Medication Safety

A Case Study on the Safety Impact of Implementing Smart Patient-Controlled Analgesic Pumps at a Tertiary Care Academic Medical Center

Mai Tran, PharmD; Scott Ciarkowski, RPh, MBA; Deborah Wagner, PharmD, FASHP; James G. Stevenson, PharmD, FASHP

Pain has historically been undertreated in the hospital setting. As reported by Grass,[1] at least 50% of postsurgical patients receiving traditional intramuscular (IM) opioid injection experience insufficient pain relief. In 1963 it was first demonstrated that small intravenous (IV) doses of opioids provide better patient pain relief than conventional IM injections. This discovery led to the development of patient-controlled analgesia (PCA) technologies in the late 1960s, with the advent of the first commercially available PCA pump in 1976.[1] Today, PCA pumps are widely used in the inpatient setting as one of several possible methods of analgesia.

PCA refers to the IV "on-demand" delivery of analgesics to patients in need of pain control through PCA pumps. PCA pumps normally deliver analgesics through two mechanisms: (1) a fixed-demand dose, or (2) a fixed-demand dose and a continuous infusion at a constant rate. There are several safety features associated with PCA pumps, including a lockout interval and dose limits. Lockout intervals are programmed to set a time constraint on how often the patient can demand analgesic delivery, which prevents excessive dosing. Dose limits are set limits to the maximum amount of analgesic the patient can receive during a specified interval of time.

Despite the many benefits seen with PCA therapy, several risks are associated with its use. Of all medication errors, those associated with intravenous (IV) infusion of high-risk medications, such as opiates, have been identified as having the greatest potential for patient harm.[2] Inadvertent programming errors of an infusion device such as a PCA "can deliver a massive, unintended overdose of high-alert medications, resulting in patient harm, including catastrophic consequences."[3(p. 84)]

Moreover, between 1998 and 2003, data from MEDMARX® (Quantros, Inc., Marlborough, Massachusetts), the national voluntary adverse event reporting database, and U.S. Pharmacopeia reports showed that the risk for patient harm increased by greater than 3.5 times when PCA pumps were involved in therapy.[4]

As for the types of errors that can occur with PCA therapy,

Article-at-a-Glance

Background: As with the use of any therapy involving opioids, patient-controlled analgesia (PCA)–related errors can lead to overdose and even death. "Smart" (computerized) pumps have medication safety enhancements, particularly those related to operator errors during administration, to improve overall safety and efficacy. After the occurrence of PCA–related errors that occurred at a tertiary care academic medical center, an analysis of PCA errors was conducted. The introduction of smart pumps was identified as a possible solution, and the medical center adopted the technology in 2006. A study was conducted to investigate the impact of implementation.

Methods and Results: The study had three primary objectives: (1) to evaluate history logs stored in the smart PCA pumps to characterize the nature of hard and soft stop alerts and identify potential errors that may have been averted, (2) to examine the impact of smart PCA pumps on voluntarily reported PCA therapy–related errors, and (3) to assess nursing perceptions regarding the improvement in safety due to the introduction of smart PCA pumps. The smart pumps potentially prevented 159 errors for the January–June 2007 period; upper hard limits had the most number of alerts, representing avoidance of errors with the greatest potential to be detrimental to the patient. In addition, pump-programming errors due to wrong concentration were eliminated after implementation. Finally, nursing staff perceived smart pumps to be valuable in improving patient safety.

