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Patient-Controlled Analgesia-Related Medication Errors in the Postoperative Period

Causes and Prevention

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Abstract

Patient-controlled analgesia (PCA) is a common and effective means of managing postoperative pain. Unfortunately, the complex processes and equipment associated with the setup, programming and administration of intravenous or epidural PCA have allowed it to become a significant source of preventable medication errors. These errors can be classified into two major categories: human (operator) errors and equipment errors (malfunctions). Such errors are potentially harmful to patients, time-consuming for hospital staff and costly for healthcare providers. The objective of this article is to describe PCA medication errors and examine systems and modalities that may help reduce the incidence of system-related errors. Data from the US FDA's Manufacturer and User Facility Device Experience (MAUDE) database indicate that 6.5% of intravenous PCA-related events were due to operator error. Most (81%) of these errors were due to pump misprogramming, of which almost half were associated with patient harm; 76.4% of adverse events were attributed to device malfunction (e.g. due to frayed wires or a crack in the drug cartridge), although only 0.5% of these were associated

with harm to patients. In a report based on data from MEDMARX®, a voluntary database that captures reports on medication errors, 7.9% of the PCA-related errors captured over a 5-year period were described as causing harm to patients. Technological advances, such as improved PCA pump designs based on ergonomic and cognitive engineering principles, the use of barcode technology and other 'smart pump' safety features, and new postoperative pain management modalities, may play a significant role in reducing the future incidence and severity of PCA medication errors.

An estimated 44 000–100 000 fatalities and 1.3 million injuries occur each year as a result of medical treatment.[1-3] Studies have shown that 19.4% of adverse events are treatment related.[1,3] Some of these are the result of medication errors, which are preventable mistakes that may occur at any point during the medication delivery process, including ordering, transcribing, dispensing and administering medication and patient monitoring.[4] It has been reported that errors occur in 5.3% of all medication orders.[2] Actual medication error rates, however, are likely to be higher, as most medication errors are not documented.[5] Each year, medication errors result in approximately 7000 deaths,[2] as well as other serious adverse drug events (ADEs).

Although not all ADEs are the result of medication errors (e.g. predictable adverse effects accompanying drug treatment such as hair loss following chemotherapy), 30–50% of ADEs are attributable to this cause.[6,7] Additional consequences of medication errors in the hospital setting include prolonged patient hospitalization, consumption of staff time and increased resource utilization. For example, the annual incremental healthcare costs associated with medication errors in the US were estimated in 2006 to be approximately $US3.5 billion.[8] Given this, and the fact that 1.33% of medication errors cause harm to the patient,[9] reducing the incidence of medication errors would significantly improve the current status of healthcare in the US.[10,11] Achieving significant reductions in medication error incidence rates is an important initiative that will require involvement from multiple sectors of the healthcare system.

Identifying the sources of medication errors is important to correct the causes. In the hospital setting, patient-controlled analgesia (PCA) is a known source of errors,[9,12] especially in postoperative care. Primarily administered via intravenous (IV) or epidural administration routes, PCA is commonly and effectively used to manage acute pain.[13-20] This analgesic modality has revolutionized postoperative pain management by allowing patients control over their own pain relief, thereby reducing lapses in pain relief (analgesic gaps).[13,16,21,22] A meta-analysis[23] of 55 randomized controlled trials that evaluated PCA versus conventional analgesia found that PCA provided better pain control and increased patient satisfaction. In addition, PCA may be a more time-efficient option for nurses, allowing them time to take care of other patients rather than attending to analgesic delivery needs. However, while effective, PCA use has introduced new sources of medication errors. One analysis[24] estimated that more than 13 million patients receive IV PCA in the US annually, and approximately 4.5% of those patients experience an error. One possible explanation for these errors is that IV and epidural PCA administration involve processes that require the coordination of several hospital departments, and the programming of PCA pumps requires attention to detail.[25] Furthermore, PCA pumps utilize different types and dosages of opioids, which are described by the Institute for Safe Medication Practices as 'high-alert' medications and are associated with a significant number of medication errors.[26] Combining the 'high alert' status of opioids with the complex equipment and processes associated with epidural and IV PCA presents an opportunity for numerous medication errors, some potentially fatal, resulting from human- or equipment-related factors. The objective of this

review article is to describe PCA medication errors and examine systems and modalities that may help reduce the future incidence of these errors.

