

# MEDICATION SAFETY



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## Learning Objectives

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1. Understand the nature and implications of care deficiencies affecting the safety and quality of drug use to pharmacy practice.
2. Assess the importance of medication safety in terms of patient outcomes, and financial burden, and societal impact.
3. Evaluate health care organizational structure and system processes that contribute to medication safety.
4. Assess actions taken in response to an error in respect to improving subsequent medication safety.
5. Assess different methods for evaluating, categorizing, and reporting drug errors and measuring medication safety.
6. Analyze the different roles and perspectives of important health care stakeholders in regard to medication safety.

## Introduction

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Providing safe and effective drug therapy to patients is the core purpose of the practice and profession of pharmacy. The use, misuse, or underuse of drugs presents a clear risk for patient harm. Safe drug practices improve patient care through using drugs most effectively while preventing avoidable patient injury resulting from drug therapy. The benefits and risks of drug therapy are a function of the inherent properties of the pharmacological agents used, the inherent physiology and pathophysiology of the patient, and the care processes involved in the use of drugs. This chapter primarily focuses on improving patient outcomes through the implementation of safe medication use processes and practices. Medication safety encompasses each of the following: patient and caregiver actions and interactions, culture, organizational structure, educational aspects, health

care technologies, governmental roles and initiatives, accreditation standards, economics, legal issues, and ethical considerations. A primary goal of medication safety is preventing an injury from a drug (or lack of indicated drug), defined as an adverse drug event (ADE); however, not all ADEs are preventable. Adverse drug reactions (ADRs) are defined in many ways, but typically refer to actual patient harm resulting from an unintended, undesired, or excessive response to drug therapy, and usually are considered those that are nonpreventable. Adverse drug events that result from error or deficiency in care are considered preventable.

Drug errors are perceived and defined in many ways and a consistent concept of what constitutes a drug error is critical to understanding the many aspects of medication safety. The National Coordinating Council for Medication Error Reporting Program (NCC MERP) provides a useful and well-accepted definition of a drug error:

“A drug error is any preventable event that may cause or lead to inappropriate medication use or patient harm, whereas the drug 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.”

Medication safety is best thought of in a broader quality of care framework than simply error prevention. Medication safety should be considered the providing of the best-known quality of care consistently to the appropriate patients in the safest manner possible. This broad definition of medication safety recognizes that failure to appropriately and optimally care for patients produces harm just as simple errors in care delivery do. Thus, medication safety involves not only error prevention, but also effective and consistent application of pharmaceutical care principles and knowledge in the care of patients. The broader definition of medication safety also encompasses the concept that

## Abbreviations in this Chapter

ADC	Automated dispensing cabinet	IOM	Institute of Medicine
ADE	Adverse drug event	ISMP	Institute for Safe Medication Practices
ADR	Adverse drug reaction	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
AHA	American Hospital Association	MAR	Medication administration record
AHRQ	Agency for Healthcare Research and Quality	NCC MERP	National Coordinating Council for Medication Error Reporting Program
ASHP	American Society of Health-System Pharmacists	NCQA	National Committee for Quality Assurance
CDER	Center for Drug Evaluation and Research	NQF	National Quality Forum
CMS	Centers for Medicare and Medicaid Services	P&T	Pharmacy and therapeutics
CNS	Central nervous system	PDA	Personal digital assistant
CPOE	Computerized physician order entry	PDCA	Plan-Do-Check-Act
FDA	Food and Drug Administration	PPAG	Pediatric Pharmacy Advocacy Group
FMA	Failure mode analysis	PRO	Peer-review organization
FMEA	Failure mode effect analysis	PSRS	Patient Safety Reporting System
HEDIS	Health Plan Employer Data and Information Set	QuIC	Quality Interagency Coordinating (Task Force)
HEMEA	Human error mode and effects analysis	RCA	Root cause analysis
ICU	Intensive care unit	USP	United States Pharmacopeia
IHI	Institute for Healthcare Improvement	VA	Veterans Affairs
INR	International normalized ratio	VAERS	Vaccine Adverse Event Reporting System

wasteful expenditure of limited health care resources impair access to needed care, thereby producing patient harm.

Effective and consistent implementation of well-accepted medication safety processes is a complex and difficult task. Leadership, adequate health system resources, cultural change, application of technological advances, improved caregiver skills, and increased patient involvement are all key to improving medication safety. Appreciation for and knowledge of the many aspects of medication safety are necessary for pharmacists to fulfill their professional responsibility to safely care for patients and provide leadership in medication safety. This chapter provides a broad overview of medication safety and provides references to resources for the pharmacist to further improve his or her understanding of drug and patient safety.