Conclusions: Smart PCA pumps had an important positive impact on PCA–related patient safety at the medical center. Other facilities should adopt PCA devices with additional safety features such as bar-code verification of the drug and concentration, as well as dosage limits, to prevent pump-programming errors.

there are two main categories: human errors and equipment errors. Schein et al. identified 13 categories of PCA–related safety hazards—wrong analgesic, pump misprogramming, false triggering (that is, short circuit), false triggering by proxy, drug accumulation in IV deadspace, runaway fluid column due to "siphoning" or other means, PCA pump malfunction due to hardware failure, PCA pump malfunction due to software design error, retrograde flow of PCA analgesic into a second IV set due to catheter blockade, bad medical judgment in formulating PCA prescription or order, anaphylaxis, unknown sensitivity of the patient to opioids resulting in respiratory depression, and reprogramming with criminal intent.[5]

In a retrospective review of MEDMARX data to examine the magnitude, frequency, and nature of medication errors associated with PCA, Hicks and colleagues found that 6.5% (624) of the 9,571 PCA–related errors that occurred between July 1, 2000 and June 30, 2005, led to patient harm. Human factors were identified as the leading cause of PCA–related errors, and the majority of the errors occurred in the drug administration phase. These administration errors fall under the categories identified by Schein et al. and include improper doses or amounts of opioid given, failure to match drug concentration with pump programming, omission errors such as forgetting to turn the pump on, or giving the wrong drug.[6]

Although the types of errors associated with PCA pumps vary widely, they all can lead to the same end result—respiratory depression and death. To help prevent serious patient harm and improve patient outcomes with PCA therapy, "smart" (computerized) pumps were developed. Smart PCA pumps are PCA pumps with medication safety enhancements to improve overall safety and efficacy, particularly those related to operator errors during administration. One feature that smart PCA pumps may have is a bar-code scanner. When an opioid syringe is scanned, the bar-code scanner automatically selects the medication and concentration of opioid so that these parameters do not need to be manually programmed. This helps to prevent pump misprogramming. This bar-code verification step is required and cannot be bypassed. Another important feature that is available in many smart pumps is software for the creation of drug libraries contained within the pump, which allow upper and lower dosage limits to be set for each medication and within individual patient care areas. With this feature, if a pump is programmed above or below a medication dosage limit, the user will be alerted that an error may have occurred. Some alerts, known as "soft alerts," will have an override option to allow the user to continue with the programmed input. Other alerts, known as "hard alerts," will not allow the user to override, and the user will have to reprogram his or her input within the limits defined in the pump's drug library. Such soft and hard alerts help users recognize possible programming errors before they have a chance to cause harm to the patient. Most smart pumps also have memory logs that record the history of programming errors, alerts, reprogramming events, and overrides. This technology is valuable for quality assurance purposes. Finally, many smart pumps also have a verification screen, which reflects back programming to the user and asks the user to verify that the input is correct. This functionality of the smart PCA pump provides the user with another opportunity to detect and prevent errors before medication administration to the patient.

Table 1. Sample Adult Normal Patient Drug Library—Morphine 1 mg/mL*

	Loading Dose	PCA Dose	Con't Rate	4-Hour Limit
Lower hard limit	0.1 mg	0.1 mg	0.1 mg	n/a
Lower soft limit	0.5 mg	n/a	n/a	n/a
Upper soft limit	5 mg	2 mg	2 mg	30 mg
Upper hard limit	5.1 mg	2.5 mg	4 mg	60 mg

* PCA, patient-controlled analgesia; Con't, constant; n/a. not applicable.

After the occurrence of PCA—related errors that occurred at the University of Michigan Health System (UMHS; Ann Arbor, Michigan), and because of the high-risk nature of the medications used with PCA pumps, an analysis of PCA errors that occurred at UMHS for the January 1–November 1, 2005, period was conducted. The analysis showed incorrect pump programming for PCA dosing, continuous infusions, and settings of four-hour limits for infusions as the most frequent causes of error. Because of the nature of the errors, the implementation of smart pumps was identified as a possible solution. As a result, UMHS adopted smart pump technology* in June 2006. Before the implementation of the smart pumps, drug libraries that include both soft and hard limits were developed for both adult and pediatric care areas. An example of the UMHS drug library for an opiate-naïve adult patient [Adult Normal Patient] on morphine 1 mg/mL can be seen in Table 1 (above). Five months after the new PCA pumps were put into place, one month of data was collected and analyzed. The results indicated that a total of 81 potential errors were prevented through the use of smart pumps in pediatric and adult clinical care areas, providing a total potential error reduction of 9.5% in patients on PCA therapy in the month of data analyzed.[7]

* Information about the smart pump model and vendor can be obtained by e-mail request from the author [JGS].

