PSNet
PATIENT SAFETY NETWORK

Multifactorial Medication Mishap

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Case Objectives

- Understand the system-based causes of medication errors.
- Describe a model for a systems approach to error analysis.
- Identify weaknesses or failures in key elements of the medication use system.
- Select effective risk reduction strategies to prevent medication errors.

The Case

A previously healthy 50-year-old man was hospitalized while recovering from an uncomplicated spine surgery. Although he remained in moderate pain, clinicians planned to transition him from intravenous to oral opioids prior to discharge. The patient experienced nausea with pills but told the bedside nurse he had taken liquid opioids in the past without difficulty.

The nurse informed the physician that the patient was having significant pain, and liquid opioids had been effective in the past. When the physician searched for liquid oxycodone in the computerized prescriber order entry (CPOE) system, multiple options appeared on the list—two formulations for tablets and two for liquid (the standard 5 mg per 5 mL concentration and a more concentrated 20 mg per mL formulation). At this hospital, the CPOE system listed each choice twice, one entry with the generic name and one entry with a brand name. In all, the physician saw eight different choices for oxycodone products. The physician chose the concentrated oxycodone liquid product, and ordered a 5-mg dose.

All medication orders at the hospital had to be verified by a pharmacist. The pharmacist reviewing this order recognized that the higher concentration was atypical for inpatients but assumed it was chosen to limit the volume of fluid given to the patient. The pharmacist verified the order and, to minimize the risk of error, added a comment to both the electronic medication administration record (eMAR) and the patient-specific label that the volume to be given was 0.25 mL (5 mg). For added safety, the pharmacist personally retrieved, labeled, and delivered the drug and a calibrated syringe to the bedside nurse to clarify that this was a high concentration formulation for which the volume to administer was 0.25 mL (a smaller volume than would typically be delivered).

Shortly thereafter, the nurse went to the bedside to administer the drug to the patient for his ongoing pain. She gave the patient 2.5 mL (50 mg) of liquid oxycodone, a volume that she was more used to giving, and then left for her break. A covering nurse checked on the patient and found him unconscious—a code blue was called. The patient was given naloxone (an agent that reverses the effect of opioids), and he responded well. He was transferred to the intensive care unit for ongoing monitoring and a continuous infusion of naloxone to block the effect of the oxycodone. By the following morning, the patient had returned to his baseline with no apparent adverse effects.

The Commentary

Medication errors in the hospital are all too common. Although it may seem that the only error in this case was the nurse giving the wrong amount of medication to the patient, many latent errors contributed to harm reaching the patient. Medication errors are rarely caused by failure of a single element or the fault of a single practitioner.(1) For example, in a root cause analysis (RCA) of a fatal medication error in which a nurse administered the wrong medication by intravenous route, an external review found four main proximate causes and multiple performance-shaping factors that contributed to the event.(2) To prevent similar errors from occurring, the reviewers identified more than 15 suggested changes that spanned the medication use system at the hospital.(2) Because medication errors are often multifactorial, analysis of errors should always identify weaknesses in the system and corrective plans should include risk reduction strategies that span multiple processes.

Systems Approach to Medication Errors

The goal of a system-based analysis of errors is to discover underlying system failures that are amenable to correction. In their landmark study using a systems analysis of adverse drug events, Leape and colleagues identified several domains where underlying problems occurred. These domains included lack of information about the patient, drug stocking and delivery problems, and inadequate standardization.(3) Similarly, the Institute for Safe Medication Practices (ISMP) has identified 10 key system elements that have the greatest influence on safe medication use (Table 1).(4) Although other categorizations also exist, this commentary will use ISMP's model to analyze the case. Readers who also wish to analyze errors in this manner can use a worksheet available on ISMP's Web site (http://www.ismp.org/tools/AssessERR.pdf).

Developing Effective Risk Reduction Strategies

Identifying errors in the system may indicate where changes need to be made. There are two objectives of safe system design: (i) to make it difficult for individuals to make mistakes and (ii) to permit the detection and correction of errors before harm occurs.(3) However, designing effective strategies to make the system safer is difficult. It is easy to implement low leverage strategies ("weak" interventions) as a quick fix for an error. For example, a simple response to this case would be to tell the nurse to read the medication label and electronic medication administration record (eMAR) more carefully, the pharmacist to give better instructions, and the physician to be more careful when using the CPOE system. Such strategies are unlikely to prevent an error from occurring again as they rely on humans to avoid mistakes. Instead, higher leverage strategies ("strong" interventions) that prevent human errors from propagating through the system

should be implemented.

