

FEATURED ARTICLE

# The Rate and Costs Attributable to Intravenous Patient-Controlled Analgesia Errors

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## Abstract

**Purpose:** To estimate the rates and costs of intravenous patient-controlled analgesia (IV PCA) errors from the hospital or integrated health system perspective.

**Methods:** This study used a cost-accounting methodology to estimate the costs attributable to IV PCA errors in the United States. Data for the study were obtained from the MEDMARX and Manufacturer and User Facility Device Experience (MAUDE) datasets, published literature, and expert opinions. MEDMARX is a voluntary, anonymous, medication-error-reporting database owned and operated by the United States Pharmacopeia. MAUDE is a mandatory, device-error-reporting database maintained by the US Food and Drug Administration. Levels of care rendered as a result of the IV PCA errors were estimated by applying clinical assumptions (validated by an expert advisory panel) to each of the 7 error consequences considered in this analysis. Variable and opportunity costs (2006 values) were considered, including medication, laboratory, lost revenue, and labor. The corresponding costs were applied to the error consequences to derive the estimated mean cost for each error cause. The numbers of errors documented in each dataset and the published literature were used to extrapolate the rate of IV PCA errors annually.

**Results:** The average cost per error event was \$733 in the MEDMARX dataset and \$552 in the MAUDE dataset. Harmful IV PCA errors were 120 to 250 times more costly than nonharmful errors. The annual error rates were estimated as 407 IV PCA-related errors and 17 device-related errors per 10,000 people within the United States.

**Conclusion:** Analysis of 2 datasets, MEDMARX and MAUDE, revealed that IV PCA medication- and device-related errors are costly to hospitals and integrated health systems and represent a significant burden on the US health system. This study provided a novel approach to estimating the associated costs of undesired IV PCA-related events. Additional research is needed to validate the methodology (as applied to this area) and results.

**Key Words**—adverse reactions, drugs, errors, MAUDE, medication, medication device, MEDMARX, patient-controlled analgesia

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## INTRODUCTION

Opioid analgesics are the cornerstone of treatment for postoperative pain. Intravenous patient-controlled analgesia (IV PCA) is a preferred route of administration because of its quick delivery and subsequent onset of pain relief, established efficacy, and sense of

empowerment given the patient.<sup>1</sup> Although IV PCA has many advantages, the narrow therapeutic index of opioids and the potential for human error can lead to serious safety issues that increase treatment costs and limit use, while also compromising quality of care. The PCA process is complex and

requires numerous steps before achieving the desired analgesic relief. These include obtaining and maintaining (eg, cleaning, repairing) pumps, replacing supplies (eg, pumps, analgesia, catheters, tubing, batteries), identifying an adequate storage area, pump training, preparing pump for patient use,

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patient training, evaluating IV access, troubleshooting the alarm, addressing complications, and pump reprogramming.<sup>2,4</sup> Further complications with the use of IV PCA pumps include the involvement of numerous hospital departments (eg, central supply, biomedical engineering, pharmacy, nursing), requiring synchronization to ensure optimal pain relief is achieved.<sup>3</sup> In addition, various types of pumps and narcotics are commonly used within an institution, requiring specialized training among hospital staff. Together, these intricacies create high potential for error throughout the entire medication prescribing, dispensing, and administration process.<sup>5,6</sup>

Preliminary evidence indicates that the complexities associated with IV PCA administration lead to unnecessary errors. More specifically, IV PCA administration has been associated with preventable adverse consequences caused by operator error<sup>6-12</sup> and device malfunction.<sup>7</sup> For example, operator errors occur when the PCA pump is inappropriately programmed for administration of an opioid at a rate that deviates from physician orders. Furthermore, Sikirica et al found that PCA pump-related errors carry a 4.3-fold risk (6.5% vs 1.5%) of causing patient harm compared with non-PCA pump-related errors.<sup>12,13</sup> As a consequence of these well-established challenges associated with IV PCA administration, The Joint Commission (TJC) has intensified its attention toward minimizing avoidable medication errors, such as those associated with IV PCA pumps. More specifically, as one of the 2005 National Patient Safety Goals focused on improving safety of infusion pumps, including IV PCA pumps, TJC requires intrinsic free-flow protection on all IV PCA infu-

sion pumps.<sup>14</sup> Although large accreditation bodies such as TJC play an important role in enhancing patient safety, improved PCA technology is needed to resolve these issues.

The need is especially evident when considering costs and consequences of medical errors. The Institute of Medicine report, *Preventing Medication Errors: Quality Chasm Series*, estimates that, on average, hospital patients experience 1 medication error per day,<sup>5</sup> which can cost the health care system \$37.6 billion annually (\$17 billion associated with preventable errors).<sup>8</sup> However, the rate and costs of IV PCA medication- and device-related errors have not been established. Therefore, the objective of this study was to examine the rate and costs associated with IV PCA medication- and device-related errors from the hospital or integrated health system perspective.