## Historical Context

The importance of ensuring that preventable patient harm from medical care is avoided has been recognized since antiquity—as illustrated by the often-quoted statement of Hippocrates: “primum non nocere” (translated as “first do no harm”). The standard operating procedures of pharmacy practice are founded in the ideal of ensuring safe care for patients. The modern era of medication safety can

be traced back to many seminal studies conducted from 1950 through 1980 that demonstrated a high frequency of ADEs. However, recognition that many ADEs resulted from deficiencies in the quality of care was not fully appreciated. The groundbreaking work on pharmacy-based unit dose drug distribution systems and parenteral preparation services as a method of reducing errors provided early evidence of the effectiveness of safety systems in reducing patient risk. The 1970s and 1980s witnessed the expanding concept of pharmaceutical care, prevention of drug-related problems, and publication of systematic studies of poor patient outcomes resulting from deficiencies in medication use. At that time, the important concept of learning from error was introduced. The landmark Harvard Medical Practice Study in 1991 provided strong evidence that preventable adverse outcomes, in particular ADEs, were common in hospitals in the United States, but it failed to elicit widespread response from health care, the public, or regulatory bodies. The 1990s revealed a rapidly expanding body of evidence regarding drug errors and the establishment of the Institute for Safe Medication Practices (ISMP) and other patient and professional safety advocacy groups. The publication of numerous articles describing the frequency of ADEs as well as articles in the lay media describing serious and often fatal medical errors in the late 1990s prompted a growing awareness of the problem within government, health care purchasers, and

Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370–6.

Leape LL, Brennan TA, Laird NM, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;324(6):377–84.

health care itself. These events focused widespread attention on the deficiencies in the quality of medical care and resulting negative impact on patient outcomes from all health care stakeholders.

The 1999 release of the Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, is recognized as a watershed moment in the patient safety movement. This document compiled and evaluated previously available information regarding the problem of medical error. This report estimated that 44,000–98,000 people die each year in the United States because of medical errors, and it focused attention on the problem of errors in patient care. The IOM report substantially changed the direction of the approach to medication safety from one of questioning the size of the problem to one of how to better understand and correct the problem. Numerous efforts by government, regulatory, and accrediting bodies; private industry purchasers of health care; patient advocacy groups; and health care organizations created an environment of rapidly expanding patient safety awareness, knowledge, and initiatives involving most aspects of patient care. Three additional reports from the IOM further defined the problem of suboptimal quality of care, lack of quality standards and regulations, and the inadequate skills of health care providers as the major contributors to patient safety deficiencies. Together, these reports detail recommendations for creating a high-quality health care delivery system. Currently, major safety efforts are focusing on improving the safety and quality culture of medical care and introducing technology into the medication use processes. Although the discipline of medication safety is still evolving rapidly, substantial information exists with which caregivers can improve the safety of drug therapy for their patients.

## Deficiencies in Medication Safety

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### Medication Safety and Quality of Care

All pharmacists have encountered errors in their practices, yet disagreement exists regarding the overall scope and impact of medication safety deficiencies. This is a result of the difficulties of accurately and consistently detecting drug errors and measuring the resulting impact on

patient outcome. Nonetheless, the information that is available today provides strong evidence that drug errors and deficiencies in quality of care occur frequently, and all too often, lead to considerable avoidable patient harm and resource expenditure. Available medication safety studies provide information regarding medication safety deficiencies in various care settings and patient populations. Studies have examined the frequency of errors in the various processes of delivering care, the impact of care deficiencies on patient outcomes and costs, and, in some cases, the relationship between process deficiencies and patient outcomes.

Although it is obvious that medication use in a manner other than that considered the best practice increases the risk for poor patient outcomes, such common quality of care problems are not always thought of specifically as drug errors or safety deficiencies. Although suboptimal quality of care may result in frank drug errors, leading to obvious patient harm, more commonly poor quality care processes produce subtle (unnoticed by the caregiver), but real, patient harm. Because of the variability of patient response to drug therapy and the delayed and subtle nature of the association of suboptimal quality of care and patient outcomes, it is extremely difficult for caregivers to recognize a cause-and-effect relationship. In many cases, poor patient outcomes are attributed to patient characteristics rather than associated with the actual causative deficiencies in the provision of care. Demonstrating the relationship between care quality and outcomes is difficult, but in well-designed and systematic studies, the role of antecedent safety and quality deficiencies in producing or contributing to ADEs is clearly demonstrated. It is probable that unrecognized poor-quality patient care contributes to considerably more preventable ADEs than frank and obvious errors in care delivery. Although this chapter primarily focuses on drug errors, to appreciate strategies to truly improve medication safety, caregivers must view medication safety from the broader quality of care perspective. Useful and familiar concepts for pharmacists to apply when assessing the quality of patient care processes most likely to produce ADEs are the identification of drug-related problems and drug misadventures. Drug-related problems are defined as any drug-related event amenable to detection, treatment, or prevention, whereas drug misadventures are any unexpected adverse result in the medication use process. Thus, by

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Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. *JAMA* 1995;274:29–34.

Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995;274:35–43.

Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. *JAMA* 1997;277:307–11.

Institute of Medicine. Committee on Quality of Health Care in America. *Crossing the Quality Chasm: a New Health System for the 21st Century*. Washington, D.C.: National Academies Press, 2001.

Institute of Medicine. Board on Health Care Services. *Priority Areas for National Action: Transforming Health Care Quality*. Washington, D.C.: National Academies Press, 2003.

Institute of Medicine. Committee on the Health Professions Education Summit. *Health Profession, Education: A Bridge to Quality*. Washington, D.C.: National Academies Press, 2003.

Cipolle RJ, Strand LM, Morley PC. *Pharmaceutical Care Practice*. New York, NY: McGraw Hill, 1998.

Manasse HR. Medication use in an imperfect world. Drug misadventuring as an issue of public policy. *Am J Hosp Pharm* 1989;46:929–44.

