Institute for Safe Medication Practices
a nonprofit organization

PCA Drug Libraries:

Designing, Implementing, and Analyzing CQI Reports to Optimize Patient Safety

A CONTINUING EDUCATION PROGRAM FOR PHARMACISTS AND NURSES

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LEARNING OBJECTIVES

After studying this monograph, the reader should be able to:

1. Describe the recommendations of the Institute of Medicine (IOM) report *Preventing Medication Errors* on infusion therapy and the current state of "smart" pump use in U.S. hospitals.
2. Understand the causes of serious adverse drug events associated with PCA infusion.
3. Organize a multidisciplinary team to build a drug library for safe PCA administration.
4. Describe how to utilize data from PCA smart pumps for continuous quality improvement.

Pharmacy Continuing Education

Continuing education (CE) credit will be provided by the Pediatric Pharmacy Advocacy Group (PPAG). PPAG is an approved provider of continuing pharmacy education by the Accreditation Council for Pharmacy Education. This program (180-999-07-504-H04) is approved for 1.5 contact hours (.15 CEUs) of CE credit, and is provided free of charge. Pharmacists who complete the program may take the test and print their CE statements from the Institute of Safe Medication Practices (ISMP) website at www.ismp.org/druglibraryce/default.asp. The release date of this program is May 1, 2007 and the expiration date is May 1, 2010.

Nursing Continuing Education

Debora Simmons Bennett is approved by the California Board of Nurse Examiners as a provider of continuing nursing education. This program (CEP 13677) is approved for 1.0 contact hours (0.1 CEUs) of continuing nursing education. Nurses who complete the program may take the test and print their CE statements from the ISMP website at www.ismp.org/druglibraryce/default.asp. The release date of this program is May 1, 2007 and the expiration date is May 1, 2010.

DISCLOSURE STATEMENTS

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Background on Value and Implementation of Smart Pump Technology for PCA

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The use of the term "smart" pumps refers to drug infusion devices that allow specific drug infusion protocols to be entered into a drug library with pre-defined dose limits. If a medication dose that lies outside of established limits or clinical parameters is programmed into the pump, the pump will halt or provide an alert, informing the clinician that the dose is outside the recommended range established for that hospital or healthcare system. Smart pumps can also integrate patient monitoring and other patient parameters, such as age or clinical condition.

In 2003, the Institute for Safe Medication Practices (ISMP) published recommendations for the safe use of patient-controlled analgesia (PCA) delivered by infusion pumps in the July 24 issue of the *ISMP Medication Safety Alert!* newsletter. Recommendations for PCA safe practices included standardization, limiting the type of pumps utilized in a facility to promote proficiency in programming, and eliminating PCA-by-proxy that occurs when a healthcare practitioner or family member presses the patient's pump activation button for him or her. ISMP also noted that smart pump technology had not been developed for PCA pump therapy.

INCIDENCE OF PROGRAMMING ERRORS

Unpublished preliminary results from the 2004 ISMP Medication Safety Self Assessment® for Hospitals provide perspective on the implementation process for infusion pumps. Fifty-five percent of respondents said that they had fully implemented a multidisciplinary team, involving pharmacists, risk managers, nurses and other hospital personnel in purchasing decisions for medication devices, and 33% reported partial multidisciplinary team involvement in those decisions. Also, 97% reported that the types of PCA pumps used in their hospital are limited to two or less to maximize competency in their use. Self-assessment participants also were asked if literature searches and a failure mode and effects analysis (FMEA) were conducted before they brought new devices into their facility. Results showed that only 22% of participants were fully completing FMEA and literature searches and 37% partially performed them at their facility before they purchased new drug infusion devices.

Adachi and colleagues addressed the role of FMEA in a 2005 study (*Am J Health-Syst Pharm* 2005; 62: 917-20). The study, which was conducted at a 400 bed hospital in San Jose, California, looked at the use of FMEA in improving the safety of IV drug administration. One-fifth of medication errors reported in the facility were attributed to wrong dose errors. Further investigation found that 40% of those errors involved administration of the wrong dose when programming an IV pump. This step in the process also was associated with the highest criticality index of errors reported.

From the FMEA, several safeguards were instituted, such as standardization of drug concentrations used in the facility and incorporating minimum and maximum dose parameters in the IV pump drug library. Results after implementation of the safeguards showed a decrease in programming errors to approximately half of what was reported before the intervention. In 2003, pump-related errors accounted for 22% of dosing errors, compared with 41% in 2002.

USE OF SMART PUMPS TO IMPROVE MEDICATION SAFETY

The 2004 ISMP Medication Safety Self Assessment® for Hospitals also contained an item on the degree of implementation of smart pump technology to help prevent wrong dose infusion errors due to misprogramming of the pump, miscalculation of doses, or an inaccurately prescribed dose or infusion rate. Sixteen percent of respondents reported that they were using smart pump technology throughout their institution for this reason, and another 16% were using it on a partial basis.