In the rank order of error-reduction strategies (Table 2), high leverage strategies create lasting change in the system. Fail-safes, constraints, and forcing functions are types of strategies that improve the system with minimal reliance on human vigilance and memory. On the other hand, providing education and information and drafting rules and policies are easy to implement but often rely on human vigilance. These low leverage strategies are likely to only be effective if combined with interventions that target systems issues.(5,6)

System-Based Analysis

A robust system-based analysis of this error might discover failures that are amenable to higher leverage solutions to prevent future occurrence. Rigorous analysis of medications errors should use the ISMP model and examine the 10 key system elements (Table 1). Applying the framework in the analysis of this case reveals a substantial number of failures and areas for clear system improvement.

Patient Information

Both the pharmacist and the physician in this case were likely unaware of key patient information which may have contributed to the error. For example, the physician may not have known the patient's opioid-use history, such as which liquid opioid he used in the past, and thus could not reorder that specific medication and dose. It appears the pharmacist was not directly aware of the patient's opioid use in the past and assumed the patient was a candidate for concentrated oxycodone. To prevent similar gaps in the future, the institution should ensure that information about a patient's diagnoses, allergies and adverse reactions to medications (including the inability to tolerate specific formulations of medications), and patient-monitoring information is readily available to all practitioners.

Drug Information

All three practitioners lacked pertinent drug information to make safe decisions. The physician was unaware that liquid oxycodone comes in two concentrations, the pharmacist did not know that the concentrated product was not appropriate for an opioid-naïve patient, and the nurse, who was unfamiliar with the concentrated formulation, did not realize that the volume to be administered was indeed much less than to what she was accustomed. Multiple steps can be taken to prevent these knowledge gaps in the future. Up-to-date drug information should be available to all practitioners, and practitioners should know how to use these references. High-alert medications, such as concentrated oxycodone, should have additional safeguards that guide practitioners to their appropriate use. For example, a pain order set, guideline, or protocol could be used to identify when a patient is ready for escalation to more potent pain medications. Finally, restrict prescribing of certain medications, especially those that are used rarely, to specialized practitioners who are familiar with their use (e.g., a pain specialist in this case).

Communication of Drug Information

Not only were there issues with knowledge about the drug, but the lack of clear communication of drug information also contributed to the error. The list of choices that resulted when oxycodone was searched in the CPOE system was confusing. Even though there were four distinct oxycodone products, eight were

listed due to duplication. Furthermore, the concentrated liquid was not sufficiently distinct from the regular product on that list. Unfortunately, the pharmacist and prescriber did not communicate on the intended plan for the patient to clear up the confusion. In response, the institution should ensure that when new products are added to a hospital's formulary and built into the CPOE system and all aspects of the user interface should be examined. If medications are restricted to certain patient populations, that restriction should be reflected in the CPOE system. For example, if concentrated oxycodone is restricted to ordering by pain specialists, this drug should not be available on the list of medications available to general practitioners in the CPOE system. There should be clear lines of communication between all practitioners. If a pharmacist or nurse has concerns about the appropriateness of a medication order, he should feel comfortable and obligated to question the prescriber.

Drug Standardization, Storage, and Distribution

The manner in which the medications were stored and distributed contributed to the error in this case as well. For distribution, the pharmacist dispensed the entire bottle of oxycodone, and the nurse was required to measure out the patient-specific dose. Ideally, medications should be dispensed from the pharmacy in the most ready-to-use form, which minimizes manipulation by the nurse. Pharmacies should dispense liquid medications that come in bulk bottles in unit-dose cups or oral syringes for those with standardized dosages or in oral syringes with the patient-specific dose already drawn into the syringe for the nurse.

Staff Competency and Education

Knowledge gaps in the safe use of opioids may have also contributed to this error. It is not clear if the physician, pharmacist, and nurse had adequate training on the optimal use of opioids for acute pain. According to an opioid knowledge assessment conducted by the Pennsylvania Hospital Engagement Network Adverse Drug Event Collaboration, practitioners of all levels had a weak understanding of important aspects of safe opioid use. The study suggests that organizations educate and assess staff understanding regarding effects of opioids on sedation and respiratory depression, differences between opioid-naïve and opioid-tolerant patients, indications for long-acting opioids, equianalgesic dosing among opioids, and required monitoring.(7)

Patient Education

Although it is not discussed directly in the case, the patient may not have been aware of the medication he was taking. Furthermore, he may not have been able to request the same opioid he tolerated in the past because he did not know the name. To help them prevent errors, patients and families should be empowered to detect medication errors by encouraging them to ask questions about their medications and the purpose of their medications and by explaining the safeguards that are being used to ensure they are receiving the right medication and dose.