1. Analgesia as a Contributor to Patient Risk

Many types of medication errors occur with analgesia treatment. One review of the biomedical literature published in 2003 indicated that analgesics were associated with 12.8% of all preventable ADEs;[27] only cardiovascular drugs (17.9%) and psychoactive and CNS agents (15.3%) were associated with more preventable ADEs. Opioids are the most common analgesics used during PCA treatment and are associated with more analgesic-related medication errors than any other drug class.[27-35] In particular, opioids have been cited as the most common 'intended' analgesics in instances when an incorrect drug was administered to patients.[36] In 2006, the 5 Million Lives Campaign, an initiative intended to reduce medication-related harm for 5 million patients between December 2006 and December 2008, noted opioids as one of four groups of medications (along with anticoagulants, insulin and sedatives) that are particularly likely to cause harm to patients, even when used as intended.[37] Common ADEs associated with opioids that may occur with correct or erroneous administration include nausea and vomiting, pruritus and constipation.[38,39] However, opioids may also be associated with respiratory depression, which can be fatal.[23] The incidence of respiratory depression in patients treated with opioids via PCA ranges from 0.1% to 3.9%, depending on the opioid used and the method of administration.[17]

While opioids may be associated with ADEs and pose an inherently increased risk of medication errors, opioid use during PCA treatment in particular may be associated with a number of unique medication errors.[14,17,40-51] As illustrated in figure 1, the administration of PCA requires a prescription from a licensed prescriber, preparation by the pharmacist, the assembly and programming of a PCA pump by a nurse or physician, and PCA pump activation by the patient.[25] As a result, there are multiple steps during drug delivery at which various types of medication errors (e.g. administration of the wrong analgesic, PCA pump misprogramming or false triggering of the PCA pump) may occur.

2. Classification of Patient-Controlled Analgesia (PCA) Errors

Having identified PCA as a frequent source of medication errors, it is then important to classify the various types of errors that may occur. By doing so, one can pinpoint areas of system-, process- or device-related medication errors that can be targeted to reduce future errors. The National Coordinating Council for Medication Error Reporting and Prevention *Taxonomy of Medication Errors* describes five main causes of medication errors: communication, name confusion, labelling, human factors and packaging /design.[52] While appropriate for categorizing the causes of medication errors on a general level, this taxonomy is less suited for categorizing PCA-related errors, a significant source of which is the technology used to deliver PCA. Accordingly, Doyle[53] previously described a taxonomy for categorizing potential PCA-related safety hazards using 13 different error groups (table I). By definition, not all of these PCA-related hazards have the potential to result in true medication errors (for example, unknown patient sensitivity to opioids or pump reprogramming with criminal intent). However, failure to recognize or avoid most of these hazards can result in medication errors and potential harm to the patient. Ultimately, the hazards encountered with PCA use can be divided into two main overarching categories: human errors and equipment errors.

2.1 Potential Causes of Human-Related PCA Errors

Errors in prescribing or ordering contribute substantially to preventable ADEs.[28] In a prospective observational study of patients in a medical/surgical intensive care unit,[54] most preventable ADEs occurred during drug

