

The Academy of Managed Care Pharmacy's *Concepts in Managed Care Pharmacy*

Medication Errors

Medication errors are among the most common medical errors, harming at least 1.5 million people every year. The extra medical costs of treating drug-related injuries occurring in hospitals alone are at least to \$3.5 billion a year, and this estimate does not take into account lost wages and productivity or additional health care costs, the report says.¹ Medication error morbidity and mortality costs are estimated to run \$77 billion dollars per year.² Patient safety is a major public health concern. The Academy of Managed Care Pharmacy (AMCP) recognizes the importance of this issue and supports programs that help achieve the goal of improved patient safety and prevention of medication errors. *AMCP's Framework for Quality Drug Therapy*,³ emphasizes and promotes public safety, continuous monitoring for accuracy in dispensing, reliability in the transmission of prescription and medication orders, and continuous review and upgrade of pharmacy operating systems.

What are Medication Errors?

The National Coordinating Council for Medication Error and Prevention (NCCMERP) has approved the following as its working definition of medication error:

"... 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".

This concept paper focuses on the types of medication errors that take place in the ambulatory setting--that is, among patients who self-administer their medications, rather than those patients receiving medications in a clinic or hospital setting. The types of errors that occur in this

¹Institute of Medicine, Committee on Identifying and Preventing Medication Errors, *Preventing Medication Errors*. National Academies Press; 2007:124-25.

² Matthew C. Grissinger, et al., "The Role of Managed Care Pharmacy in Reducing Medication Errors," *Journal of Managed Care Pharmacy* 9, no. 1 (2003): 62-65.

³ Academy of Managed Care Pharmacy, *AMCP's Framework for Quality Drug Therapy*, <http://www.fmcenet.org/index.cfm?p=132D8447> (accessed February 17, 2010).

environment differ from those that occur in institutional settings; this paper will not address the issues and efforts undertaken by pharmacy colleagues in those practice settings.

How Do Medication Errors Occur?

The provision of drug therapy by a medical provider to a patient is a complex process. Errors can occur at any step along the way, from prescribing to the ultimate provision of the drug to the patient. Common causes of medication error include incorrect diagnosis, prescribing errors, dose miscalculations, poor drug distribution practices, drug and drug device related problems, incorrect drug administration, failed communication and lack of patient education.⁴

One of the largest causes of therapeutic medication misadventures is incorrectly prescribed medication. The number of patient deaths resulting from drug errors has increased from 198,000 in 1995 to 218,000 in 2000. The cost of these misadventures to the US economy is more than \$177 billion per year.⁵

Preventable errors occur because systems for safely prescribing and ordering medication are not appropriately used.

- A widely recognized cause of error is illegible handwritten prescriptions.
- Errors may result from insufficient or missing information about co-prescribed medications, past dose-response relationships, laboratory values and allergic sensitivities.
- Errors in prescribing can occur when an incorrect drug or dose is selected, or when a regimen is too complex.
- When prescriptions are transmitted orally, sound-alike names may cause error.
- Similarly, drugs with similar-looking names can be incorrectly dispensed when prescriptions are handwritten.
- Errors may occur because a prescription is never transmitted to a pharmacy, or a prescription is never filled by the patient.
- Physician sampling of medications can contribute to medication errors due to the lack of both adequate documentation and drug utilization review.

The term *dispensing error* refers to medication errors linked to the pharmacy or to whatever health care professional dispenses the medication. These include errors of commission (e.g. dispensing the wrong drug, wrong dose or an incorrect entry into the computer system) and those of omission (e.g. failure to counsel the patient, screen for interactions or ambiguous language on a label). Errors may be potential -- detected and corrected prior to the administration of the medication to the patient.⁶ The three most common dispensing errors are: dispensing an

⁴ Cohen Michael R., *Medication Errors*, 2nd edition. (Washington, DC: American Pharmaceutical Association, 2007), 55-66.

⁵ Wendel Erin. Pharmacists Survey Gives Insight into the Impact of the Economic Downturn on Patients, Pharmacy Practice, and their Communities. *Journal of the American Pharmacists Association*, March 24, 2009. <http://www.pharmacist.com/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=18987> (Accessed February 16, 2010).

⁶ Cohen, 205-234

incorrect medication, dosage strength or dosage form; miscalculating a dose; and failing to identify drug interactions or contraindications.