The 2005 American Society of Health-System Pharmacists National Survey of Pharmacy Practice in Hospital Settings (*Am J Health-Syst Pharm* 2006; 63:327-45) reported that the use of smart pump technology in hospitals is increasing. Results showed that 32% of hospitals use smart pump technology, with the extent of use varying by hospital size. Of those hospitals that had smart pumps, 84% used them throughout the hospital. Although 77% had extensive drug libraries built into the pumps,

the majority gave users the ability to "opt out" of using safety limits within the drug library.

In 2005, Rothschild and colleagues published the results of a controlled trial on the ability of smart infusion pumps to improve medication safety in critically ill patients at the Brigham and Women's Hospital in Massachusetts (*Crit Care Med* 2005; 33(5): 533-40). The results of the study concluded that frequent medication errors and adverse drug events could be detected by the use of smart pump technology. Although the study showed that implementation of this technology did not measurably impact the medication error rate, this outcome could possibly be attributed to poor compliance in utilizing the safety software. Many users chose to "opt out" of using the drug libraries and thus bypass the maximum dose warnings available in the safety software of these devices.

The study authors concluded that smart pump technology holds great promise and that "nursing behavioral factors" must be addressed to maximize their potential for improving medication safety.

IOM REPORT RECOMMENDATIONS

The 2006 Institute of Medicine (IOM) Quality Chasm Series report *Preventing Medication Errors* advocates a national agenda for reducing medication errors and outlines a comprehensive approach to decreasing their incidence. One of the major recommendations included in the report is widespread adoption of healthcare information technology by healthcare facilities.

The IOM report states that all healthcare organizations should immediately make complete patient information decision support tools available to clinicians and patients. It also suggests that to deliver safe care, healthcare organizations should make effective use of well-designed technologies, including smart infusion pumps.

The report notes that many medication errors resulting in patient harm involve infusion devices, with the most common cause of the errors being incorrect pump programming (*Preventing Medication Errors: Quality Chasm Series*. National Academy of Sciences; 2006: 256). The fact that even small data entry errors can result in numerous unforeseen medical complications that cause patient harm supports the use of smart pumps.

Another key recommendation in the report is a call for industry and government to collaborate on the establishment of standards that affect drug-related health information technologies. The IOM committee suggests that bar coding and smart pumps are widely recommended technologies for which more rigorous testing and sharing of information appears warranted.

The IOM committee strongly supports the importance of communicating necessary clinical information among all who require it, and notes that a key feature of pharmacy database systems, infusion pumps, and bar-code and decision-support applications is the alert function that warns clinicians of potential medication safety problems. This recommendation again emphasizes that having drug libraries with predefined dosing limits as part of infusion pump technology is vital.

Institute of Medicine (IOM) Recommendations/Observations Related to Smart Pump Technology Include:

- All healthcare organizations should immediately make complete patient safety information and decision support tools available to clinicians and patients.
- A key feature of pharmacy database systems, infusion pumps, and bar code and decision-support applications, is the alert function that warns clinicians of the potential medication safety problems.
- To deliver safer patient care, healthcare organizations should make effective use of well-designed technologies…these include smart pump technologies.
- Industry and government should collaborate to establish standards affecting drug-related health information technologies.

SUMMARY

More and more hospitals are implementing smart pump technology. This will have a positive impact on patient safety if drug libraries with pre-defined dose limits and alert functions are incorporated to aid in recognition of errors before the initiation of an infusion.

The 2006 IOM report *Preventing Medication Errors* recommends smart pumps as one technology for medication administration safety and notes that further clinical decision support standardization and studies need to be done. ■

Overview of PCA Infusion Errors

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OPIATES INVOLVED IN MEDICATION ERRORS

High-alert medications bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. Opiate narcotics commonly used in patient-controlled analgesia (PCA), such as morphine, hydromorphone, and fentanyl are considered to be high-alert medications.

One study has shown that approximately one out of four error reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) involve high-alert medications. Of those reports, 44% involved pain management medications often used for PCA, including morphine, hydromorphone, meperidine, and fentanyl.

In addition, PA-PSRS found that 21% of look-alike name errors involved opiate narcotics and included name confusion between morphine and meperidine, as well as immediate release and sustained release opiate products.

FACTORS THAT CONTRIBUTE TO ERRORS WITH PCA THERAPY

Improper Patient Selection

Since an important safety feature with PCA is that the patient delivers each dose, candidates for PCA should have the mental alertness and cognitive, physical, and psychological ability to manage their own pain. However, the benefits of PCA have led some healthcare providers to extend its use to less-than-ideal candidates such as infants, young children, and confused elderly patients.

