Chapter 34

Medication Safety

Learning Objectives

1. Define medication error and explain the common types of medication errors as described by national organizations.
2. Discuss the impact of medication errors and the role of pharmacy and other departments in preventing errors.
3. List common causes of medication errors and identify risk factors that increase the potential for medication errors.
4. List medications identified as having a high risk of causing death or serious injury.
5. Describe methods for monitoring and detecting medication errors.
6. Describe the types of documentation and reporting that should be completed when a medication error occurs.
7. Describe methods used to assess medication errors and describe the tools that may be used when evaluating medication errors.
8. Describe and discuss strategies for preventing and reducing the risk of medication errors for each phase of the medication-use process (i.e., selection/procurement, storing, ordering/transcribing, preparing/dispensing, administering, and monitoring).
9. List the types of barriers to improving medication safety and give examples of each type.

Impact of Medication Errors

Adverse drug events (ADEs) are injuries associated with the medication-use process and contribute to a significant amount of patient morbidity and mortality each year. ADEs encompass both medication errors and adverse drug reactions (ADRs).[1] The term *medication error* is used to describe an error that occurs at any phase of the medication-use process (i.e., selection/procurement, storing, ordering/transcribing, preparing/dispensing, administering, and monitoring). ADRs involve an unintended response to a drug used in an accepted manner.[2] Although ADRs are an important cause of ADEs, this discussion will focus on the detection, reporting, evaluation, and prevention of medication errors to improve medication safety.

Although there are inherent risks when using any medication, many medication errors are preventable.[3,4] Media coverage of several fatal ADEs raised public awareness, which led to congressional hearings on this issue.

The exact number of medication errors is unknown because available studies do not use standardized, consistent definitions and they lack comparable measurements, methodologies, and patient populations. It is also suspected that many errors are not discovered and/or reported. However, data from studies conducted in the United States reveal that many patients die or are injured by medication errors and the associated costs are enormous. Studies estimate the following:

- One medication error occurs for each hospitalized patient each day. Fortunately, most are not significant.[5]
- Each ADE can increase length of hospital stay by approximately 2 days.[6,7]

- ADEs increase hospital costs by an average of $1,900 to $2,500 per patient for each event (excluding malpractice costs and costs of injuries to patients).[6,7]
- $177.4 billion was spent in 2000 for injuries caused by medication errors.[8]
- Medication errors contribute to 7,000 deaths each year (inpatient and outpatient).[9]
- Approximately 1.3 million patients are injured each year as the result of medication errors.[10]
- Fatal medication errors tripled between 1983 and 1993.[11]

The rise in medication errors over the years is attributed to many factors including

- increased number of medications on the market
- increased use of more high-risk medications and complex therapy regimens
- increased similarity in drug names, appearance, and packaging
- increased length of shifts and workload for healthcare workers
- decreased number of qualified personnel per shift

To ensure the safe use of medications, healthcare organizations must give a high priority to improving medication-use processes. Administration, medical staff, nursing services, pharmacy, risk management, and other disciplines must collaborate to report and analyze medication errors (i.e., actual occurrences and near misses). Organizations must also be proactive in identifying high-risk areas in its medication-use system and in implementing best practices that will lead to improved patient safety.

The pharmacy department has an essential role in medication safety because it is responsible for procurement, distribution, and control of all medications used in a healthcare organization. To ensure the safe use of medications, the pharmacy staff must

- ensure accurate, timely dispensing of medications
- ensure the integrity of medications
- maintain accurate patient medication profiles
- monitor medication use for appropriateness and safety
- provide accurate, up-to-date drug information to other healthcare professionals, patients, and caregivers
- educate other healthcare professionals, patients, and caregivers about the safe and effective use of medications
- participate in the reporting and analysis of medication errors
- collaborate with other departments to evaluate and improve the medication-use system

Other departments also have important roles in medication safety. Nursing and departments involved in the preparation and administration of medications (e.g., respiratory therapy and diagnostic imaging services) must ensure that medications are prepared and administered safely, patients are monitored appropriately, and patient information is provided and documented accurately. Each department should also participate in the medication error reporting process. Physicians must also participate in the medication error reporting and analysis process, as well as ensure that medication orders are appropriate, complete, and clear and that patients are monitored appropriately. Information systems must ensure that technology supports the provision of accurate, up-to-date patient information to all who need it. Safety and quality or risk management staff must ensure that medication use is monitored, evaluated, and improved in collaboration with other departments. The organization's administration must provide the leadership and resources needed to ensure safe medication-use processes.