## **METHODS**

### **Study Data**

Two nationally recognized error-reporting databases were used: the United States Pharmacopeia's (USP's) *MEDMARX* and the US Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database. The *MEDMARX* dataset is maintained by USP and is a voluntary, anonymous, internet-accessible medication-error-reporting program designed for use by hospitals and health care systems.<sup>15</sup> Voluntary reporting provides a mechanism for identification and focus on types of serious errors that may occur too infrequently for detection of practice vulnerabilities by individual health care organizations. Thus, the primary purpose of voluntary reporting is to determine causes of errors or adverse events and to identify

solutions, which in turn enables learning, thereby promoting safety. In contrast, mandatory reporting systems improve patient safety by ensuring public accountability. *MEDMARX* was established in 1998 and contains more than 1.3 million medication-error records from more than 875 facilities nationwide, making it the largest medication-error database of its kind in the world. The *MEDMARX* dataset contains information on medication errors, such as error types, causes, locations within a health care facility, level of staff involved, products, actions taken, and factors contributing to the error. Based on the availability of accessible *MEDMARX* data, IV PCA errors reported between July 1, 2000, and June 30, 2005, (a 5-year time frame) were used for the cost analysis portion of this study. Because the *MEDMARX* program contains a number of structured and free text fields, this sample was manually identified by a clinician to ensure that it contained IV-specific errors (eg, incorrect flow rates, missing decimal places, dosage strength errors [mcg vs mg]). One of the structured fields is the intended route of administration (including "intravenous" administrations), an optional field that is not selected in some records. Therefore, free text searches within the error description field were performed using structured queries to isolate text strings without regard to capitalization or punctuation; wild-card characters were used to expand the number of possible records. On identification of all records with text matching the search, clinical staff (eg, nurses or pharmacists) reviewed the error description.

PCA errors reported to the *MEDMARX* dataset between July 1, 2003, and June 30, 2004, were

used to estimate the annual error count. This 12-month period was chosen to match the time period of the available national data also used in the same calculation.

US Medical Device Reporting (MDR) regulations require that users, facilities, product distributors, and manufacturers report problems using the MEDWATCH 3500A form. MDR data are available to the public via the MAUDE database.<sup>16</sup> This dataset includes information about problems that occur with medical devices, such as product malfunctions, injuries, and deaths. A sample of IV PCA device-related events reported to the FDA between January 1, 2002, and December 31, 2003, was manually reviewed and used in this analysis. The objective of the manual review was to search the narrative text (based on available data from the MAUDE database) to identify resource utilization associated with each event. Subsequently, cost was assigned to each event based on the level and type of resource used.

### Error Cost Analysis

A cost-accounting methodology was used to estimate the costs attributable to both harmful and nonharmful IV PCA medication-related errors.<sup>17,18</sup> Mean costs were calculated for each type of error cause (see Table 1) and stratified by whether the event was associated with patient harm. Within both databases, the users report the perceived cause of error for each event. An event that resulted in patient harm was defined as an unintended and unwanted outcome that negatively affected a patient's health to the extent that treatment was required or permanent damage resulted. In the *MED-MARX* dataset, the user indicates whether the error resulted in harm. In the MAUDE dataset, the harm-

ful status of the device-related events was not available in the raw data; therefore, prior research reported by Hankin et al<sup>2</sup> (a descriptive analysis of the MAUDE dataset using data from January 1, 2002, through December 31, 2003) was used to extrapolate the proportion of harmful and nonharmful events from the manually reviewed sample to the entire dataset.

The first component of this analysis was identification of the level of care rendered as a result of the IV PCA error to ascertain the types of resources expended by the facility in response to the error. Within the *MEDMARX* database, respondents document the consequences of the error by choosing 1 or more of the 17 consequences found in Table 2. USP researchers reclassified the consequences into 7 similar categories, which were used in this analysis. No variables within the MAUDE dataset captured the level of care required following an error; thus, the text description of each error report within the MAUDE sample was independently reviewed by a clinician, assessed for level of care rendered, and categorized into the corresponding *MEDMARX* categories. Because specifics about the level of care and services rendered (eg, the amount of antidote used) were not available in either dataset, published literature and expert opinions were used to establish assumptions about the clinical care required to treat the errors. An advisory committee was convened to test and refine all clinical and economic assumptions applied in this study (see Table 3). This advisory panel consisted of 5 clinicians and health care administrators and was made up of nurses, medication-error researchers, clinical pharmacists, pharmacy directors, and the chief financial officer of a hospital who

represented various hospitals and integrated health care systems throughout the United States. See Table 3 for a detailed description of each of the assumptions.

Based on the consensus clinical assumptions, costs were assigned using data from published literature and physician fee schedules (see Table 4).<sup>19</sup> All costs considered in this study were derived from the perspective of a hospital or an integrated health care system. Three cost components (variable, labor, and opportunity costs) were considered in this study. Variable costs were those expenditures that fluctuated as an immediate result of the error<sup>20</sup> and included costs associated with additional drug therapy, laboratory encounters, physician encounters, radiology encounters, hospital length of stay, and medical supplies. Labor costs considered the time required by a nurse, pharmacist, or pharmacy technician to address the consequences associated with the error event. Opportunity costs were the highest-valued alternatives that were forgone when something else was produced.<sup>21</sup> These types of costs are extremely important considerations when quantifying the economic impact of medication- and device-related errors because they often result in additional resource use that would not have occurred if the error had not occurred. The resources consumed as a result of the error could have been applied toward generation of additional revenue for the institution. Opportunity costs considered in this study were the missed revenues that could have been generated for the hospital had the error not occurred. For example, some IV PCA errors require a laboratory test to examine a patient's arterial blood gas (ABG). If the error had not occurred, the cost of performing the ABG could

