0.1)	2 (<0.1)
Optometrists	0	0	0	0	1 (0.1)	1 (<0.1)
Radiologists	0	0	2	0	0	2 (<0.1)
Total no. errors	606	1413	2132	2142	1932	8225

^aYears begin July 1 and end June 30.

^bLPNs = licensed practical nurses.

^cLVNs = licensed vocational nurses.

■ PRACTICE REPORTS Medication errors

These findings are supported by recent national initiatives to reduce error, such as the third National Patient Safety Goal (NPSG) established by the Joint Commission.¹⁶ The NPSG deals broadly with the

safe use of medications and would be applicable to the processes involved in PCA. As part of the program, institutions are encouraged to review the PCA process and to comply with the goals through

strategies such as failure-mode and effects analysis, root-cause analysis, and focus groups working directly with PCA equipment.

The leading type of error identified in this study was an improper

Table 11.
Locations of Errors in Patient-Controlled Analgesia by Year^a

Location ^b	No. (%) Errors					
	2000	2001	2002	2003	2004	Total
Perioperative	35 (5.8)	111 (8.5)	155 (7.0)	163 (6.5)	152 (7.0)	616 (7.0)
Operating room	1 (0.2)	10 (0.8)	26 (1.2)	20 (0.8)	16 (0.7)	73 (0.8)
Postanesthesia care unit	34 (5.6)	98 (7.5)	124 (5.6)	126 (5.0)	128 (5.9)	510 (5.8)
Outpatient surgery	0	3 (0.2)	4 (0.2)	12 (0.5)	4 (0.2)	23 (0.3)
Endoscopy	0	0	1 (<0.1)	2 (0.1)	0	3 (<0.1)
Preoperative holding area	0	0	0	3 (0.1)	4 (0.2)	7 (0.1)
Maternity	16 (2.7)	48 (3.7)	64 (2.9)	81 (3.2)	56 (2.6)	265 (3.0)
Maternity	9 (1.5)	23 (1.8)	43 (1.9)	36 (1.4)	21 (1.0)	132 (1.5)
Labor or delivery	7 (1.2)	25 (1.9)	18 (0.8)	41 (1.6)	28 (1.3)	119 (1.4)
Obstetrics recovery	0	0	3 (0.1)	4 (0.2)	7 (0.3)	14 (0.2)
Critical care	31 (5.1)	69 (5.3)	138 (6.2)	142 (5.7)	155 (7.0)	535 (6.1)
Coronary ICU	0	13 (1.0)	22 (1.0)	14 (0.6)	13 (0.6)	62 (0.7)
General ICU	0	0	6 (0.3)	35 (1.4)	44 (2.0)	85 (1.0)
Medical ICU	10 (1.7)	25 (1.9)	75 (3.4)	44 (1.8)	42 (1.9)	196 (2.2)
Neonatal ICU	0	0	0	2 (0.1)	1 (<0.1)	3 (<0.1)
Pediatric ICU	0	6 (0.5)	2 (0.1)	2 (0.1)	6 (0.3)	16 (0.2)
Surgical ICU	19 (3.2)	21 (1.6)	28 (1.3)	36 (1.4)	42 (1.9)	146 (1.7)
Emergency	2 (0.3)	4 (0.3)	5 (0.2)	9 (0.4)	7 (0.3)	27 (0.3)
Pharmacy	73 (12.1)	180 (13.9)	244 (10.9)	238 (9.5)	260 (12.1)	995 (11.3)
Inpatient	72 (12.0)	177 (13.6)	244 (10.9)	237 (9.5)	260 (12.1)	990 (11.3)
Outpatient	1 (0.2)	3 (0.2)	0	1 (<0.1)	0	5 (0.1)
Nursing	442 (73.4)	880 (67.7)	1596 (71.5)	1842 (73.8)	1503 (69.7)	6263 (71.3)
Nursing unit	434 (72.1)	854 (65.7)	1551 (69.5)	1783 (71.4)	1442 (66.9)	6064 (69.0)
Pediatrics	2 (0.3)	14 (1.1)	19 (0.9)	29 (1.2)	29 (1.3)	93 (1.1)
Oncology	6 (1.0)	12 (0.9)	22 (1.0)	19 (0.8)	14 (0.6)	73 (0.8)
Orthopedics	0	0	0	5 (0.2)	13 (0.6)	18 (0.2)
Rehabilitation unit	0	0	0	0	1 (<0.1)	1 (<0.1)
Transplant unit	0	0	1 (<0.1)	5 (0.2)	3 (0.1)	9 (0.1)
Nursery	0	0	3 (0.1)	1 (<0.1)	1 (<0.1)	5 (0.1)
Other	5 (0.8)	11 (0.8)	36 (1.6)	31 (1.2)	31 (1.4)	114 (1.3)
Patient's home	2 (0.3)	0	6 (0.3)	1 (<0.1)	0	9 (0.1)
Radiology	1 (0.2)	1 (0.1)	9 (0.4)	1 (<0.1)	3 (0.1)	15 (0.2)
Nuclear medicine	0	0	0	1 (<0.1)	0	1 (<0.1)
Other hospital	2 (0.3)	8 (0.6)	11 (0.5)	8 (0.3)	18 (0.8)	47 (0.5)
Dialysis	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Hospice	0	0	0	2 (0.1)	2 (0.1)	4 (<0.1)
Long-term care	0	2 (0.2)	9 (0.4)	7 (0.3)	6 (0.3)	24 (0.3)
Cardiopulmonary department	0	0	0	7 (0.3)	0	7 (0.1)
Materials management	0	0	0	0	1 (<0.1)	1 (<0.1)
Admitting department	0	0	0	3 (0.1)	1 (<0.1)	4 (<0.1)
Total no. errors	602	1299	2233	2497	2157	8788

^aYears begin July 1 and end June 30.