Errors caused by drug administration can be made by the health care provider or by the patient themselves. Much of the problem in drug administration is communication. Patients are often unaware that errors can happen and often do not take an active role in understanding what is being communicated to them. Errors most often occur when communication is unclear regarding: drug name, drug appearance, why the patient is taking the drug, how much and how often to take it, when is the best time to take it, how long to take it, what common side effects could occur, what to do about a missed dose, common interactions with other drugs or foods, and whether this new drug replaces or augments other therapy. Over-the-counter medications can lead to medication errors because labels may not be sufficiently read or understood, and health care providers are often unaware when patients are taking over-the-counter medications.

The types of errors described above are primarily errors of commission. There are also errors of omission, such as the failure to administer a drug that was prescribed or not administering a drug in a timely manner. Although they are much more difficult to identify through systematic reporting tools, errors of omission must also be addressed through process improvement efforts in order to truly improve patient safety in a comprehensive manner.

Attitudes About Medication Errors

Medical professionals, including physicians, nurses and pharmacists, do not deliberately commit medication errors. They are trained to deliver “error free” health care. However, when errors are discovered, there is an attitude of placing “blame” on the professional(s) involved in the incident. Formal punishment by the individual’s profession is sometimes administered, resulting in fines, license suspension or even license revocation. More importantly, the individual may be punished by the lost respect of his or her fellow health care professionals, which may be even more devastating than a professional reprimand.⁷

Where medication errors are concerned, the question of who was involved is of less importance than what, how and why the system went wrong.⁸ An investigation of medication errors should begin with an analysis of the drug use and delivery channels within a health care system, rather than result in punitive action directly targeted to the health care provider involved with the error. Although there is no acceptable level of error within the medical care system, the goal of health care organizations should be to evaluate errors when they occur and to make changes in the drug delivery process to prevent them from reoccurring in the future or elsewhere. AMCP encourages all medical professionals to take responsibility in efforts to identify, monitor, evaluate and prevent medication errors, and believes that managed care organizations should establish a non-threatening, non-punitive and confidential environment that encourages health professionals to report medication errors in a timely manner.⁹

⁷ Cohen., 1.4

⁸ Cohen, 4.55

⁹ Academy of Managed Care Pharmacy, *Policy Digest: Recommendations to Reduce Medication Errors* (2006).

Reporting Medication Errors

Health care professionals and consumers have the opportunity to report the occurrence of medication errors to a variety of organizations. Examples include the Institute of Safe Medication Practices (ISMP) and the Food and Drug Administration (FDA). These organizations collectively review error submissions. Case reports are published to educate health care professionals regarding errors and near errors. In some cases, the FDA may work with drug manufacturers and others to inform them about concerns with pharmaceutical labeling, packaging and nomenclature to make appropriate changes to reduce the risk of medication errors.¹⁰

AMCP has voiced support for a medication error reporting system that encourages participation and provides confidentiality and protection of the information reported and the person(s) reporting. To be successful a medication error reporting system must have protections for those reporting. Often, pharmacists view mandatory reporting laws and regulations as punitive, especially if public disclosure is included. Compliance with such programs is likely to be less than optimal since the results of reporting could include lawsuits, regulatory enforcement actions, forfeiture of pharmacy license, and loss of professional reputation with accompanying loss of business.¹¹

Regulatory and advocacy activity provides for improving monitoring of medication errors. The FDA MedWatch reporting system provides a comprehensive sentry position for many medication errors to be reported. Although designed primarily for reporting adverse events from medication use, FDA's MedWatch is an appropriate venue to discover medication errors, such as prescribing misadventures and look-alike, sound-alike errors leading to adverse reactions. Many state boards of pharmacy have begun medication error reporting initiatives to detect trends in ambulatory dispensing errors. At this point in time, most are limited to mandatory internal reporting systems within a setting, as is the case in California, where errors must be logged and open for board inspection during routine visits and complaint investigation. Many physician boards and associations participate in prescribing error investigations, driven primarily by peer review and consumer complaint resolution.

Managed Care Pharmacy and Medication Errors

The vast majority of prescriptions filled in the United States are paid for and administered by managed care organizations. These organizations can influence health care providers and their professional societies as well as consumers to encourage medication error reporting and prevention. Quality improvement programs within managed care organizations include mechanisms for reporting medication errors, examining and evaluating causes of errors, analyzing aggregate data to determine trends and making necessary changes within their health care delivery system to prevent errors from occurring.

¹⁰ Institute for Safe Medication Practices, *The USP-ISMP Medication Errors Reporting Program*. <https://www.ismp.org/orderforms/reporterrortoismmp.asp> (March 18, 2010).