Manasse HR. Medication use in an imperfect world. Drug misadventuring as an issue of public policy. Part II. *Am J Hosp Pharm* 1989;46:1141–52.

optimizing the quality of drug therapy through consistent application of medication safety practices, drug therapy knowledge, and the principles and practices of pharmaceutical care, pharmacists will improve medication safety and outcomes for their patients.

### Overall Impact of ADE

Estimates rank ADEs as the fourth to sixth leading cause of death in the United States, accounting for more than 7000 deaths and more than 1 million serious drug-related injuries per year. More than 20% of Americans report they or their loved ones have experienced a serious medical error, many related to medication use. Many ADEs are preventable or ameliorable (i.e., appropriate monitoring and care could have reduced the severity of ADEs). The true frequency of ADEs resulting from medication use safety and quality deficiencies is not known because of the nature of such events, the lack of consensus definitions, and the inadequacies of present methods to identify and quantify the problem. Available information demonstrates that both preventable and nonpreventable ADEs occur commonly in all patient care environments. The reported frequency of errors and preventable ADEs varies considerably based on the methodology used, the definition of ADE and error, and the care setting examined. Estimates based on data collected using spontaneous voluntary reports or specific ADE documentation in the medical record are consistently lower than those that use more effective drug-related problem identification techniques, such as caregiver interviews, caregiver ADE prevention intervention data, patient interviews, laboratory monitoring, identification of ADE triggers, and computerized medical record review. Similarly, determining of whether a potential ADE exists, or whether an actual ADE was preventable or ameliorable, depends on criteria and definitions used. Based on these limitations, it is likely that the available studies reporting ADE frequency and preventability underestimate the magnitude of problem.

### *Adverse Drug Event-related Societal and Financial Costs*

The ADE-related societal and financial costs are substantial. Annually, ADEs occur in more than 2 million individuals and 1 million people are hospitalized as a result. In long-term care facilities, about 175,000 preventable ADEs occur annually, almost 10% of which are fatal or life threatening. Information from autopsy reports suggests that ADE-related deaths are a growing problem in the United States. An estimated 20–60% of all ADEs in many care settings and patient populations are considered preventable

in that they result from some deficiency in the provision of drug therapy (a drug error as defined by NCC MERP). This allows an estimate of the impact of the problem of medication safety deficiencies to be made when information regarding ADEs, but not drug errors, is available. Obvious serious and severe ADEs are frequently the result of errors and deficiencies in care. Based on this information, the high likelihood that some error in care delivery occurred should always be considered whenever a practitioner encounters a patient experiencing an ADE or inadequate drug response.

The negative societal impact of medication safety deficiencies extends well beyond the direct harm it causes patients, their families, and loved ones. The public's trust and confidence in health care clearly are affected. More than 50% of the public consider medical errors to be common or somewhat common. Two-thirds of the public feel that the quality of medical care in the United States is a significant problem. Fear of receiving the wrong drug is the most common concern of patients being admitted to the hospital.

The direct cost of ADEs to the United States economy in 2001 is estimated at \$177 billion, which is more than double the amount from 1995. This amount approximates the total United States expenditures for pharmaceuticals in 2001. The cost of ADEs in hospitals is estimated to be \$2000–\$5000 per occurrence and in a 400-bed hospital \$2–\$5 million per year. Given estimates that 20–60% of ADEs are preventable, a large proportion of expenditures resulting from ADEs are likely to be avoidable with improved quality of care. Considering the increasing cost of health care and resource limitations, this largely avoidable expenditure is of major societal concern. Thus, the financial costs of preventable ADEs provides a strong economic- and business-based argument for implementing improved medication safety practices. Additional costs resulting from ADEs include the high cost of health insurance, malpractice insurance, legal costs, and malpractice awards. Malpractice claims related to drug-related injury constitute a large proportion of lawsuits brought against health care providers and organizations. Throughout a 9-year period, claims related to ADEs constituted 6% of all claims to one insurance company, of which 66% were preventable. The average indemnity plus expense cost for preventable ADE claims in outpatients was about \$74,000, whereas that of hospitalized patients exceeded \$325,000.

Medical errors impact both caregivers and the organizations where they work. Caregivers involved in drug errors often are referred to as the “second victim” of errors. Short- and long-term effects on caregiver performance may be considerable, and the likelihood of continuing their careers in health care may be jeopardized. Errors can create

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Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA* 1998;279:1200–5.

Wiffen P, Gill M, Edwards J, Moore A. Adverse drug reactions in hospital patients. A systematic review of the prospective and retrospective studies. *Bandolier Extra*. June 2002. Available at [www.ebandolier.com](http://www.ebandolier.com). Accessed February 2003.

Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med* 2002;347:1933–40.

Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc* 2001;41:192–9.

considerable loss of organizational prestige, compromise teamwork, and create inefficient functioning.

### Frequency and Nature of Patient Harm

The frequency and impact of ADEs has been investigated in many care environments. The nature and impact of ADEs expectedly varies based on the care setting, patient population, and availability and quality of medical care. Pharmacists should be knowledgeable about and actively identify drugs and care processes presenting the greatest patient risk in the setting within which they practice.