Table 2. Edit Variance Report Data*

	Upper Hard Limit Alerts	Lower Hard Limit Alerts	Upper Soft Limit Alerts with Edits	Lower Soft Limit Alerts with Edits	Total Potential Errors Prevented	Total Significant† (% of Total Potential)
Fentanyl					**18**	**12 (67%)**
–Adult normal	7	6	3	1	17	11 (65%)
–Adult high	0	0	0	0	0	0
–Adult max	0	0	0	1	1	1 (100%)
Hydromorphone					**55**	**33 (60%)**
–Adult normal	31	6	12	0	49	33 (67%)
–Adult high	2	3	1	0	6	0 (0%)
–Adult max	0	0	0	0	0	0
Morphine					**86**	**51 (59%)**
–Adult normal	35	13	25	0	73	38 (52%)
–Adult high	4	7	1	1	13	13 (100%)
–Adult max	0	0	0	0	0	0
Total	**79**	35	42	3	**159**	**96 (60%)**

* PCA, patient-controlled analgesia.
† Errors ≥ 50% in magnitude from limit.

On the basis of this research conducted at UMHS, as well as the literature, it is evident that the use of regular PCA pumps can lead to very serious, and potentially fatal, errors. We conducted a study to further investigate the impact of the implementation of smart PCA pumps at UMHS, with a focus on the following three primary objectives:

1. To evaluate history logs stored in the smart PCA pumps to characterize the nature of hard and soft stop alerts and identify potential errors that may have been averted
2. To examine the impact of smart PCA pumps on voluntarily reported errors related to PCA therapy
3. To assess nursing perceptions regarding the improvement in safety due to the introduction of smart PCA pumps

Methods and Results

Objective 1

Methods. Data from the smart pumps in the adult clinical care areas at UMHS were reviewed for the January–June 2007 period to determine the types and frequencies of potential errors that were detected by the pump software and user interface. The data were reviewed in the form of two reports: (1) an edit variance report, which recorded hard and soft alerts that led to input edits, and (2) an override report, which recorded bypassed alerts. Several data points from the edit variance report were excluded from analysis because they did not indicate an edit in input values (these data points represented soft alerts that belonged on the override report; it is unclear why they appeared on the edit variance report).

Table 3. Override Report Data

	Upper Soft Limit Alerts (Bypassed)	Lower Soft Limit Alerts (Bypassed)	Total
Fentanyl			**86**
–Adult normal	52	2	54
–Adult high	0	0	0
–Adult max	19	13	32
Hydromorphone			**134**
–Adult normal	98	0	98
–Adult high	32	4	36
–Adult max	0	0	0
Morphine			**306**
–Adult normal	209	8	217
–Adult high	88	1	89
–Adult max	0	0	0
Total	498	28	**526**

Results. Table 2 (above) and Table 3 (above) summarize the data collected from the pumps. The data from the edit variance report (summarized in Table 2) show that the smart PCA pumps potentially prevented 159 errors in the adult clinical care area for the January–June 2007 period. Of the 159 errors, 96 (60%) were potentially significant, as the input values differed by ≥ 50% in magnitude from the limits set in the drug libraries. Of the three opiates used in PCA pumps at UMHS, morphine had the greatest number of total potential errors prevented. This finding reflects the fact that morphine is the opiate most often used in the PCA pumps at UMHS (76.1%). However, in a breakdown of each individual opiate, 15% of fentanyl programming triggered an input edit, in comparison with 5% of hydro-

morphone programming and only 2% of morphine programming. Also of interest is the finding that the upper hard limits had the most number of alerts (79/159, or 50%) of the four different categories of alerts. One could argue that these are the most important types of alerts because they completely stop the user from inputting values that are too high for the patient and that could lead to an overdose.