¹¹ Academy of Managed Care Pharmacy, *Where We Stand: Confidentiality and Protection of Medication Error Reporting*. <http://www.amcp.org/amcp.ark?p=AA39F78E> (accessed March 18, 2010).

Managed care has taken an active role in developing and adopting technologies and systems designed to curtail the number of medication errors. Managed care organizations provide tools including online drug utilization review and real-time prescription processing blocks when a medication is clearly inappropriate based on therapeutic duplication, medication dosage or drug interaction.

Keys to Error Prevention

Patient Education

Health care professionals must provide adequate patient education about the appropriate use of their medications as part of any error prevention program. Proper education empowers the patient to participate in their health care and safeguard against errors. Some examples of instructions to patients that can help prevent medication errors are:

1. Know the names and indications of your medications
2. Read the medication information sheet provided by your pharmacists
3. Do not share your medications
4. Check the expiration date of your medications and dispose of expired drugs
5. Learn about proper drug storage
6. Keep medication out of the reach of children
7. Learn about potential drug interactions and warnings

The responsibility for the prevention of medical errors rests not only with health care professionals and health care systems but also with the patients themselves. By being informed not only about the names of their medications but the reasons for their use, the times they should be administered and the correct dose, patients can act as the final check in the system. The practice of carrying a continually updated list of medications can be invaluable in the event of an emergency or if patients cannot speak for themselves. This reduces the chance of miscommunications or misinformation. When patients take an active and informed role in his or her health care, many errors can be prevented.

Prior Authorization

Prior authorization programs are used by managed health care systems as a tool to assist in providing quality, cost-effective prescription drug benefits. Improving patient safety by promoting appropriate drug use is an integral function of prior authorization programs. Medication errors can be reduced by prior authorization systems in various ways. First, a health plan may limit coverage to FDA-approved uses as well as unapproved uses that are substantiated by appropriate and adequate medical evidence. Prior authorization may be used to protect against adverse events in highly contraindicated populations. For example, prior approval should be required for Accutane[®] to ensure that no pregnant women receive this medication because it has a high incidence of causing birth defects. A prior authorization program may also be employed to ensure that patients do not receive certain drugs, such as antibiotics, for exceedingly long durations that could put patients at increased risk for adverse events. Overall, a well-

designed prior authorization program is a useful tool in promoting patient safety and reducing medication errors.

Electronic Technology

Bar Coding

One way in which electronic technology can improve patient safety and reduce medication errors is through the use of standard machine-readable codes ("bar codes"). Medication bar coding is a tool that can help ensure that the right medication and the right dose are administered to the right patient. Today's technology imbeds increasing amounts of information within a scannable bar code on even the smallest packages. The NCCMERP recommends that the US Food and Drug Administration (FDA), the United States Pharmacopeia (USP), and pharmaceutical manufacturers collaborate to have the following information imbedded into a medication bar code:¹²

- National Drug Code (NDC) number which identifies the unique drug, dosage form, and strength
- Lot/Control/Batch number, which assists in cases of product recalls
- Expiration date, which helps to ensure that patients do not receive expired medications

Electronic Prescription Record

An electronic prescription record (EPR) contains all the data legally required to fill, label, dispense and/or submit a payment request for a prescription. Pharmacists use the record as a tool to reduce medication errors by guarding against drug interactions, duplicate therapy and drug contraindications. The EPR can also help reduce medication errors by helping pharmacists monitor and audit utilization and by facilitating communication between health care providers to improve patient care. In time, managed health care systems will link the EPR with other medical record systems, allowing prescribers to directly transmit prescriptions to the pharmacy of the patient's choosing. This integration of the patient's entire pharmacy and medical record will improve care through a process of total patient management, including the reduction of medication errors.

E-prescribing

Utilization of electronic prescribing by entering orders on a computer, better known as Computerized Physician Order Entry (CPOE), is a technology that could help prevent many medication errors. CPOE systems allow physicians to enter prescription orders into a computer or other device directly, thus eliminating or significantly reducing the need for handwritten orders. E-prescribing and CPOE can reduce medication errors by eliminating illegible and poorly handwritten prescriptions, ensuring proper terminology and abbreviations, and preventing ambiguous orders and omitted information.¹³ More advanced CPOE software incorporates additional safety features that allow the physician to have access to accurate patient information,

¹² National Coordinating Council for Medication Error Reporting and Prevention, *Recommendations for Bar Code Labels on Pharmaceutical (Drug) Products to Reduce Medication Errors*, June 5, 2007. <http://www.nccmerp.org/council/council2007-06-05.html> (accessed February 16, 2010).