### *Ambulatory and Community Setting*

In a community setting, it is estimated that ADEs occur in 5–35% of patients. Of these adverse events, more than 10–30% are preventable and 25–50% are ameliorable. Fifteen to 35% of these ADEs are severe, an even higher proportion (40%) of which is preventable or ameliorable. Preventable ADEs are a common reason for patients to seek outpatient medical care. Two to 15% of emergency department visits are a result of an ADE, up to 70% of which may be preventable. Adverse drug events are a common cause of patients seeking care through ambulatory care sites and emergency departments. Many studies demonstrate that 3–7% of adult and 2–3% of pediatric hospital admissions are results of ADEs, a large proportion (30–60%) of which is preventable. After being discharged from a hospital, 12% of patients experience a significant ADE, 25% of which are preventable and another 40% is ameliorable. As expected, the frequency of ADEs increases as the number of drugs used increases.

Drugs most commonly associated with ADEs in the ambulatory setting are central nervous system (CNS) or psychiatric agents, cardiovascular agents, antimicrobials, diuretics, nonopiate and opiate analgesics, antidiabetic agents, anticoagulants and antiplatelet agents, corticosteroids, electrolytes, gastrointestinal agents, and antihypertensives. The most common types of error are wrong drug choice, dosing errors, inadequate laboratory or symptom monitoring, delayed response to patient symptom and complaints or to laboratory results, inadequate patient education and communication, allergy to drug, and drug-drug or drug-patient condition interactions.

Preventable ADEs are commonly the end result of a failure of multiple steps within the medication use process. Studies identified the most common medication use process steps in which care deficiencies lead to ADEs. In community-dwelling patients, deficiencies in prescribing and monitoring drug therapy contribute to 50–60% of ADEs, patient actions or communication failure between patient and caregivers contribute to 20%, whereas errors in dispensing account for only 2%.

One in five patients receiving home care or home infusion therapy experiences an ADE. Higher drug use in

these patients and poorer patient cognition is associated with a greater frequency of ADEs. The most commonly encountered ADE in home care involves the gastrointestinal tract and CNS. The most common drugs associated with ADEs in the home care setting are cardiovascular agents, antimicrobials, CNS agents, hormonal agents, and analgesics.

### *Long-term Care Facilities*

Adverse drug events occur in patients in long-term care facilities at a rate of two per 100 patient-months, more than 40% of which are serious or fatal. More than 50% of all ADEs may be preventable, and it has been found that the most serious ADEs are the most preventable (more than 70%). The most commonly encountered ADEs involve CNS effects, falls, bleeding, and gastrointestinal effects. The most common drugs associated with ADEs in the long-term care facility setting at the present time are CNS agents, antimicrobials, anticoagulants, cardiovascular agents, antidiabetic agents, and hormonal agents. The most common types of drug errors involve wrong dose and drug-drug interactions, whereas monitoring errors involve inadequate laboratory monitoring or delayed response to laboratory or patient condition. In long-term care facility patients, deficiencies in prescribing and monitoring of drug therapy most commonly are associated with ADEs, contributing to 65–70% of cases. Administration errors contributed to 3% of ADEs, whereas transcription and dispensing errors both contributed to less than 1% of ADEs.

### *Hospitalized Patients*

In the hospital setting, ADEs occur in about 10–30% of patients, and 3–7% of patients experience a significant, serious, or life-threatening ADE. Many more patients experience errors in care without immediately discernible harm. In hospitalized patients, 30–60% of ADEs are considered preventable, and similar to other settings, an even higher proportion of severe ADEs are preventable. Adverse drug events contribute to one in five adult deaths in hospitals and increase hospital length of stay by 1–3 days. The most common type of ADE encountered in hospitalized adults are CNS effects, gastrointestinal effects, cardiovascular effects, metabolic effects, allergic reactions, and fluid and electrolyte imbalance. Drugs most commonly associated with ADEs in hospitalized adults are cardiovascular agents; antimicrobial agents; anticoagulants; opiate analgesics; antidiabetics; sedative hypnotics, psychiatric agents, and other CNS agents; electrolytes; respiratory agents; and chemotherapeutic agents.

The impact of medication safety deficiencies has been evaluated in many specific hospitalized patient populations thought to be at particular risk for errors and resultant poor outcomes. The elderly receive more drugs and are more susceptible to harm when errors and deficiencies do occur.

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Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003;138:161–7.

Gurwitz J, Field TS, Harrold HR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003;289:1107–16.

Gurwitz JH, Field TS, Avorn J, et al. Incidence and preventability of adverse drug events in nursing homes. *Am J Med* 2000;109:87–94.

Patients in intensive care units (ICUs) also experience more ADEs than those outside the ICU because of the existence of higher acuity of care, more medical conditions, and the attendant increased number and potential toxicity of drugs prescribed and administered. Pediatric patients particularly are vulnerable to ADEs resulting from errors. Those patients experience ADEs at a rate of 2–17 per 100 admissions, with 30–50% being preventable. The frequency of ADEs appears related to the severity of patient illness and acuity of care. Drugs most commonly associated with ADEs in hospitalized children are antimicrobial agents, opiate analgesics, sedative hypnotics, and other CNS agents, cardiovascular agents, electrolytes, and respiratory agents. In hospitalized adult and pediatric patients, deficiencies in prescribing and monitoring of drug therapy contribute to 50–70% of ADEs. Deficiencies in administration account for 25–40%, and transcription errors and dispensing errors each account for 10–15% of ADEs.