The data from the override report (summarized in Table 3) show that 526 soft alerts were bypassed in the January–June 2007 period, accounting for 92% of the total number of soft alerts that occurred during this period. This means not only that a large number of soft alerts were false alarms but also that 45 soft alerts actually detected an error and resulted in a change in programming (Table 2). A breakdown of the bypassed soft alerts shows that 8% were related to loading-dose programming, 18% were related to demand-dose programming, 52% were related to four-hour dose-limit programming, and 22% were related to continuous-infusion-rate programming. Of the 526 bypassed soft alerts, 498 (95%) were due to upper soft limit values, and 209 (40%) were due specifically to the upper soft limit value of the adult normal library for morphine. On the basis of this information, further investigation should be conducted to determine if this upper soft limit value should be adjusted to reduce the number of unnecessary alerts and to prevent "alert fatigue."

Objective 2

Methods. Data from the UMHS voluntary adverse event reporting system[2] was evaluated during two periods. Because smart pump implementation occurred in June 2006, January–December 2005 was defined as the pre–smart pump period, and January–December 2007 was defined as the post–smart pump period. The number of patients receiving PCA therapy in both 2005 and 2007 was approximately equal, with 16,349 patients for 2005 and 16,249 patients for 2007. Therefore, any differences in the number of reported errors between the two years are unlikely to be due to differences in pump utilization but could have been influenced by underreporting, as well as changes in reporting rates due to hospital initiatives to improve reporting of medication errors.

Results. First, the PCA–related errors reported for the two periods via the reporting system were examined to determine what types of errors would be affected by implementing smart pumps. It was determined that smart pumps, because of their bar-code scanners and programmed drug libraries, had the greatest impact on errors relating to wrong doses or volumes of analgesic given. The study was not designed to assess whether improvements to the human design features of a smart pump contributed to error detection other than how the forced function of the bar-code scanner and defined soft and hard limits of the drug library affected the number of errors reported.

Information on the types of errors affected by smart pump implementation was then further broken down to determine the possible causes for patients to receive the wrong doses or volumes of analgesic. Eight categories, similar to the categories of PCA–related safety hazards created by Schein et al.,[4] were identified and are listed in Table 4 (page 116).

Wrong-dose/volume errors. When comparing the wrong dose/volume errors of 2005 to those of 2007, it was noted that for both years, pump-programming errors made up the majority of wrong dose/volume errors. Pump-programming errors accounted for 50% (20/40) of wrong dose/volume errors in 2005 versus 30% (13/43) in 2007, representing a 35% reduction (nonsignificant, either by z-test [a large-sample normal approximation of the poisson yielded a p value of .19] or chi-square test [p value of .065]).

Missed orders. The second largest category of errors for both years was missed orders, accounting for 23% (9/40) of wrong dose/volume errors in 2005 and 26% (11/43) of wrong dose/volume errors in 2007.

Prescribing Errors. The third largest category for both years was prescribing errors, accounting for 15% (6/40) of wrong dose/volume errors in 2005 and 16% (7/43) of wrong dose/volume errors in 2007.

Detailed results of the data are provided in Table 5 (page 116).

Pump-Programming Errors. Because smart PCA pumps are likely to have the most impact on pump-programming errors and because such errors made up the majority of wrong dose/volume errors in both 2005 and 2007, pump-programming errors were further analyzed. Seven categories of errors in pump programming were identified (as listed in Table 5): wrong interval, wrong dose, wrong four-hour dosing limit, wrong concentration, wrong drug, wrong drug library, and wrong continuous infusion setting.

