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Medication Errors in Retail Pharmacies: Wrong Patient, Wrong Instructions.

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The Case

Case #1: A 65-year-old woman with a history of acute myeloid lymphoma called her oncology physician's office with symptoms of chemotherapy-induced nausea. After a prescription was called into her local pharmacy, the patient presented to the pharmacy to pick up her prescription for ondansetron. She was asked to provide her last name, but no other identifying information. After several unsuccessful calls from the oncology office to check on the patient over the next few days, the physician's staff called 911. Paramedics found that the patient had collapsed at home. Upon arrival at the hospital, she was diagnosed with severe dehydration, hypotension, and acute kidney injury requiring aggressive fluid resuscitation. Upon further investigation, it was discovered that the patient was inadvertently dispensed spironolactone that was meant for a different patient with the same last name.

Case #2: A 66-year-old woman was prescribed estradiol vaginal tablets (10 mcg) for post-menopausal symptoms. After five weeks of taking the prescribed medication according to the instructions provided by her pharmacy, she noticed an increase in headaches and vulvovaginal itching, both of which were possible adverse effects listed in the medication handout. At her follow-up appointment to discuss her symptoms with her provider, it was found that the prescription instructions were incorrectly transcribed as "1 tablet twice per day" versus the prescribed "1 tablet twice per week". The patient was instructed to hold off taking the estradiol for one week and resume with the correct dose the following week. The patient informed the pharmacy of the error, for which the pharmacist acknowledged the mistake, apologized, and reassured the patient that they would investigate the matter. The patient was never given any follow-up information by the pharmacy. When she went to the pharmacy a month later to pick up her refill, she noted that the refill still had the incorrect instructions on the package.

The Commentary

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Background

Medication errors in the community pharmacy setting have the potential to occur in any step of the medication use process: prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, and monitoring.[1] Every year, 7,000 to 9,000 patients die as a result of medication errors in the United States.[2] The most common medication dispensing error types are incorrect medication, incorrect doses, and incorrect directions.[3] A national observational study completed in 2003 at 59 randomly selected community pharmacies in six metropolitan areas estimated that 51.5 million dispensing errors occur among the 3 billion prescriptions dispensed annually in the United States, or four errors per day in a typical pharmacy filling 250 prescriptions daily.[4] A more recent meta-analysis of this study and eight others estimated a similar error rate of 1.5% in community pharmacies.[1]

Both patient cases discussed herein resulted from human error by pharmacy staff. Human error is defined as inevitable, unpredictable, and unintentional failure in the way we perceive, think, or behave.[5] Human error may occur under conditions involving emotional stress, lack of motivation, high workload, poor communication, insufficient staff, distraction related to noise or interruption, and missed patient information.[6] Case #1 is an example of dispensing the correct medication to the wrong patient, due to the failure to use two forms of identification (e.g., full name and date of birth, full name and telephone number) to confirm the patient's identity. Case #2 is an example of dispensing the correct medication with incorrectly transcribed prescription instructions that advanced through the verification stage; "wrong label instructions" were the most common type of error identified in the study by Flynn et al.[4]

In a geographically diverse sample that included 429 community pharmacies, cognitive errors influenced by organizational conditions, tasks, physical environment, and automated-dispensing technology were perceived by pharmacists to account for approximately 80 percent of dispensing errors.[7] While the scientific literature on the prevention of medication errors in community pharmacies in the United States is relatively limited, systemwide approaches should be implemented to increase patient safety. Some examples include: the use of two patient identifiers, mandatory counseling of patients about their drugs, utilization of a medication error reporting system, adoption of transparency in error reporting, standardization of pharmacy personnel training, and use of Clinical Decision Support System (CDSS) software.

A Systematic Approach to Improving Patient Safety

Although most medication errors can be directly attributed to human error, human error is often a result of poor system design. It is imperative to understand how system-based approaches can mitigate and reduce human error. The current recommended approach to reduce the risk for errors includes development of

safeguards at every level of the medication use process. The goal of these safeguards is to catch errors prior to them reaching the patient or causing patient harm.[8]

The 8 R's

It is commonly recognized that the risk of error in medication dispensing and administration can be reduced by adhering to the "eight rights" of medication use. The eight rights are: the right patient, the right drug, the right time, the right dose, the right route, the right documentation, for the right reason, and the right response. These criteria should be adhered to through all the steps of the medication dispensing process; together they provide a safeguard that reduces human error prior to the point at which the medication reaches or is administered to the patient.[9] Additionally, The Joint Commission requires that during all patient encounters, two unique patient identifiers must be confirmed prior to providing care, treatment, or services. Patient identifiers are defined as "information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended." Some acceptable patient identifiers include patient name, assigned identification number (such as medical record number), date of birth, telephone number, home address, or another person-specific identifier.[10]

In Case #1, the requirement to utilize two patient identifiers was not met due to recognition of the patient's last name by pharmacy personnel. As opposed to two unique patient identifiers, such as patient's first and last name, street address, and/or date of birth, the pharmacy staff required only a last name from the patient. This resulted in the patient receiving a medication that was intended for a different patient with the same last name. Not meeting this Joint Commission requirement and failing to follow the patient safety safeguard of the 8 R's led to both patient harm as well as a Health Insurance Portability and Accountability Act (HIPAA) violation.