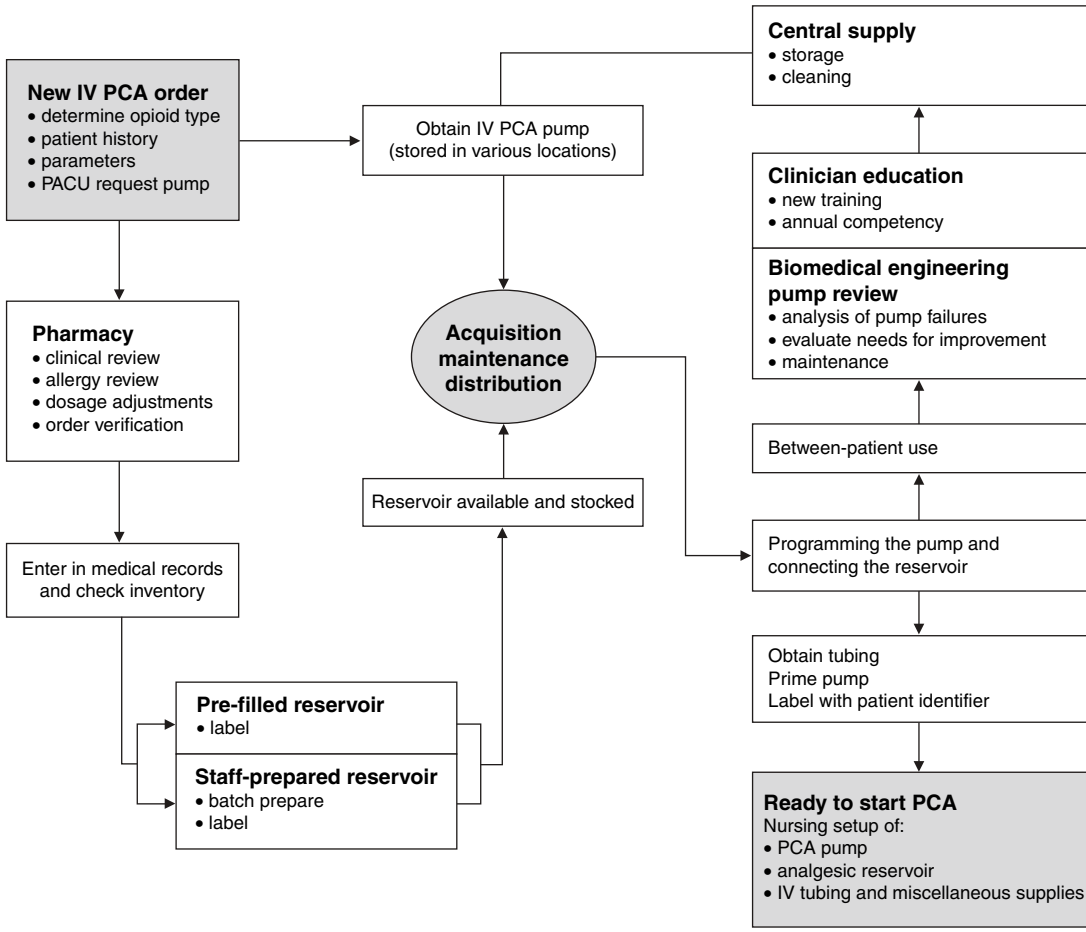

Fig. 1. Steps involved in the administration of intravenous (IV) patient-controlled analgesia (PCA).[25] This diagram demonstrates the complexity of the process of administering IV PCA, from the starting point of patient screening to the endpoint of actual administration (reproduced from Hutchison et al.,[25] with permission from Hospital Pharmacy). **PACU** = postanaesthesia care unit.

prescription (77%). A larger prospective study of 4031 adult patients admitted to 11 medical and surgical units in two tertiary-care hospitals over a 6-month period likewise found that a majority (56%) of medication errors occurred at the ordering stage, with incorrect dosing as the most common ordering error, followed by inappropriate medication choice, prescription of a medication to which the patient was allergic, ordering at the wrong frequency of administration, and failure to anticipate a drug-drug interaction.[28] Execution of treatment is another step in the process of providing medication where human error may occur. In fact, in a prospective observational study of critically ill patients,[55] the most common of 277 serious medical errors were associated with both the medication ordering process and execution of treatment, including wrong dosage (22.4%) and duplicate medication orders (7.6%).