**Table 1. Causes and Definitions of Errors in the *MEDMARX* and *MAUDE* Datasets**

<i>Error Cause</i>	<i>Definition</i>
<b>MEDMARX Data</b>	
Communication	Errors that USP classified as resulting from abbreviations, communication, decimal point, handwriting illegibility, missing leading zero, use of nonmetric units, trailing zero, verbal order, or written order.
Name	Errors that USP classified as resulting from brand/generic sound-alike names, brand/generic look-alike names, or prefix/suffix misinterpretation.
Storage	Errors that USP classified as resulting from involvement of dispensing device, label design, packaging design, reference material, and repackaging of similar products.
Human	Errors that USP classified as resulting from calculation error, computer entry, incorrect medication activation, knowledge deficit, inadequate monitoring, patient identification failure, performance deficit, procedure not followed, inaccurate transcription, or unlabeled syringe/container.
System	Errors that USP classified as resulting from blanket orders, computer software, dosage-form confusion, drug distribution system, information management system, measuring device, preprinted medication order form, system safeguards, or workflow disruption.
Contraindicated	Errors that USP classified as resulting from contraindications caused by drug allergy, drug/drug, drug/food, disease, or pregnancy/breast-feeding.
Default	Errors that are not assigned by USP to any of the other categories, including errors resulting from computerized prescriber order entry, wrong diluent, documentation, drug shortage, or nonformulary drug.
Equipment	Equipment-related errors are those errors that USP classified as resulting from equipment failure or equipment design issues or when errors involved a fax/scanner.
<b>MAUDE Data</b>	
Device safety events	Errors that resulted from problems with the battery, display board, or software failures, which led to failure to deliver drug on demand, faulty alarm system, defective one-way valve or clamp, or lack of free-flow protection.
Indeterminate events	Errors that could not be categorized into any of the other 4 error categories (patient-, device-, operator-, or ADR-related errors).
Operator errors	Errors caused by failure to clamp or unclamp tubing, improperly loading a syringe or cartridge, or not responding to safety alarms.
Patient-related events	Errors that resulted from patients' misunderstanding of how PCA therapy works, including confusion regarding operation of the demand button, mistaking the PCA button for the call button, family members operating the demand button, or intentional tampering with the device.
Opioid adverse events	Adverse reactions are defined as harm directly caused by an intravenous PCA opioid prescribed at usual doses.
ADR = adverse drug reaction; MAUDE = Manufacturer and User Facility Device Experience; PCA = patient-controlled analgesia; USP = United States Pharmacopeia.	

have been used to treat a patient who did not experience an IV PCA-related error event and, accordingly, could have generated additional revenue. This logic is consistent with current hospital reimbursement trends, which indicate that the hospital, under capitated reimbursement, will not be reim-

bursed for an ABG associated with an error that occurred within the hospital. As a consequence, the cost of the ABG to the hospital could be applied to another patient, which would result in revenue generation for the hospital.

When possible, clinical consequences of the IV PCA error were

mapped to current procedural terminology (CPT) codes (see Table 3). Published physician fee schedules were then applied to the specific CPT code to derive an estimated variable cost. The fee schedules provided an estimated range of charges for both public and private insurers; therefore, a midpoint of

**Table 2. Categories of Intravenous Patient-Controlled Analgesia Error Consequences Within the MEDMARX Dataset**

<i>Level of Care Rendered</i>	<i>Reclassification*</i>
Observation initiated/increased Vital-sign monitoring initiated/increased	Observation
Drug therapy initiated/changed Oxygen administered	Drug therapy change
Laboratory test performed Radiology or other diagnostic tests	Diagnostic tests
Hospitalization, initial Hospitalization, prolonged 1 to 5 days Hospitalization, prolonged 5 to 10 days Hospitalization, prolonged 10 days or more	Hospitalization affected
Antidote administered Narcotic antagonist administered	Antidote/Antagonist
Airways established/ventilated Cardiac defibrillation performed CPR administered Surgery	Life-sustaining intervention
None	None

\*The reclassified error consequences were used within this analysis; CPR = cardiopulmonary resuscitation.

the ranges was used. Considering that physician fee schedules provided estimates that reflected charges and not actual costs, a cost-to-charge ratio (CCR = 0.4) was applied to the midpoints to derive estimated institutional costs.<sup>22</sup> When CPT codes could not be assigned, literature-based cost estimates were ascribed. See Table 4 for variable cost estimates used in this analysis.

Similar to variable costs, opportunity cost values were derived based on institutional charges obtained from physician fee schedules and the published literature.<sup>19,23</sup> In contrast to the variable costs, no CCR was applied because the estimates already reflected the amount of revenue that the institution could have generated if the error event had not occurred.