### Frequency of Deficiencies and Errors in Major Medication Use Process Steps

Preventable ADEs are an end result of one or more errors or deficiencies in the medication use process. The medication use system is a complex process, involving multiple individuals, and multiple steps and handoffs, all presenting opportunities for errors. Errors occur frequently in the medication use process; however, many errors are detected or averted before actually altering patient care. Other errors eventually reach the patient but cause no harm or only minor and reversible adverse effects. About one in 100 errors in medication use system processes reach the patient and cause some adverse effect. Given the large number of opportunities for error in the medication use process, the 1% chance of an ADE from an error is significant given the known frequency of errors in major steps of the process. The type of error and drug(s) involved often determine whether patient harm occurs. The relative frequency of drug errors will depend on the specific care environment and medication use process step examined. Predicting which and when specific errors in care processes produce patient harm is difficult because of the nature of the medication use system and of error. Errors occurring earlier in the process, such as prescribing, are detected and averted more often than those occurring later in the process, such as dispensing, drug administration, and patient adherence to therapy.

The frequency of errors occurring in the various steps of the medication use process depends on the exact design of the particular processes used in a given medication use system and staff knowledge, skills, and performance. The frequency and nature of errors and care deficiencies in each of the major steps of the medication use process have been investigated. Deficiencies and errors in the various steps of the medication use process should be examined to understand how improvements in these care processes can reduce patient risk.

### *Drug History and Patient Assessment*

Patient assessment and drug history taking by prescribers and other caregivers often are deficient. Decisions regarding patient care often are based on assessment of medication use and response. Obtaining an inaccurate drug history and using such information may lead to subsequent errors in care. Failure to properly identify the presence of conditions for which drugs are indicated or contraindicated, mistakenly determining the presence of an indication for drugs, or failure to properly assess patient response to drug therapy are common causes of poor medication use. Limited information exists regarding the frequency of deficiencies in these processes. Extrapolating from the available data on improvements made when pharmacists participate in obtaining drug histories and assessing medication use suggests problems occur in 25–40% of patients. Patient assessment deficiencies also occur because of poor documentation or lack of available patient information. In the ambulatory setting, more than 75% of a patient's medical records will contain a discrepancy with the drug regimens the patient actually is taking. Most common, discrepancies involve omissions of the drugs the patient was taking (50%), recording a drug the patient was not taking (29%), and recording of the wrong dose or frequency (20%).

### *Drug Prescribing and Monitoring of Drug Therapy*

Deficiencies in prescribing and monitoring drug therapy contribute to 60–70% of actual and potential ADEs, depending on the care setting. Errors in the prescribing process occur at a rate of 3–20% of all prescriptions. Errors with potential to produce a significant ADE occur in about 2–10% of prescriptions in the outpatient setting and 0.5–10% of orders in the hospital setting. Prescribing contraindicated drugs occurs 12–40% of the time with elderly patients. In long-term care facilities, inappropriate drugs are prescribed for more than 15–40% of patients. Prescribing errors most commonly occur during the prescription writing process; however, most serious errors occur during the drug therapy planning and decision-making process.

The most common types of errors by prescribers are drug choice, dosing (overdoses and underdoses), dose frequency, omission of indicated drug, wrong dosage form, wrong route, allergy to a prescribed drug, duplicate drug therapy, drug-drug interactions, excessively prolonged drug therapy, and inadequate patient education and communication. Prescribing is an early step in the medication use process; therefore, ADE defenses, such as pharmacist prescription and therapy review, often are operative to detect and prevent propagation of an error to the point of impacting patient care.

Inadequate monitoring and assessment of drug therapy and failure to take appropriate action when an ADE is imminent or occurs contribute to a large proportion (60%) of ADEs and the failure to ameliorate ADEs once they occur. The most common deficiencies in monitoring involve inadequate monitoring of drug response and ADEs, inadequate laboratory monitoring, and failure to respond to

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Kaushal R, Bates DW, Landrigan R, et al. Medication errors and adverse drug events pediatric inpatients. JAMA 2001;285:2114–20.

signs and symptoms of ADEs. The importance of effective caregiver and patient education and communication in monitoring of drug therapy and preventing and ameliorating ADEs cannot be overstated.

### *Documenting and Transcribing*

Discrepancies and deficiencies in documentation of drug therapy and other important aspects of care occur commonly in all care settings. Inaccurately recorded patient drug therapy in medical records is found in more than 50% of ambulatory patient records. Drug documentation and order transcription errors occur frequently and account for at least 10% of preventable ADEs in hospitals. Because of the tight coupling between the transcribing and drug administration processes, transcribing errors commonly lead to drug administration errors in hospitals. Errors in drug therapy documentation include failure to document accurately and completely a patient drug use history, failure to document accurately patient response to therapy, failure to document allergies and other important patient information, and failure to document drug administration. Drug order transcription errors most commonly involve wrong frequency, missed drugs, omitted doses, wrong time, extra doses, wrong dose, and failure to note known allergy.

### *Drug Preparation and Dispensing*

The problem of dispensing errors is familiar to all pharmacists. In the community and outpatient pharmacy setting, errors occur at a rate of 1–12%, most of which are detected before patient use. The estimated frequency of completed dispensing errors with potential for significant patient harm is 0.1–1.5% in the outpatient setting (7–10% of all pharmacy dispensing errors). The most common errors in community pharmacy are wrong label instructions or wrong label information (65% of all errors), wrong quantity dispensed, wrong strength of correct drug, wrong drug dispensed, failure to dispense ordered drugs, and wrong dosage form. The quality and effectiveness of patient counseling and education is frequently suboptimal.