Definition of Medication Errors

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) was organized in 1995 to foster the reporting, evaluation, and prevention of medication errors. Its steering committee is composed of consumer and professional organizations and regulatory agencies. Examples of members include

American Medical Association (AMA)
American Nurses Association (ANA)
American Pharmaceutical Association (APhA)
American Society of Health-System Pharmacists (ASHP)
Food and Drug Administration (FDA)
The Institute for Safe Medication Practices (ISMP)
The Joint Commission™
National Association of Boards of Pharmacy (NABP)
United States Pharmacopeia (USP)

The NCC MERP developed a standard definition of a *medication error* 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 healthcare professional, patient, or consumer. Such events may be related to professional practice and healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."[12] In 2001, NCC MERP revised the definition of harm to include pain that may result from harm. This definition includes actual as well as potential medication errors. Actual medication errors are those where the patient receives the medication. Potential errors (near misses) are errors caught prior to administering medication to the patient. It is important to identify and evaluate potential as well as actual medication errors so that possible sources of future errors can be identified, the medication-use processes improved, and the potential for errors reduced.

NCC MERP has also established measurements of error impact, which will be discussed later in this chapter.

Types of Medication Errors

In order to analyze medication errors, it is helpful to categorize the errors by type. ASHP has developed a standard system for categorizing medication errors by type. Table 34-1 lists and defines the 12 types of medication errors identified by ASHP.[13]

Causes of Medication Errors

The causes of medication errors are varied and complex. They usually involve multiple causes and are the result of weaknesses in the medication-use system. While it is tempting to focus on individuals involved in medication errors, it is unrealistic to expect human performance to be free of errors because all humans make mistakes. Corrections that focus on one person or incident do not address the underlying causes of errors and do not produce long-term improvements that prevent future errors. To create lasting improvement and significantly reduce the potential for future errors, the focus must be on *what* caused the error, not *who* caused the error. ISMP has identified common causes of medication errors in 10 categories (see Table 34-2).[14]

TABLE 34-1. Types of Medication Errors[a]

TYPE	DEFINITION
Prescribing error	Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors that reach the patient
Omission error[b]	The failure to administer an ordered dose to a patient before the next scheduled dose, if any
Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual healthcare facility)
Unauthorized drug error[c]	Administration of a medication not authorized by a legitimate prescriber for the patient
Improper dose error[d]	Administration of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the patient (i.e., one or more dosage units in addition to those that were ordered)
Wrong dosage form error[e]	Administration of a drug product in a different dosage form than ordered by the physician
Wrong drug preparation error[f]	Drug product incorrectly formulated or manipulated before administration
Wrong administration technique error[g]	Inappropriate procedure or improper technique in the administration of a drug
Deteriorated drug error[h]	Administration of a drug that has expired or for which the physical or chemical dosage form integrity has been compromised
Monitoring error	Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy

TABLE 34-1. Types of Medication Errors[a] (Continued)

TYPE	DEFINITION
Compliance error	Inappropriate patient behavior regarding adherence to a prescribed medication regimen
Other medication error	Any medication error that does not fall into one of the above predefined categories

[a]The categories may not be mutually exclusive because of the multidisciplinary and multifactorial nature of medication errors.

[b]Assumes no prescribing error. Excluded would be (1) a patient's refusal to take the medication or (2) a decision not to administer the dose because of recognized contraindications. If an explanation for the omission is apparent (e.g., patient was away from nursing unit for tests or medication was not available), that reason should be documented in the appropriate records.

[c]This would include, for example, a wrong drug, a dose given to the wrong patient, unordered drugs, and doses given outside a stated set of clinical guidelines or protocols.

[d]Excluded would be (1) allowable deviations based on préset ranges established by individual healthcare organizations in consideration of measuring devices routinely provided to those who administer drugs to patients (e.g., not administering a dose based on a patient's measured temperature or blood glucose level) or other factors such as conversion of doses expressed in the apothecary system to the metric system and (2) topical dosage forms for which medication orders are not expressed quantitatively.

[e]Excluded would be accepted protocols (established by the pharmacy and therapeutics committee or its equivalent) that authorize pharmacists to dispense alternate dosage forms for patients with special needs (e.g., liquid formulations for patients with nasogastric tubes or those who have difficulty swallowing), as allowed by state regulations.

[f]This would include, for example, incorrect dilution or reconstitution, mixing drugs that are physically or chemically incompatible, and inadequate product packaging.

[g]This would include doses administered (1) via the wrong route (different from the route prescribed) or (2) via the correct route but at the wrong site (e.g., left eye instead of right), and (3) at the wrong rate of administration.