Labor costs for pharmacists, pharmacy technicians, and nurses were derived based on the estimated number of hours required for treating the error event. Time-and-

motion studies and the data from the Bureau of Labor Statistics (BLS) were used to derive labor cost estimates.<sup>24-26</sup> The cost of benefits as a percentage (29.8%) of total compensation was added to the median hourly wage.<sup>27</sup> Based on the 2005 BLS data, it was estimated that the median hourly wages were \$57.51 for pharmacists, \$12.07 for pharmacy technicians, and \$34.92 for registered nurses. All nursing wages were applied using the median hourly wage for a registered nurse. This approach may have slightly inflated the expected cost because other nurses, such as licensed practical nurses or nurse aides, may have been involved with the error event.

The costs were then applied to each of the consequences found within the 2 error-reporting datasets to calculate the average cost per cause of error (see Table 5 for an example). All costs were inflated using the consumer price index for

medical care to reflect 2006 US dollars.

**Annual Rate of Intravenous Patient-Controlled Analgesia Errors**

An annual rate of IV PCA errors was derived by estimating the annual number of IV PCA errors (numerator) and the number of patients receiving IV PCA (denominator) in the United States. Although the annual number of reported occurrences of IV PCA errors could have been obtained from the respective error databases, adjustment of the incidence rates was necessary to account for significant underreporting of errors. To estimate the annual number of IV PCA errors in the United States, the rate of underreporting of errors (estimated from the literature) was applied to 12-month error counts from each of the datasets. Data from 3 studies indicated that only between 1.2% and 7.7% of all medication errors are reported.<sup>28-31</sup> In this analysis, a midpoint of 4.45% was used to estimate the total number of reported IV PCA errors. However, to account for the wide range of reported medication errors, estimates were varied between 1.2% and 7.7% to determine its influence on the overall error rate.

The MEDMARX PCA medication-error count between July 1, 2003, and June 30, 2004, was used as an estimate of the 12-month medication-error count. This count was chosen so that the study would be consistent with the available national data (the 2004 National Center for Health Statistics data). After excluding the unrelated events, Hankin et al identified 1,993 IV PCA-related MAUDE events over 2 years; therefore, the current analysis used 997 as the estimated annual PCA error frequency (1,993/2).<sup>2</sup>

**Table 3. Clinical Assumptions for Each Intravenous Patient-Controlled Analgesia Error Consequence**

<i>Consequence</i>	<i>Frequency/Amount</i>	<i>Activity Performed<sup>a</sup></i>	<i>Source<sup>b</sup></i>
Observation	100%	Additional physician encounter (CPT: 99233)	Expert opinion
	100%	Use of pulse oximeter (CPT: 94762)	Expert opinion
	38.5 minutes	Nursing time <sup>c</sup>	Expert opinion Burke et al <sup>25</sup>
Drug therapy changes	75%	Reduce PCA dose	Expert opinion
	14%	Switch to different PCA <sup>d</sup>	Expert opinion
	11%	Switch to IV infusion <sup>e</sup>	Expert opinion
	50%	Oxygen	Expert opinion
	8.28 minutes	Pharmacist time <sup>f</sup>	Thielke et al <sup>26</sup> Mordin et al <sup>4</sup>
	15.77 minutes	Pharmacy technician time <sup>g</sup>	Thielke et al <sup>26</sup> Mordin et al <sup>4</sup>
Diagnostic tests	98.52 minutes	Nursing time <sup>h</sup>	Mordin et al <sup>4</sup>
	2.5%	Bronchoscopy (CPT: 31622; 87070; 87205) <sup>i</sup>	Expert opinion
	5%	Chest x-ray (CPT: 71020)	Expert opinion
	25%	Arterial blood gas (CPT: 82803)	Expert opinion
	100%	Basic metabolic panel (CPT: 80048)	Expert opinion
Hospitalization affected	15 minutes	Nursing time	Expert opinion
	2.2 days	Days of additional hospitalization <sup>j</sup>	Bates et al <sup>23</sup>
Antidote/Antagonist	100%	Naloxone	
	12.97 minutes	Nursing time	Mordin et al <sup>4</sup>
	0.36 minutes	Pharmacist time	Thielke et al <sup>26</sup>
	5.97 minutes	Pharmacy technician time	Thielke et al <sup>26</sup>
Life-sustaining intervention	100%	Transfer to intensive care unit <sup>l</sup>	Bates et al <sup>23</sup>
None		No additional care was provided	