Once a medication is ordered, errors in the hospital pharmacy's medication ordering and dispensing process may contribute to medication errors. Such errors include a failure to identify provider ordering errors (e.g. incorrect dosing or prescription of a medication to which a patient is

allergic). While the biomedical literature does not specifically identify pharmacy ordering and dispensing as a source of PCA-related errors, mistakes in ordering and dispensing are a notable source of medication errors in general[28,56,57] and are errors to which current IV and epidural PCA modalities are not immune. Most hospital prescriptions are filled in a two-step process, in which pharmacy technicians fill drug orders and pharmacists verify the orders.[56] This protocol is effective for catching many prescription errors before the product leaves the pharmacy. Reported rates of pharmacy dispensing errors range from 0.0041% to 3.6%.[28,56,58-60]

However, errors may still occur despite this two-step process and can have significant and even fatal consequences. In one observational study of a tertiary-care hospital pharmacy, 3.6% of all orders were filled improperly by pharmacy technicians, and 0.75% of all orders were approved to leave the pharmacy with undetected errors.[56] The errors identified in that study included dispensing of incorrect medications (36%), incorrect medication strength (35%) and incorrect dosage form (21%).[56] Given the annual number of medication orders filled by the hospital pharmacy where the study was conducted (6 million), these data suggested that 45 000 dispensing errors would have left the pharmacy each year, with 10 600 having the potential for patient harm.[56]

Table I. Patient-controlled analgesia (PCA)-related safety hazards[53]

Use of wrong analgesic or wrong analgesic cartridge
Accidental pump misprogramming
False triggering (e.g. PCA button short circuit)
False triggering by proxy (e.g. activation of PCA pump by nurse/visitors)
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[a]
Retrograde flow of PCA analgesic into a second IV set due to catheter blockade
Bad medical judgement in formulating a PCA prescription or order
Anaphylaxis
Unknown sensitivity of the patient to opioids resulting in respiratory depression
Reprogramming with criminal intent[a]

a Hazard is theoretical at this time.

IV = intravenous.

Finally, human-related PCA medication errors may result from errors that occur during pump programming or pump activation.[7,14,17,40-46,49,50] The use of PCA pumps is relatively complex[25] and often requires significant training for proper setup and monitoring. Complicating the situation, poorly designed interfaces on some PCA pumps have been cited as a significant source of PCA pump-related human errors.[47,48,61-63] Because of the complexity of PCA pumps, stringent protocols are required to help reduce the risk of errors; dangerous errors, including the administration of an incorrect drug, may result when these protocols are not followed.[17] Other sources of human error include accidental activation of drug delivery by the patient or family members,[64,65] PCA pump activation by proxy (i.e. someone other than the patient),[51] misunderstanding of device use by the patient[66] and poor judgement by physicians in prescribing drugs or considering the risk of a known ADE,[53] all of which have the potential to result in preventable opioid-related ADEs. Variability in drug names, concentrations, dose limits and administration practices[67] also make it difficult to standardize PCA safety recommendations, and have the potential to result in the administration of the wrong drug, the wrong dose, the wrong infusion time and/or the wrong lockout interval.

2.2 Potential Causes of Equipment-Related PCA Errors

Pump malfunction or other equipment-related errors are another significant source of PCA medication errors.[68-71] Potential causes of equipment-related PCA errors include short circuits caused by frayed wires,[72] poorly designed pump user interfaces,[73] drug accumulation in IV deadspace[74] and siphoning due to a crack in the drug cartridge,[75] any of which may lead to either false triggering or accidental drug delivery by the PCA device. Malfunctions of PCA pumps have

also been reported when they were used in a hyperbaric environment[76] or in close proximity to an MRI machine.[77] All of these errors have the potential to result in under- and/or over-dosing.

3. Device and Medication Error Reporting Databases

To determine the impact of the many theoretical hazards associated with PCA use, medication error databases may be utilized to determine the actual significance and incidence of PCA-related errors. There are two major error-reporting databases that can be used to track the incidence, type and severity of PCA-related medication errors: (i) the US FDA's Manufacturer and User Facility Device Experience (MAUDE) database; and (ii) the United States Pharmacopeia (USP) MEDMARX® database.

