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Provider issues related to patient controlled analgesia and nurse controlled analgesia errors in a pediatric hospital

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BOSTON UNIVERSITY

SCHOOL OF MEDICINE

Thesis

**PROVIDER ISSUES RELATED TO PATIENT CONTROLLED ANALGESIA
AND NURSE CONTROLLED ANALGESIA ERRORS IN A PEDIATRIC
HOSPITAL**

by

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ABSTRACT

Background

Medical errors are a danger to patient safety and a significant cause of morbidity and mortality. Additionally, they increase expenditures in an already significantly indebted U.S. health care system. Much confusion exists about definitions of medical errors, which include medication errors and adverse drug events (ADEs). Several federal and international organizations have attempted to standardize definitions in order to streamline data collection, but until these standards are universally adopted, error reports and trends are still subject to questions of validity. Reporting errors, in general, has become a more socially acceptable practice in health care with the advent of several anonymous reporting databases. There have also been several initiatives aimed at reducing the incidence of errors, which range from national programs to intrafacility guidelines. Several pieces of health information technology (HIT) have made an impact on error incidence and data collection, although there is much room for improvement. Patient controlled analgesia (PCA) pumps for pain management have been in existence for decades, and “smart pump” software has improved their safety and ease of programming. PCA use in children presents challenges to clinicians, and the

characteristics of providers who write PCA orders and those who program PCA pumps may play a role in the incidence of events related to PCA. This study seeks to elucidate trends in errors as they related to these different PCA providers in a pediatric hospital in the northeastern U.S. and provide recommendations for how PCA practice can be improved in this facility.

Methods

Safety Event Reporting System (SERS) reports of PCA events (n = 117) during the period of 2004 – 2012 were analyzed retrospectively to determine several key variables for data analysis. The main focus of this analysis was those variable trends related to providers, including: proportion of events caused by human error, proportion of events related to subcategories of human error, proportion of types of prescribers involved in PCA events, proportion of errors in medical and surgical patients, proportion of errors occurring on day and night shifts for the nursing staff, and proportion of events that were dosing mistakes. Statistical analysis was performed for these results when possible to determine significance.

Results

Human errors were implicated in 84.1% of events, whereas PCA pump mechanical errors and software errors were implicated in 7.1% and 7.9% of events, respectively. Statistically significant differences were found in all variables tested, including the proportion of nursing errors (60.9%) versus prescriber errors (28.7%) ($p < 0.0002$). For types of prescribers, the proportion of PCA events occurring when a M.D. wrote the PCA order (56.41%) was statistically different than when a N.P. wrote the PCA

order (39.32%) ($p = 0.0129$). More surgical patients (61.5%) were affected by PCA events than medical patients (36.8%) ($p < 0.0002$). There were more events occurring on the nursing staff day shift (59.8%) than the night shift (36.8%) ($p = 0.0004$). Finally, dosing mistakes (66.7%) were implicated in significantly more PCA events than any other error type (33.3%) ($p < 0.0002$).

Conclusion

Several recommendations for improving the safety of PCA in pediatric pain management are justified by the results of this data analysis. First, further education and simulation for entering PCA orders into the CPOE system is needed for all prescribers. Secondly, further education and simulation in PCA pump programming and system set-up is needed for all nursing staff members. In regard to prescriber credentials, it is recommended that Pain Treatment Service (PTS) staff members train M.D. residents in writing PCA orders and entering them into the CPOE system. Finally, it is recommended that the SERS management team publish standardized error report content and entry format in order to streamline data analysis for quality improvement (QI) purposes.

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ABBREVIATIONS

AACA	authorized agent controlled analgesia
AANP	American Association of Nurse Practitioners
AAPA	American Academy of Physician Assistants
ACGME	Accreditation Council for Graduate Medical Education
ADE	adverse drug event
ADN	Associate Degree in Nursing
ADR	adverse drug reaction
AE	adverse event
AHRQ	Agency for Healthcare Research and Quality
ANA	American Nurses Association
BCH	Boston Children's Hospital
BSN	Bachelor of Science in Nursing
BWH	Brigham and Women's Hospital
CBER	Center for Biologics Evaluation and Research
CCA	caregiver controlled analgesia
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDS	clinical decision support
CICU	cardiovascular intensive care unit
CME	continuing medical education
CNS	central nervous system

COGME	Council on Graduate Medical Education
CPOE	computerized physician order entry
ECRI	Emergency Care Research Institute
EHR	electronic health record
EMR	electronic medical record
EtCO ₂	end-tidal carbon dioxide
FAERS	FDA Adverse Event Reporting System
FDA	U.S. Food and Drug Administration
HCIF	Health Care Improvement Foundation
HIE	health information exchange
HIT	health information technology
ICP	Intermediate Care Program
IM	intramuscular
IN	intranasal
IOM	Institute of Medicine
IRB	Institutional Review Board
ISMP	Institute for Safe Medication Practices
IV	intravenous
JCAHO	Joint Commission for Accreditation of Healthcare Organizations
MAR	Medication Administration Record
MAUDE	Manufacturer and User Facility Device Experience Database
M.D.	Doctor of Allopathic Medicine

MERP	medication error reporting program
MICU	medical intensive care unit
MRN	medical record number
MSICU	medical surgical intensive care unit
NACNEP	National Advisory Council on Nurse Education and Practice
NASHP	National Academy for State Health Policy
NCA	nurse controlled analgesia
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NCLEX	National Council Licensure Examination
NICU	neonatal intensive care unit
NIH	National Institutes of Health
NMDA	<i>N</i> -methyl- <i>D</i> -aspartate
NOW	immediate medication order
N.P.	Nurse Practitioner
P.A.	Physician Assistant
PCA	patient controlled analgesia
PGY	post-graduate year
PICU	pediatric intensive care unit
POCT	point of care testing
PRN	as-needed medication order
PTS	Pain Treatment Service
QI	quality improvement

RD	respiratory depression
R.N.	registered nurse
RR	respiratory rate
SC	subcutaneous
SERS	Safety Event Reporting System
SL	sublingual
SPN	Society of Pediatric Nurses
SpO ₂	oxygen saturation
USP	United States Pharmacopeia
WHO	World Health Organization

INTRODUCTION

Medical Errors – Definitions and Confusion

People who require medical treatment have a reasonable expectation that appropriate care will be provided toward a positive health outcome. However, adverse events (AEs) are a major threat to patient safety that must be constantly monitored. More importantly, clinical staff must be regularly educated about proper clinical practice guidelines and operation of new health care technologies, as well as implementation of error prevention strategies.

AEs can be the result of complications that cannot be prevented, such as some postoperative infections or intraoperative hemorrhage, or they can be the result of preventable medical errors (Van Den Bos et al., 2011). The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which includes the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO), defines AEs as “any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment” (Nebeker, Barach, & Samore, 2004).

AEs associated with medications occur more frequently than others (ICH, 1994), and these events have additional descriptive terminology. Adverse drug reactions (ADRs) from approved and marketed medications are defined jointly by FDA and WHO, and recognized by the Clinical Center Pharmacy Department of the National Institutes of Health (NIH) as: “A response to a drug which is noxious and unintended and which

occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function” (ICH, 1994; Chamberlain, 2011). This implies a causal association between the action of the drug and the event in a patient. Standardization of the term ADR aims at removing the term “side effect” from medical vernacular when describing negative events, since side effects could mean negative, positive or neutral reactions (ICH, 1994; Nebeker et al., 2004).

Adverse drug events (ADEs) are negative events associated with the prescribing or use of medications. FDA considers ADE and AE to be synonymous, in which there may not be a causal relationship between the drug and the event in question. Adding to the confusion, patient safety literature tends to imply causality in defining ADE and AE (Nebeker et al., 2004; Lisby, Nielsen, Brock, & Mainz, 2010). Nebeker and colleagues recommend adopting a simplified version of the Institute of Medicine’s (IOM) definition for ADE: “an injury resulting from the use of a drug.” Under this definition, ADEs encompass all ADRs, and are closely related to medication errors (Figure 1). Medication errors have been defined by The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as:

...any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (NCC MERP, 2012).

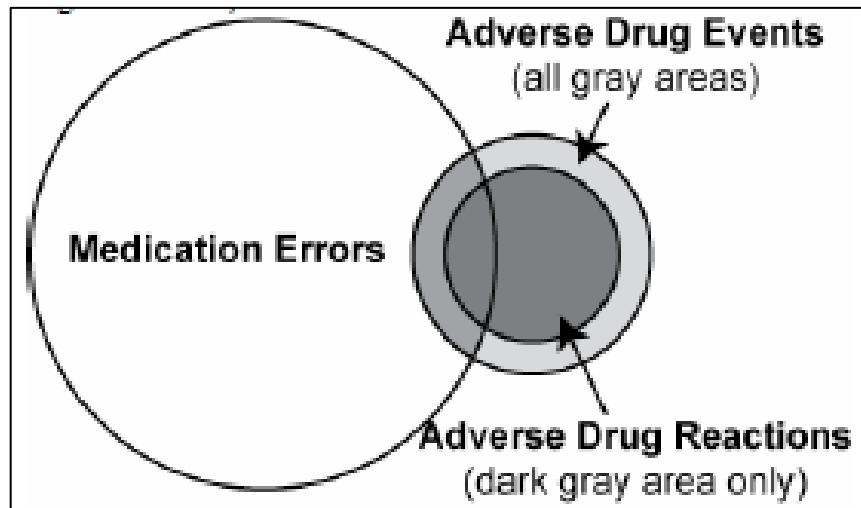


Figure 1 – Relationship between ADEs, ADRs, and medication errors. All ADRs are ADEs, and a sizeable proportion of ADEs are due to medication errors. Taken from Nebeker, Barach, & Samore, 2004.

The wide variety of definitions for ADEs and inconsistencies in event classifications may also be contributing to the variance in error reporting and incidence of error types (Lewis et al., 2009; Tully et al., 2009; Lisby et al., 2010). Alluded to above, NCC MERP has attempted to standardize terminology and classifications of errors by identifying key points in the medication use timeline, which include: prescribing, documenting, dispensing, administering, and monitoring (Aronson, 2009; Santell, Hicks, McMeekin & Cousins, 2003; Hicks & Becker, 2006). Literature review by Lewis and colleagues found that prescribing errors affected 50% of hospital admissions, but that many studies analyzed varied in criteria used to assess severity (Lewis et al., 2009). Uniformity in ADE reporting will allow for streamlined data collection and analysis, more accurate estimation of error incidence and prevalence, and sharing of information between health systems (Lewis et al., 2009; Lisby et al., 2010). In one study it was found

that 45 different general definitions were used to describe an ADE in literature published between 1984 and 2006, and over one hundred papers published in this time period did not provide a general definition of an ADE (Lisby et al., 2010).

Medical Errors – Incidence and Cost

Medical errors have the potential to cause additional patient harm and a significant cost burden. Of paramount importance over the monetary impact to the health care system is the impact of AEs on each patient and their loved ones. Errors can change the course of a patient's treatment, prolong hospital stays, result in lasting debilitation, and cause mortality.

A well-known article based on the results of the Harvard Medical Practice Study I estimated the incidence of AEs to be 3,691 per 100,000 patients in New York hospitals in 1984. Alarming, 27.6% of AEs were due to negligence, resulting in significantly more severe patient harm than AEs that were not associated with negligence. Of all AEs analyzed in this study, 70.5% resulted in patient disability for less than six months, 2.6% caused permanent patient disability, and 13.6% resulted in mortality (Brennan et al., 1991).

More recently, Rothschild and colleagues analyzed AE incidence among 391 critical care patients in one hospital, reporting that 120 AEs had affected 79 of these patients (Rothschild et al., 2005). Medication errors involving opioids have the potential to be more harmful than with other classes of medications, requiring heightened vigilance and attention to detail on the part of clinicians. Dy and colleagues reported 644 harmful

errors involving opioids, 23% due to underdosing and 52% due to overdosing. Morphine and hydromorphone were most often implicated in dosing errors, and oxycodone was most often involved in errors of administering the wrong analgesic (Dy, Shore, Hicks, & Morlock, 2007).

In pediatrics, Proctor and colleagues found that medical errors affected 67.2% of patients on a pediatric general surgery service, and that 32.8% of patients experienced adverse outcomes due to medical errors (Proctor, Pastore, Gerstle, & Langer, 2003). In regard to opioids, McDonnell found that 314 errors reached pediatric patients, 259 of which involved morphine. Improper dosing was cited as the most frequent type of opioid error. Forty-seven patients had symptoms related to opioids, 16 of which described pain as the symptom (McDonnell, 2011). These safety implications alone are justification for the constant comprehensive analysis of medical errors, as well as continued education and adoption of technology aimed at reducing their incidence.