<sup>a</sup>CPT in parentheses reflects the code that would be used to bill for the service rendered; <sup>b</sup>An advisory panel of pharmacists, nurses, and error researchers served as the expert panel; <sup>c</sup>It was assumed that assessment of vital signs would be necessary every 15 minutes for the first hour, then every 3 hours thereafter (11 additional encounters). Burke et al found that nursing time required for patient care varied from 3.5 to 10.7 minutes. To remain conservative, a time of 3.5 minutes was used, which translates into 38.5 minutes (3.5 × 11); <sup>d</sup>Among those who switch to a different analgesic PCA, it was assumed that 60% will require hydromorphone and 40% will require fentanyl; <sup>e</sup>Among those who switch to IV infusion therapy, 85% will require morphine and 15% will require hydromorphone; <sup>f</sup>Estimates in the literature indicate that 0.36 minutes is required for switching an individual from a PCA to an IV infusion. In addition, a prospective time-and-motion study indicated that 7.92 pharmacist-minutes are required for switching an individual to another PCA narcotic (7.92 + 0.36 = 8.28); <sup>g</sup>Estimates in the literature indicate that 5.97 minutes are required for switching an individual from a PCA to an IV infusion. In addition, a prospective time-and-motion study indicated that 9.8 pharmacy technician-minutes are required for switching an individual to another PCA narcotic (9.8 + 5.97 = 15.77); <sup>h</sup>A prospective observational study indicated that 27.47 minutes are required for a dose reduction, 35.55 to switch to a different IV PCA agent, 20.5 minutes to switch to an IV infusion, and 15 minutes for oxygen administration (27.47 + 35.55 + 20.5 + 15.0 = 98.52); <sup>i</sup>It was assumed that as a result of the bronchoscopy, patients would be billed for a fluid culture (87070) and smear (87205) in addition to the actual bronchoscopy (31622); <sup>j</sup>No additional nursing time was considered because it was assumed that the additional cost of hospitalization associated with an error included nursing costs based on the methodology used by Bates et al; CPT = current procedural terminology; IV = intravenous; PCA = patient-controlled analgesia.

## The Rate and Costs Attributable to Intravenous Patient-Controlled Analgesia Errors

**Table 4. Cost Associated With Each Intravenous Patient-Controlled Analgesia Error Consequence<sup>a</sup>**

<i>Consequence</i>	<i>Activity</i>	<i>Expected Variable Cost</i>	<i>Expected Labor</i>	<i>Expected Missed Revenue</i>	<i>Expected Total Cost</i>
Observation	Physician encounter	\$57.61		\$139.50	\$307.83
	Pulse oximeter	\$25.81		\$62.50	
	Nurse time		\$22.41		
Drug therapy change	Reduce PCA dose				\$134.51
	Switch to IV infusion	\$2.49 <sup>b</sup>		\$4.91 <sup>c</sup>	
	Switch to different IV PCA	\$4.89 <sup>d</sup>		\$9.63 <sup>c</sup>	
	Oxygen	\$12.91 <sup>e</sup>		\$31.25	
	Pharmacist time		\$7.93		
	Pharmacy technician time		\$3.17		
	Nursing time		\$57.33		
	Diagnostic tests	Bronchoscopy	\$5.87		
	Chest x-ray	\$1.40		\$3.40	
	Arterial blood gas	\$7.74		\$18.75	
	Basic metabolic panel	\$22.51		\$54.50	
	Nursing time		\$8.73		
Hospitalization affected	Additional hospitalization	\$4,681		\$9,223 <sup>c</sup>	\$13,904
Antidote/Antagonist	Naloxone	\$63.84		\$125.76 <sup>c</sup>	\$198.70
	Nursing time		\$7.55		
	Pharmacist time		\$0.35		
	Pharmacy technician time		\$1.20		
Life-sustaining intervention	Intensive care unit	\$8,715		\$17,168 <sup>c</sup>	\$25,883
None					\$0

<sup>a</sup>This study applied the expected value theorem to derive the costs contained within this table as follows:  $E(X) = \sum_x xf(x)$ , where  $\sum_x$  sums all values of the product of  $xf(x)$ .<sup>42</sup> In this scenario,  $x$  is the encounter, such as a laboratory cost or reduction in PCA dose. Similarly,  $f(x)$  is the probability of requiring the event, which is reported in Table 3. For example, the estimated cost for an ABG is \$30.98, but considering that only 25% of the population will require an ABG, the estimated cost for an ABG is \$7.74; <sup>b</sup>AWP for morphine is \$22.50 for 150 mg per 150 mL. Approximately 10% of the population experiencing a drug therapy change will require IV morphine. This translates into an expected cost of \$2.25. AWP for hydromorphone 30 mg/mL is \$11.93 (including normal saline). Approximately 2% of the population experiencing a drug therapy change will require IV hydromorphone. This translates into an expected cost of \$0.24. Thus, the expected cost for switching to an IV infusion is \$2.49 (\$2.25 + \$0.24); <sup>c</sup>It is estimated from the Bates et al article that institutions charge on average 1.97 times the actual cost of drug therapy.<sup>23</sup> Thus, the variable cost was multiplied by 1.97 to derive the estimated missed revenue cost; <sup>d</sup>AWP for hydromorphone 30 mg/mL is \$11.93 (including normal saline). Approximately 8% of the population experiencing a drug therapy change will require hydromorphone PCA. This translates into an expected cost of \$0.95. AWP for fentanyl 1,500 mcg per 150 mL is \$65.73. Approximately 6% of the population experiencing a drug therapy change will require fentanyl PCA. This translates into an expected cost of \$3.94. Thus, the total cost for switching to another PCA is \$4.89 (\$0.98 + \$3.94); <sup>e</sup>The estimated cost for oxygen therapy is \$25.81. Considering only 50% of the population will require oxygen therapy, the estimated cost is \$12.91 (0.50 × \$25.81); ABG = arterial blood gas; AWP = average wholesale price; IV = intravenous; PCA = patient-controlled analgesia.