¹³ Cohen, 196.

including patient demographic information such as age, medication history and medication allergies.

Electronic DUR

Due to the technology of the electronic prescription record, pharmacists are able to conduct prospective online drug utilization reviews (DUR). The online DUR process allows the pharmacist to conduct a review of the prescription order at the time it is presented for filling and proactively resolve potential drug-patient problems such as drug-drug interactions, over-use, under-use and medication allergies. This technology allows the pharmacist to assess the prescription order at the time of dispensing and, using information from the patient's medical and/or pharmacy record, determine the appropriateness of the prescribed medication therapy.¹⁴ Medication safety issues commonly addressed in an online DUR process include the following:

- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage
- Inappropriate duration of drug treatment
- Drug-allergy interactions
- Clinical abuse or misuse

Automated Medication Dispensing

Automated medication dispensing systems are now widely used as a less labor-intensive method of dispensing medications. Automated pharmacy dispensing systems are more efficient at performing pharmacists' tasks that require tedious, repetitive motions, high concentration and reliable record keeping, which can all lead to medication dispensing errors. When utilized appropriately, automated medication dispensing systems help to reduce medication errors and improve patient safety.¹⁵ Many automated dispensing systems utilize the bar coding technology discussed earlier to ensure the right drug, dose and dosage form is used.

Internal Quality Control Procedures

Most medication dispensing settings have developed quality evaluation procedures. These practices provide workflow evaluation and error reporting analyses, which lead to excellent protection from medication error. These procedures and evaluations have led to several changes in standard practice for ambulatory pharmacy, generally adopted as acceptable professional practice. These changes have provided additional safety checks, such as image displays, as part of the final dispensing review process, and the addition of descriptive text on prescription labels. These practices not only allow for final dispensing checks, but also allow for patient monitoring of consistency between label description and vial contents.

¹⁴ Academy of Managed Care Pharmacy, *Concepts in Managed Care Pharmacy Series: Drug Use Review*. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed March 18, 2010)

¹⁵ American Society of Consultant Pharmacists, *White Paper on Automation in Pharmacy*, 1998.

Proactive system interventions also provide additional error prevention protection. Many pharmacies and commercial dispensing systems now provide messaging during the drug selection process. When a drug is known to be subject to look-alike, sound-alike drug name confusion, the dispenser is alerted to double check that the appropriate agent has been chosen.

In many dispensing environments DUR responses and resolutions are reviewed by an overview process. When excessive overrides by a dispensing practitioner are detected, the overview process ensures that proper professional evaluation is being conducted to prevent errors such as those described in the previous DUR section.

It is very important that reporting and all subsequent activities are properly evaluated by a continuous quality improvement (CQI) process. A constantly evolving work flow improvement procedure provides maximum safety and is not designed solely for punitive reasons. Increasing pressures from litigation and liability issues should be sufficient for any ambulatory pharmacy entity to establish practices that demonstrate there are diligent efforts underway to protect patients from harmful medication errors.

Conclusion

In summary, medication errors are an unfortunate part of the health care delivery system. Health care provider attitudes must change in the approach to prevention of these errors. Patient education is an important aspect of any program to prevent medication misadventures. Organizations such as ISMP, and the FDA, as well as individual managed care organizations can help to evaluate the cause of medication errors. The collection of error data and analysis in the health care delivery process will minimize the risk of medication errors and improve patient safety.

The health care community must recognize that both people and systems contribute to medication errors. The focus should be on identifying the error-prone aspects of the medication use continuum with the goal of improving system safety and reliability through remedial action. Neither committing nor reporting an error should become the basis for disciplinary or punitive action by an employer.¹⁶ Every error should be examined to determine what elements in the system allowed it to happen. In this way, those who manage health systems can learn from error and determine what corrections are needed to prevent similar errors in the future.

Medication error reduction programs are necessary to achieve improvement in patient care and to satisfy the public demand for a safer health care system. Consumers expect a system of high integrity that will serve them well and not be a cause for peril when health care is needed. They want and deserve to be confident in the safety of the health care system. Those who pay for health care services (government, employers and individuals) would benefit from a reduction in costs that would result from the reduction in adverse events associated with medication errors.

¹⁶ Cohen, 613

Programs to detect, correct and prevent errors partnered with no-fault reporting programs are essential to satisfying this end.¹⁷

¹⁷ Academy of Managed Care Pharmacy, *Where We Stand: Confidentiality and Protection of Medication Error Reporting*. <http://www.amcp.org/amcp.ark?p=AA39F78E> (accessed March 18, 2010).