PCA use in poorly selected patients also has spurred debate about the potential for undertreatment caused by the poorly coordinated efforts of family members (who are not at the bedside continuously) and clinicians, and the inability of these patients to clearly communicate their pain level. Oversedation also has occurred in less than ideal candidates, who are at risk for respiratory depression due to co-morbid conditions such as obesity, asthma, or sleep apnea, or use of concurrent drugs that potentiate opiates.

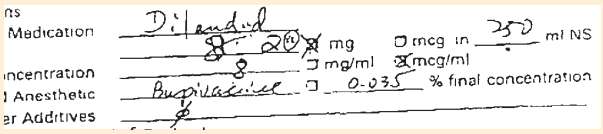
Prescription errors

The PCA order itself can be a source of error. Prescribers have made mistakes in converting oral opiate doses to the IV route (most problematic is hydromorphone, which has an oral to IV conversion range of 3:1 to 5:1) or by selecting an opiate that is not appropriate for the patient, such as prescribing meperidine for individuals with renal impairment. Occasionally, one opiate has been prescribed, but the dose has been for a different opiate.

Even with correct PCA orders, clinicians have been known to mishear verbal or misread written orders, sometimes leading to serious errors. Concurrent orders for other opiates while PCA is in use also have resulted in opiate toxicity. Problems also have occurred when patients are started on PCA therapy but have a documented allergy to the ordered medication. One example includes an order that was given for a "stat" dose of morphine, but the patient had a documented allergy to this drug. Fortunately a pharmacist caught the error and contacted the physician, but not before the nurse had used the override function to remove morphine from the automated dispensing cabinet and administered the drug to the patient.

Errors have occurred even with the use of facility-defined PCA order forms. In one case, a 70-year old patient received a tenfold overdose of hydromorphone. A physician prescribed PCA using hydromorphone 2 mg in 250 mL of sodium chloride 0.9% injection, creating a concentration of 8 mcg/mL (see Fig. 1). While writing the order on a preprinted form, he mistakenly entered the 8 mcg/mL concentration on the wrong line. He quickly recognized his mistake, scribbled over the erroneous 8 mg entry, and wrote the correct dose of 2 mg/250 mL. He then initialed and circled the change.

FIGURE 1.



Unfortunately, the pharmacist mistook the circled initials as a zero and dispensed "20" mg of hydromorphone in 250 mL normal saline, yielding a concentration of 80 mcg/mL. The bag was labeled as "20 mg/250 mL NS," but the concentration was mislabeled as "8 mcg/mL." Before administration, two nurses checked the bag using the original order, but they only verified the labeled concentration and the error was not noticed because the concentration on the order form and mislabeled bag were the same. Later, the night nurse found the error while checking the bag against the original order. The patient exhibited no ill effects.

Drug product mix-ups

Some opiates used for PCA have similar names and packaging, which has led to drug selection errors. Errors have occurred when prefilled syringes of meperidine and morphine have been packaged in similar-looking boxes. Morphine is available in prefilled syringes in two concentrations, but the packaging may not help to quickly differentiate the strengths.

Differentiating between opiates with and without preservatives may be difficult as preservative information may not be prominent on labels. Pharmacy-applied labels may look similar on extemporaneously prepared syringes or bags. Since opiates are typically in unit stock, when a new order is written, the nurse sees the order and takes the medication out of the automated dispensing cabinet (ADC), frequently with no independent double-check. These errors are rarely detected and can lead to significant overdoses.

Name similarities also have led to inadvertent mix-ups between morphine and hydromorphone, or the mistaken belief that hydromorphone is the generic name for morphine. Thirty-two percent of the opiate/narcotic look-alike name reports submitted to PA-PSRS have involved these two drugs. A number of events submitted to national reporting programs involving this combination have been fatal. Contributing factors include the fact that both drugs are available in 1 mg/mL, 2 mg/mL and 4 mg/mL prefilled syringes.

Patient harm has occurred with mix-ups between other pairs of opiates. In one report, a pharmacist prepared an epidural PCA with 50 mg of hydromorphone from a 5 mL, 10 mg/mL ampul, instead of 500 mcg of fentanyl, from two 5 mL, 50 mcg/mL ampuls. Hydromorphone was incorrectly removed from the pharmacy's own ADC module. As a result, two mothers received narcotic overdoses while in labor and they and their babies developed respiratory difficulties.

