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Impact of a Comprehensive Safety Initiative on Patient-controlled Analgesia Errors

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ABSTRACT

Background: Adverse drug events related to patient-controlled analgesia (PCA) place patients at risk.

Methods: We reviewed all critical incident reports at three tertiary care hospitals dated January 1, 2002, to February 28, 2009. In this longitudinal cohort study, critical incidents attributable to PCA errors were identified, and each incident was investigated. A safety intervention was implemented in February 2006 and involved new PCA pumps, new preprinted physician orders, nursing and patient education, a manual independent double-check, and a formal nursing transfer of accountability.

Results: A total of 25,198 patients were treated with PCA during this study, and 62 errors were found (0.25%), with 21 (0.08%) involving pump programming. All errors occurred before the safety interventions were put in place. Compared with the preintervention period, the odds ratio of a PCA error postintervention was 0.28 (95% CI = 0.14, 0.53; $P < 0.001$) whereas the odds ratio of a pump-programming error postintervention was 0.05 (95% CI = 0.001, 0.30; $P < 0.001$). Programming the wrong drug concentration was the most common programming error (10 of 21). Improper setup of intravenous tubing was also common (8 of 62), with one incident leading to respiratory arrest. Most PCA errors resulted in no harm, but there was negative impact to patients 34% of the time.

Conclusion: At less than 1%, the incidence of PCA errors is relatively low. Most errors occur during PCA administration. Safety can be improved by addressing equipment, education, and process issues.

What We Already Know about This Topic

- Patient-controlled analgesia using programmed pumps involves many steps during which errors can occur.

What This Article Tells Us That Is New

- In more than 25,000 patients using patient-controlled analgesia pumps, errors occurred in 0.25% of cases, with negative effects to one-third of these patients.
- A systems-based educational process can reduce the incidence of such errors.

THE concept for patient-controlled analgesia (PCA) was first introduced in a study conducted in the 1960s when nurses would sit at the bedside and administer intravenous opioid at patient request.[1] Since then, many devices have been developed and refined to administer patient-initiated doses. Now, PCA postoperative pain control has widespread use throughout the world. The use of the PCA has been shown to decrease postoperative pain better than nurse-controlled analgesia.[2] In addition, patient satisfaction is increased without an increase in adverse effects, with the exception of pruritus.[3,4] However, since the advent of PCA, several programming and PCA setup problems with serious and even fatal outcomes have been reported.[5–8]‡‡ When PCA pumps are involved, the chance for patient harm increases

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‡‡ Institute for Safe Medication Practices. Misprogramming PCA concentration leads to dosing errors. ISMP Medication Safety Alert. August 28, 2008. Available at: www.ismp.org/newsletters/acutecare/articles/20080828.asp. Accessed June 22, 2010.

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more than 3.5 times.[7] Some of the most serious errors occur with the programming of the pump. Incorrect medication concentration, dosage, or lockout times can lead to drastic underdosing or overdosing, resulting in either poorly controlled pain or—in extreme cases—a fatal overdose of narcotics.[9] Although the complexity of the PCA pumps and their programming software were often blamed for errors, setup errors and hardware malfunctions have also led to medication errors.[10]

The first Hamilton Acute Pain Service (APS) was formed at the McMaster University Medical Centre, Hamilton, Ontario, Canada in 1988. It was followed soon thereafter by the formation of APS teams at the other two Hamilton Health Sciences (HHS) sites. Between 2002 and 2009, the APS at the three HHS sites managed approximately 38,000 patients, of which approximately 70% received PCA. Prompted by a critical incident at HHS during which the patient received a serious overdose that required intubation and an intensive care unit stay, a PCA multidisciplinary safety panel was formed.[11] After reviewing the incident in detail, the safety panel suggested improvements to the ordering, programming, and administration of PCAs to reduce the number of associated errors and decrease the number of adverse events from PCA use. One specific recommendation was to replace old PCA pumps with newer ones that were easier to program and would monitor drug administration program parameters. New PCA pumps were purchased and deployed in spring 2006.

In addition to the acute pain safety initiatives above, a custom acute pain database (APS Manager Version 1.2; Hamilton Health Sciences, Hamilton, Ontario, Canada) was developed to collect information on APS patients for the purpose of clinical documentation, quality assurance, and research. The new database has been in use at all HHS sites since early 2002.[12] The software includes a critical incident–tracking system that is used to record the details of any critical incident that occurs among APS patients. All adverse events related to healthcare management are routinely recorded, including PCA pump malfunctions, programming errors, and setup mistakes.