In hospitals, errors occur at a rate of 1–5% of doses dispensed from the pharmacy, with a smaller rate of significant errors (1–3%). In the hospital setting, problematic areas include drug order review, pharmacy computer order entry, drug selection, drug preparation, drug labeling, wrong dose, wrong patient, wrong route, wrong formulation, and failure to note allergy or other contraindication. The use of machine-readable labels (bar codes) during the drug selection, verification, and dispensing process has the potential to reduce greatly error rates in these steps. Automated dispensing technologies, such as automated dispensing cabinets (ADCs), provide a highly accurate method of drug dispensing and reduce wrong time administration errors; but if not properly controlled and applied, they may increase the frequency of

more serious types of administration errors because of nonpharmacy caregiver access to uncontrolled drug stocks on patient care units.

Errors in the preparation of parenteral drugs occur in 6–10% of preparations and 20–35% of total parenteral nutrition preparations. Of these parenteral product preparation errors, 2% have potential for eventually producing patient harm. When parenteral drugs and fluids are prepared on nursing units, errors occur in up to 15% of preparations, with 60% having the potential for patient harm. All commonly used intravenous drug administration systems have potential safety deficiencies and require that appropriate safety processes be implemented. The most common errors in parenteral drug preparation include wrong technique, wrong dose, wrong base solution or diluent, and wrong drug.

### *Drug Administration by Health Care Providers*

Drug administration errors account for 3–30% of all preventable ADEs, depending on the care setting. Errors occur in 5–20% of all drug administrations in hospitals, 7% of which are potentially harmful. Intravenous drug administration errors occur up to 33% of administrations, a large proportion of which have significant risk for ADE. Errors also occur in 2–12% of administrations in long-term care facilities. Administration errors account for 30% of all preventable ADEs in hospitals. Drug administration errors are most commonly wrong time. Less common, but potentially of greater risk to patients, are wrong dose, omitted drug, wrong drug, wrong dose form, wrong time, and wrong administration technique. Errors in the administration of intravenous drugs are particularly common and hazardous in ICU settings and in pediatrics. Voluntary reports of severe or fatal ADEs commonly involve errors in administration technique or route.

### *Patient Compliance and Communication Deficiencies*

Fifteen percent of prescriptions are never picked up at pharmacies and 50% of patients use drugs other than as prescribed and instructed. Deficiencies in patient adherence to drug therapy contribute to 15–25% of ADEs. Patients and families commonly make errors when using drugs, such as omitting doses, taking wrong or extra doses, taking the drug at the wrong time, failure to follow food-drug instructions, taking an unauthorized drug, refusal to take the drug, continuing to take the drug when instructed to stop, and failure to comply with monitoring instructions. In the ambulatory setting, preventable ADEs or failure to ameliorate ADEs are commonly a result of poor patient-health care provider communication, which is always a joint responsibility.

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Allen-Flynn E, Pearson RE, Barker K. Observational study of accuracy in compounding IV admixtures at five hospitals. *Am J Health-Syst Pharm* 1997;54:904–12.

Allen-Flynn E, Barker KN, Carnahan BJ. National observation study of prescription dispensing accuracy and safety in 50 pharmacies. *J Am Pharm Assoc* 2003;43:191–200.

Taxis K, Barber N. Ethnographic study of incidence and severity of intravenous drug errors. *BMJ* 2003;226:684–7.

### High-alert and Problem-prone Drugs

Because most drugs have a wide therapeutic range, errors with many drugs produce only minimal or easily ameliorated ADEs. However, almost any drug can produce serious patient harm, depending on the nature of the error made, care setting, and susceptibility of the patient to harm. A group of drugs with a high risk for patient harm if any error occurs has been identified as “high-alert” drugs, which require special handling and control processes to reduce patient risk. Other less dangerous drugs with notable risk for errors also have been identified. Because high-alert drugs vary based on care environment and other factors, pharmacists should identify drugs of greatest risk in the care environment in which they practice and implement appropriate safeguards. A listing of drugs commonly considered high alert or particularly problem-prone is provided in Table 1-1.

### Medication Use System Factors Contributing to Preventable ADEs

Many major latent health care system failures leading to drug errors have been identified. As described by James Reason, these contributors include the existence of conditions which either produce errors or allow errors to occur, and error-producing conditions which are those conditions in which the chance for error is increased because of the introduction of factors which stress the system. Active failures are errors in caregiver performance (e.g., mistakes, slips, and lapses) or violation of standards of care (or both), and failure of error-averting defenses or error recovery processes (Figure 1-1).

System deficiencies that impact but reside, at least partially, outside individual health care organizations include education of health care providers, research and approval processes for pharmaceuticals, pharmaceuticals marketing, health care financing practices, and governmental oversight and regulatory processes. Many common drug use system processes and practices used within health care organizations have been identified as error prone or error producing. Reason’s model can be used as a framework to categorize both remote and more proximal systems causes of error within organizations leading specifically to preventable ADEs. Many latent system conditions external and internal to health care organizations that impact medication safety and contribute to preventable ADEs are listed in Table 1-2. More proximal problem-prone medication use processes include those related to individual caregiver performance, team functioning and coordination between caregivers, task-related functions, environmental factors, and patient-related characteristics. A partial listing of these error-producing practices and processes is provided in Table 1-3. Certain characteristics of drugs and drug regimens increase the risk for error. A partial listing of these error-producing characteristics of drugs and products is provided in Table 1-4.