PCA by Proxy

Safety features exist with PCA therapy to make sure patients do not receive too much analgesia. For example, a lockout interval exists that specifies the minimum amount of time between each dose and a maximum allowable amount during 1- or 4-hour intervals. Another "built-in" safety feature that is often overlooked is that the device is intended for *patient* use. A sedated patient will not press the button to deliver more opiate, thus avoiding toxicity. Family members and health professionals have administered doses for the patient, by proxy, which has resulted in oversedation, respiratory depression, and even death.

Of 15 reports of PCA error by proxy submitted to the U.S. Pharmacopeia (USP) medication error databases, 12 cases were caused by family members, two by a nurse, and one by a pharmacist. Based on this information, the Joint Commission issued a Sentinel Event Alert on errors related to patient-controlled analgesia by proxy (JCAHO, Sentinel event alert: patient controlled analgesia by proxy. 20 Dec 2004; access online at: www.jointcommission.org/SentinelEventsAlert/sea.33.htm).

CAUSES OF PCA PROGRAMMING ERRORS

Misprogramming of the PCA pump is by far the most frequently reported practice-related issue surrounding PCA therapy (*ISMP Medication Safety Alert!*, July 10, 2003; 8 (14)). Practitioners have the opportunity to misprogram PCA pumps by selecting the wrong concentration, wrong basal rate, wrong bolus dose, or wrong lock-out times. In addition, a nurse could enter or program a basal rate that is not ordered for a patient—for example, when there is an order for a bolus dose only.

IV pump keypad design may also cause confusion. Several tenfold dosing errors caused by close proximity of the "zero" and "decimal point" keys on IV pumps have been reported. In each case, the nurse inadvertently pressed the zero instead of the decimal point key when programming the dose.

Double key bounce and double keying is another problem. With key bounce errors, the pump records a number twice although the corresponding key is pressed just once. This can happen when partially pressing the key to a shallow depth.

A smart infusion pump, programmed with patient and drug parameters, may be able to recognize programming errors before PCA infusions begin.

It is difficult to reproduce such errors intentionally; therefore, the problem has often been wrongly attributed to user error. With double keying errors, the key is pressed twice, either intentionally (wrong rate programmed by mistake) or unintentionally. In some cases, the key was purposely pressed twice because there was a delay between when the first key was pressed and when the corresponding number appeared on the screen. These errors have occurred even with newer technology when practitioners have overridden the built-in drug libraries as well as failed to catch programming mistakes on the confirmation screen.

Other PCA pump-related issues that have contributed to mistakes when programming include:

- Pumps that do not require users to review all settings before the infusion starts.
- Pumps that require users to program the dose in mL, not mg, leading operators to overlook the amount of drug the patient is actually receiving.
- Pumps that automatically default to a prior setting if the current setting was not confirmed by pressing "Enter" within a short period of time.
- Manufacturers that have not educated hospitals that they could set default values for PCA drugs by locking out the unused range of numbers.

USE OF SMART PUMP TECHNOLOGY TO HELP REDUCE ERRORS

A smart infusion pump, programmed with patient and drug parameters, may be able to recognize programming errors before PCA infusions begin. Data from smart pumps has shown that errors with PCA therapy have been averted using this technology. The next section, "Preparation and Implementation of a Drug Library for PCA Smart Pumps" (beginning on page 7), discusses this in more detail.

ISMP also has received reports where errors associated with other non-PCA intravenous medications were prevented with the use of this new technology. For example, a physician in an emergency department wrote an order for eptifibatide but inadvertently prescribed a dose appropriate for abciximab. The eptifibatide infusion was initiated and continued for approximately 36 hours after the patient was transferred to a medical/surgical unit. The patient's mental status was deteriorating. At this point, the hospital was switching to a smart infusion pump system that performs a "test of reasonableness" before allowing the infusion to begin. As the nurse was transferring the infusion parameters from the old infusion system to this new system, safety software incorporated in the device alerted the nurse that there was a "dose out of range." The pump would not allow the nurse to continue until a pharmacist was called and the mistake was corrected.

In another case, a hospital's heparin protocol called for a loading dose of 4,000 units followed by a constant infusion of 900 units/hr. The loading dose was administered correctly, but the nurse inadvertently programmed the continuous dose as 4,000 units/hr. Since the pump limit for heparin as a continuous infusion was set at 2,000 units/hr, the infusion device would not start until the dose was corrected.

These mistakes may have gone undetected without the use of smart pumps with preprogrammed limits.

SAFE PRACTICE RECOMMENDATIONS TO PREVENT ERRORS ASSOCIATED WITH PCA THERAPY

PCA errors can be deadly. Special precautions are needed when administering narcotics to patients using this method of delivery, including the following:

1. Limit choices

- Limit the variety of medications used for PCA.
- Restrict fentanyl PCA administration to anesthesia or pain management team members only.

2. Improve access to information

- Develop a quick reference sheet on PCA that includes programming tips as well as maximum dose warnings for each PCA medication in use.