To assess the success of the HHS PCA initiatives, we compared the incidence of PCA errors in the preintervention cohort (February 2002 to February 2006) with those of the postintervention cohort (March 2006 to February 2009). This longitudinal before–after study was designed to determine error type and incidence rates.

Materials and Methods

Population

The study received research ethics board approval from the HHS Research Ethics Board (Hamilton, Ontario, Canada). After obtaining HHS Research Ethics Board approval, data were extracted from the APS database and directly from patient medical records for cases where there was a documented PCA error. The Research Ethics Board waived the requirement for subject consent and authorization because the information was used in a manner that ensured confidentiality. PCA errors were identified during rounds by the APS acute pain team, which consisted of a pain nurse and a staff anesthesiologist. The three APS sites at HHS all have formal acute pain services with nurse coverage during weekdays. One site, the general site, has a full-time nurse practitioner whereas the other two sites have registered nurses that rotate onto APS for daily or weekly assignments. Anesthesiologists are assigned to cover APS for 1–3-day assignments during weekdays. On-call staff cover APS after hours and on weekends and holidays. During daily rounds, the acute pain team interviews each patient, conducts a focused physical examination, and reviews patient medical records. Approximately 2,500 patients are managed by the three APS sites on an annual basis.

Each HHS patient enrolled in the APS had an electronic report filed into the APS Manager database system, which is available at all HHS sites. Each report includes patient demographics, admission details, type of surgery, surgeon, anesthesiologist, anesthesia type, analgesia orders, and pain visit details (*i.e.*, pain scores, satisfaction, ambulation, diet status, analgesia adverse effects). For cases where a critical incident (*e.g.*, drug error, pump-programming error, respiratory depression) occurred, an electronic reporting form was completed with the details of the event, including outcomes and actions taken. The pain nurses were responsible for investigating critical incidents, reviewing them with anesthesia staff, and entering them into the reporting system.

Case Classification

Two reviewers (B.B., A.M.) obtained and examined all HHS APS critical incident reports (n = 642) dating from February 1, 2002, to February 28, 2009. Each report was reviewed to determine whether the event involved a PCA setup, programming, or administration error. Any discrepancies were resolved through consensus or discussion with a third reviewer (J.E.P.). For extracted cases, the event type and details were determined from the reports. Cases where the cause of the critical incident was attributed to patient factors were excluded from this study (fig. 1). For example, a patient who experienced severe respiratory depression without any identifiable errors in PCA administration (despite an appropriate order) would have been excluded from this analysis. For patients in whom multiple errors occurred, the most serious error was counted for the overall event rate.

Selected cases (where the event was related to the PCA setup, programming, or administration) were classified into event types. The taxonomy for these categories was modified from the taxonomy suggested by Doyle[13] (see table, Supplemental Digital Content 1, http://links.lww.com/ALN/A644).

Error types and outcomes were also categorized according to a modified version of the National Coordinating Council for Medication Error Reporting and Preventing Category

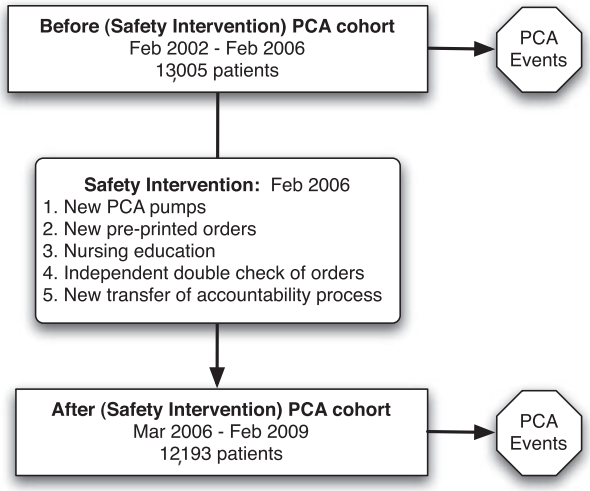

Fig. 1. Study timeline. PCA = patient-controlled analgesia.

Index.§§ This index is broadly broken into four major outcome groups: no error; error, no harm; error, harm; and error, death. Error outcomes are listed in the table, Supplemental Digital Content 2, http://links.lww.com/ALN/A645.