[h]This would include, for example, administration of expired drugs and improperly stored drugs.

Source: Reprinted from Reference 13.

TABLE 34-2. Common Causes of Medication Errors

COMMON CAUSES OF ERRORS	EXAMPLES
Lack of patient information	Patient misidentified Patient allergies not known Patient weight unavailable for dosing medications Pertinent laboratory values not available
Lack of drug information	Incomplete information about patients' home medications Computer warnings on unsafe doses and drug interactions overlooked or ignored Inadequate or outdated drug information resources

TABLE 34-2. Common Causes of Medication Errors (Continued)

COMMON CAUSES OF ERRORS	EXAMPLES
Failed communication	Illegible handwritten orders Ambiguous or incomplete orders Inaccurate transcription of orders Use of apothecary and avoirdupois systems of measurement Inappropriate use of zeroes and decimal points Use of inappropriate abbreviations Failure to clarify unclear orders Verbal orders misheard
Unclear/confusing medication names, labels, and packages	Confusing or ambiguous labels Look-alike, sound-alike medication names Mislabeled/unlabeled medications Labels obscuring information on containers
Unsafe medication standardization, storage, and distribution practices	IV admixtures prepared outside of the pharmacy Storage of chemicals, reagents, and fixatives with medications Nonstandard medication administration times Multiple concentrations of injectable medications stored in patient care areas Failure to stock standardized concentrations and commercially premixed products Access to pharmacy by nonpharmacy personnel after hours
Unsafe medication delivery devices	IV pump programming errors Oral liquid medications packaged in containers with Luer connections IV line mix-ups IV pumps without free flow protection

TABLE 34-2. Common Causes of Medication Errors (Continued)

COMMON CAUSES OF ERRORS	EXAMPLES
Environmental factors and staffing patterns	Cluttered, disorganized medication storage and preparation areas Noise and distractions Poor lighting Staff fatigue Inadequate staffing levels Frequent interruptions in workflow
Inadequate staff orientation, education, supervision, and competency validation	New or reassigned staff required to prepare and administer medications without proper education or supervision Staff lack of knowledge of appropriate medication use in specific patient populations (e.g., pediatrics, geriatrics) Staff lack of knowledge of new medications
Inadequate patient education	Patients reluctant to ask questions Patients do not understand information provided because of language barriers Low literacy
Lack of supportive culture and quality processes	Lack of independent double checks in medication-use process Focus on individual performance improvement rather than system improvements Focus on reduction of the number of errors reported Lack of budgetary support for medication safety Culture of secrecy and blame

Risk Factors

Because certain risk factors increase the potential for medication errors, being aware of these factors is important when designing and assessing safe medication-use systems.

Some medications have a high risk of causing death or serious injury if they are not used appropriately. Table 34-3 lists some of the high-risk medications identified by ISMP and examples of their associated risk factors.[15]

TABLE 34-3. Examples of Medications Having a High Risk of Causing Death or Serious Injury

MEDICATION	RISK FACTORS/POTENTIAL SOURCES OF ERROR
Insulin	Failing to double-check insulin doses before administering the drug Look-alike, sound-alike names (e.g., Lantus and Lente) and look-alike packages Confusing insulin vials with heparin vials Writing *U* for *units* (which can be interpreted as a zero) Setting the wrong rate of delivery for an infusion control device
Opiates	Storing injectable narcotics in floor stock Concentrated forms of oral liquids stored with standard solutions Confusing hydromorphone and morphine Writing *MS* or *MSO4* for morphine sulfate, which may be interpreted as magnesium sulfate Setting the wrong concentration and rate in patient-controlled analgesia (PCA) devices
Potassium chloride/ phosphate concentrate	Storing potassium chloride/phosphate concentrate injections in floor stock Preparing injectable potassium products in the facility Ordering unusual concentrations Ordering by package size (e.g., vials, ampules)
Anticoagulants (unfractionated heparin, low molecular weight heparin, warfarin)	Unclear labeling of concentration and total volume Errors in setting pumps for unfractionated heparin Stocking multiple concentrations of heparin in patient care areas Using multiple-dose containers of heparin Confusing heparin vials with insulin vials and low molecular weight heparin syringes with heparin flush syringes Unrecognized concomitant use of more than one anticoagulant
Sodium chloride solutions above 0.9%	Storing sodium chloride solutions above 0.9% in floor stock Having unneeded and unusual concentrations of sodium chloride available in the facility Failing to double-check medications and concentrations

TABLE 34-3. Examples of Medications Having a High Risk of Causing Death or Serious Injury (Continued)