3.1 Manufacturer and User Facility Device Experience (MAUDE) Database

The FDA Medical Device Reporting regulations require device manufacturers and user facilities to report any postmarketing complaints or adverse events related to device malfunctions, including serious injuries and deaths.[78] The MAUDE database is the publicly available repository of these reports.[78] Each error report includes information about patient outcomes that result from the event, information about the device used during the event and narrative text provided by the device reporter and/or device manufacturer about the events, their causes, patient outcomes and results of any manufacturer device testing. In order to assess the nature of IV PCA-related error reports, an analysis of the MAUDE database between January 2002 and December 2003 was undertaken.[79] Of the 2009 IV PCA-related events identified, 1590 events (79.1%) were possibly related to the PCA device. Specifically, 76.4% of events were suspected to have resulted from device defects, including a defective reed switch; a defective motor; and battery, display board or software problems.[79] Pump manufacturers confirmed 64.9% of the suspected device malfunctions. Of the 2009 IV PCA-related reports, 131 (6.5%) were suspected to be due to operator (i.e. human) error; an overwhelming number of these (106) were the result of PCA pump programming errors.[79] Upon further review of the error reports to determine patient outcomes associated with IV PCA-related events, only 0.5% of events possibly related to device malfunction were associated with harm to the patient; conversely, 48.1% (63 of 131) of events related to operator error and 29.1% (48 of 165) of events related to over-delivery of drug by indeterminate cause were associated with harm to the patient. Collectively, these data suggest that equipment errors are the leading cause of PCA-related medication errors recorded in the MAUDE database. However, the MAUDE database may not have fully captured events that were considered to be unrelated to device malfunction, such as prescribing errors.

3.2 MEDMARX® Database

MEDMARX is a voluntary and anonymous online medication error reporting database that contains over 1.3 million reported medication errors.[80] One of the largest voluntary reporting databases in the US, MEDMARX was developed by the USP and unlike the MAUDE database, which only records device-related errors, receives reports about any type of medication error, including those that might be device-related. In one analysis,[81] the USP examined the frequency and type of PCA-related errors reported during a 5-year period (1998–2003) and found that a total of 5377 PCA-related errors were reported during this timeframe. Of these, 7.9% were described as having caused harm to the patient. This frequency is 3.5-fold greater than the average overall harm rate for MEDMARX errors.[81] The most common PCA-related errors identified by the MEDMARX system included improper dose/quantity (38.9%), unauthorized drug (18.4%) and omission error (17.6%).[81]

In a more recent analysis of the MEDMARX database,[82] the frequency, type and cause of PCA-related errors reported from 2000 to 2005 were examined. Of 919 241 errors recorded in the database during this time period, 9571 involved

PCA. The most common causes of PCA-related errors included human factors (69.8%) and equipment-related factors (19.5%). Events that resulted in patient harm were more common for PCA-related errors (6.5% of events) compared with non-PCA-related errors (1.5% of events); therefore, the overall risk of harm was 4.3-fold higher for PCA-related errors compared with non-PCA-related errors.[82] Like the observations in the aforementioned MAUDE database analysis,[79] these findings suggest that improvements to current PCA processes and modalities are needed to reduce the incidence of medication errors.

4. Reducing PCA Medication Errors

The Institute of Medicine has suggested that the majority of medication errors ultimately result from failure of the healthcare system as a whole.[2] Improving patient safety requires system-wide changes. Innovations and improvements to existing PCA practices, the development of new PCA modalities and the evolution of computer pump technology will all be likely to play a role in reducing the incidence and severity of PCA-related medication errors in the future. New PCA modalities should aim to reduce system-related errors rather than only addressing the human-related errors that may occur.

Advances in infusion pump technology are important for reducing IV infusion pump-related medication errors.[83,84] For example, 'smart' infusion pumps have been developed to help reduce the risk of pump programming errors. These pumps provide feedback to the programmer regarding drug doses and infusion rates and have drug libraries incorporated into their programs.[83,84] Even so, the potential for medication errors is not completely eliminated with smart pump technology. This was demonstrated when one smart IV pump (ALARIS Medical Systems [now Cardinal Health] Guardrails, version 5.0, Dublin, OH, USA) was subjected to failure modes and effects analysis, a common human factors method used to prospectively isolate and remove known and potential flaws from a system, process or equipment design before it reaches the user.[85] For example, while the new smart IV pump design reduced sources of incorrect dosing, errors due to tubing misplacement were identified that could cause over- or under-infusion of the drug and were not evident in a non-smart IV pump (Deltec 3000, Deltec Inc. [now Smiths Medical MD, Inc.], St Paul, MN, USA).[85] This case example illustrated the challenges associated with new complex pump technology, namely that intended improvements in design may bring about unintended new hazards.