Finally, errors were further evaluated to determine the stage at which the mistake occurred (*e.g.*, prescription, dispensing, transcription, administration). If the error was related to programming, patient medical records were further evaluated to determine the step at which the mistake occurred (*i.e.*, drug name, drug concentration, dose, lockout time, or 4-h limit).

Safety Intervention: February 2006

The panel proposed several safety enhancement changes that were implemented in February 2006, including: the purchase of new PCA pumps that were easier to program and had "soft" and "hard" medication limits, revised standardized preprinted PCA orders, a nurse-education blitz on the use and setup of the new PCA pumps, an independent nurse double-check of the PCA program settings incorporated into the orders, a new policy whereby nurses review PCA program settings during each shift and on shift handover, and the implementation of a mandatory critical incident reporting program. The original PCA pumps (Lifecare 4100 Plus II; Abbott Laboratories, Montreal, Quebec, Canada) were replaced with new ones (Alaris PCA module; CareFusion Corporation, Toronto, Ontario, Canada).

Statistical Analysis

For our primary objective, we determined the number and incidence of PCA pump-programming errors that occurred among the preintervention and postintervention cohorts. All errors were assigned to either the preintervention (before February 2006) or postintervention (after February 2006) cohort. Baseline sample size was determined by the number of PCA patient medical records captured from 2002 until 2006, the date when adverse-event recording began to the date of new pump deployment. After the safety intervention, we acquired PCA patient records until the postintervention cohort was similar in size to the baseline sample. The effect of the intervention on incidence error rates was expressed as an odds ratio with a 95% CI and an associated P value. P values are reported to three decimal places with P values less than 0.001 reported as $P < 0.001$. The criterion for statistical significance was set *a priori* at an α level of 0.05. We did not adjust the overall level of significance for multiple testing because the global aim of analyses was exploratory. For the comparison of odds ratios, it was assumed that there was an independent assessment of the odds for both time periods (preintervention and postintervention). To achieve an independent assessment, individuals were only included in the sample once. When the same patient was involved in multiple errors, only the most serious error was recorded for the purposes of this study. The secondary objective of describing error category and error type was to establish prevalence rates for each. Statistical analyses were performed using Stata 10.1 (StataCorp LP, College Station, TX).

Results

Over the 7-yr period of the study, a total of 25,198 patients received PCA treatment; 13,005 preintervention and 12,193 postintervention. During that time, there was a total of 62 PCA errors, with 49 (79%) occurring before the safety intervention and 13 (21%) after. Of all PCA errors, 21 were programming errors. All 21 programming errors occurred in the preintervention cohort. When comparing the number of errors that occurred in the postintervention period with those occurred before the intervention, the odds ratio of PCA error was 0.28 (95% CI = 0.14, 0.53; $P < 0.001$), and the odds ratio of the pump-programming error was 0.05 (95% CI = 0.001, 0.30; $P = 0.001$; fig. 2).

The most common causes of PCA errors were pump-programming errors (33.9%), orders given by non-APS physicians (14.6%), and inadequate nurse education (12.9%; fig. 3). It is noteworthy that PCA by proxy occurred in 7.8% of errors documented whereas pump hardware failure was noted in 1.6% of errors.

For the total errors, 77.4% involved incorrect doses (48 of 62), with 59.6% of such errors being an overdose and 17.7% being an underdose. Faulty PCA setup was noted in 12.9% of errors and usually involved improper intravenous tubing setup (fig. 4). Breaking down the 21 PCA programming errors, the following data-entry errors occurred: wrong concentration (48%), wrong dose (5%), wrong dose and wrong concentration (10%), wrong lockout (5%), continuous infusion added when it was not ordered (5%), continuous infusion discontinued without order (10%), 4-h limit not programmed (10%), wrong 4-h limit programmed (5%).

§§ National Coordinating Council for Medication Error Reporting and Preventing. NCC MERP Taxonomy of Medication Errors. Available at: http://www.nccmerp.org/pdf/taxo2001-07-31.pdf. Accessed September 28, 2010.