3. Improve label readability

- Match the sequence of information that appears on PCA medication labels and order sets with the sequence of information that must be entered into the PCA pump (or entered into PCA protocols or other related documentation, if applicable).

4. Highlight the drug concentration on labels

5. Program default settings

- Actively query the pump manufacturer to learn about any safety features available with your PCA pumps, and fully employ their use.
- Standardize the concentrations of PCA medications, and whenever possible, set default values for each concentration or lock out inappropriate ranges for the concentrations that the organization does not use.
- If a pump allows default settings to be entered, select "zero" to force an entry.
- Check if pumps can be set to a maximum bolus dose for each medication (at least a maximum volume for each drug).
- Perform regular biomedical checks on the pumps to ensure proper default settings.
- Educate staff about situations where the pump will default to a standard setting.

6. Introduce new pumps slowly

- After performing FMEA on any new PCA pump, introduce the pump initially in a small controlled setting to ensure that the safety features are operational, and to uncover any unanticipated problems.

7. Consider possibility of error

- If the patient is not responding to the PCA doses, consider the possibility an error, especially before administering a bolus dose. Re-verify the drug, concentration, pump settings, and line attachment.

8. Employ double-checks

- Clearly define a manual *independent* double-check process for clinicians to follow when verifying PCA medications, pump settings via a confirmation screen, the patient, and line attachments.
- When possible, use bar-code technology; when available, use "smart" PCA pumps that can alert clinicians to potential programming errors. Note that until an organization implements smart pumps that are adapted for bar coding, automated checks will not replace manual independent double-checks to verify dimensions not covered by the automation.

9. Assess proximity of the PCA pump to the general infusion pump

- To decrease the potential for IV line mix-ups and possible medication errors, the PCA and general infusion pump should not be placed too close to each other.

10. Educate patients

- Educate patients about the proper use of PCA before initiation. Start during the preoperative testing visit so patients are not too groggy to understand. Warn family members and visitors about the danger of PCA by proxy.

SUMMARY

PCA therapy has considerable potential to improve pain management. However, errors with PCA happen, sometimes with tragic consequences. Smart infusion pumps can help in the fight against medication errors.

However, if individual practitioners rely too heavily on technology or abdicate too much of their role to machines, errors will continue to occur. Practitioners still need to read labels, request independent double-checks, question orders for drugs/doses that are illegible or appear unsafe, employ proper patient identification techniques, and use smart pump technology as it is intended to be used.

Error-reduction strategies for PCA therapy should include a balanced approach of practice-related, system-related, product-related, and device-related efforts. By embracing proven prevention strategies, practitioners can help reduce the risks associated with this technology and improve patient safety. ■

Preparation and Implementation of a Drug Library for PCA Smart Pumps

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The University of Michigan (UM) has found that implementing smart pump technology can be a useful tool for preventing errors in patient-controlled analgesia (PCA). UM encompasses a 865-bed academic medical center with a voluntary, non-punitive, web-based error reporting system. Errors, or potential situations for error, are reported through the program to the risk management department. Opiate analgesics are the second most frequent drug class reported.

UM decided to adopt smart pump technology for PCA due to compelling data showing the need for error reduction, a risk management philosophy of zero tolerance for harm, and an organizational quest for continuous quality improvement. The following is an account of UM's process and experience.

PROGRAM ERRORS IDENTIFIED

From January 1 to November 1, 2005, 57 incidents involving intravenous (IV) PCA therapy were reported. About 26% of those incidents involved the wrong dose or the wrong concentration, which parallels national data.

Out of the 57 incidents initially identified, incorrect pump settings for drug concentration were the most frequently reported error. During this time period, the pumps utilized for PCA analgesia allowed bar-code scanning for morphine therapy in the concentration of 1 mg/mL as well as 5 mg/mL. However, two other opiates that were being used for therapy—hydromorphone and fentanyl—were not able to be bar-code scanned. The medications had bar codes on the syringes, but they did not identify what the medication was or the concentration of the syringe.

Hydromorphone ultimately became the drug most associated with PCA therapy errors. Due to the inability to bar-code scan hydromorphone, nurses had to input the concentration of the drug into the syringe pump. However, because of the design of the standard PCA order form, the first entry the nurses made was frequently the PCA dose instead of the drug concentration.

This data entry misstep causes multi-fold dosing errors. For example, assume the concentration of hydromorphone provided by pharmacy is 1 mg/mL and the user entered the concentration as 0.1 mg/mL. If the PCA dose is entered as 0.5 mg, the pump would calculate the infusion volume to be 5 mL. In this example, the concentration programmed was actually 0.1 mg/mL, resulting is a tenfold overdose.