In a comparison of pump-programming errors of 2005 to those of 2007, there was one very drastic difference. As shown in Table 5, while 10 (42%) pump-programming errors were due to wrong concentration in 2005, in 2007 there were no reports of pump-programming errors due to wrong concentration (p = .009, chi-square test). Elimination of reported wrong-concentration errors was likely attributable to the mandatory bar-code scanning feature of smart PCA pumps. Another notable difference between the two years is that drug libraries became a feature of the new, smart pumps in 2007, thereby introducing a new

Table 4. Error Categories with Descriptions and Examples*

Error Category	Description	Example
Pump programming	Programming the wrong medication, concentration, dose, and so on, into the pump	Programming for a hydromorphone concentration of 0.2 mg/mL when 0.5 mg/mL was actually ordered and given
Missed orders	Failure to recognize an order to change a patient's current PCA settings	A nurse overlooking an order written to decrease a patient's continuous infusion dose
Prescribing errors	Inappropriate prescribing leading to sub- or supratherapeutic effects for a patient	A physician failing to dose morphine based on a patient's weight, pain level, and/or previous use of opiates, thereby giving a subtherapeutic dose
Pump malfunctions	Failure of the pump to properly function	A pump failing to deliver the correct "on-demand" dose of analgesic to a patient when requested
Dispensing errors	Errors in the preparation and dispensing of PCA syringes	A syringe of analgesic being mislabeled as fentanyl 50 mcg/mL when it should have been labeled as fentanyl 20 mcg/mL
Administration/ preparation errors	Failure to appropriately set up the PCA pump to ensure efficacy for the patient	A patient not being connected to his or her PCA tubing while the pump is running
PCA by proxy	Persons other than the patient pressing the "on-demand" button to deliver small-bolus doses of analgesic	A visitor pressing the "on-demand" button for a patient while the patient is sleeping because he or she does not want the patient to awaken because of pain
Deficits in patient education	Failure to properly inform the patient of the functions of the PCA pump	A patient never being given his or her "on-demand" PCA button or told how to use it

* PCA, patient-controlled analgesia.

potential source of error in programming—that is, selecting the wrong drug library (one such error occurred in 2007).

Severity of Errors. To address any changes in the severity of errors that may have occurred due to the implementation of smart PCA pumps, the adverse event reporting system's reports of error severity from both 2005 and 2007 were examined. Errors were categorized into the nine standard categories defined by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).[8] During both years, category C (event occurred and reached the patient but no harm) errors made up the majority of errors, accounting for 71% (50/70) of reported errors in 2005, and 44% (35/79) of reported errors in 2007. One notable difference between the two years is an increase in the number of more severe (category D, E, F, G, H, and I) errors in 2007 compared with 2005. In 2005 these categories accounted for 16% (11/70) of reported errors, while in 2007 these categories accounted for 46% (36/79) of reported errors.

Further examination of the specific error incidents indicated that most of the severe errors in 2007 were due to oversedation requiring naloxone use. However, there was a potential confounding factor to explain this finding. In 2006 there was a deliberate action to encourage the reporting of any patient care situation that required the use of naloxone, which significantly increased the reporting of oversedation with subsequent naloxone administration. Detailed results of the error-severity data are shown in Table 6 (page 117).

Table 5. Adverse Event Reporting System Reporting Data, 2005 Versus 2007*

Wrong-Dose/Wrong-Volume Errors	2005	2007
Pump programming†	20 (50%)	13 (30%)
Order missed	9 (23%)	11 (26%)
Prescribing error	6 (15%)	7 (16%)
Pump malfunction	0 (0%)	0 (0%)
Dispensing error	1 (3%)	1 (2%)
Administration/preparation error	3 (8%)	6 (14%)
PCA by proxy	1 (3%)	4 (9%)
Patient education	0 (0%)	1 (2%)
Total Reported Errors	**40**	**43**

Programming Errors†	2005	2007
Wrong interval	4 (17%)	3 (19%)
Wrong dose	5 (21%)	3 (19%)
Wrong 4-hour dose limit	3 (13%)	5 (31%)
Wrong concentration	10 (42%)	0 (0%)
Wrong continuous infusion setting	2 (8%)	4 (25%)
Wrong drug	0 (0%)	0 (0%)
Wrong-drug library	0 (0%)	1 (6%)
Total Programming Errors	**24**	**16**

*PCA, patient-controlled analgesia.
† Several pump programming errors involved more than one category.