Aside from the human cost, the monetary cost of medical errors in U.S. health care adds more debt to a system already plagued by uncontrollable spending. In 2008, it was estimated that the annual direct cost of measureable AEs in the U.S. that resulted in harm to patients was \$17.1 billion (Van Den Bos et al., 2011). Table 1 shows the costliest of these errors included in the study. Progress toward solving this issue includes monitoring and reporting errors for analysis and potential system change, creating provider checklists for quality assurance, utilization of computerized physician order entry (CPOE) systems, and additional caregiver education both before and after an event

has happened. Both the human and monetary costs of medical errors are an unacceptable reality that is cause for improvement of U.S. health care delivery.

Table 1 – Costliest medical errors in 2008. Central line infections were the costliest single event, whereas postoperative infections and pressure ulcers were the most costly overall due to their high incidence. Taken from Van Den Bos et al., 2011.

Medical Errors With The Largest Annual Cost, 2008					
Error	Probability of error	Number of medical injuries	Number of medical errors	Medical cost per medical error (\$)	Total medical cost of medical errors (\$ millions)
Postoperative infection	91% or more	265,995	252,695	13,312	3,364
Pressure ulcer	91% or more	394,699	374,964	8,730	3,273
Mechanical complication of noncardiac device, implant, or graft	10–35%	268,353	60,380	17,709	1,069
Postlaminectomy syndrome	10–35%	505,881	113,823	8,739	995
Hemorrhage complicating a procedure	36–65%	156,433	78,216	8,665	678
Infection due to central venous catheter	91% or more	7,434	7,062	83,365	589
Pneumothorax (collapsed lung)	36–65%	51,119	25,559	22,256	569
Infection following infusion, injection, transfusion, or vaccination	91% or more	9,321	8,855	63,911	566
Other complications of internal prosthetic device, implant, and graft	Less than 10%	535,666	26,783	14,851	398
Ventral (abdominal) hernia without mention of obstruction or gangrene	10–35%	239,156	53,810	6,359	342

Reporting Medical Errors

Once an ADE has occurred, immediate medical management of the error – if necessary – must be performed. Secondly, clinical staff must communicate the ADE occurrence and its effect on the treatment plan to the patient and their family. Thirdly, the error must be reported. Reporting ADEs in a systematic manner allows for accurate data analysis leading to identification of problem areas that become targets for quality improvement (QI) initiatives. Ultimately, the goal of reporting errors is to improve the

safety and quality of health care delivered to patients through education and dissemination of information within the medical community.

There are several avenues that allow a practitioner to report such events.

MedWatch is a well-known national ADE reporting program operated by FDA that has been in operation for two decades. The Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (MERP) is a national error reporting program that was jointly developed by ISMP and the U.S. Pharmacopeia (USP) for free ADE reporting by individual practitioners (Santell et al., 2003).

Additionally, the FDA operates two databases that promote the safety observation of approved therapeutic products on the medical market. The FDA Adverse Event Reporting System (FAERS) compiles data from reported ADRs to be reviewed by analysts in both the FDA Center for Drug Evaluation and Research (CDER) and the FDA Center for Biologics Evaluation and Research (CBER). Further evaluation and regulation of approved products based on the reported findings from FAERS are then issued to ensure their safety and efficacy for consumers (FDA, 2012). Aside from FAERS, FDA reports of medical device errors are compiled in the Manufacturer and User Facility Device Experience (MAUDE) database. Equivalent to the ADR reporting and evaluation process, MAUDE reports AEs due to medical devices to analysts in the Center for Devices and Radiological Health (CDRH) (FDA, 2012). Of considerable interest is the fact that all of these databases operate on a voluntary reporting basis, potentially misrepresenting the quantity and severity of medical errors occurring in the U.S. health care system.

Private companies are constantly developing software, logistics, and management solutions to streamline the future functioning of the U.S. health care system. Quantros, Inc. partnered with USP in 1998 to develop MEDMARX, a subscription-only internet-accessible database that was designed to augment MedWatch and ISMP MERP. MEDMARX is the largest medical error database of more than 40,000 ADR reports and 1.3 million medication error reports (Quantros, Inc., 2009). It allows hospitals and other health systems to confidentially and anonymously report and track AEs using NCC MERP standardized taxonomy, creating quantifiable data that can be readily analyzed and shared with the medical community (Santell et al., 2003).

Santell and colleagues analyzed ADE reports submitted to MEDMARX between 1999 and 2001, finding that 154,816 errors from 403 different health care facilities were reported (Table 2). These errors included 4.5% that caused patient harm and nineteen fatalities. Over the three-year period of this study, the number of ADEs reported increased exponentially, highlighting more widespread usage of MEDMARX software in the medical community. Table 2 shows the top ten causes of errors reported for each year during the study (Santell et al., 2003).

Hicks and Becker examined intravenous (IV) ADEs occurring between 2000 and 2004 reported to MEDMARX. They found that the incidence of harm in IV-related ADEs remained higher than in overall errors throughout the duration of the study. Interestingly, the authors doubt the validity of their data that showed a decline in the percentage of harmful errors, given the exponential increase in facilities reporting events to MEDMARX throughout the study period. This explanation is further backed by data

in Figure 1 showing a steady increase in total number of IV-related ADE report records during the four-year period (Hicks & Becker, 2006).

Table 2 – Top ten causes of medical errors from 1999–2001 in MEDMARX. Sample sizes of ADE reports increased dramatically over the 3-year study period. Taken from Santell et al., 2003.

1999 (n = 7241)	2000 (n = 38,895)	2001 (n = 94,498)
Performance deficit (48%)	Performance deficit (42%)	Performance deficit (38%)
Procedure/protocol not followed (21%)	Procedure/protocol not followed (20%)	Procedure/protocol not followed (20%)
Knowledge deficit (12%)	Transcription inaccurate/omitted (14%)	Transcription inaccurate/omitted (15%)
Documentation (10%)	Documentation (13%)	Documentation (12%)
Communication (10%)	Computer entry (10%)	Computer entry (11%)
Transcription inaccurate/omitted (10%)	Communication (10%)	Knowledge deficit (10%)
Computer entry (9%)	Knowledge deficit (9%)	Communication (10%)
Drug distribution system (6%)	Drug distribution system (4%)	Written order (6%)
System safeguards inadequate (5%)	Written order (4%)	Drug distribution system (4%)
Handwriting illegible/unclear (4%)	Handwriting illegible/unclear (4%)	Handwriting illegible/unclear (3%)

Based on the trend seen in these two studies, it seems too early to capture the true incidence of ADEs using MEDMARX because of the steadily increasing participation by more health care organizations. However, the organizational usage of nationwide confidential and anonymous standardized error reporting systems like MEDMARX have the potential to offer valuable information once their utilization becomes uniformly mainstream within the medical community.

Aside from the logistics of reporting ADEs and their value in estimating incidence and prevalence in facilities and health care organizations, there are interpersonal factors that may influence if and how errors are reported. Personnel may underreport or fail to report AEs due to the fear of consequence – both professionally and socially (Schmidt & Bottoni, 2003; Banning, 2006; Milch et al., 2006). Milch and colleagues found in their

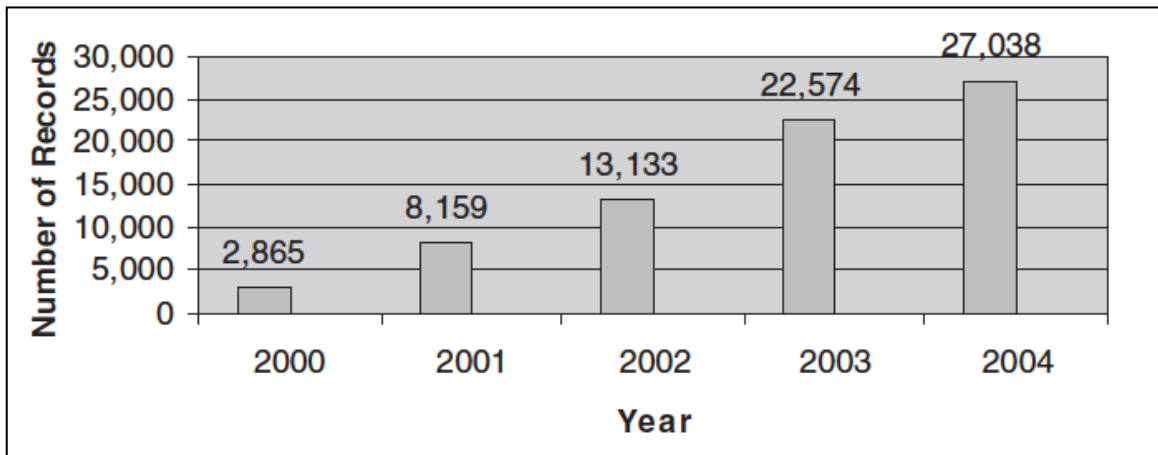


Figure 2 – IV ADE reports from 2000–2004 in MEDMARX. A steady increase in the number of ADE reports was seen throughout the duration of this study, highlighting the increased utilization of MEDMARX by more health care organizations. Taken from Hicks & Becker, 2006.

sample of 26 hospitals that while 47% of errors were reported by registered nurses (R.N.s), only 1.4% were reported by physicians. They discuss that this finding may be due to the fact that nurses receive training specific to reporting and systematic evaluation of AEs, while physicians do not receive any training of this nature (Milch et al., 2006). Physicians have advocated for additional training on their role in handling errors (Boyle, O’Connell, Platt, & Albert, 2006). There may also be knowledge deficits about error reporting procedures. Kaldjian and colleagues surveyed faculty and resident physicians, finding that only 62.3% of faculty and 49.5% of residents knew how to report errors. Also, they found evidence of underreporting based on the lack of severity of the outcome to the patient; near misses and AEs that did not result in any harm were often unreported (Kaldjian et al., 2008).

Patients and their families deserve full disclosure of AE occurrences, regardless of their designated severity level. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) requires licensed practitioners in hospitals to inform patients and families if outcomes vary from what was anticipated (JCAHO, 2004). Near misses and errors that do not change a patient's course of treatment do not have mandatory reporting standards (Boyle et al., 2006). Despite the JCAHO rules, a large study found a significant gap between physicians' attitudes and practice of disclosing errors that caused harm to patients (Kaldjian et al., 2007). Additionally, it was found that even when physicians did disclose errors to patients, they often orchestrated their words carefully. Patients often seek an apology, but physicians avoid this for reasons of possible legal liability. This same study found that physicians were troubled when errors occurred, but did not know where to seek emotional support (Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003). It is clear that errors affect both patients and practitioners. Full disclosure of events is ethical and necessary, which can contribute to strengthening the provider-patient relationship and ultimately delivering the best medical care available (Boyle et al., 2006).

Measures to Reduce the Incidence of Medical Errors

The IOM Quality of Health Care in America Committee issued a report in September 1999 called "To Err Is Human: Building a Safer Health System" to address the unacceptable frequency of medical errors in U.S. Health Care. This report acknowledges the faulty systems, processes, and conditions that lead to errors, which is

more common than any individual's action or omission. A four-tiered strategy was recommended in the report, comprised of:

- Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
- Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems.
- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care.
- Implementing safety systems in health care organizations to ensure safe practices at the delivery level (Committee on Quality of Health Care in America, 1999).

In response, government agencies (Agency for Healthcare Research and Quality [AHRQ], National Academy for State Health Policy [NASHP]), medical professional groups (Council on Graduate Medical Education [COGME], National Advisory Council on Nurse Education and Practice [NACNEP], and others), and private sector ventures (Leapfrog Group) have mobilized to launch an unprecedented interdisciplinary collaborative effort to systematically improve every facet of health delivery in regard to error prevention and education (Committee on Quality of Health Care in America, 1999).

Several other initiatives have been tested for their effect on error reduction.

Landrigan and colleagues reported findings from a randomized trial assessing the incidence of errors committed by physician interns who worked a traditional weekly schedule versus an intervention schedule that reduced the number of hours worked in a week and removed extended work shifts (24 hours or more). They found that interns

working a traditional schedule made nearly 36% more serious medical errors than the intervention group, including 1.2 times as many serious medication errors and 5.6 times as many serious diagnostic errors. Based on their findings, it is clear that changes in physician training must be included in the overall medical reform to reduce errors above and beyond the scheduling reforms enacted in 2003 by the Accreditation Council for Graduate Medical Education (ACGME) (Landrigan et al., 2004). A similar study examining RN shifts in Australia reported that sleeplessness and fatigue were significant predictors of error occurrence, indicating the need for scheduling reform in nursing as well (Dorrian et al., 2006).

Specifically related to ADEs, there have been initiatives to reduce medication errors in one or more steps of the aforementioned medication use timeline. At the multi-facility level, the Health Care Improvement Foundation (HCIF) implemented the Regional Medication Safety Program for Hospitals in the Delaware Valley in 2001, in partnership with the Emergency Care Research Institute (ECRI) and ISMP. This program focused on 16 medication safety goals as the basis for its error reduction strategy, all of which fall under the four domains of: institutional culture, infrastructure, clinical practice, and technology. The goals emphasize continued education and pharmacist involvement, and could potentially serve as a model for a nationwide systems approach to error reduction. The program has hosted several educational seminars for medical, risk management, pharmacy, and managed care staff; information sessions for hospital trustees, administration, and staff; and comprehensive training sessions for hospital safety personnel. JCAHO rated this program in its top five collaborative

initiatives for patient safety, coinciding with many of their safety guidelines (McCarter, Centafont, Daly, Kokoricha, & Leander Po, 2003).