**Table 1-1. Examples of High-alert Drugs**

---

Abciximab
Amiodarone
Argatroban
Bivalirudin
Calcium
Calcium channel blockers intravenous
Chemotherapeutic agents
Chloral hydrate
Colchicine intravenous
Diazepam intravenous
Dalteparin
Digoxin
Dobutamine
Dopamine
Enoxaparin
Epinephrine
Eptifibatide
Esmolol
Fosphenytoin
Heparins
Ibutilide
Insulin
Isoproterenol
Lepirudin
Lidocaine
Lorazepam intravenous
Magnesium intravenous
Methotrexate
Midazolam
Narcotic analgesics
Neuromuscular blocking agents
Nitroglycerin
Nitroprusside
Norepinephrine
Oral hypoglycemics
Pentobarbital
Phenylephrine
Phenytoin
Potassium salts
Propofol
Propranolol injection
Sodium chloride intravenous solutions greater than 0.9%
Theophylline
Thiopental
Tinzaparin
Tirofiban
Vasopressin
Warfarin

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Reason JT. Human Error. Cambridge, England: Cambridge University Press, 1990.

Dean B, Schachter M, Vincent D, Barber B. Causes of prescribing error in hospital inpatients: a prospective study. Lancet 2002;359:373–8.

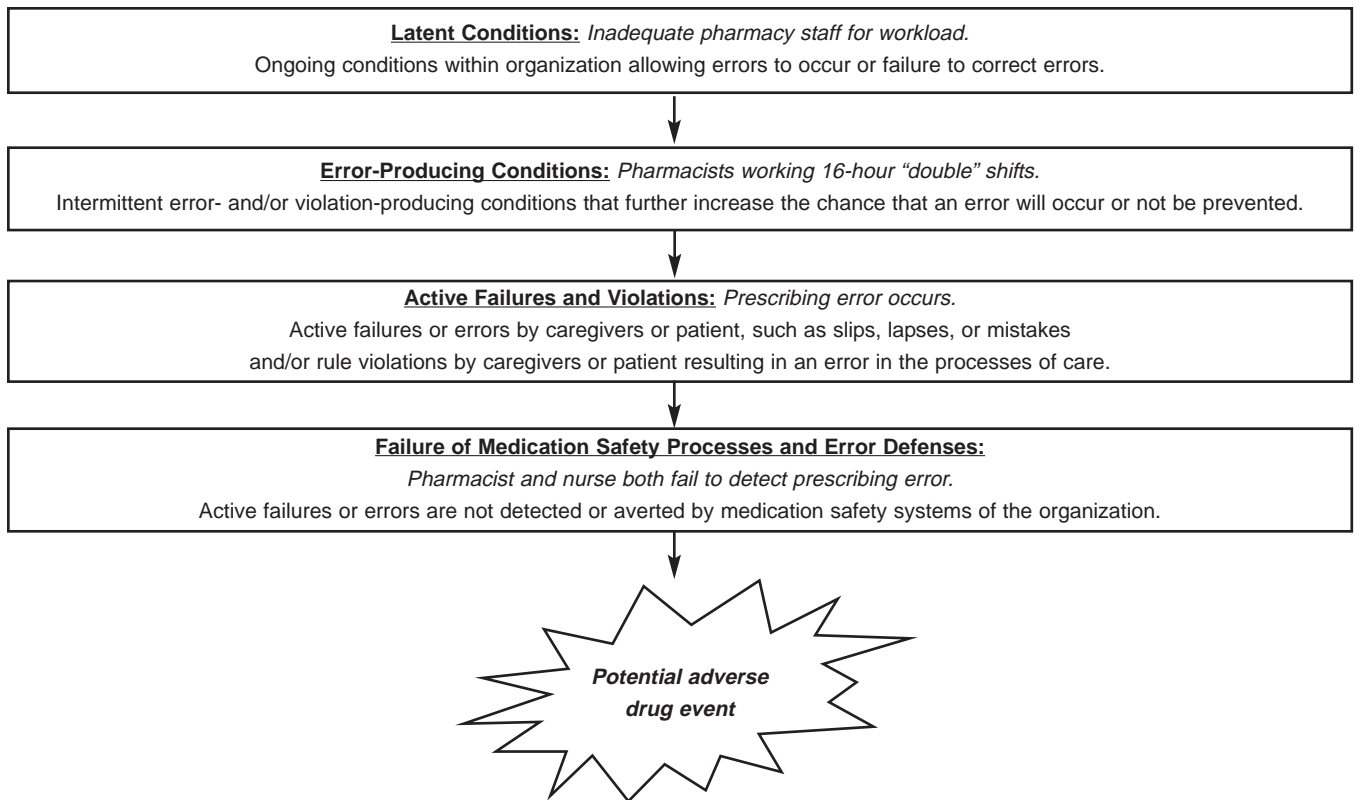


Figure 1-1. Reason's model of organizational accidents applied to medication safety. In this example, the latent condition of inadequate pharmacy staffing is present. When staff resign, some of the pharmacists work "double shifts" and become fatigued. A serious prescribing error occurs, such errors are common but usually averted by the pharmacist on order review. In this case, the error is not detected by a tired pharmacist or by the nurse and, therefore, not prevented by the safety systems.