Quality Processes and Risk Management

Lastly, more robust quality control processes may reduce the likelihood of this type of error. For example, the nurse did not have another practitioner independently double-check the medication before administering it. Although they should not be the only safeguard and should be used judiciously, independent double checks (the procedure in which two clinicians independently check each component of

prescribing, dispensing, and administering a medication) can detect up to 95% of errors.(8) While the case does not detail the hospital's processes surrounding identifying, reporting, and analyzing medication errors, all organizations should actively cultivate a culture in which error reporting is encouraged and non-punitive and leads to meaningful change. Using errors and near misses to identify systems issues should be done in an interdisciplinary manner. Proactive risk assessment tools, such as failure mode and effects analysis (FMEA), will help institutions ensure that new medications, processes, and services are implemented safely.

Conclusion

This case highlights the different system weaknesses that together resulted in an error harming the patient. Although it would be easy to fault the individuals involved, the absence of prescribing criteria for and restriction of concentrated oxycodone, the lack of a standard dispensing practice that minimizes nursing manipulation, and the need for staff education and guidance on such high-alert medications, among other factors, contributed to this event. To ensure all gaps in the system are addressed, a rigorous analysis using a model, such as ISMP's Key Elements of the Medication-Use System that is used here, should be employed. Furthermore, when designing changes, hospitals should adopt high leverage risk reduction strategies as much as possible. For example, instead of telling the nurse to read the label more carefully next time, the manipulation of the medication can be taken out of the nurse's responsibility. Although the patient did not experience any lasting adverse consequences in this case, adopting strategies that address system weaknesses will decrease the risk that an error of this type will reach another patient.

Take-Home Points

- Medication errors are multifactorial; they are rarely due to only one failure mode or individual.
- When analyzing medication errors, employ a systems approach by identifying weaknesses throughout the medication use system.
- When choosing risk reduction strategies to implement, focus on those that do not rely on human vigilance or memory.
- Use proactive risk assessment tools whenever new medications, processes, and services are implemented to prevent errors.

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Tables

Table 1. ISMP's Key Elements of the Medication-Use System.(4)

KEY ELEMENT	DESCRIPTION
Patient information	• Pertinent demographic and clinical information (e.g., age, weight, allergies, diagnoses, and pregnancy status) • Patient-monitoring information (e.g., laboratory values)
Drug information	• Up-to-date drug information provided through online references, protocols, order sets, computerized drug information systems, patient profiles, and regular clinical activities by pharmacists in patient care areas or the pharmacy
Communication of drug information	• Standardized communication of drug orders and information among practitioners through collaborative teamwork via all channels of interaction, including electronic systems (e.g., CPOE)
Drug labeling, packaging, and nomenclature	• Avoidance of drug names that look-alike or sound-like • Proper labeling of medications

Drug standardization, storage, and distribution	• Standardization of drug administration times and drug concentrations • Minimizing the availability of medications (e.g., reducing hospital floor stock) • Restricting access to high-alert drugs and hazardous chemicals • Distributing or dispensing medications from the pharmacy in the most ready to use form
Medication device acquisition, use, and monitoring	• Assessment of drug delivery devices before purchase and during use • Implementation of appropriate fail-safe protections (e.g., incompatible connections for various tubings and catheters) • Limiting the types of similar devices to promote familiarity
Environmental factors, workflow, and staffing patterns	• Factors that often contribute to medications errors include poor lighting, noise, cluttered work space, interruptions, and excessive workload
Staff competency and education	• Ongoing assessment of health care providers' baseline competencies and education about new medications, nonformulary medications, high-alert medications, and error prevention
Patient education	• Patient education about medications and how to protect themselves from errors • Encouragement of patient input n quality improvement and safety initiatives
Quality processes and risk management	• Systems for identifying, reporting, analyzing, and reducing the risk of medication errors • Cultivation of a just culture of safety

Table 2. Rank Order of Risk Reduction Strategies.(5,6)

POWER (LEVERAGE)	ERROR REDUCTION STRATEGY	DESCRIPTION

Fail-safes and constraints	• Prevent malfunctioning or unintentional operation by reverting back to a safe state if failure occurs • Restrict access to medications or conditions that may require special training for safe use
Forcing functions	• Procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding
Automation and computerization	• Use of automation and computerization to lessen human fallibility by limiting reliance on memory

Standardization	• Creation of a uniform model to adhere to when performing various functions to reduce the complexity and variation of a specific process
Redundancies	• Inclusion of duplicate steps or multiple individuals to a process to force additional checks in the system
Reminders and checklists	• Alerts and warnings to make important information highly visible • References to help make important information readily available and to assist with remembering steps
Rules and policies	• Rules and policies guide staff toward an intended positive outcome
Education and information	• Activities to impart knowledge and skills about medications and their safe use • Verification of knowledge and skills
Suggestions to be more careful or vigilant	• An ineffective strategy to prevent errors

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