On a smaller scale, Cox and colleagues describe measures taken to lower ADE incidence in the Maine Medical Center through system improvement. Recording of pediatric inpatient weights, hepatic, and renal function became standard protocol in order to reduce guesswork by the pharmacy when calculating dosages. This resulted in a drastic reduction in pharmacy interventions due to missing weights. Unnecessary verbal orders that commonly result in transcription errors were eliminated by forming a QI taskforce representing 20 services in the hospital. This QI team restricted the types of situations that would permit verbal orders, reduced the number of personnel allowed to enter verbal orders, and modified their electronic medical record (EMR) system to alert physicians to unsigned orders for inpatients. This QI approach resulted in a reduction of unsigned verbal orders at patient discharge from 7% to nearly 1%. CPOE order forms were modified for a more user-friendly experience, which boosted utilization rates among resident physicians from 55% to 86% – further reducing verbal orders. Reporting of pharmacy interventions electronically during the prescription or transcription process of the medication use timeline became standard protocol, resulting in reports of potentially life-threatening errors as the majority. This led to the development of several internal pharmacy QI initiatives. Lastly, handwritten incident report forms signed by the person responsible for the incident were done away with in favor of an anonymous electronic reporting system, nearly doubling the number of AEs reported during the reporting period

(Cox et al., 2001). This anecdote of comprehensive system change is a reproducible adaptation of the IOM strategy in a single facility.

Similarities in medication trade names and appearances have been known to cause confusion and contribute to ADEs. This can be caused by factors such as clinical similarity and poorly handwritten prescriptions. Some common examples of confused proprietary drug names include: Celebrex (celecoxib), Cerebyx (fosphenytoin), and Celexa (citalopram). The FDA and pharmaceutical manufacturers have an opportunity to enact changes in labeling, packaging, and software that will prevent confusion among new medications that are marketed (Hoffman & Proulx, 2003). For medications already on the market, the ISMP, FDA, JCAHO, and several other health care safety agencies have advocated for the use of “Tall Man” letters to help differentiate between similar drug names. The ISMP released an alphabetized list of medications using Tall Man lettering. Some of those that were FDA-approved are included in Table 3 (ISMP, 2011).

Filik and colleagues studied the effect of Tall Man letters using both eye-tracking technology and timed response recognition. In the eye movement study, Tall Man letters proved to be effective in reducing mistakes when selecting names from an array used to simulate shelves containing medications in a pharmacy (Filik, Purdy, Gale, & Gerrett, 2004). In the timed responses experiment, it was found that although Tall Man letters did not make drug names less confusable, they increased attention which led to less recognition mistakes (Filik, Purdy, Gale, & Gerrett, 2006). Darker and colleagues experimented with three different types of Tall Man lettering as compared to Natural (first letter capitalized) and Uppercase format, and found that Tall Man proved to be

Table 3 – ISMP list of medications using Tall Man letters. Commonly confused drug names pairs are given. The capitalized portion of the name is meant to highlight the dissimilarity. Taken from ISMP, 2011.

Table 1. FDA-Approved List of Generic Drug Names with Tall Man Letters	
Drug Name with Tall Man Letters	Confused with
aceta ZOLAMIDE	aceto HEXAMIDE
aceto HEXAMIDE	aceta ZOLAMIDE
bu PROPion	bus PIRone
bus PIRone	bu PROPion
chlorpro MAZINE	chlorpro PAMIDE
chlorpro PAMIDE	chlorpro MAZINE
clomi PHENE	clomi PRAMINE
clomi PRAMINE	clomi PHENE
cyclo SERINE	cyclo SPORINE
cyclo SPORINE	cyclo SERINE
DAUNO rubicin	DOXO rubicin
dimenhy DRINATE	diphenhydr AMINE
diphenhydr AMINE	dimenhy DRINATE
DOBU Tamine	DOP amine
DOP amine	DOBU Tamine

more effective than Natural, but not more effective than Uppercase. The authors explain that this is the result of the size of characters in Uppercase lettering and their legibility. This is contrary to popular belief that the contrast in appearance between uppercase and lowercase letters in Tall Man formats is what makes them effective (Darker, Gerret, Filik, Purdy, & Gale, 2011). To date, there are no mandated rules on what to capitalize, which could potentially introduce a new factor that perpetuates drug name confusion (Darker et al., 2011). However, FDA and ISMP are pushing for the use of their tall man lettering scheme to promote standardization in practice (Grissinger, 2012).

In Canada, better drug labeling standards have been developed by CSA International for pharmaceutical manufacturers (Figure 2). The chief alteration to drug labels is the introduction of a critical information panel, which includes: the generic name

for the drug, concentration, and total amount per total volume. This information is presented in black text on a white background, and the trade name must not be larger than the generic (Orser, 2000).

All strategies that are employed to reduce medical errors, whether broad or narrow in scope, multifaceted or singular in nature, should be constantly assessed for effectiveness and innovated for application in a variety of health care settings. Information sharing is critical to the global reduction of medical error frequency and incidence, leading to better prevention efforts and safer delivery of medical care.

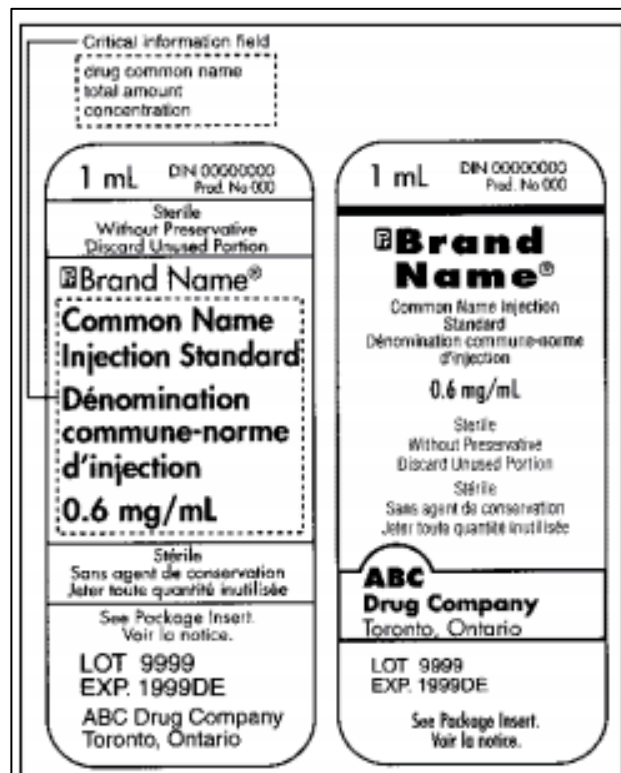


Figure 3 – Comparison of two drug labels. The label on the left is in compliance with the CSA International standards, while the label on the right is in compliance with Health Canada standards. The contents of the critical information panel are clearly visible in new label format. Taken from Orser, 2000.

Technology Impact on Medical Errors

Application of new technologies has the potential to streamline health care delivery and management, as well as contribute to reducing the frequency and incidence of medical errors. However, as with any new implementation, there are unforeseen errors created that require additional management whilst in the process of reducing existing errors (Bates, 2000; Bates et al., 2001; Tully et al., 2009). Health Information Technology (HIT) is the blanket term used to describe various tools that are developed to transmit and manage health information for the benefit of consumers, providers, payers, insurers, and any other stakeholders in health care systems (Goldstein & Blumenthal, 2008). These products are not yet at the stage of seamless utilization and consumer satisfaction, but their persistent evolution holds promise for the future (Mandl & Kohane, 2012).

Several pieces of HIT exist today, with some more refined and widely used than others: electronic medical records (EMR), also known as electronic health records (EHR); computerized physician order entry (CPOE) systems; and clinical decision support (CDS) systems. Many EMR systems have CPOE and CDS functionality built-in. Also barcode patient identification systems to automate the data entry process have been implemented in most facilities, although they are not foolproof either (Bates, 2000; Bates et al., 2001; Kaushal & Bates, 2002; McCarter et al., 2003). Nichols and colleagues described errors due to manual data entry when the barcode system malfunctions, incorrect medical record numbers (MRN) due to facility transfer, patients with multiple wristbands, and reuse of expired MRNs for new wristbands (Nichols et al., 2004). While

this is not the full list of HIT advances that are currently in practice, these are the most highly acclaimed and criticized for their impact on health care delivery.

EMR systems are the flagship of the HIT movement. They possess various functionalities making them more beneficial than traditional paper records, including: electronic patient data collection and storage, immediate record accessibility for medical providers, electronic order entry (CPOE), and presentation of standard care options to aid in clinical decision-making (CDS) (Goldstein & Blumenthal, 2008). The Institute of Medicine (IOM) has cited a total of eight electronic functionalities for EHRs (IOM, 2003). However, EMR systems are not panacea for AEs in health care. People must still perform procedures correctly, make complex decisions affecting patient care based on experience, and effectively communicate with the health care team. EMRs can increase organization and efficiency, link information, and automatically check for problems, freeing providers to make them more available for patients (Bates, 2000; Kumar & Aldrich, 2010).

The EMR systems of today possess inherent limitations. For one, there are no nationwide standards or structured data definitions put in place by regulatory bodies in the U.S., leading to widespread incompatibility between systems (Kumar & Aldrich, 2010). Health Information Exchange (HIE) is a vision of EMR systems that can only be accomplished through interconnectivity that allows clinicians in any setting and any location to access and share information about any patient under their care (Goldstein & Blumenthal, 2008). This interoperability problem is perpetuated by the number of EMR manufacturers presently in competition with one another in pursuit of a product that

revolutionizes health care management. Mandl and Kohane report the existence of more than 700 companies that produce around 1750 distinct certified EMR products. No single system has proven to be the most beneficial over others because not enough time has elapsed to truly measure and compare efficacy and cost-effectiveness. However, there are Medicare and Medicaid EHR Incentive Programs for providers that include use of certain systems over others for participation in an effort to standardize data sharing between groups. But, these sponsored systems are often considered to be not the most valuable, limiting the worth of EMR utilization among participating providers (Mandl & Kohane, 2012).

CPOE systems are the most highly advocated HIT and have had the greatest impact in reducing the incidence of ADEs. They have been proven effective in catching both potential ADEs and actual ADEs, although the effect was greater in potential ADEs (Bates et al., 1998). They provide a complete and structured medication order including: dose, route, and frequency; and will not allow an order to be submitted without entering all three parameters. Orders appear on-screen in clearly legible computerized text (Figure 3), avoiding handwritten script interpretations and potential mistakes. Most importantly, orders are automatically checked for appropriate parameters based on the patient's weight and organ function, as well as against the rest of the patient's orders, lab values, allergies, and any other pertinent information in the EMR for contraindications (Bates, 2000).

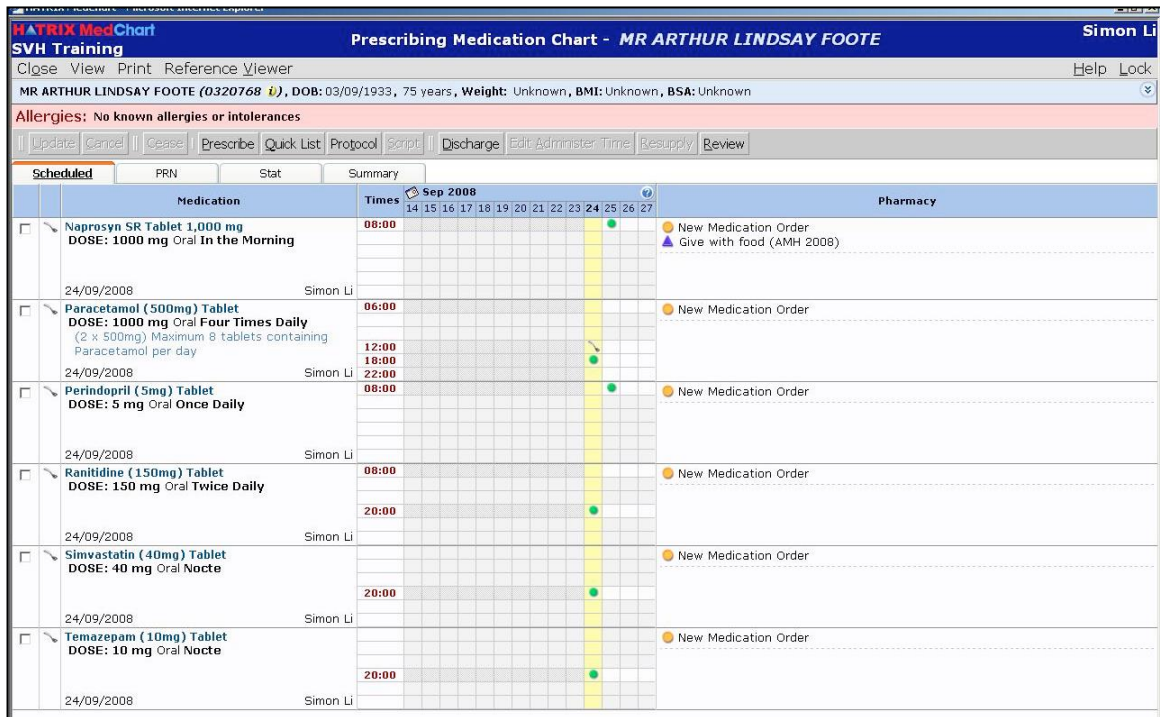


Figure 4 – CPOE interface screen shot. Clear, legible orders with critical patient information can be seen in this example of a CPOE system. Taken from Magrabi, Li, Day, & Coiera, 2010.