**Table 5. Example Calculation of Average Intravenous Patient-Controlled Analgesia Error Event Cost**

Event Number	Patient Outcomes	Itemized Costs	Event Cost
1	Antidote + hospitalization	\$199 + \$13,904	\$14,103
2	No action	\$0	\$0
3	Antidote	\$199	\$199
4	Observation + drug therapy change	\$308 + \$134	\$442
5	No action	\$0	\$0
Average cost per occurrence of communication error			\$1,166

**Table 6. MEDMARX: Expected US Annual Intravenous Patient-Controlled Analgesia Error Rates<sup>a</sup>**

Error Type	Overall Events/10,000 <sup>a</sup>	Harmful Events/10,000 <sup>b</sup>	Nonharmful Events/10,000 <sup>b</sup>
Overall annual rate	406.84	41.96	364.88
Communication	67.17	8.29	58.88
Name confusion	5.87	0.35	5.53
Storage	57.16	5.01	52.15
Human	322.91	33.67	289.24
System	72.35	7.94	64.41
Contraindicated	5.70	1.38	4.32
Equipment	102.23	18.48	83.75
Miscellaneous <sup>c</sup>	50.42	2.42	48.01

<sup>a</sup>The total harmful event rates and nonharmful event rates may not equal the overall event rates because of rounding; <sup>b</sup>Values sum to a value greater than the total because the users had the ability to report more than 1 error cause per event; <sup>c</sup>Includes errors involving computerized prescriber order entry, wrong diluent, documentation, drug shortage, and nonformulary drug.

The total number of patients receiving IV PCA who were at risk for having an error was not available in the error-reporting systems because these databases capture only reported error events. Instead, the annual number of surgeries within the United States and the percent of patients prescribed IV PCA after surgery was used to estimate the number of patients receiving IV PCA (estimate from national data).<sup>32</sup> The National Center for Health Statistics data estimated that 45,023,000 patients underwent surgery in the United States in 2004<sup>32</sup> and that an estimated 28.9% of patients required IV PCA therapy following surgery.<sup>33</sup> Thus, it was estimated that 13,011,647 patients require IV PCA therapy annually (28.9% of 45,023,000).

Because of known characteristics of the datasets, 2 slightly different formulas were used to estimate the annual error rates. Because MAUDE is part of a mandatory reporting system, it was assumed that all US hospitals contributed to the reported data. The annual rate of device-related errors was estimated using the following formula:

$$\text{Annual rate/10,000 patients} = \frac{\text{PCA errors frequency} \times 10,000}{4.45\% \times 13,011,647}$$

According to USP, only 10.6% of US hospitals report errors to the MEDMARX database; thus, an additional term was added to the formula as an adjustment. The following formula was used to represent the annual IV PCA error rate

for the MEDMARX data:

$$\text{Annual rate/10,000 patients} = \frac{\text{PCA errors frequency} \times 10,000}{4.45\% \times 10.6\% \times 13,011,647}$$

## RESULTS

### Error Rate Analysis

A total of 2,497 PCA errors were reported to MEDMARX within the 12-month period from July 1, 2003, to June 30, 2004, yielding 406.8 medication errors per 10,000 patients who received IV PCA annually within the United States (see Table 6). Varying error-reporting estimates from 1.2% to 7.7% (midpoint, 4.45%) yielded 1,508.6 and 235.1 medication errors per 10,000 patients, respectively. The most frequent cause of IV PCA errors was human-related,

**Table 7. MAUDE: Expected US Annual Intravenous Patient-Controlled Analgesia Error Rates<sup>a</sup>**

<i>Event Type</i>	<i>Percentage Harmful<sup>b</sup> (%)</i>	<i>Event Type Distribution<sup>c</sup> (%)</i>	<i>Overall Rate<sup>d</sup> (Events/10,000)</i>	<i>Harmful<sup>e</sup> (Events/10,000)</i>	<i>Nonharmful<sup>f</sup> (Events/10,000)</i>
Overall annual rate			17.22	1.30	15.91
Device safety events	0.50	79.78	13.74	0.07	13.67
Indeterminate events	21.70	11.79	2.03	0.44	1.59
Operator errors	48.09	6.57	1.13	0.54	0.59
Patient-related events	33.33	0.60	0.10	0.03	0.07
Opioid adverse event <sup>g</sup>	100.00	1.25	0.22	0.22	Not applicable

<sup>a</sup>The total harmful event rates and nonharmful event rates may not equal the overall event rates because of rounding; <sup>b</sup>Based on harm rates reported by Hankin et al<sup>2</sup>; <sup>c</sup>Distribution is based on the frequency of each event type divided by the sum of all the events based on data from Hankin et al<sup>2</sup>; <sup>d</sup>Overall Rate = Distribution × 0.001722 (derived PCA error rate); <sup>e</sup>Harmful = Harm Rate × Overall Rate; <sup>f</sup>Nonharmful = (1 – Harm Rate) × Overall Rate; <sup>g</sup>Opioid adverse events are harmful events by definition; MAUDE = Manufacturer and User Facility Device Experience.