The development of new postoperative pain management modalities that move away from infusion pumps may address the drawbacks of current techniques and potentially reduce medication errors. One example of such a modality is the needle-free, preprogrammed, self-contained fentanyl HCl iontophoretic transdermal system (fentanyl ITS; IONSYS™, Ortho-McNeil, Inc., Raritan, NJ, USA). As described in section 2.1, the use of current PCA pump modalities is complex, requiring the coordination of multiple steps between several hospital departments for the administration of analgesia, such as pump acquisition, maintenance, distribution and setup; drug reservoir ordering and acquisition; and training of hospital staff on proper programming and maintenance of the system.[25] In contrast, the design of fentanyl ITS eliminates the risk of programming errors and pharmacy mistakes, and substantially reduces the number of steps and hospital departments involved.

In order to compare the potential of new PCA modalities to reduce the risk of medication errors, it is useful to use models of human cognition, such as Rasmussen's 'skills-rules-knowledge' model,[86] the cognitive levels of which span the spectrum from automatic ('skills'-based) to analytical ('knowledge'-based). Using this model, two broad categories of behaviour requiring different levels of cognitive demand can be identified: 'analytical'- or knowledge-based behaviour and 'perceptual'- or skills- and rules-based behaviour.[86] Based on cognitive demands, the administration of IV PCA requires working at the 'knowledge-based' or 'analytical' level, which is generally slow, demanding, serial and more error-prone. However, using a modality such as

fentanyl ITS promotes working at the 'perceptual-based' level, which is generally fast, effortless and less error prone.[86]

The use of computers and information technology has also been suggested to be one of the primary ways to reduce the incidence of medication errors.[1,87-93] Computerized physician order entry systems allow physicians to order medication electronically (as opposed to handwriting orders), help standardize clinical practice, improve interdepartmental communication, and capture data for tracking and research purposes.[90,91] Clinical decision support systems aid physicians in making decisions regarding drug choice and dosage regimens, and may incorporate patient- and pathogen-specific information as well.[89] Computerized drug allergy checking systems show promise in being able to significantly reduce the incidence of preventable allergic reactions,[90,94,95] and barcode technology has been shown to substantially decrease dispensing errors and reduce the risk of potential ADEs.[92] Alerts issued by barcode technology have also been shown to limit administration errors by reducing errors associated with giving the incorrect medication, treating the wrong patient or giving medication at the wrong time.[92,96]

Technological advancements, such as smart pumps, fentanyl ITS and improved information technology, have the potential to significantly decrease the incidence of PCA-related medication errors. However, it is important to note that the complete elimination of errors may not be feasible. The key to reducing medication errors in the future is to minimize the opportunities for their occurrence by limiting the requirement of hospital staff members to work at the 'knowledge-based' or 'analytical' level, and by implementing systems and modalities that promote working at the 'perceptual-based' level, which, by nature, will better synchronize mechanical design with innate human cognition processes.

5. Conclusions

Medication errors associated with PCA administration are a significant source of preventable patient morbidity, mortality and hospital resource utilization. Many PCA-related errors are particularly dangerous because the medications involved (i.e. opioids) have narrow therapeutic indexes, and relatively small mistakes in dosing concentrations or lockout intervals can have serious or even fatal consequences. In addition, patients are generally in a medically vulnerable state when undergoing PCA treatment, which may limit their ability to alert hospital staff members when something is wrong.

Many PCA-related medication errors result from human errors, highlighting the potential safety hazards of PCA modalities that have a complex design, as well as the need for system-wide improvement. Technological advances, such as improved PCA infusion pumps and new post-operative pain management modalities, may play a significant role in reducing the future incidence and severity of PCA medication errors. Increased use of computerized ordering systems and databases may also provide insight into the sources of PCA medication errors and may eventually lead to improved guidelines and standard practices for limiting their incidence.

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