CPOE systems are not immune to problems. Although they eliminate handwritten order interpretation errors, errant keystrokes present a new error potential (McCarter et al., 2003). Koppel and colleagues conducted an extensive survey of staff in a large tertiary care hospital to gain information about CPOE system factors that could precipitate ADEs. Their data identified two general areas of concern: information errors and human-machine interface flaws. A few of the identified causes for ADEs in each area are explained:

The first information error identified was assumed dose information, meaning house staff relied on the CPOE system to determine dosages rather than clinical

guidelines. Medication discontinuation failures were also identified due to a lack of alert when orders are duplicated, since discontinuation orders occur through a different process. Procedure-linked medication discontinuation faults occur when procedures are cancelled that have accompanying medications, since the medication must be discontinued manually instead of automatically with the procedure cancellation. Allergy information delay occurs because feedback on allergies from a patient's history is only received after an order has already been entered into CPOE. Conflicting or duplicative medication orders occur because the CPOE system is not linked to other hospital systems (Koppel et al., 2005).

The first human-machine interface flaw was wrong patient selection due to an alphabetized list of patient names, leading to similar names being selected and inappropriate ordering. Wrong medication selection occurs because up to 20 screens must be viewed in some cases for a complete list of a patient's medications, leading to uncertainty in the screen viewer. Unclear log on/log off from previous CPOE users can lead to unintended orders for patients or patients not receiving intended orders. Inflexible ordering screens do not allow for entry of nonstandard specifications, and off-formulary medications must be ordered on a separate screen that may not reach the pharmacy (Koppel et al., 2005).

Studies have reported user frustration with CPOE, electing to bypass the order entry process in favor of archaic written and verbal orders. Also, a lack of linkage between CPOE and pharmacy systems commonly results in duplicate entries of orders. Medication administration records (MAR) will then show discrepancies between CPOE

and pharmacy, leading to manual verification and unneeded increased workload for hospital staff (Bates et al., 2001).

Clinical decision support (CDS) software has been built into many CPOE systems and broader EMR infrastructures, but also exists independently of these two HITs in some facilities (Bates, 2000; Kaushal & Bates, 2002). The crucial feature of CDS systems is real-time alerting of clinicians with computer-generated messages when critical patient laboratory results are available, which eliminates significant delays in treatment that occur when clinicians are alerted via telephone (Bates et al., 2001). Advanced CDS also may incorporate patient-specific or pathogen-specific information while providing recommendations to clinicians (Kaushal & Bates, 2002).

Pediatric patients can benefit the most from effective HIT that reduces medication errors and ADEs. Although the general implementation approach is the same in pediatrics as it is in adult medical care, HIT manufacturers must design more flexible programs and practitioners must be wary of technological limitations. CPOE systems with built-in advanced CDS must have the capability for constant updates of patients' weight, since all pediatric dosing strategies are weight-based. They must also have customized checks since normal laboratory values change throughout the normal progression of childhood (Kaushal, Barker, & Bates, 2001). As with the implementation of any new technology, pediatric CPOE must be constantly evaluated for various effects on patients and practice. Han and colleagues actually found that a commercially sold CPOE system that was implemented in a large tertiary children's hospital resulted in higher mortality rates than before implementation (Han et al., 2005). Pediatric CDS

should contain drug libraries with pediatric dose ranges and built-in alerts, and it should also be contextualized for pediatric health issues, like the neonatal period. Also, EMR systems should have medication-reconciliation tools, as well as linkage of immunization records to vaccination order forms.

Similar barriers exist in adoption of EMR systems in pediatrics as in adult health care, including lack of nationwide standards or data definitions, which must be based on original pediatric data rather than adult data extrapolations (Kim & Lehmann, 2008). Pediatric-specific HIT must be constantly refined and studied for clinical efficacy and effectiveness. In the future, information technologies can be made available to children and families to empower them to make well-informed health care decisions (Weitzman, 2001).

PCA Pumps and PCA Errors

Mechanical infusion medication delivery devices are advanced pieces of equipment that have been in-use for several decades. For pain management, patient controlled analgesia (PCA) pumps were developed in the 1970s in response to research that showed intermittent IV doses of opioids (the most commonly used class of analgesics) provided better coverage of pain than intramuscular (IM) injections of opioids (Macintyre, 2005; Mann, Ouro-Bang'na, & Eledjam, 2005; Tran, Ciarkowski, Wagner, & Stevenson, 2012). These machines offer patients better control of their own pain management, allowing for self-administration of analgesics for immediate relief. PCA avoids potential delays in pain management caused by conventional clinician-

administered doses of analgesics. Clinician-administered pain management requires time for clinicians to be aware of a patient's pain, and additional time to administer medication, all while the patient unnecessarily experiences pain. This mode of pain management is usually used postoperatively, after particularly painful procedures (Miaskowski, 2005; Momeni, Crucitti, & De Kock, 2006).

PCA pumps offer two delivery modes for analgesics: continuous infusion for baseline pain relief and operator-controlled bolus doses for on-demand pain relief (Mann et al., 2005). The operator control is a handheld button that must be depressed to activate the bolus delivery system. "PCA by Proxy" is anyone other than the patient pressing the button to deliver a bolus dose to the patient, whether authorized or unauthorized (Noah, 2003; Wuhrman et al., 2007; D'Arcy, 2008). Authorized agent controlled analgesia (AACA) refers to prescribed activation of the bolus delivery function by another person for patients who cannot perform this function (Wuhrman et al., 2007). AACA includes nurse controlled analgesia (NCA) and caregiver controlled analgesia (CCA). CCA is usually one family member who is given the sole responsibility for controlling the on-demand pain relief for their loved one (Pasero & McCaffery, 2005; Wuhrman et al., 2007). AACA protocols vary widely from hospital to hospital. For instance, the Pain Treatment Service (PTS) in a world-renowned pediatric hospital in the northeastern United States instituted a policy that allows for PCA and NCA, but CCA is only allowed in rare circumstances with approval from a PTS attending physician (Solodiuk, 2010).

Regardless of who activates the on-demand bolus dose, PCA pumps have several built-in safety features. PCA hardware includes the drug reservoir and the on-demand

control (Figure 4), which are designed so that access to the reservoir or the programming features is impossible without an administrative key or code (Mann et al., 2005). PCA pumps are equipped with several programming features that allow for safe use. First, a loading dose is delivered to the patient in order to achieve an effective analgesic therapeutic window. A background infusion rate is set to maintain the patient's pain relief within the therapeutic window. A bolus dose is set to be delivered to the patient for on-demand pain relief when activated. To avoid patient-induced overdose, a lockout interval is set so that a specified period of time must elapse before another bolus dose can safely be delivered to the patient, regardless of how many times the on-demand button is pressed. Also, 1-hour and 4-hour limits can be set for maximum amount of medication delivered, and the pump will alert providers once the limit is reached (Macintyre, 2005; Mann et al., 2005; Momeni et al., 2006; Cranwell-Bruce, 2009).

“Smart pump” software is another safety feature of newer PCA pumps. This technology helps prevent programming errors by using a barcode scanning system that automatically enters the concentration information directly from the barcode on the medication cartridge before it is loaded into the pump. Also, many smart pumps have the capacity to store drug libraries that aid in programming dosing information by offering upper and lower dosage limits derived from individual patient information (Harding, 2012; Tran et al., 2012). These limits can be “soft” or “hard” depending on the PCA model. Soft limits alert the programmer when limits have been breached, but they allow for an override in order to maintain the setting that prompted the alert. Hard limits, on the other hand, do not have an override option and the settings must be reprogrammed



Figure 5 – Abbott Lifecare PCA III®. The on-demand bolus dose button, medication cartridge, tubing, and programming interface are clearly seen. Taken from Lifecare® PCA 3 System Operating Manual: 430-04565-003, Abbott Laboratories, North Chicago, IL.

within the limits (Tran et al., 2012; Maddox, Williams, Oglesby, Butler, & Colclasure, 2006; Maddox, Oglesby, Williams, Fields, & Danello, 2008). These alerts catch many potential ADEs before they have a chance to reach patients. An important QI-based feature of smart pumps is the memory log that stores information about each programming entry, error, alert, and override, as well as reprogramming information. For

a final safety checkpoint, a display screen shows the programmer all of the pump settings at the end of the process that prompts their verification (Tran et al., 2012). New-age smart PCA pumps provide a platform that contains fewer avenues for programmer error, making PCA therapy a much less risky experience for pain management patients.

There are several external safety monitoring devices that are commonly used in conjunction with PCA therapy. Since the most dangerous ADE associated with opioid therapy is respiratory depression (RD), continuous respiratory monitoring is necessary to reduce the incidence of RD and its harmful effects if left untreated. Respiratory rate (RR), oxygen saturation (SpO₂), and end-tidal carbon dioxide (EtCO₂) are commonly monitored to ensure that patients do not succumb to RD (Maddox et al., 2006; Maddox et al., 2008). Many facilities use pulse oximetry to measure SpO₂, which is a commonly unreliable measurement since many patients receive supplemental oxygen that can mask desaturation even at low RR until it reaches a dangerous level and patients become apneic. The most reliable monitoring for opioid ADE uses capnography, which simultaneously measures EtCO₂, RR, quality of respirations, and apneic episodes (Maddox et al., 2006; D’Arcy, 2007; D’Arcy, 2008). Many facilities have pain management policies that require respiratory monitoring during PCA therapy for high-risk patients who have:

- compromised airway.
- significant kidney disease.
- history of respiratory depression with opioid use.
- large opioid dose for patient’s weight and/or condition.
- significant lung disease in patients who are not ventilated.

- somnolence.
- significant liver disease.
- opioid [naivety] (use of opioids – scheduled or PRN for less than 72 hours) and concurrent use of other medication capable of central nervous system (CNS) depression (e.g. benzodiazepines).
- morbid obesity.
- muscle weakness.
- patients less than 6 months of age with opioid infusions and on NCA.
- opioid [naivety with continuous infusions] (Solodiuk, 2010).

In pediatrics, this list indicates the majority of patients for respiratory monitoring during PCA therapy. Several advanced smart PCA platforms also contain built-in pulse oximetry and noninvasive capnography, providing clinicians with trending data on oxygenation and ventilation in addition to smart pump features (Maddox et al., 2006).

PCA pumps are versatile with various treatment plans, and they can deliver analgesics through different routes. IV and epidural are the most commonly prescribed, but also oral, transdermal, subcutaneous (SC), sublingual (SL), intranasal (IN), and inhalation routes have been used in PCA therapy, although very rarely (Miaskowski, 2005; Pasero & McCaffery, 2005; Palmer & Miller, 2010). The most common medication used in PCA is morphine, but the pump can be loaded with different medications, including Dilaudid (hydromorphone), fentanyl, sufentanil, remifentanil, oxycodone, pethidine (meperidine), piritamide, and tramadol (Macintyre, 2005; Momeni et al., 2006; Palmer & Miller, 2010). Adjuvant analgesics can also be loaded in addition to opioids to potentiate their analgesic properties while reducing adverse effects. These include: ketamine (a NMDA antagonist), naloxone (an opioid competitive antagonist),

and clonidine (an α_2 -adrenoreceptor agonist) (Momeni et al., 2006). Also, antiemetics have been added to PCA solutions in some cases to manage the potential adverse effects of opioids (Macintyre, 2005).

Due to the various programmable parameters and versatility in medications and routes of administration, potential for errors are a concern especially in earlier-age, non-smart pumps. In smart pump PCA systems without barcoding, medication mix-ups and keystroke errors resulting in wrong drug concentration have been reported. Independent of smart pumps, errors in prescriptions due to mistakes in oral to IV conversion ratios, and improper patient selection have been reported (Cohen & Smetzer, 2005; Hicks, Sikirica, Nelson, Schein, & Cousins, 2008; Etches, 1994; Baxter, 1994).

Although much less common than human error in programming or prescription, software flaws have caused programming errors. Reported flaws include: reversion to default concentration settings for medications when using a higher concentration (especially in Abbott Lifecare PCA II[®] and APM Infusers[®] models), verification screens that do not display all parameters for a final check, and required entry of dose in milliliters rather than milligrams (Cohen & Smetzer, 2005; Grissinger, 2008). Human errors in setting up the PCA system have been reported, including: improper IV placement, blockage of tubing, and disconnection from medication reservoir (Hankin, Schein, Clark, & Panchal, 2007; Paul et al., 2010). Even rarer are mechanical flaws due to cracked drug syringes or cassettes that can cause siphoning (free flow) of the medication into the PCA system (Cohen & Smetzer, 2005).