**Table 8. MEDMARX: Mean Intravenous Patient-Controlled Analgesia Error-Related Costs**

	<i>Overall Error Costs (SD)</i>	<i>Harmful Error Costs (SD)</i>	<i>Nonharmful Error Costs (SD)</i>
Overall	\$733 (3,984)	\$6,621 (10,746)	\$55 (137)
Communication	\$1,166 (5,096)	\$8,984 (11,958)	\$65 (162)
Name confusion	\$90 (224)	\$814 (0)	\$44 (132)
Storage	\$233 (1,783)	\$2,137 (5,760)	\$50 (132)
Human factors	\$714 (3,913)	\$6,380 (10,552)	\$54 (137)
Systems error	\$892 (4,595)	\$7,630 (11,994)	\$61 (150)
Contraindicated	\$584 (2,403)	\$2,098 (4,776)	\$99 (200)
Equipment related	\$1,189 (5,014)	\$6,118 (10,493)	\$101 (177)
Default	\$401 (2,667)	\$7,940 (9,737)	\$22 (89)

SD = standard deviation.

contributing 322.9 errors per 10,000, followed by equipment-related (102.2 errors per 10,000) and communication-related (67.2 errors per 10,000). The frequency distribution of the causes of errors was consistent across harmful and nonharmful errors, except that equipment-related errors accounted for 83.8 errors per 10,000 for harmful IV PCA errors and only 18.5 errors per 10,000 for non-harmful errors.

Using the PCA error frequency reported by Hankin et al,<sup>2</sup> IV PCA device errors translated into 17.2 error events per 10,000 patients

who received IV PCA annually within the United States (see Table 7). Varying error-reporting estimates from 1.2% to 7.7% (mid-point, 4.45%) yielded 63.8 and 9.95 device errors per 10,000 patients, respectively. The most frequent device error was associated with device safety-related events (13.7 per 10,000). In contrast, the most common device-error cause among harmful events was operator-related events.

**Cost Analysis**

The error cost analysis involved a sample of 2,356 unique

IV PCA error records from the MEDMARX dataset. Note that the cost analysis sample of 2,356 unique records was refined by manual review to ensure that all records were IV PCA specific. This sample was different from the error count of 2,497 used in the MEDMARX error rate analysis, which was the total number of PCA errors reported during the specified 12-month period. After applying the estimated cost per consequence associated with IV PCA errors within the MEDMARX database, the average (standard deviation) IV PCA

**Table 9. MAUDE: Mean Intravenous Patient-Controlled Analgesia Error-Related Costs**

	Nonharmful Mean Cost, Dollars (SD) <sup>a</sup>	Harmful Mean Cost, Dollars (SD)	Percentage Harmful <sup>b</sup>	Weighted Average Cost (Dollars) <sup>c</sup>
Overall	\$28	\$6,943	7.6	\$552
Device safety events	\$0	\$3,483 (9,294)	0.5	\$18
Indeterminate events	\$142 (1,804)	\$6,120 (11,219)	21.7	\$1,439
Operator errors	\$361 (2,910)	\$5,756 (10,681)	48.1	\$2,955
Patient-related events	\$11 (31)	\$199 (not applicable) <sup>d</sup>	33.3	\$74
Opioid adverse event <sup>e</sup>	0	\$13,803 (15,707)	100 <sup>e</sup>	\$13,803

<sup>a</sup>Not available for overall costs and weighted averages because the calculation used aggregate percentages from Hankin et al<sup>2</sup>; <sup>b</sup>Based on harm rates reported by Hankin et al<sup>2</sup>; <sup>c</sup>Weighted Average Cost = (Harm Rate × Harmful Mean Cost) + ([1 – Harm Rate] × Nonharmful Mean Cost); <sup>d</sup>Standard deviation calculation not possible because of too few cases; <sup>e</sup>Opioid adverse events are harmful events by definition; MAUDE = Manufacturer and User Facility Device Experience; SD = standard deviation.

error-related cost was estimated as \$733 (\$3,984; see Table 8). Among all causes of error, communication- and equipment-related errors were the most costly (\$1,166 and \$1,189, respectively); the most costly harmful errors were communication-related (\$8,984). Overall, harmful errors were 120 times more costly than nonharmful errors (\$6,621 versus \$55).

Based on the mean cost of \$733 per error, an error rate of 406.8 errors per 10,000 patients, and a total of 13,011,647 patients who require PCA annually, it was estimated that errors related to IV PCA account for \$388 million annually in additional health care expenditure for patients in the United States.

Among the device-related error events captured within the MAUDE dataset, the average cost per error was estimated at \$552. The most costly cause of error was related to opioid adverse events (\$13,803), followed by operator-related errors (\$2,955; see Table 9). Similar to the MEDMARX data, the MAUDE data indicated that harmful events were about 250 times more costly than nonharmful events (\$6,943 vs \$28). Among harmful device events,

opioid adverse events accounted for \$13,803 per event, followed by indeterminate events (\$6,120) and operator-related errors (\$5,756).

Based on the estimated 17.2 events per 10,000 and \$552 mean cost per event, IV PCA-related events account for \$12 million in additional care for patients in the United States annually.