Objective 3

Methods. A survey was administered to nurses involved in using PCA pumps to determine whether they perceived any changes in the safety of their patients when using the smart PCA pumps in comparison to the regular PCA pumps. The survey targeted adult care nurses who (1) worked in hospital units with

Table 6. Error Severity for 2005 and 2007

	2005	2007
Not specified	1 (1%)	0 (0%)
A: Potential for error/unsafe conditions	3 (4%)	4 (5%)
B: Near miss. Event occurred but did not reach patient.	5 (7%)	4 (5%)
C: No harm. Event occurred and reached patient.	50 (71%)	35 (44%)
D: No harm. Patient required increased observation/monitoring and/or additional lab tests/procedures.	2 (3%)	17 (22%)
E: Temporary harm. Patient required intervention.	7 (10%)	15 (19%)
F: Temporary harm. Patient required initial or prolonged hospitalization.	2 (3%)	1 (1%)
G: Permanent harm.	0 (0%)	0 (0%)
H: Patient required intervention to sustain life.	0 (0%)	3 (4%)
I: Patient died due to error.	0 (0%)	0 (0%)
Total	**70**	**79**

the largest percentage of PCA pump utilization and who (2) began employment at UMHS in 2005 or earlier, so that they would have had experience with both previous and new PCA technology. All nurses meeting these criteria were given an opportunity to respond to the survey, which was distributed through an e-mailed hyperlink to a website. The e-mailed request for survey participation was sent to the nurses on three separate occasions to maximize the number of responses. The survey response rate was approximately 32%, or 128 nurses. The survey included two preliminary questions asking the nurses when they started working at UMHS and whether or not they had experience working with the PCA pumps in use at UMHS before implementation of the currently used smart PCA pumps. Nurses who started working at UMHS after 2005 or nurses who did not have experience with the old PCA pumps were asked to stop taking the survey. However, 13 nurses (10%) continued to take the survey despite not meeting the preliminary requirements. This is a limitation to the study; because the survey was anonymous, it was not possible to separate the responses of these nurses from the responses of the other nurses who met the preliminary requirements.

Results. In terms of the new features, the results of the survey showed that nurses overwhelmingly felt that the additional features of the smart PCA pumps, including the bar-code scanner, preset dose limits, and verification/review screen, provided additional safety benefits to their patients. The survey asked the nurses to rate each of these features on a scale of 1–4, where a score of 4 signifies that the feature provides "significant additional safety benefits," and a score of 1 signifies that the feature provides "no additional safety benefits." As shown in Table 7 (page 118), the bar-code scanner was perceived to be the most beneficial, with a mean score of 3.74.

In terms of ease of use, the survey results also showed that a majority of the nurses felt that the smart PCA pumps are easier to use than the standard PCA pumps. As shown in Table 8 (page 118), on a scale of 1–4, with 1 being "no easier to use" and 4 being "much easier to use," 42% of the nurses rated the smart PCA pumps with a score of 3, and 32% of the nurses rated the smart PCA pumps with a score of 4. Only 6% of the nurses felt that the smart PCA pumps were no easier to use than the old PCA pumps.

When the nurses were asked to what degree they felt that the smart PCA pumps reduced the occurrence of errors in comparison with the old PCA pumps, 100% of them responded that the smart PCA pumps reduced the occurrence of errors to some degree (on a scale of 1–4, 1 signified "no reduction" and 4, "significant reduction").

Finally, when asked how much more confident they were that their patients were receiving the correct dose of their medications when using the smart PCA pumps in comparison with the old PCA pumps, 45% of the nurses stated that the smart PCA pumps give them much more confidence (score of 4), while 9% stated that the smart pumps do not provide any additional confidence (score of 1).