Pediatric Pain Management, PCA, and ADEs

Pediatric patients are especially susceptible to medication errors and ADEs for a variety of reasons. First off, they require weight-based dosing and dilutions of medications that were formulated for adults, leading to more calculations and conversions than adult patients; hence, more potential for errors. Additionally, feedback about potential ADRs and improper administration is limited due to underdeveloped communication skills in children (Berde & Sethna, 2002; Kaushal et al., 2001). Most importantly, compensatory mechanisms are less effective in children than in adults, making children more likely to experience harmful physiologic effects of overdose or omission. A study of two academic pediatric hospitals found that potential ADE rates were three times as high in these institutions as in adult hospitals. Also, this study found that drug ordering was most often implicated in potential ADEs, followed by incorrect dosing (Kaushal et al., 2001).

Aside from blatant errors, appropriate practice of pediatric pain management also presents challenges to clinicians. As children grow and develop, the pharmacokinetics and pharmacodynamics of medications change as the physiology of their target organs and metabolic machinery change. For instance, hepatic clearance of medications is reduced in neonates as compared to adults, while it is increased in two- to six-year-old children. In neonates, this is due to underdeveloped hepatic enzymes, including cytochrome P450, which is mostly implicated in drug metabolism. In contrast, two- to six-year-old children have a more mature arsenal of hepatic enzymes, as well as a larger ratio of liver mass to body mass than adults, leading to a higher rate of clearance per unit

of medication than adults (Berde & Sethna, 2002). Renal function matures during the first 12 months of life, making preterm newborns especially susceptible to renal toxicity from medication administration due to decreased renal clearance. Other factors complicating normalized medication dosing in pediatrics include: proportion of body water to body weight, genetic variability affecting enzymatic function, and plasma protein concentration and binding kinetics, among others (Berde & Sethna, 2002).

PCA was once the most widely utilized modality for the management of pain in postoperative pediatric patients (Kost-Byerly, 2002; Verghese & Hannallah, 2010). It is regarded as a safe and effective treatment for moderate to severe pain in children five years of age and older (Kost-Byerly, 2002; Joseph, 2007). As in adults, pediatric PCA provides better analgesic relief not only due to the pharmacological effect, but immediate self-administration of medication decreasing the time from the onset of pain to the onset of analgesia, as well as constant titration of medication to meet the demand of patients' ever-changing pain levels. The advent of smart pump technology with various programmable parameters, safety limits, and storage of drug libraries in new-age PCA devices enhances the safety of PCA use in children (Manrique-Rodriguez et al., 2012). Clinicians argue that "...IV-PCA should be available to any child who understands the concept of pushing a button to take away the pain" (Kost-Byerly, 2002).

Although postoperative pain is the most common indication for pediatric PCA, it is widely used for more effective analgesia in pediatric oncology patients with chronic pain and pediatric sickle cell patients experiencing acute pain due to a vaso-occlusive crisis (Pounder, 1992; McDonald & Cooper, 2001). Children who are younger than five

or who do not have the physical or cognitive capability to operate PCA on-demand usually receive exclusively a continuous IV opioid infusion, NCA, or CCA (Berde & Sethna, 2002; Kost-Byerly, 2002). Although continuous infusion provides better analgesic coverage, patients generally exhibit a higher level of sedation (Kost-Byerly, 2002).

Morphine is the most common opioid analgesic prescribed for pediatric PCA, and it is dosed according to the patient's body weight (McDonald & Cooper, 2001; Verghese & Hannallah, 2010). However, the pharmacokinetic and pharmacodynamic profile of each medication determines its suitability for an individual patient. Hydromorphone or fentanyl may be used over morphine due to adverse effects (nausea, vomiting, etc.) that prevent its continued administration (McDonald & Cooper, 2001). Less widely-used opioids may be used because of compromised clearance due to malfunctioning organ systems. For instance, morphine PCA is contraindicated in renal failure due to retention of a renal-excreted metabolite that retains opioid activity, greatly increasing the duration of sedation (Vetter, 1992). Fentanyl is generally used in renal failure because of its metabolism in the liver to inactive metabolites (Tobias & Baker, 1992). The synthetic opioid, piritamide, has demonstrated efficacy in pediatric PCA with a lower incidence of nausea and vomiting than morphine, making it another suitable alternative for analgesia in children (Petrat, Klein, & Meissner, 1997). Tramadol PCA has been observed in adults and as a continuous IV infusion in pediatrics, but not in pediatric PCA. It also has a lower incidence of opioid adverse effects due to its inhibitory effect in the CNS, but it requires further study for application in pediatric PCA (Shipton, 2000).

PCA parameters in children, like adults, are typically set for the minimum amount of medication to achieve a balance of appropriate analgesia and a low incidence of adverse effects (McDonald & Cooper, 2001). However, many facilities have predetermined guidelines for setting baseline PCA parameters. The PTS in the aforementioned pediatric hospital in the northeastern United States starts morphine PCA patients with a 0.02 mg/kg on-demand bolus, 7-minute lockout interval, 4-hour limit of 0.3 mg/kg, and a background infusion rate of 0.01 to 0.015 mg/kg/hour (Berde & Sethna, 2002). Background infusions are more often used in children than in adults, since studies have reported better sleep quality and duration with lower utilization of on-demand boluses throughout the night (McDonald & Cooper, 2001).

The safety of pediatric PCA has been assessed in several studies. Voepel-Lewis and colleagues compared the prevalence and risk of ADEs between pediatric PCA and NCA/CCA in a renowned pediatric hospital. They found that although there was no difference between the groups, approximately 25% of postoperative PCA (including NCA and CCA) patients experienced a clinically significant ADE that required intervention. PCA patients experienced more “threshold events,” requiring a dosing change or supplemental oxygen administration, while NCA/CCA patients experienced more “rescue events,” requiring naloxone reversal, airway management, or transfer to PICU (Voepel-Lewis, Marinkovic, Kostrzewa, Tait, & Malviya, 2008).

Angheliescu and colleagues analyzed the safety of PCA, NCA, and CCA in their population of pediatric oncology patients during two different time periods. Although previous studies have reported a higher incidence of errors during CCA than during PCA

(Monitto et al., 2000; Voepel-Lewis et al., 2008), the opposite was found in their population. The authors attribute this to the nature of their oncology patients and their families, who are exceedingly vigilant and highly involved in their child's care (Angheliescu, Burgoyne, Oakes, & Wallace, 2005; Angheliescu et al., 2012). This finding highlights the importance of selecting appropriate candidates to administer CCA, and ensuring adequate education and comprehension of their role as a caregiver.

Pediatric PCA, NCA, and CCA must endure constant surveillance and standardized ADE reporting in order to improve the safety of this analgesic modality in such a vulnerable patient population. Many pediatric patients indicated for PCA therapy suffer from chronic conditions, such as sickle cell anemia and cancer, demanding heightened clinical vigilance since a significantly higher rate of iatrogenic ADEs were found to occur in these patients versus pediatric patients without chronic conditions (Ahuja, Zhao, & Xiang, 2012). It was also found that potential ADE rates were significantly higher in neonates in the NICU, which mostly involved the drug ordering stage in the medication use timeline (Kaushal et al., 2001). Of the aforementioned technologies that were developed to improve the delivery of medical care, CPOE and CDS systems were identified as having the greatest potential in the reduction of errors in pediatric inpatients. Combined with refined communication between clinicians and pharmacists, standardized documentation, and constant pain assessment, the future of pediatric pain management promises an institutional culture of safety (Fortescue et al., 2003).

Pediatric PCA Provider Characteristics at the Study Site

Several different types of providers have an influence on the safety and delivery of PCA therapy in pain management. Since the ratio of certain types providers to others involved in PCA therapy tends to vary from hospital to hospital, provider characteristics for the pediatric hospital that is the present study site are described below.

First, two types of physicians generally prescribe PCA in this facility: pediatric anesthesiology fellows and medicine-pediatrics residents. Fellows have more education and experience than residents (given that physicians must first complete a residency before pursuing a fellowship), and they also have a narrower field of clinical practice than residents. Specifically at the study facility, pediatric anesthesiology fellows have one-year program that is ACGME accredited. There is also a two-year program option in which fellows have the opportunity for more individualized training and experience during the second year. The typical rotations for the first year include: 7 months of perioperative anesthesia, 2 months of cardiac anesthesia, 3 weeks of MSICU, and 1 month of pain medicine and regional anesthesia (BCH, 2013). Medicine-pediatrics residents, on the other hand, only perform brief rotations in the study facility as part of a partnership between the study facility and the parent hospital for their residency program. The time spent in the study facility practicing PCA orders varies between four weeks during Post Graduate Year (PGY)-1 and PGY-3 and 8 weeks during PGY-4 (BWH, 2013). In lay terms, PGY-1 and PGY-3 refer to one year and three years since completion of medical school, respectively.

Other than physicians, N.P.s and Physician Assistants (P.A.s) are also PCA prescribers at the study facility, although vastly more N.P.s prescribe PCA than do P.A.s. N.P.s and P.A.s that prescribe PCA in the study hospital only practice within PTS. Becoming a N.P. requires a master's or doctoral degree, which includes advanced clinical training beyond the requirements of R.N. training (AANP, 2013). Typical P.A. training spans 27 months, in which P.A.s are licensed to prescribe medication under the supervision of a physician. Additionally, P.A.s must complete 100 hours of continuing medication education (CME) every two years to maintain licensure (AAPA, 2013).

Staff R.N.s who program PCA pumps have varying educational pathways. A Diploma in Nursing is conferred by a hospital-based educational program, an Associate Degree in Nursing (ADN) is a two-year program through community colleges and hospital-based programs, and a Bachelor of Science in Nursing (BSN) is a four-year degree conferred by colleges and universities. To obtain licensure to practice as a R.N., all nursing program graduates must pass the National Council Licensure Examination (NCLEX)-RN (ANA, 2013). Since there is no undergraduate program specifically for pediatric nursing, additional education and training in pediatrics are generally obtained through the employing organization (SPN, 2013). At the study hospital, potential R.N. hires undergo a comprehensive orientation program that includes one full day of hospital orientation, one full day of classroom nursing orientation, online competency courses, and clinical skills simulation training (BCH, 2013).

The ratio of certain providers to others in the study hospital generally follows the type of clinical service provided to the patient: surgical or medical. For surgical patients,

all PCA orders are written by PTS N.P.s and pediatric anesthesiology fellows. In contrast, for medical patients, the majority of PCA orders are written by medicine-pediatrics residents, with PTS providing the pain management consultation before PCA orders are written. It is important to note that 90% of PTS shifts are covered by N.P.s.

A significant gap found during the literature review is a lack of investigation into the characteristics of providers that may influence the incidence rate and proportion of PCA errors in pediatric pain management. This study seeks to help fill in this gap in the literature by relating data trends with PCA provider characteristics in the study hospital.

OBJECTIVES

Aside from the obvious negative impact that medical errors can have, learning from these events will have a positive impact on the quality of patient care delivered in any facility. This can only occur through extensive review of documented instances, providing data for strategic and comprehensive approaches to reducing ADE incidence and recurrence. Many of these preventable errors are due to the human factors, emphasizing the importance of intra- and interdepartmental communication between clinical and pharmacy teams. Combined with appropriate training for using error-reducing HIT, the rate of clinician-caused errors should continue to be reduced.

The same applies to PCA use in pediatric pain management. Therefore, the objective of the present study is to identify provider issues in the setting of pediatric PCA errors in a 400-bed pediatric hospital in the northeastern United States through data analysis. During the period of this study, Abbott Lifecare PCA III[®] devices were the

only model used at this facility. This retrospective review includes data analysis from PCA event descriptions voluntarily reported to the Safety Event Reporting System (SERS) and data abstracted from EMR charts for each patient affected by a PCA event. The data will be quantified to produce descriptive statistics in order to display potential trends in these errors. The trends will be used to suggest changes in pain management practice to improve PCA patient safety and quality of care delivered.

More specifically, several data points for which there is relatively little literature support will be analyzed for their influence on PCA events and correlation with provider characteristics:

- Hospital unit where the event occurred
- Year that the event occurred, within the study period of 2004 – 2012
- “Final Severity Assessment” level that the event was classified, as determined by the SERS management team
- Source of the event (e.g., human, software, mechanical) based on the event description entered into SERS by the nursing staff on-shift
- Subtypes of human errors (e.g., nurse, prescriber, pharmacy) based on the event description entered into SERS by the nursing staff on-shift
- Credentials of the clinician that wrote the PCA order (e.g., M.D., N.P., P.A., Pharmacy) based on analysis of PCA pump histories entered in the Medication Administration Record (MAR)
- Type of patient affected by the event (medical or surgical)
- Nursing staff shift (day or night)
- Type of event (e.g. dosing mistake)
- Difference in actual dose minus intended dose for all dosing errors

The relationship between medical error incidence, documented strategies and technologies developed to reduce error incidence, and PCA safety in pediatrics is the driving force for the present study. Introducing the human factor on the part of providers

as it relates these factors will contribute to QI in the context of PCA therapy in this pediatric hospital.