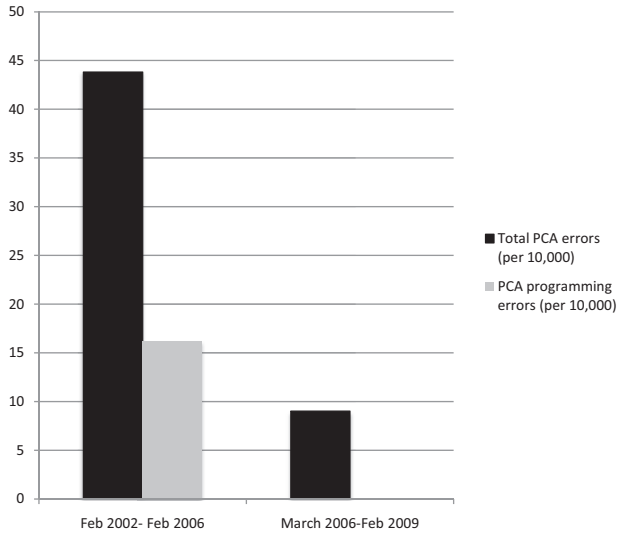

Fig. 2. Number of patient-controlled analgesia errors and programming errors per 10,000 patients, before and after safety intervention. *$P < 0.001$ (preintervention *vs*. postintervention error rate). PCA = patient-controlled analgesia.

For concentration programming errors, 9 of 10 errors underestimated drug concentration, resulting in anywhere from a 2-fold to 50-fold increase in dose.

The consequences of the PCA errors were no harm (66%) and some harm (34%). Patient harm included respiratory depression (16%) requiring oxygen and/or naloxone administration, uncontrolled pain (13%), and sedation (6%). Although three of patients suffered respiratory depression significant enough to cause cyanosis or oxygen saturations lower than 80%, there were no documented deaths attributable to PCA errors during the study period.

Seventy-five percent of PCA errors observed were discovered on surgical wards, with 10% occurring in the recovery room (where all the PCA pumps were initially set up), 8% in the intensive/coronary care unit, 5% on medical wards, and 1.8% on pediatric wards. Errors were discovered by APS nurses (48%), ward nurses (19%), APS physicians (5%),

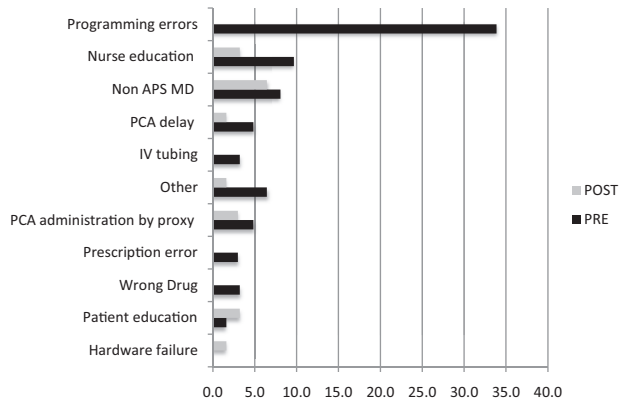

Fig. 3. Causes of patient-controlled analgesia errors in percentage of total pump errors. APS = Hamilton Acute Pain Service, McMaster University Medical Centre (Hamilton, Ontario, Canada); IV = intravenous; MD = medical doctor; PCA = patient-controlled analgesia.

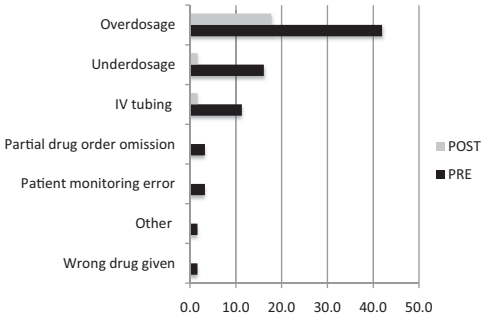

Fig. 4. Types of patient-controlled analgesia errors as percentage of total errors. IV = intravenous.

pharmacists (2%), and others (26%). Errors occurred at every stage in the drug-order workflow: prescribing (1.5%), dispensing (1.5%), order transcription (8%), and drug administration (89%).

Discussion

The current study involved a prospective cohort of 25,198 patients over a 7-yr period. It showed that there were fewer PCA errors overall and also fewer pump-programming errors after a safety intervention that involved the purchase of new PCA pumps, new preprinted orders with suggested dosing, nursing education, a manual independent double-check, and a new nursing transfer-of-accountability process. It is noteworthy that comparisons in incidence rates were based on historical controls. Therefore, it is possible that the observed reduction in errors was the result of factors other than our safety interventions.