Mandatory Counseling and Labeling Practices

The federal Omnibus Budget Reconciliation Act of 1990 (OBRA-90) requires that in all U.S. states, in order to qualify for federally funded Medicaid programs, prospective drug use review of each prescription must be conducted and discussion of medications with patients must be offered at the point of sale.[11] Most states implement the OBRA-90 mandate by only requiring pharmacists to offer to counsel, which can be waived by the patient, versus mandatory counseling. The implementation of first-fill counseling reinforces understanding of the patient's treatment plan, specific indication, and monitoring parameters.[2] Through this practice pharmacists may be able to verify that the patient has sufficient knowledge of administration and indication for taking the prescribed medication(s).

In Case #1, the implementation and practice of mandatory counseling could have alerted the patient that the dispensed medication was for an alternate indication. This would have provided an opportunity for the patient to inform the pharmacist of their actual condition and thus prevent potential harm.

Implementation of an Error Reporting Process

Reporting medication errors is a practice that may be done by both health care professionals and consumers. The Institute of Safe Medication Practices (ISMP) and the United States Food and Drug Administration (FDA) are examples of organizations to which medication errors can be reported.[12,13,14] The purpose of the medication error reporting system is not to punish reporting individuals, but rather to bring awareness to providers, improve monitoring, and to identify potential mitigating solutions.[15] Well-established error reporting systems allow for the identification of common themes and trends among the medication mishaps reported, providing data on which to base design approaches for improving medication safety.[1] Additionally, reporting errors provides some accountability to patients.

Reporting the original error in Case #2 may have mitigated the second occurrence of the transcriptional error. Pharmacies also can use error reporting to track trends and themes of medication errors within their specific environment in order to develop medication error-prevention strategies to address specific local issues.

Transparency in Error Reporting

Patient engagement and transparency regarding pharmacy errors can provide a level of accountability in preventing medication errors in the community pharmacy setting. Hong et al. recommends bidirectional communication between pharmacists and patients involving disclosure of protocols in place for managing medication errors.[16] Patient engagement can result in identification of previously overlooked errors not captured by traditional error prevention techniques.[17] Future evaluations of community pharmacies in terms of their levels of demonstrated transparency may reveal additional opportunities to reduce medication errors.

In Case #2, the patient engaged with and informed pharmacy personnel of the medication labeling error. Unfortunately, the pharmacy failed to communicate to the patient specific plans, or implement them, for preventing the error from occurring again.

Standardized Pharmacy Personnel Training

Training of pharmacy personnel on the dispensing process and prevention of medication errors is essential to ensure that all staff members are applying safe practices appropriately and consistently. Staff should be routinely educated about updated protocols, policies and procedures related to medication use, new medications being used in the pharmacy, high-alert medications, and medication errors. Additionally, staff should be educated on error prevention strategies. Especially when used in conjunction with other prevention strategies to prevent patient harm, staff education can be very effective.[8] Moreover, well-trained pharmacy personnel allow pharmacists to spend more time engaging patients.[18]

In Case #1, the medication error may have been avoided if staff had been trained to consistently verify two patient identifiers.

Clinical Decision Support Systems

Use of CDSS software improves medication safety by augmenting clinicians' ability to make safe and effective medical decisions. Using CDSS software that reviews drug dosing, duplications of therapy, and drug-drug interactions may reduce medication errors.[19]

In Case #2, the patient was incorrectly instructed to take one tablet twice daily as opposed to the correct dosing of one tablet twice weekly due to incorrect instructions on the label, which resulted in the patient being overdosed. The implementation of CDSS software would have alerted pharmacy staff that the dose was incorrect during the transcription process, thus providing an opportunity to correct the mistake.

Take-Home Points

- Adhering to the 8 R's of medication safety for pharmacists, which includes: right patient, right drug, right time, right dose, the right route, the right documentation, for the right reason, and the right response, can reduce the risk for patient harm.
- Mandatory counseling of patients for all first-fill medications can aid in verifying patient understanding of administration, monitoring, and indication for prescribed medications, and additionally acts as safeguard at the final step of medication dispensing.
- Implementing an error reporting process allows tracking and assessment of error trends that can be used to reduce medication errors at the system level and also provides accountability to patients.
- Standardizing training of pharmacy personnel ensures staff are educated in the proper safety protocols for pharmacy operations.
- Using CDSS software aids clinicians in medical decision-making and reduces medication errors by providing safeguards on drug dosing, duplication of therapy, and drug-drug interactions.

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