METHODS

Data Collection

The Institutional Review Board (IRB) reviewed the study protocol and granted permission to access patient charts in the EMR system for a retrospective review and data abstraction via patient MRNs entered into SERS. Two reviewers (T.S., B.Q.) obtained and examined all reports in the “PCA Events” category of SERS (n = 117) from February 10, 2004 to December 8, 2012. As part of a larger comprehensive review of PCA errors reported to SERS, each event description was reviewed to classify and determine the interplay of several identifiable variables. Variables that could not be ascertained from the SERS report were abstracted from patient charts in the EMR system. Any discrepancies between the two reviewers were resolved through consensus or group discussion with a third reviewer (J.S.), who is an experienced PTS pediatric nurse practitioner (N.P.) and researcher at the hospital. The third reviewer also reviewed and supervised the IRB application process, as well as the data collection procedures. All variable classifications were ultimately appraised by the third reviewer for final acceptance or revision before data compilation and statistical analyses.

For the purposes of the present study, only variables pertinent to clinicians were included in order to analyze their impact on the overall PCA error incidence rate and contributing covariates. First, the number of errors overall as a function of time and as a

function of hospital unit were included to elucidate general PCA error trends. Next, the number of events by each Final Severity Assessment level (Table 4), as determined by nursing staff members who submitted the report to SERS was totaled for comparison.

More specifically to providers, the number and percentage of human errors versus non-human errors, as well as subcategories of human error were explored to elucidate data trends. Also, the number and percentage of errors as a function of the credentials of the prescriber (e.g., M.D., N.P., P.A., Pharmacy) who wrote the PCA order that led to the error were investigated. Errors affecting medical versus surgical patients were totaled for comparison in order to determine data trends related to the types of providers that write PCA orders on the medical and surgical services. In relation to R.N.s who program PCA pumps based on prescriber orders in the CPOE, error trends on the day shift versus the night shift were totaled for comparison.

Finally, in relation to proportion of dosing mistakes, analgesic dosing errors versus non-dosing errors as designated by the chart reviewers were totaled for comparison. Also, the percentage difference in the actual dose of analgesic versus the prescribed dose, as well as the average deviation of the actual dose from the prescribed dose for dosing errors was analyzed.

Table 4 – Final severity assessment levels. Severity levels ranging from “near miss” to “moderate” impact on patients were documented in SERS during the study period.

Final Severity Assessment level	Impact on patient
0	Near Miss/Potential Harm
1	None
2	Minor
3	Moderate

Statistics

Several variables were analyzed further with a z ratio calculation for the significance of the difference between two independent proportions, using VassarStats (Poughkeepsie, NY) software. These two-tailed analyses were tested with alpha (α) level of 0.05.

First, the incidence rate of errors in 2005 was compared to 2012 to assess the significance of the difference from the beginning to the end of the study period. Also, the incidence rate of errors in 2006 was compared to 2008 to assess the significance of the difference in this two-year span. The proportions of errors committed by the floor nursing staff versus prescribers were tested for significance of difference. Also, the proportion of errors with a M.D. as the prescribing clinician was compared for significance of difference against the proportion of errors where a N.P. was the prescriber. The proportion of errors affecting surgical patients was compared to the proportion of errors affecting medical patients, as well as the proportion of errors committed during the day shift were compared to that of the night shift. Finally, the

proportion of PCA dosing errors was compared to the proportion of all other error types for significance of difference.

RESULTS

First, the number of PCA events was analyzed by hospital unit (Table 5), in order to ascertain the distribution of errors by clinical service. The highest proportion of errors (27.4%) occurred in a unit serving orthopedic and general surgery patients. Second highest proportion (15.4%) of error was a medical surgical intensive care unit (MSICU), and third (12.8%) was a unit that serves patients undergoing bone marrow transplants. A limitation of this data was that the total number of patients served in each hospital unit during the study period was unknown.

Next, PCA error incidence per 10,000 PCAs was analyzed by year during the study period (2004 – 2012) (Table 6). The two highest rates were observed in 2008 (111.59) and 2009 (111.31). To evaluate the trend in errors from the beginning to the end of the study period, PCA error incidences in 2005 (26.20) and 2012 (92.14) were compared, finding a significant difference ($p = 0.0053$) between them. To evaluate the largest difference in errors during a two-year span within the study period, error incidences in 2006 (28.83) and 2008 (111.59) were compared, again finding a significant difference ($p = 0.001$) between them. Figure 6 shows the yearly trend in PCA error incidence.

Table 7 and Figure 7 display the number and percentage of errors that were reported at each “Final Severity Assessment” level as designated by the nursing staff

reporting the error to SERS. The majority of PCA errors reported (62.4%) were Severity Level 1, meaning there was no measurable impact on the affected patient.

The source of each PCA event is displayed in Table 8, showing that the vast majority of errors were caused by a human mistake (84.1%). Figure 8 displays this data graphically. Table 9 breaks down human errors into subtypes, revealing that significantly more nursing errors (60.9%) occur than prescriber errors (28.7%) ($p < 0.0002$). Figure 9 displays the proportion of human error subtypes in a pie chart. Table 10 shows the number and frequency of errors by the credentials of the prescriber. By far, M.D. and N.P. licensed prescribers authorized the most PCA orders (56.41% and 39.32%, respectively). When compared against one another, a significant difference was found ($p = 0.0129$). Figure 10 is a graphical representation of this comparison.

Table 5 – PCA errors by hospital unit. This table shows the number and frequency of PCA errors by the hospital unit where the error occurred.

Hospital unit	Number of Errors (n)	Percent
Research and Hematology	4	3.4%
Oncology and Hematology	7	6.0%
Bone Marrow Transplant	15	12.8%
MSICU	18	15.4%
Medicine	10	8.5%
Cardiovascular	1	0.9%
CICU	1	0.9%
Neurosurgery	4	3.4%
General Surgery	1	0.9%
Orthopedics and General Surgery	32	27.4%
Transplant, Urology, and Surgery	5	4.3%
ICP	2	1.7%
MICU	1	0.9%
Surgery and Urology (satellite facility)	1	0.9%
PACU	6	5.1%
Emergency Department	9	7.7%
TOTAL	117	100.0%

Table 6 – PCA errors by year. This table shows the number and incidence of PCA errors by year during the study period.

Year	Total PCAs	Number of Errors (n)	Incidence rate per 10,000 PCAs
2004	2412	1	4.15
2005	2290	6	26.20
2006	2428	7	28.83
2007	2124	19	89.45
2008	1613	18	111.59
2009	1617	18	111.31
2010	1582	17	107.46
2011	1621	16	98.70
2012	1628	15	92.14
TOTAL	17,315	117	67.57
2005 v. 2012	p = 0.0053		
2006 v. 2008	p = 0.0010		

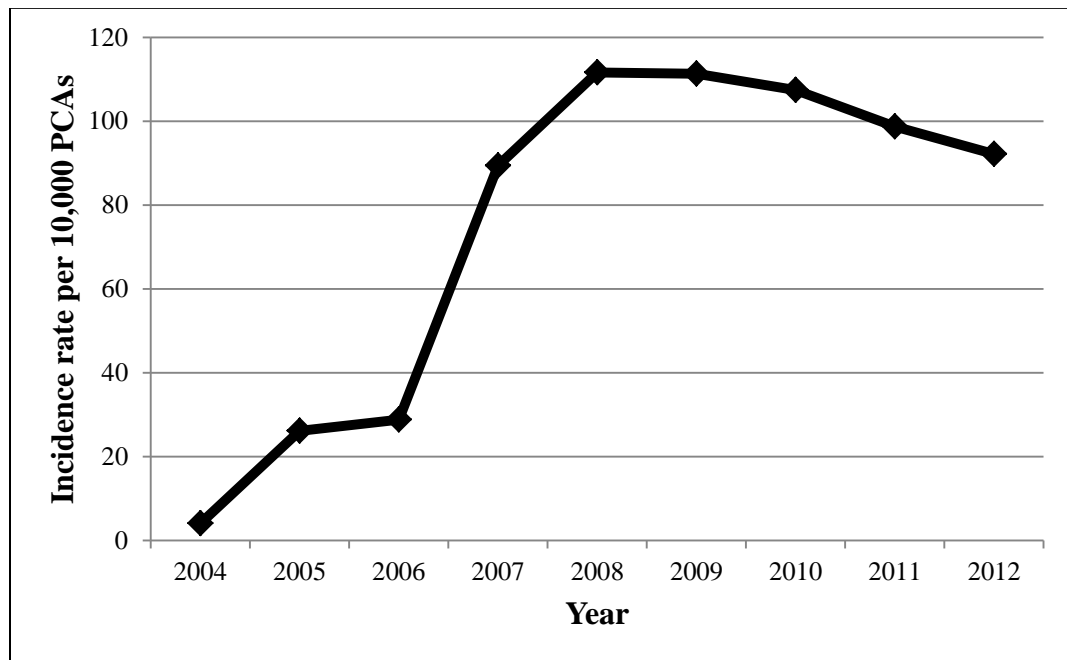


Figure 6 – PCA errors by year. A drastic increase in error incidence between 2006 and 2008 was observed. Significant differences ($p = 0.0053$; $p = 0.001$) in incidence rates were found between 2005 and 2012; 2006 and 2008, respectively.

Table 7 – Final Severity Assessment totals. This table shows the number of events at each severity level, as designated by the nursing staff.

Final Severity Assessment level	Number of Errors (n)	Percent
0 – Near Miss	10	8.5%
1 – None	73	62.4%
2 – Minor	32	27.4%
3 – Moderate	2	1.7%
TOTAL	117	100.0%

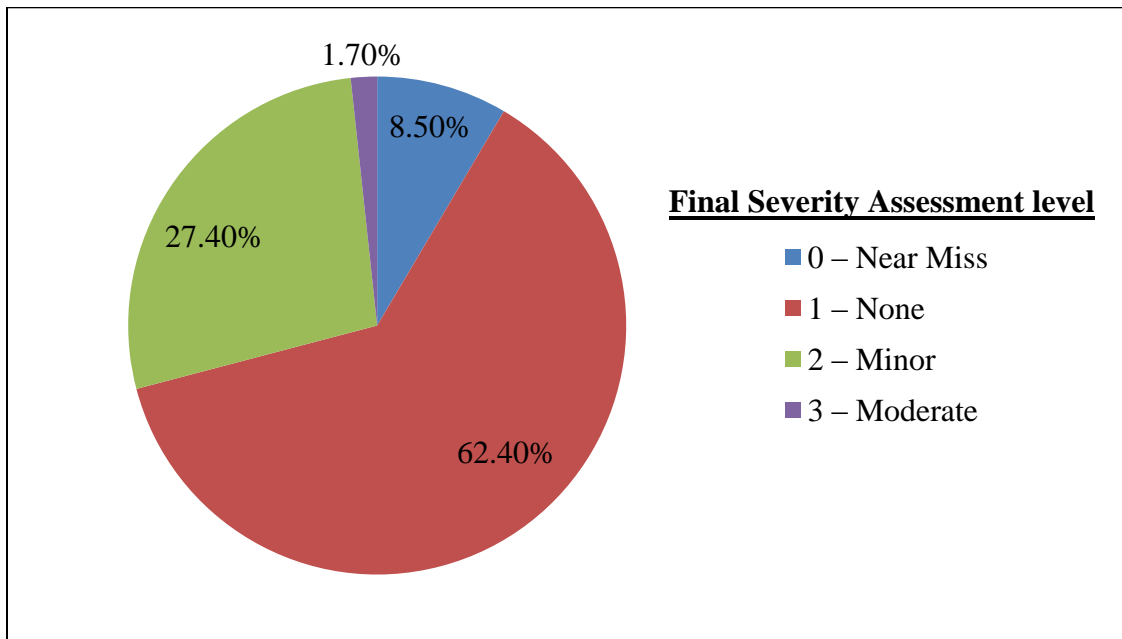


Figure 7 – Final Severity Assessment totals. The majority of errors occurred with no impact on the patient.

Table 8 – Sources of PCA errors. This table shows the number and percentage of each category of error.

Error Category	Number of Errors (n)	Percent
Human	106	84.1%
Mechanical	9	7.1%
Patient	1	0.8%
Software	10	7.9%
TOTAL	126*	100.0%

*Events that were determined to fit two or more error categories (ie. Human AND Mechanical) were counted once in each category. Hence, the sum of cases (n = 126) exceeds the number of events (n = 117).