**DISCUSSION**

The results of this study indicate that IV PCA errors occur often and support the body of evidence that IV PCA is prone to errors. Furthermore, when considering the average cost per error event, IV PCA translates into \$388 million for medication-related errors (MEDMARX data) and \$12 million for device-related errors (MAUDE data) in additional US costs annually. The combination of the high rate at which IV PCA errors occur and their high costs underscores the need for safer and less costly approaches to PCA administration.

Unfortunately, there is a paucity of research on the rate and costs associated with IV PCA errors to confirm these results. In fact, prior research investigating the rate of

IV PCA errors could not be found. Although Oderda et al reported that 2.7% of patients experience an opioid-related adverse event following surgery, these estimates included both errors and actual adverse events associated with the pharmacodynamic properties of the opioid.<sup>34</sup> Prior research has indicated that overall medication-related errors occur in 3.0% to 6.9% of all inpatient admissions.<sup>35-39</sup>

The results from this study provide additional evidence that because of the complexity of IV PCA administration, IV PCA has a high likelihood of errors.

This is the first study that quantifies the costs specifically associated with IV PCA-related errors. The Oderda et al study found that, after controlling for some possible confounding, incremental costs of opioid adverse events are approximately \$840 (2003 dollars) per event. Estimates from Oderda et al validate the range of costs identified within this study (\$522 to \$733; 2006 dollars) but suggest that these results are modest estimates and that the true costs of IV PCA errors may be greater than those documented. Consideration of the cost of IV

PCA errors relative to the cost of therapy is important. Macario and McCoy examined pharmacy-related costs associated with postoperative analgesia following hip, knee, and bilateral knee replacement<sup>40</sup> and found that the average pharmacy cost ranges from \$560 to \$922 per event.

There is room for improvement in patient safety of postoperative pain management. Despite published treatment guidelines, postoperative pain is frequently undertreated, indicating a potential for increase in the use of IV PCA.<sup>41</sup> A previous study of *MEDMARX* PCA errors found that human factors were the main cause of error, and staff issues contributed heavily to the occurrence of errors.<sup>12</sup> Research conducted by Bond et al found that the number of registered nurses and pharmacists per occupied bed increases the risk for medication errors.<sup>36</sup> The potential increase in IV PCA exposure and the existing major challenges of administration complexity and staff burden underscore the need for innovative technologies. To improve patient safety, new technologies must focus on minimizing the number of steps for analgesia administration, limiting the need for synchronization of multiple hospital departments, reducing opportunities for human error, and lessening the burden placed on nurses and pharmacists.

The results from this study found significant variation in error reporting to the 2 national systems, MAUDE and *MEDMARX*. The *MEDMARX* dataset contains responses from subscribers and reflected errors ranging from potential errors to errors resulting in death. Furthermore, the *MEDMARX* dataset is used more frequently by institutions nationwide and, consequently, generates a

higher frequency of IV PCA error estimates. In contrast, the MAUDE dataset contains reports of events “that reasonably suggest a device has or may have contributed to patient death or serious injury.”<sup>16</sup> The MAUDE dataset is administered through the FDA and, based on the lower frequency of IV PCA error estimates relative to the *MEDMARX* dataset, is less well-integrated into institutional error reporting. Based on this description, the MAUDE events may equate to a higher-risk subset of the *MEDMARX* events, which may explain the smaller number of reported events in MAUDE. Furthermore, it is not known how the environment of mandatory reporting, as compared with that of subscriber reporting, affects the reporting rate.

Recognizing the limitations of this analysis is important. Because this analysis relies on secondary data, it is limited to the type of variables requested and the accuracy of the information reported. Despite the use of 2 nationally recognized error-reporting databases, underutilization of error-reporting systems may have resulted in modest national estimates.<sup>30-33</sup> More specifically, it is recognized that most medication errors go unreported. Although underreporting was addressed in the previously discussed analysis, underreporting of medication errors significantly limits the ability to understand the true burden of IV PCA errors. Furthermore, the national estimates are projected using data from patients who have undergone surgery, but other patients may be candidates for IV PCA. Thus, it should be expected that the true frequency of IV PCA errors in the US is likely greater than the estimates reported in this analysis. In addition, the cost-accounting ap-

proach required assumptions as to the actual clinical care required as a consequence of the IV PCA error. Additional research is necessary to validate both the cost and clinical applications in the analysis. Another limitation of the analysis is that because of the limited nature of the available data, there were few data end points for cost estimation. The aggregate nature of the calculation did not allow for a full range of sensitivity analysis. It is assumed that the estimated cost is an underestimation because this study did not consider costs associated with litigation that is related to the errors, which may be substantial.

### CONCLUSION

Additional care rendered to patients harmed by IV PCA errors may lead to increased costs to the US health care system. Most errors related to IV PCA are associated with human factors, suggesting that the complexity of IV PCA pumps may increase patient care burden. Data quantifying the cost of medication errors at the therapeutic or drug level are limited. This study provides an innovative approach to estimating the cost of medication errors at the drug level; however, additional research is necessary to validate these findings. Nonetheless, results from this study underscore the need for safer technologies for administration of PCA.

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