MEDICATION	RISK FACTORS/POTENTIAL SOURCES OF ERROR
Antineoplastic (chemotherapy) agents	Dosing errors including miscalculations Use of acronyms to order chemotherapy regimens (e.g., CHOP, COPP, DAT, DAV) Look-alike, sound-alike medication names (e.g., cisplatin and carboplatin, doxorubicin and daunorubicin) Administration of vincristine intrathecally
Moderate sedation agents (midazolam, chloral hydrate)	Stocking more than one concentration in patient care areas Staff administering agents not prepared for emergencies (e.g., respiratory depression and arrest) Ordering by volume without specifying concentration
Neuromuscular blocking agents	Administration to patients not receiving ventilation support Mix-ups with look-alike vials of other medications (e.g., heparin, saline, vaccines) Preparation in unlabeled syringes

There are also other risk factors that can increase the potential for medication errors. These include the following:

1. *Environmental factors*—Examples include inadequate staffing; frequent interruptions in workflow; heavy workload; lengthy shifts and work weeks; and poorly designed work environments (e.g., poor lighting and cramped workspaces).
2. *Patient-related factors*—Examples include presence of multiple disease states and co-morbidities; polypharmacy; age-related factors (e.g., need for dosage adjustments, changes in body functions such as renal and hepatic function, changes in sensory and cognitive abilities); low literacy levels or illiteracy; language barriers, and the need for special dosage forms and routes of administration.
3. *Healthcare provider-related factors*—Examples include new or inexperienced staff; poor communication among healthcare providers; multiple practitioners caring for the patient; and multiple services involved in the patient's care (e.g., the patient may progressively move from the emergency room, to the ICU, to a medical-surgical unit, then to a long-term care facility).
4. *Information systems factors*—Examples include systems that are unable to share common patient data (e.g., physician order entry, pharmacy computer systems, point-of-care systems).
5. *Organizational factors*—Examples include no standardization of procedures in healthcare facilities; inadequate access to patient-related information; complex medication-use procedures and documentation systems.

Monitoring for and Identifying Medication Errors

Many errors are not discovered because no reliable methods are in place to detect them. Monitoring for medication errors should be an integral part of the healthcare organization's medication-use improvement plan for all processes in the medication-use system (i.e., selection/procurement, storing, ordering/transcribing, preparing/dispensing, administering, and monitoring). Monitoring systems should detect potential as well as actual errors to help identify and correct problems in the medication-use system before they actually occur. Effective monitoring and detection of medication errors is a collaborative effort requiring all participants in the healthcare process, including patients, to be proactive.

Identifying medication errors can be improved by using a combination of monitoring mechanisms. Examples of methods to improve the detection of medication errors include the following[16]:

1. *Direct observation of persons who prepare and administer medications*—Direct observation is the most effective method for identifying preparation and administration techniques that lead to medication errors.
2. *Evaluation of missing doses*—Medication errors, such as administration of duplicate doses, may be detected when missing doses are identified and investigated. Not all missing doses are the result of an error; some missing doses are justified. For example, the need to administer the first dose earlier than expected can result in a missed dose.
3. *Evaluation of excess doses*—The presence of excess doses in the patient's medication supply (e.g., unit-dose cassette) may indicate omission errors or administration of incorrect dose. Excess doses can be identified by daily reconciliation of pharmacy dispensing records with the nursing medication administration record (MAR) and the patient's medication supply. However, the presence of excess doses may be justified. Some common reasons for justified excess doses include: the patient may not take anything by mouth before a procedure, the medication is discontinued after it was delivered, or the patient refused the dose.
4. *Random chart review*—This technique involves reviewing the patient's chart for information indicating a medication error has occurred. For example, the administration of flumazenil may indicate the use of an excessive amount of benzodiazepines.
5. *Computerized error detection*—Many pharmacy computer systems have the ability to flag potential errors by screening medication orders against the patient's drug allergies, checking medication orders for drug-drug interactions, appropriateness of dose, and other problems. Other computer systems can utilize bar-code technology to pinpoint errors in the loading and retrieving of medications in automated dispensing systems and in the administration of medications via point of administration verification and computerized MARs.
6. *Voluntary reporting*—A system of reporting medication errors that is voluntary, confidential, and nonpunitive can encourage monitoring and identification of errors.

Reporting Medication Errors

Healthcare workers are often reluctant to report medication errors because they fear disciplinary action, embarrassment, and intimidation. An organization that supports confidential, nonpunitive, and voluntary reporting, with a focus on systems improvement, is more likely to encourage reporting.