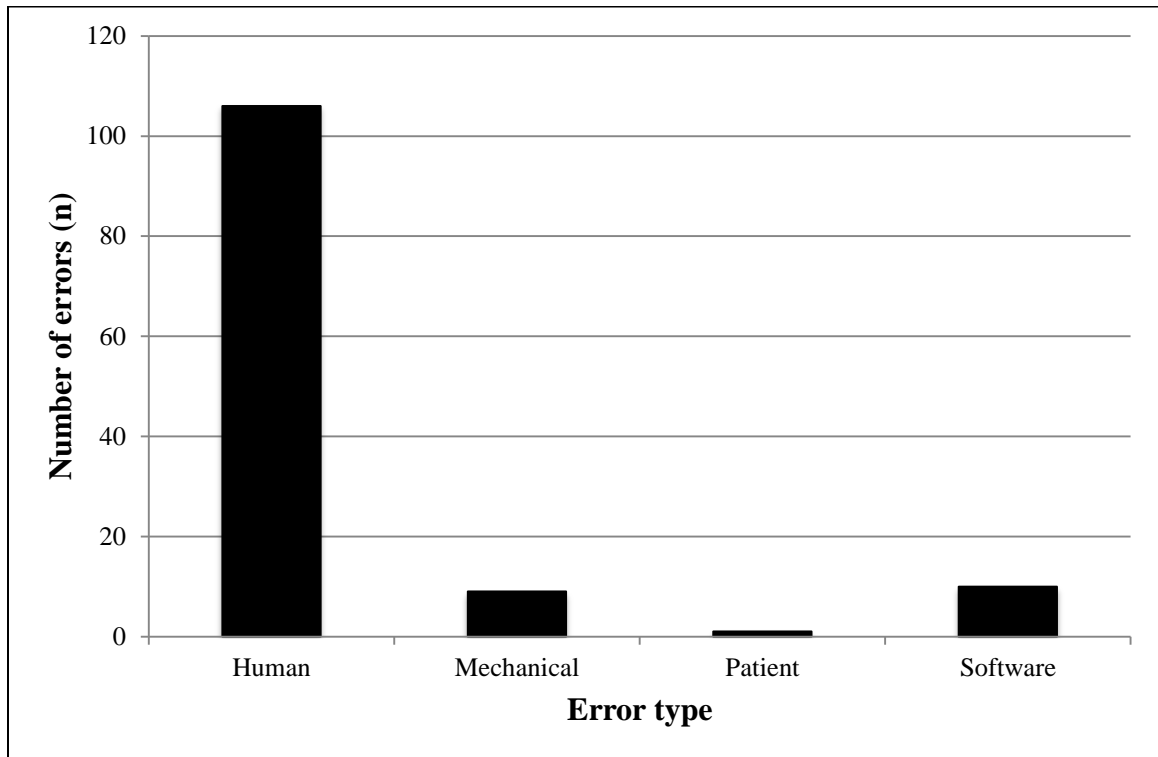


Figure 8 – Sources of PCA errors. This graph shows the number of errors (n) for each error category.

Table 9 – Sources of PCA human errors. This table shows the number and percentage of each subcategory of human error.

Human Error Subcategory	Number of Errors (n)	Percent
Nurse	70	60.9%
Prescriber	33	28.7%
Pharmacy	9	7.8%
Other	3	2.6%
TOTAL	115*	100.0%
Nurse v. Prescriber	p < 0.0002	

*Events that were determined to fit two or more error categories (ie. Nurse AND Prescriber) were counted once in each category.

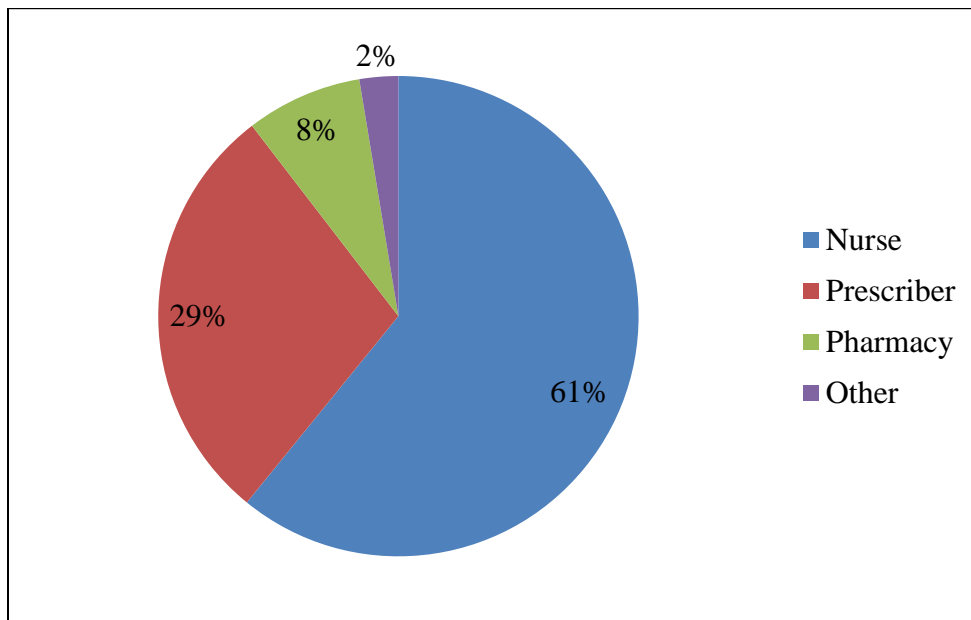


Figure 9 – Sources of PCA human errors. A significant difference ($p < 0.0002$) in proportion of errors committed by nurses and prescribers was observed.

Table 10 – PCA errors by prescriber credentials. This table shows the number and percent of PCA errors by the credentials of the prescriber that wrote the PCA order.

Prescriber Credentials	Number of Errors (n)	Percent
M.D.*	66	56.41%
N.P.	46	39.32%
P.A.	1	0.85%
Pharmacy	1	0.85%
Not Applicable	2	1.71%
Unknown	1	0.85%
TOTAL	117	100.00%
M.D. v. N.P.	p = 0.0129	

*One event where the prescriber was a D.O. was included in the M.D. total errors (n = 66).

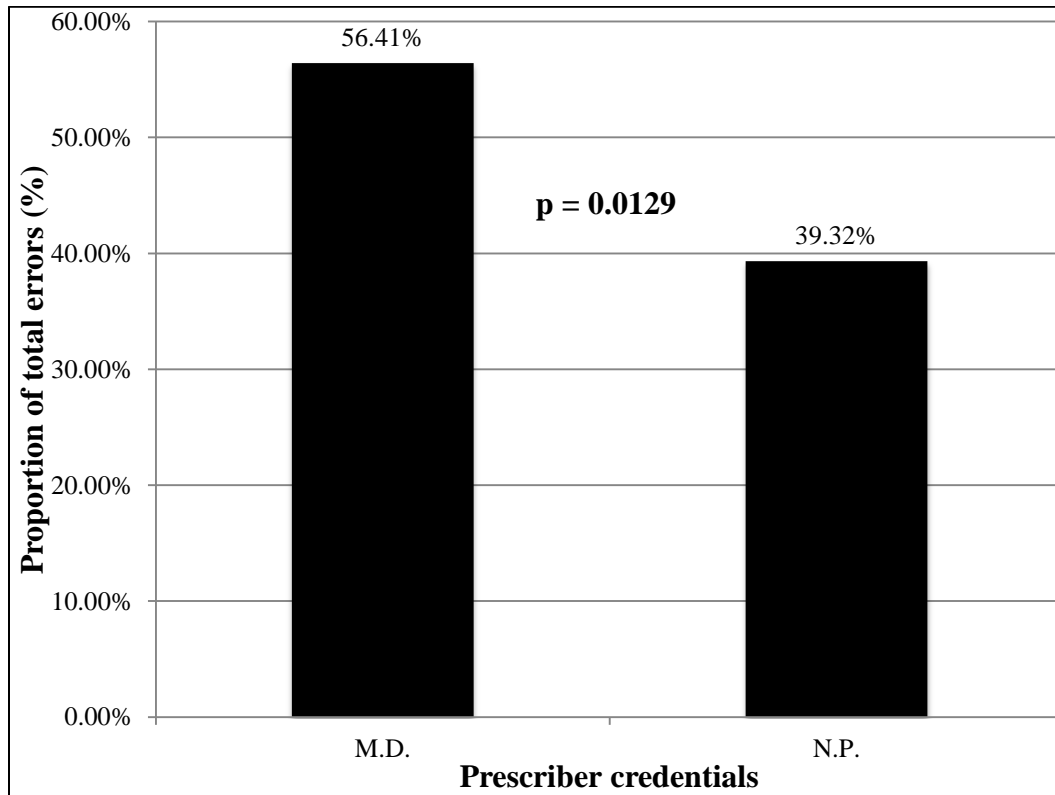


Figure 10 – PCA error percentage by M.D. versus N.P. A significant difference (p = 0.0129) in the proportion of errors between the two types of prescribers was observed.

Error number and proportion in surgical patients (61.5%) and medical patients (36.8%) receiving PCA therapy is shown in Table 11, and displayed graphically in Figure 11. The difference in proportion of errors affecting the two types of patients was found to be significant ($p < 0.0002$).

Table 12 breaks down the number and percentage of PCA errors that occurred by nursing shift, revealing that significantly more ($p = 0.0004$) errors occurred during the day shift (59.8%) than during the night shift (36.8%). Figure 12 shows a pie chart representation of this discrepancy between the two nursing staff shifts.

The proportion of PCA dosing errors (66.7%) was compared to the proportion of all other error types combined (33.3%) in Table 13, which was found to be significantly different ($p < 0.0002$). This data is represented in a pie chart in Figure 13. Finally, Table 14 contains distribution data from the calculated difference of the actual dose minus the intended dose in milligrams [mg]. These data show the average dosing error is 16.7 mg more than the intended dose, and the maximum dosing error reported to SERS was 527.5 mg more than the intended dose.

Table 11 – PCA errors in medical and surgical patients. This table shows the number and percentage of errors affecting each type of patient. A significant difference ($p < 0.0002$) in errors was observed between the two patient types.

Patient Type	Errors (n)	Percent
Surgical	72	61.5%
Medical	43	36.8%
Not Applicable	2	1.7%
TOTAL	117	100.0%
Surgical v. Medical	p < 0.0002	

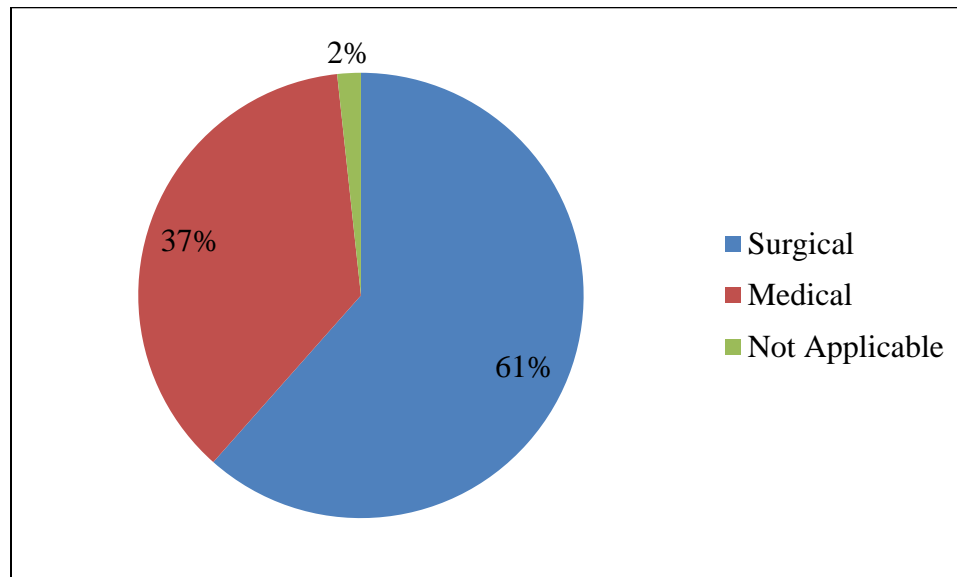


Figure 11 – PCA errors in medical and surgical patients. A significant difference ($p < 0.0002$) in the proportion of errors affecting surgical and medical patients was observed.

Table 12 – PCA errors by nursing shift. This table shows the number and percent of PCA errors by the nursing staff shift when the error occurred.