^bICU = intensive care unit.

dosage or quantity of analgesic medication. The risk of respiratory depression, a well-known adverse effect of PCA,⁹ is obviously heightened when excessive dosages are administered. These findings suggest that incorrect programming of the PCA infusion device is often the source of errors; this occurs most often during the administration phase. Operator errors during infusion setup (programming) involved the bolus dose, the lockout interval, and the basal rate. These results are consistent with the literature.²

Another reason for excessive dosages was PCA by proxy. In 2004 the Joint Commission issued a sentinel-event alert focusing on PCA by proxy.¹⁷ It recommended educating staff working with PCA devices, as well as teaching family members about the proper use of the PCA pump and the dangers when someone other than the patient activates the controller.

Errors due to an unauthorized or wrong drug were also common. These errors occur for a number of reasons, including confusion between generic names that either look or sound alike. This study found that two drugs (hydromorphone and morphine) were often switched because of name confusion. The manufacturer's use of "tall-man" lettering may help staff visually distinguish among packages, although this product pair was not originally in FDA's name-differentiation project. The packaging may be similar for PCA drug products, which can contribute to the error as well, especially when the products are retrieved from automated dispensing devices that are not directly linked to pharmacy information systems and bar-code medication administration (BCMA) systems. As more institutions adopt BCMA, the risk of administering the wrong drug during PCA may decrease.

Staff are encouraged not to override prompts from automated dis-

ensing devices. Rather, pharmacists should be consulted to assist in resolving any alerts.

The Medmarx program contains more than 60 selection options for the cause of an error. Aligning these options with the NCCMERP taxonomy affords an opportunity to cluster related choices for analysis. Each cluster identifies a different risk for a medication error and requires different interventions to address the cause. Human errors were overwhelmingly present in the sample and included miscalculation, not following policies and procedures, selecting the wrong drug from the dispensing device, and confusion about drug names and concentrations. Miscalculation occurred during the initial programming of the PCA device or during subsequent changes to the infusion variables, leading to multiple errors involving an improper dosage or quantity. Misinterpretation of drug concentrations was also implicated, as was staff confusion between hydromorphone and morphine and between morphine and meperidine, a finding consistent with errors involving an unauthorized or wrong drug. Independent double-checks by two qualified individuals for the right product, the right calculations, and the right pump settings should be performed routinely.

The PCA error records implicated equipment-related issues as the cause of the second largest error cluster. The finding is consistent with the requirement for accurately programming the bolus dose, the basal infusion rate, and the lockout interval. According to the Institute for Safe Medication Practices (ISMP), misprogramming a PCA pump is rather easy, given the sequence of screens pertaining to the drug, the bolus dose, the infusion rate, and the lockout interval.¹⁸ Even with experience and independent double-checking, medication errors can occur during PCA setup. ISMP recommends restricting the number of medications

used for PCA to eliminate some of the confusion that can arise when selecting drugs from the PCA screen. Institutions should provide readily available reference material specific to each drug for staff members to consult during the setup process. For institutions that provide medication labels for PCA, ISMP recommends designing labels in which the drug concentration is prominent and clearly legible.

The most commonly identified contributing factor was distraction. Distractions may lead a person to forget to perform a key task and thus may contribute to the chain of events that produces an error.¹⁹ Because of the situational nature of distractions, they are difficult to anticipate and control.

The contributing factor of staff inexperience was noted in one fourth of the PCA error records. This finding suggests unfamiliarity among some with PCA processes. This is an organizational or system failure. A frequent action after such events was to provide training, but it would be far better to ensure that staff are fully trained before errors can occur.

Voluntary reporting systems have been criticized for inherent underreporting.¹² Nevertheless, widely deployed voluntary systems such as Medmarx afford an economical and practical alternative to real-time data collection and are a suitable source of data for analysis. This study did not determine the rate of PCA errors, although the sample was large and was representative of all U.S. hospitals. Rather, the study encompasses only the rate of reporting of such errors. Hospitals participating in Medmarx have opted to self-report errors and thus endorse an open culture of reporting; this may bias the results. Generalization of these findings to other populations should be made with caution.

A better understanding of the major determinants of medication errors, such as the intersection of hu-

man factors with equipment-related factors, could potentially lead to error reduction. Alternative routes of administration in pain management include the intranasal route (for either nonopioid or opioid agents) and the iontophoretic route; these options may address some of the issues of PCA by proxy, but their full effect on patient safety needs further evaluation. Given the findings of this study, additional measures should be taken to address PCA errors to improve overall patient safety and care.

Conclusion

Events during all phases of the medication-use process contributed to PCA-related medication errors, many of which harmed patients. Institutions should assess and correct the weaknesses identified to reduce PCA errors, improve safety, and conserve resources.

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