Programming the wrong drug concentration dose was the common PCA error, with most of these errors resulting in a significant drug overdose. PCA pump setup errors were another common finding. Most of PCA error cases resulted in no harm, but there were some negative effects for patients (34%), with respiratory depression being the most common adverse effect (16%). The majority of PCA errors were discovered on surgical wards and as identified by APS nurses during their rounds. None of the patients in this study died as a consequence of a pump-programming error, although one patient required naloxone and bag mask ventilation for resuscitation from respiratory depression.[11] Vicente *et al.*[9] estimated that mortality rates from pump-programming errors could be between 1 in 33,000 and 1 in 338,800. If that estimate is accurate, even the large sample size in the current study was likely too small to estimate mortality risk from PCA misprogramming.

The new pumps purchased by our facilities had a more user-friendly interface than the original pumps. Specifically, all PCA order parameters (*i.e.*, drug, concentration, dose, lockout, and 4-h limit) can be programmed and reviewed from a single screen. By contrast, only one programming parameter could be programmed or reviewed at a time with the original pumps. Consequently, clinical staff had to scroll through five screens to review pump-program parameters.

Furthermore, the original pumps automatically returned to a default minimum drug concentration setting of 0.1 mg/ml. If this setting was not changed manually, it could result in a 50-fold overdose given that our facilities used morphine syringes that were 5 mg/ml.‖‖ The new pumps also had "hard" (no user override) and "soft" (user override) dosage limits, and this self-monitoring technology may have also had a positive effect. Vicente *et al.*[9] argued that device manufacturers could work with clinical staff and human factors engineers to redesign PCA pump interfaces to minimize programming errors. The results from this study support the recommendations of Vicente *et al.*, demonstrating that the new pumps with an improved interface resulted in fewer programming errors.

Bates *et al.*[14] analyzed all adverse drug events in 11 medical and surgical units in two tertiary care hospitals in Boston, Massachusetts. During 6 months, they found 247 adverse events with analgesics being the most common drug class involved (30%). They found that the most common stages of error were ordering (56%) and administration (34%). By contrast, our study found that the most common stage of error was administration (89%). Drug administration encompasses all of the steps involved in setting up a PCA drug order: setting up the patient's intravenous tubing with proper placement of the one-way valve, attaching the pump tubing to the patient's intravenous connection, selecting the correct drug syringe and loading it into the pump, programming the pump, removing the intravenous clamp, and starting the PCA pump. Given that PCA drug administration involves more steps and is more complex than most hospital drug orders, it is not surprising that the PCA drug errors documented at our facilities mostly involved administration errors.

Preprinted physician orders for PCAs were another new safety intervention. The new orders were designed to match the programming parameters of the new pumps. The order set includes all the information necessary to make a complete PCA prescription, including the three choices for opioids (morphine, fentanyl, and hydromorphone) with their associated concentrations. A recent study[15] of preprinted drug orders in a pediatric emergency department in Toronto found that preprinted orders reduced the incidence of drug errors by 45%. The use of a computerized physician order entry system would have the potential to reduce error even more than preprinted orders. Preprinted orders can suggest dosage ranges for physicians, but nothing prevents physicians from ordering dosages that are too high; computerized physician order-entry systems can give real-time feedback to physicians regarding dosages when the order is being entered.[16]

Nurses were trained regarding the use of the new order sets, pumps, and transfer-of-accountability process. Given the number of steps a PCA prescription requires, nurse education is essential to ensuring that PCA orders are administered accurately and safely.[17] At our institution, nurses who will be responsible for taking care of patients with PCAs are required to complete a formal acute pain course that gives hands-on experience with pump programming. The transfer-of-accountability process introduced in these three hospitals formalizes the handover of clinical care when providers change shifts. PCA order details and monitoring protocols were included in this transfer of information.[18] The last safety intervention involved the use of mandatory manual independent double-checks, a process whereby a second nurse is required to check and then sign off that all of the PCA pump-programming parameters were correct after the PCA programming had been done by the primary nurse. This practice was adapted based on the recommendations of the Institute for Safe Medical Practice Alert.‡‡ These mandatory manual independent double-checks were considered an improvement from the original workflow (where there was no double-check), but not as good as the recommended automatic double-check.

In conclusion, our findings suggest that the combination of well designed (*i.e.*, easy to program) PCA pumps, preprinted physician orders, nursing education, independent manual double-checks, and a transfer-of-accountability process is effective in reducing overall PCA administration errors and PCA pump-programming errors. Although the incidence of PCA errors is relatively low (less than 1%), most errors occur during administration. Further improvements in safety are possible with the use of barcode readers and computerized physician order-entry systems, but the effect of such interventions requires further investigation.

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