Incorrect PCA dosing was the second most common error reported to the system, and incorrect continuous infusions were third. Incorrect continuous infusions not only included an incorrect infusion rate, but incorrect time intervals as well. The fourth most reported error was the incorrect setting of 4-hour limits for infusions.

CONTRIBUTING FACTORS CONSIDERED

Although double-check processes were in place prior to implementing the smart PCA pumps, it was recognized that human intervention coupled with the multi-tasking required of all healthcare workers makes the double-check a less than reliable intervention to prevent errors.

Initial recommendations to address these factors included adequate bar coding of all PCA syringes and use of an integral bar-code reader to help prevent incorrect programming of concentrations, as well as mandatory annual PCA education and competency for all nurses administering IV PCA.

A recommendation also was made to our senior management team that other technology should be considered to decrease the chance of errors with PCA therapy. As many errors identified involved the incorrect programming of drug concentrations, smart pump technology was recognized as a safety strategy that could potentially eliminate 33% of programming errors.

WORKGROUPS ESTABLISHED

To move forward with the exploration of smart pump technology, a multidisciplinary team within our organization was identified and workgroups established. Workgroups focused on vendors, contracts, software, servers, and equipment implementation. A timeline also was established—our goal was to be at the implementation stage within six months.

One of the largest obstacles faced during implementation was determining what would be required to adopt the technology, including equipment, database support, report designs, and wireless sets for patient care areas.

It was decided that a pharmacist was the best person to be the clinical team leader, as pharmacy deals with every aspect of patient care across our organization. Two teams were formed, one for adult services and one for pediatrics. Team members included a pharmacist from each of the hospitals, not including the lead pharmacist, clinical nurse specialists, a nurse from educational services, and staff nurses.

DRUG LIBRARIES DEVELOPED

The smart PCA pump utilizes a drug library with unique entries for each drug and its corresponding assigned clinical care areas (CCAs). Opiates provided in higher concentrations (e.g., hydromorphone 5 mg/mL) have limited CCAs in which that drug and concentration may be used. For example, if a syringe containing hydromorphone 5 mg/mL is placed into the smart PCA pump, read by the integral bar-code reader, and a CCA selected is "NORMAL ADULT," the pump prints on the screen that the drug/concentration is not allowed for this CCA. This would alert the nurse that the wrong concentration or wrong CCA has been selected.

Adult vs. Pediatric

The smart pump chosen by UM has the option of programming 18 CCAs with 25 different drugs per area. For the adult drug library, different CCAs were identified based upon patient need and parameters established for each dosing area. Adult normal dosing is used for those patients believed to be opiate naïve. High dosing is used for those adult patients who have been identified as more opiate tolerant, and have been receiving analgesics prior to admission to the institution. Maximum dosing is utilized for end-of-life care, as well as for patients with cancer. The goal was to create rational clinical parameters, which were written within a range of safety.

FIGURE 1.

Sample Pediatric Drug Library Template (used to develop all pediatric libraries by weight)

MORPHINE	LHL (Lower Hard Limit)	LSL (Lower Soft Limit)	USL (Upper Soft Limit)	UHL (Upper Hard Limit)
Loading Dose	0.1 mg	0.05 mg/kg	0.1 mg/kg	0.15 mg/kg
Continuous Rate	0.01 mg/kg/hr	0.005 mg/kg/hr	0.03 mg/kg/hr	0.08 mg/kg/hr
PCA Dose	0.1 mg	0.01 mg/kg	0.03 mg/kg	0.08 mg/kg
Dose Limit	0.1 mg	4 times hourly rate	0.4 mg/kg	0.6 mg/kg
Time Interval	5 minutes	6 minutes	30 minutes	60 minutes

Pediatric drug libraries were based upon potency relationship and patient weight, grouped within ranges. CCAs were created based on narrow dose/weight ranges. The range features 2.5 kg for the youngest patient, widening to 5 kg and then to 10 kg as the age of the child increases. See Fig. 1 on previous page for an example.

Pump Parameters

Each patient population in UM's drug libraries was restricted to the use of certain drug concentrations specifically appropriate for that population. If the drug is allowed in a given CCA, then each parameter entered thereafter is checked against the library. The library contains "soft limits"—best described as warning messages to alert healthcare practitioners to test the reasonableness of a parameter that is higher than normally expected. However, the nurse has the ability to confirm the entered parameter and continue on to the next programming step. If a "hard limit" alert is triggered, the parameter entered is not allowed and the nurse must reprogram the dose not to exceed the hard limit.

Development of limits was a challenge and parameters were revised multiple times before endorsement and approval was gained from the appropriate committees. The goal was for alerts not to appear so frequently that they became routine and therefore potentially ignored, which would have little safety value. We also needed to be able to accommodate the needs of patients who had cancer but were just starting on opioid therapy as well as those who were more opiate tolerant or had a history of substance abuse.