Discussion

The results of our study show that smart PCA pumps had an important positive impact on PCA–related patient safety at UMHS; wrong concentration errors were eliminated, and 159 errors in the adult clinical care area were potentially prevented during a six-month period. Smart PCA pumps have particularly had an impact on errors involving upper hard limits—the errors with the most potential to be detrimental to the patient. These findings were largely reflected in the survey results, which showed that the nursing staff felt that the smart pumps were useful in decreasing the occurrence of PCA–related errors and improving patient safety.

Draper et al. found that pump-programming overrides were identified as a major contributing factor to a patient receiving a dose of fentanyl in less than half the anticipated time.[9] Accordingly, further investigation should be conducted to examine the impact of the upper soft limit values of the drug libraries.[6] These limits were frequently bypassed during the course of our study, and further research is needed to determine if these values should be increased to prevent "alert fatigue" from unnecessary alerts.

Table 7. Nursing Survey Questions and Responses: Features*

On a scale of 1–4, to what degree do you believe the following features of the smart PCA pumps provide added safety to patients in comparison to the old PCA pumps?

	4 (Significant Additional Safety)	3	2	1 (No Additional Safety)	No Opinion	Mean Score
Bar-code scanner	82% –60	15% –11	0% 0	0% 0	3% –2	3.74
Preset dose limits (soft alerts)	58% –41	28% –20	8% –6	0% 0	6% –4	3.32
Preset dose limits (hard alerts)	64% –46	22% –16	8% –6	0% 0	6% –4	3.39
Verification/review screen	77% –54	20% –14	1% –1	0% 0	1% –1	3.71

* PCA, patient-controlled analgesia.

Table 8. Nursing Survey Questions and Responses: Ease of Use, Reduction of Occurrence of Errors, Patient's Receipt of Correct Dose*

	4	3	2	1	Mean Score
On a scale of 1–4, how much easier do you feel the use of the smart PCA pumps is compared to the older PCA pumps? (1 = no easier to use, 4 = much easier to use)	32% (22)	42% (29)	20% (14)	6% (4)	3.00
On a scale of 1–4, to what degree do you think the smart PCA pumps have reduced the occurrence of errors in comparison to the old PCA pumps? (1 = no reduction, 4 = significant reduction)	26% (18)	54% (37)	20% (14)	0% (0)	3.06
On a scale of 1–4, how much more confident are you that your patients are getting the correct dose of their medications when using the smart PCA pups in comparison to the old PCA pumps? (1 = no more confident, 4 = much more confident)	45% (31)	29% (20)	17% (12)	9% (6)	3.10

* PCA, patient-controlled analgesia.

This is particularly true for the upper soft limit value of morphine, which accounted for 40% of the total number of soft alert overrides. At UMHS, data from the PCA smart pumps were used to further tighten the soft limits to avoid potentially nuisance alerts for the PCA pump programmer. Those data were also used in the development of standard PCA order sets in the computerized provider order entry system for opiate-naïve and opiate-tolerant patient populations. Furthermore, PCA prescribing restrictions were eliminated for the patient's admitting service to ensure prescriber education on PCA therapy and accountability for PCA prescribing, while the acute pain service made the transition to a consultative role rather than the sole provider for PCA therapy. The institution's pain management committee provides continual monitoring of the prescribing, pump programming, and alerts and overrides associated with PCA therapy.