Shift	Number of Errors (n)	Percent
Day	70	59.8%
Night	43	36.8%
Unknown	3	2.6%
Both	1	0.9%
TOTAL	117	100.0%
Day v. Night	p = 0.0004	

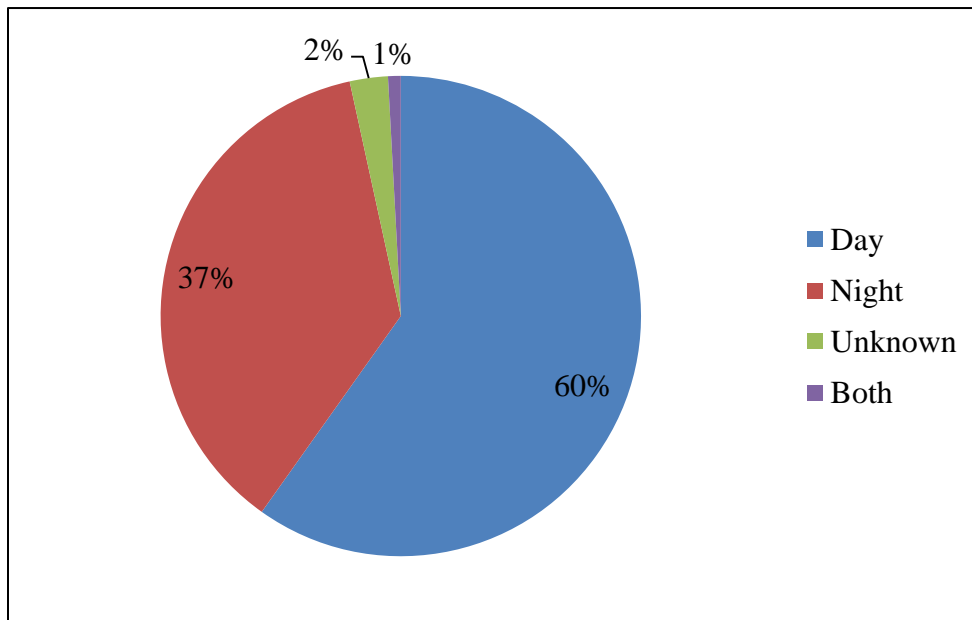


Figure 12 – PCA errors by nursing shift. The majority of errors occurred during the day shift. A significant difference ($p = 0.0004$) in proportion of errors was observed between day and night shifts.

Table 13 – PCA dosing errors. The majority of errors occurred in the pump programming phase of the medication use timeline, resulting in dosing errors.

Type	Errors (n)	Percent
Dosing	78	66.7%
Other	39	33.3%
TOTAL	117	100.0%
Dosing v. Other	p < 0.0002	

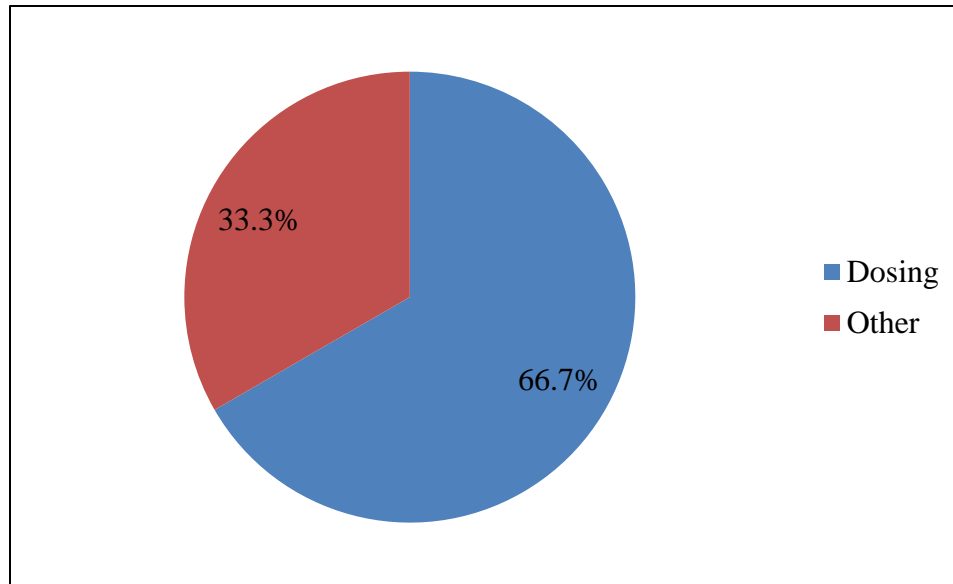


Figure 13 – PCA dosing errors. This graph displays the percentage of PCA errors that were determined to be dosing errors. A significant difference ($p < 0.0002$) in proportion of dosing errors and all other error types combined was observed.

Table 14 – Difference of actual dose minus intended dose. All dosing calculations in milligrams [mg].

Difference of Actual Dose (morphine equivalent in mg*) minus Intended Dose (morphine equivalent in mg*)						n = 78
Minimum	Maximum	Mean	Median	75th Percentile	25th Percentile	
-25	527.5	16.7	1.2	5	0.1	

*All PCA orders written for hydromorphone or fentanyl were converted into IV morphine equivalents for statistical calculations.

DISCUSSION

Results

This study analyzed PCA error incidence and percentages from a multitude of variables that may be related to human error by clinical providers. The aim was to provide information about error patterns for internal QI purposes, as well as dissemination of information to the rest of the medical community at large.

First, more errors occurred in the Orthopedics and General Surgery Unit (27.4%) than any other unit. This is an interesting finding given that patients receiving PCA therapy on the various medical services tend to be more complicated cases than surgical patients receiving PCA, with multiple medications and conditions affecting the efficacy of their pain management. Likewise, this finding is inconsistent with results reported by Brennan et al., in the Results of the Harvard Medical Practice Study I, which found that far more AEs occurred in the General Medicine unit. However, PCA is mostly prescribed to surgical patients in the study facility, making up a larger portion of total PCAs.

The number of PCA errors by year elucidated several interesting findings. First, out of 2412 total PCAs in 2004, only one error event was reported to SERS. Likewise, only six errors were reported in 2005 and seven reported in 2006. This indicates that error reporting to SERS had not become a standard of practice until 2007, when 19 errors were reported.

Statistically, the incidence rates of PCA events reported in 2005 and 2012 (the beginning and end of the study period) were found to be significantly different ($p = 0.0053$). This also could indicate that the process of programming PCA settings in conjunction with orders from CPOE systems and other relatively new HIT has not yet been streamlined or universally adopted in all units of the study facility. The two-year span with the highest increase in incidence of reported PCA events, 2006 and 2008, was also found to have significantly different error incidence rates ($p = 0.001$). Again, this can be attributed to lack of HIT system continuity between hospital units and PCA pump misprogramming due to incorrect parameters or errant CPOE orders.

The vast majority of errors were designated as human errors, with significantly more errors caused by the nursing staff than caused by prescribers ($p < 0.0002$). The proportion of errors caused by both types of providers involved in delivering PCA therapy is unacceptable, indicating that further education and simulation exercises are needed. This is true for both entering PCA orders in the CPOE system on the part of prescribers and programming orders into the PCA pump interface on the part of the nursing staff. In addition to pump misprogramming, other errors caused by the nursing

staff included incorrect set-up: incorrect medication cartridge, tubing, and/or IV placement.

In relation to PCA prescribers, the proportion of errors reported when the prescribing clinician was a M.D. was significantly different ($p = 0.0129$) than the proportion of errors reported when the prescribing clinician was a N.P. This is a surprising finding given that N.P.s on PTS write more PCA orders than do M.D. residents. Interestingly, in this facility M.D. medicine-pediatrics residents receive relatively little training on PCA orders as compared to their N.P. counterparts. This is due to the aforementioned timeline of medicine-pediatrics residents, who only spend a relatively short time in their training at the study hospital, and much less of that devoted to solely prescribing PCA. In contrast, N.P.s and some of the fellows with PTS are career pediatric pain management practitioners, with a larger proportion of their clinical practice devoted to prescribing PCA. This is an important distinction that could play a role in the difference in error proportions between these two disciplines of practice. Also, this discrepancy may be due to miscommunication between physicians entering PCA orders in the CPOE system and the nursing staff who use these orders to program the PCA pump parameters. The staffing ratio of M.D.s to N.P.s was not obtained for this variable analysis, which is a limitation of its validity.

Surgical patients undergoing PCA therapy were affected by a significantly higher proportion of errors than were medical patients ($p < 0.0002$). Again, this finding is inconsistent with Brennan et al., and perplexing because surgical patients tend to be simpler PCA candidates than medical patients. Also, this is surprising given that PCA

orders for all surgical patients in the study facility are written by N.P.s. Also, this may be due to the transfer of care for postsurgical patients from PACU to an observation unit or ICU which may or may not have been utilizing the EMR system to verify and continue PCA orders.

PCA error frequency between the day (59.8%) and night (36.8%) work shifts for the nursing staff were compared and found to be significantly different ($p = 0.0004$). This may be due to fact that most surgeries at this pediatric hospital are performed during the day shift, requiring a transfer of care from the PACU to an observation unit or ICU. It may also be due to inadequate staffing levels during the day shift, forcing nurses to multitask and reduce assessment time per patient.

Finally, there were significantly more dosing errors (66.7%) than all other types of errors combined (33.3%; $p < 0.0002$). There are numerous causes for PCA dosing errors, ranging from errant keystrokes by prescribers in the CPOE system when ordering PCA, to misplacing a decimal point when programming pump parameters, to miscalculation of IV opioid dose by pediatric weight. The majority of PCA dosing error reports in SERS were designated as Severity Level 1-None indicating no clinical findings or changes in the patient's condition as a result of the errant dose. A handful of reports indicate underdosing of patients causing inadequate pain management, which were designated as Severity Level 2-Minor. Several reports of overdose resulted in RD and somnolence, in which the opioid medication was titrated down in PCA and the patient monitored until normal RR and consciousness were restored. There were only two cases of overdose that were designated Severity Level 3-Moderate. The first resulted in RD

and hypotension as a result of the 4-hour lockout never being set on morphine PCA. The patient received 3 mg more morphine during the 4-hour period than intended had the lockout been set correctly. The error was managed by stopping PCA and administering normal saline IV bolus to flush the catheter line of the excess morphine. The second Severity Level 3-Moderate overdose resulted in the patient becoming apneic with SpO₂ levels dipping into the mid- to low-80% range. This error was managed by stopping the patient's continuous morphine infusion and removing the on-demand PCA bolus trigger. It was determined that the patient was oversedated in PACU after receiving 20 mg of morphine IV in addition to initiation of morphine PCA before being transferred to the Orthopedics and General Surgery Unit. There were no reports of overdoses requiring "rescue events" such as naloxone administration or advanced airway management at the bedside.

Future Directions

First, although significance cannot be determined due to a lack of data about the total number of PCAs on each hospital unit, heightened vigilance and attention to detail by clinical staff in the Orthopedics and General Surgery unit could have an impact on this proportion of the total number of PCA errors in relation to the other units in the hospital.

Mentioned earlier, the proportion of errors caused by both prescribers and nurses involved in delivering PCA therapy is unacceptable, indicating that further education and simulation exercises are needed. It is recommended that all PCA prescribers undergo yearly refresher courses focused on proper PCA order entry in the CPOE system. Also, it

was discussed that in addition to pump misprogramming, PCA system set-up was also included in human errors caused by nurses. Therefore, it is recommended that the nursing staff undergo further education on pump programming using the PCA interface and more comprehensive education regarding correct PCA system set-up and operation.

Given the educational discrepancy between medicine-pediatrics residents rotating in the study facility and members of the PTS team, it is recommended that PTS conduct training sessions for residents. These training sessions should be focused on proper PCA parameters and pain management practice tendencies based on the experiences of PTS practitioners.

It is encouraging to note the institutional shift toward reporting to SERS any PCA event that could potentially cause an ADE as a standard of practice. Increased provider education about the importance of compiling and analyzing data from errors for QI purposes, as well as a no-fault culture inherent in anonymous error reporting have contributed to this development. Consistent with Cox et al., improved error reporting as a standard of practice will increase knowledge about error occurrences and pave the way for meaningful QI initiatives. Due to the wide variance in the content of PCA event descriptions entered into SERS, it is recommended that the SERS management team publish an event entry protocol that features a standardized format and content to be mandated throughout the facility.

Additionally, streamlining the transfer of care process between hospital units by mandating that every unit must consistently utilize newly-implemented HIT systems may reduce the confusion of multiple orders that must be transcribed from the computer

screen to paper and vice versa during this process. In turn, this uniformity of information sharing between hospital units may reduce the chance for error when patients are transferred.

Constant educational reinforcement of licensed prescribers and nursing staff about proper use of the EMR and CPOE systems will increase their usage and cut down on providers who elect to bypass the systems for their own convenience. Additionally, multiple checkpoints between the prescriber, pharmacy, and pump programmer are essential to ensuring the safety of PCA medication orders and subsequent administration to patients.

CONCLUSION

In conclusion, the aim of this study was to describe PCA/NCA errors using descriptive statistics to highlight implications for providers and potential areas for improvement. It was found that the vast majority of PCA errors were caused by human factors, including incorrect PCA medication order entry into the CPOE system and PCA pump misprogramming, among others. The implementation of HIT at this pediatric hospital has the potential to reduce the risk for errors and decrease cost. Neither of these potentials has been realized thus far, and it is clear that adoption remains in the lag phase. As health care delivery technologies become more complex and capable of streamlining processes, manufacturers must be increasingly cognizant of their products' user-friendliness. In the case of HIT systems and PCA pump interfaces, continued refinement

by manufacturers is necessary to approach the positive impact on health care promised by these products.

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