The pump allows for considerably larger dose ranges than we wished to use for our drug library. For example, fentanyl in a concentration of 10 mcg/mL concentrations, can be programmed using a loading dose range as little as 1/10 of the drug concentration (1 mcg in this example) or as large as ten times (100 mcg) the drug concentration. Our libraries used much tighter dosing ranges. Using the same example of fentanyl 10 mcg/mL and a CCA based on a pediatric weight of 5–7.4 kg, the loading dose range for this drug is only 1 to 14 mcg.

IMPLEMENTATION PLANNED

The workgroups decided to have a two-week implementation that included installation of new IV PCA pumps, new adult PCA orders, and a newly revised PCA policy to ensure a complete change.

Two weeks before implementation, a series of 20-minute inservices were held to impart information on the new policies, such as required independent double checks for all PCA parameters programmed. Nurses also were being educated on nurse-controlled and caregiver-assisted PCA dosing, sleep apnea, and obesity, as well as specific PCA information concerning the CCAs. More than 850 nurses attended the inservices, which included super-users—individuals identified as being able to serve as a resource for nurses newer to the institution.

The goal was for alerts not to appear so frequently that they became routine and therefore potentially ignored, which would have little safety value.

The 0.5 mg/mL concentration of hydromophone was selected for training, since both pediatric and adult nurses would be administering it and hydromophone was the medication most associated with PCA errors. Every nurse who attended the inservice demonstrated the ability to program a pump and run through a skills checklist. Nurses were able to view their own errors, as well as see the pump catch the error and potentially prevent patient harm.

The inservice was designed to encourage critical thinking. Staff were encouraged to ask whether an order was too low or high, a dose was being tapered, an override was appropriate, or whether a patient was opioid tolerant. The nurses were encouraged to think about whether to call the prescriber when what they were seeing on the order did not match what was seen clinically.

DATA SUBSEQUENT TO IMPLEMENTATION

During June of 2006, two weeks after the program was implemented, there were a total of 2,950 PCAs programmed. There were no pump alerts triggered for 88% of the CCAs programmed. Approximately 8% of alerts were overrides, meaning alerts were triggered and the responding nurses decided that the overrides were appropriate for the patient. Hard limit editing occurred in 2.5% of the pump data entries.

TABLE 1.

Pediatric Error Prevention Rates Using Smart PCA Pumps

Drug	Total # Patients	Hard Limit Alerts (% of total patients)	Soft Limit Alerts with Edits (% of total patients)	Total Potential Errors Prevented (% of total)
Morphine	144	8 (5.6)	2 (1.4)	10 (6.9)
Hydromorphone	48	14 (29.2)	2 (4.2)	16 (33.3)
Fentanyl	1	0 (0)	0 (0)	0 (0)
TOTALS	**193**	**22 (11.4)**	**4 (2.1)**	**26 (13.5)**

TABLE 2.

Adult Error Prevention Rates Using Smart PCA Pumps

Drug	Total # Patients	Hard Limit Alerts (% of total patients)	Soft Limit Alerts with Edits (% of total patients)	Total Potential Errors Prevented (% of total)
Morphine	490	10 (2)	9 (1.8)	19 (3.9)
Hydromorphone	161	26 (16.1)	9 (5.6)	35 (21.7)
Fentanyl	11	1 (9.1)	0 (0)	1 (9.1)
TOTALS	**662**	**37 (5.6)**	**18 (2.7)**	**55 (8.3)**

Data from September 2006 does not show a significant difference from the June 2006 data. In September, 2,400 doses of PCA were administered—89% of those were programmed correctly. Of the alerts that were triggered, 7% of the entries were overridden, and 2.4% exceeded the hard limits in the PCA libraries.

PATIENT SAFETY BENEFITS

In an effort to demonstrate the potential patient safety benefits observed with the PCA smart pump, one month of data was examined. Data were collected approximately five months after implementation. This provided sufficient time for all end users to gain experience and confidence in using the new technology.

To our knowledge, since introduction of the smart PCA pumps, errors involving the initial programming step of entering a drug concentration have been eliminated. Pharmacy now prepares all concentrations of PCAs and places a pharmacy-generated bar-coded label on the barrel of the syringe. To eliminate the possibility that pharmacy could label syringes incorrectly, human independent double-checks are validated using a table-top fluorometer. When the syringe is placed into the smart PCA pump, the pump automatically reads the bar code and populates the drug name and strength on the screen for the nurse to check and confirm.