A similar smart pump implementation process was conducted in 2004 at Saint Joseph Hospital in Lexington, Kentucky.[3] Analysis of error data showed an overall improvement in the safety of IV medication administration, comparable to what was found in our study at UMHS. One factor identified and implemented by researchers at Saint Joseph Hospital to further improve IV medication administration safety that could also be considered is the implementation of patient-controlled analgesia pumps with end-tidal CO_2 monitoring devices for automatic safety lockout. Capnography allows continuous and instantaneous measurement of end-tidal CO_2 and may be used independently or commonly combined with pulse-oximetry equipment. This could contribute to safety improvement efforts by monitoring to prevent respiratory depression in patients on PCA therapy. This would be particularly useful in patients who are very sensitive to opioid therapy, despite proper dosing and programming. Several root cause analyses conducted at the Veterans Health Administration have found that this technology could have prevented more than 60% of adverse events related to PCA pumps.[10] At the present time, PCA infusion devices have limited end-tidal CO_2 monitoring capacity but may be more common in the future. Pulse oximetry is currently used routinely

with PCA therapy at UMHS as a safety enhancement.

Another area to consider for further advancement of smart PCA pumps is developing a method to correlate the PCA medication order to pump programming to ensure that the programming and the order are synchronized before allowing the pump to start. This would prevent any errors that could occur if programming were incorrect but still within drug library limits. Although manufacturers of PCA pumps have this as a future design objective, none of the vendors currently have this capability.

Limitations

There are several limitations to this study. Some safety features of smart PCA pumps, such as the bar-code scanner catching a wrong drug or a wrong concentration, cannot be captured in a report. As such, it is not possible to quantify the number of errors that were potentially prevented because of this feature, and the smart PCA pumps may be even more effective in preventing PCA–related errors than has been shown here. Another limitation is that the smart pumps do not capture individual patient identification data, so that it is not possible to look back and track patient outcomes. Several limitations relate to the nursing survey. The internal validity of the survey results could have been affected by variables other than the implementation of smart PCA pumps, such as an improvement in the legibility of PCA medication orders (for example, computerized provider order entry was implemented during the two study periods), which could have altered nursing perceptions on the improvement in PCA safety. In addition, the survey results may have low external validity because only nurses at UMHS were surveyed. However, the results may be generalizable to other hospitals with similar staff and patient demographics. Finally, the analysis of the voluntary adverse event reporting system data (study objective 2) includes only a percentage of the total number of PCA–related errors because reporting of errors was voluntary.

Implications

On the basis of our experience, other facilities should adopt PCA devices with additional safety features such as bar-code verification of the drug and concentration, as well as dosage limits, to prevent pump-programming errors. It is critical that hospitals plan to evaluate the data collected by their devices to determine the effectiveness of their soft and hard dose alerts, in addition to other potential opportunities to improve safety in PCA delivery.

A key to success in reducing the potential for medication errors is standardization. Individual health care systems should review and evaluate the current concentrations of infusions used within their facilities and collaborate with nursing and pharmacy to streamline the variability of concentrations available. This will assist in the development of both soft and hard dose alert alarms. Systems should also determine what electronic data from the memory logs are important from a quality perspective and dedicate resources necessary for the continuous review of the data, which can be integrated among nursing, pharmacy, and biomedical personnel. Health care providers should also continue to work with manufacturers of patient care information systems and PCA pumps to move toward a more integrated system in which automatic programming of the pump directly from a verified PCA order can occur without the potential for human programming errors. J

Mai Tran, PharmD, formerly Doctor of Pharmacy student, University of Michigan College of Pharmacy, Ann Arbor, Michigan, is Pharmacist at CVS/Pharmacy, Durham, North Carolina. **Scott Ciarkowski, RPh, MBA,** is Medication Safety Coordinator, University of Michigan Health System, Ann Arbor, and College of Pharmacy. **Deborah Wagner, PharmD, FASHP,** is Pediatric Patient Safety Coordinator and Associate Professor, University of Michigan Health System. **James G. Stevenson,** is Chief Pharmacy Officer, University of Michigan Hospitals and Health Centers, Ann Arbor, Michigan; Associate Dean for Clinical Sciences and Chair, Department of Clinical, Social and Administrative Sciences, University of Michigan College of Pharmacy; and and a member of *The Joint Commission on Quality and Patient Safety*'s Editorial Advisory Board. Please address correspondence to James G. Stevenson, jimsteve@med.umich.edu.

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