If one assumes that all recorded hard stops and all soft stops with subsequent parameter changes may have resulted in errors without the smart pump library, it is possible to determine an approximate total number of errors prevented. Tables 1 and 2 summarize UM's one–month data analysis. Fig. 2 shows an example of an error report that can be generated from a PCA pump to provide data on errors that have been avoided.

The data suggest several points worthy of mention. The number of potential errors with hydromorphone is higher than with morphine. We believe this is due to misunderstanding of the dosing relationship between morphine and hydromorphone. Because of this, the drug libraries for hydromorphone have tighter parameters, which helps to explain why more hard and soft limit alerts were observed in both the pediatric and adult populations.

The data collected for a single month in 2006 reflect a potential of 81 errors prevented with the use of a smart PCA pump for a total potential error reduction of 9.5% in patients who are receiving PCA therapy. Given the seriousness of opiate-associated medication errors, this represents a substantial improvement in patient safety.

SUMMARY

For successful implementation of PCA smart pump technology, which can make a significant impact on patient safety, it is important to organize a multidisciplinary team and identify critical team members for development of a drug library.

Drug libraries should be developed to meet the needs of the opiate naïve patient as well as cancer patients and those more tolerant to opioids. Staff education should be developed to foster the critical thinking of end users. The drug libraries for pediatric patients, by necessity, must be established with tighter limits to maximize the safety of patients receiving opioid pain management therapy. ■

FIGURE 2.

Sample Report of Hard Limit Alert Details

Medication/Concentration	Rule Set	Limit	Limit Violate	Initial Value	Final Value
Adult Normal					
Morphine 30 mg/30 mL	Continuous Rate	4 mg/hr	↑Upper	40 mg/hr	1 mg/hr
Dilaudid 15 mg/30 mL	Loading Dose	2 mg	↑Upper	20 mg	0.2 mg
Pediatric 25–29.9 Kg					
Dilaudid 3000 mcg/30 mL	Continuous Rate	330 mcg/hr	↑Upper	1000 mcg/hr	100 mcg/hr

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Self-Assessment Questions

To take the continuing education (CE) test, please go to the ISMP website (www.ismp.org/druglibraryce/default.asp) and complete the answer sheet and evaluation. A passing grade of 70% is required to qualify for CE credit. Upon successful completion of the test, you will be able to print your CE statement. If online access is not available, please mail the completed test along with your name, address, and contact information to: ISMP, c/o Continuing Education, 1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006. You can contact ISMP directly at 215-947-7797.

1. The most common cause of errors in the use of drug infusion devices is (are):

a) Inaccurately prescribed dose
b) Miscalculation of dose
c) Incorrect pump programming
d) All of the above

2. The Institute of Medicine recommendations and observations related to smart pumps include(s):

a) A key feature of pharmacy database systems, infusion pumps, and bar-code and decision-support applications, is the alert function that warns clinicians of the potential medication safety problems
b) To deliver safe drug care, healthcare organizations should make effective use of well-designed technologies…these include smart pump technologies
c) Industry and government should collaborate to establish standards affecting drug-related health information technologies
d) All of the above

3. According to the 2004 ISMP Medication Safety Self Assessment for Hospitals®, how many hospitals are using smart pump technology to prevent wrong dose infusion errors?

a) 5%
b) 16%
c) 27%
d) 40%

4. Medications involved in reported errors with PCA therapy have occurred with:

a) Morphine
b) Fentanyl
c) Hydromorphone
d) Meperidine
e) All of the above

5. Safe practice recommendations to prevent errors associated with PCA therapy include all of the following except:

a) Limit the variety of medications used for PCA
b) Highlight the drug concentration on labels
c) Develop a reference sheet on PCA that includes programming tips and maximum dose warnings
d) Allow pumps to automatically default to prior settings if current settings are not confirmed
e) Employ double-checks

6. PCA by proxy, which refers to family or others aside from the patient controlling the dosing button, has resulted in:

a) Better patient pain control
b) Less respiratory depression
c) Oversedation, respiratory depression, and death
d) None of the above

7. What principles were used to develop the University of Michigan's drug libraries for their pediatric patient population?

a) Proportions
b) Weights
c) Potency relationships
d) All of the above

8. If a nurse places a syringe in an IV PCA pump with an integrated bar-code reader, which is specifically bar coded with a drug and its concentration, the pump will read the bar code and allow programming:

a) If the drug and concentration are correct for the CCA chosen
b) If the ordered dose is within the predetermined parameter range
c) If the dose is incorrect, but is still within the parameters identified
d) All of the above

9. Drug libraries for smart infusion pumps should contain lower and upper hard stop limits in order to realize their full potential for preventing errors in prescribing and pump programming.

a) True
b) False

10. A "soft limit" will generate an alert but allow the healthcare practitioner to bypass the alert without any further action.

a) True
b) False

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