Adapted with permission from the BMJ Publishing Group. Vincent C, Taylor-Adams S, Hewett D, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. *BMJ* 2000;320:777–81.

### How and When do Process Errors and Deficiencies in Care Produce Patient Harm?

Performance deficiencies consistently are demonstrated in one or more of the many medication use system care processes provided to patients unnecessarily harmed by drug errors. As previously discussed, medication use system process errors occur at a high frequency, but because of the system constraints, patient tolerance of care deviations, and other factors, noticeable failures in care and significant patient harm occur much less commonly. Despite the low chance that any given individual process error will produce harm, all errors in the medication use process have the potential to result in patient harm. Patient harm may result from an isolated single error in care, but more commonly involves multiple errors, deficiencies in care, and failure of system error defenses. An ADE resulting from drug errors is the net result of the nature and potential for the error(s) to produce harm, failure of error defenses, individual patient susceptibility to the insult created by the error(s) in care, and the effectiveness of the response to reverse or ameliorate the insult.

The complexity of the relationship between error and preventable patient harm must be considered to understand what changes will truly prevent errors. Many types of errors commonly occur, but seldom or never cause patient harm;

some errors only produce ADEs in specific patient types or situations, and other errors produce harm whenever they occur. Poor patient outcomes commonly result from a cascade of events involving many deficiencies in care. In many cases, minor errors and poor decision-making accumulate and cascade, eventually producing harm in which it is difficult to identify a single or even limited number of causes.

The relationship between an error and patient harm is complex and involves interrelations and interactions among the agent (drug or drugs), host (the individual patient), vector/vehicle (how drug is delivered/not delivered), and the environment (physical, social, organizational structure and processes, and biological environment).

Errors occurring in early stages of the medication use process have a higher likelihood of being detected and averted before altering the care of (reaching) the patient because of the multiple error defenses, safety nets, or checks and balances. Errors occurring in situations with fewer safety nets in place to avert an error are more likely to alter the care provided to a patient and, therefore, more likely to produce patient harm. Two more commonly applied theories of accidents, which view error in human performance and systems as inevitable, are the Normal Accident Theory and the High Reliability Organization

**Table 1-2. Framework for Latent Conditions, Error-producing Conditions, and Proximal System Causes of Preventable Drug Errors**

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**Drug Approval and Regulation, Drug Research, and Marketing**

- Inadequate evaluation of medication safety profile before to marketing
- Steering of drug research to overestimate benefit and avoid proper ADE risk assessment
- Inadequate or ineffective postmarketing surveillance
- Submission of only positive research outcomes to the FDA or publication
- Marketing practices leading to false sense of safety regarding medication use
- Marketing practices leading to medication use with increased risk for ADE (e.g., use in unapproved indications or populations)
- Lack of centralized governmental or other body focused on safety
- Lack of consistent availability of drug products due to drug “shortages”

**Institutional Context**

- Inconsistent leadership message and policies
- Inadequate culture of safety and quality
- Failure to provide adequate personnel and other resources
- Inadequate application of available technologies

**Organizational and Management Factors**

- Inadequate supervision of caregivers
- Failure to address and resolve conflicts
- Failure to establish proper safety procedures
- Permitting work-arounds and violations of safety procedures and rules
- Inadequate access to important equipment, materials, or other resources

**Work Environment Factors**

- High staff workload
- Poor work environment
- Time constraints
- Poor organizational structure and processes
- Cross covering and caring for unfamiliar patients
- Drug control and storage problems
- Drug product characteristics (e.g., look-alike packaging, drug product names, and confusing preparation procedures)
- Poorly designed equipment and devices

**Team Factors**

- Poor coordination and communication with other caregivers
- Process breakdowns during handoffs
- Intimidating or abusive behaviors
- Authority gradient
- Cultural differences between professions and disciplines
- Isolated decision-making processes
- Failure to properly assign or assume responsibility

**Individual (Staff) Factors**

- Inexperience
  - Lack of knowledge of drug therapy
  - Lack of knowledge regarding important patient factors related to drug therapy
  - Errors in development of drug therapy plan
  - Slips and memory lapses
  - Rule violations
  - Drug order writing, transcription, and documentation errors
  - Drug preparation errors
  - Faulty drug identity checking
  - Failure to appropriately use drug delivery devices (i.e., setting infusion pumps)
  - Failure to establish or perform proper drug therapy monitoring
-

**Table 1-2. Framework for Latent Conditions, Error Producing Conditions, and Proximal System Causes of Preventable Drug Errors (Continued)**

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**Individual (Staff) Factors (Continued)**

- Failure to accurately reconcile drug therapy
- Long hours and fatigue, poor health
- Poor morale or mental health

**Task Factors**

- Lack of availability or difficulty obtaining important patient information
- Lack of availability or difficulty obtaining important drug therapy information
- Lack of standardization and established procedures and protocols
- Complex multistep work functions
- Function requiring high level of reliance on individual performance
- Performance of nonroutine tasks

**Patient Factors**

- Highly complex patient
  - Language barriers
  - Cultural barriers
  - Uncooperative or difficult
  - Ineffective communication between patient and caregivers
  - Noncompliance
- 

ADE = adverse drug event; FDA = Food and Drug Administration.

Theory. The Normal Accident Theory suggests that errors and accidents are inevitable, with greater risk for error as complexity increases and process is tightly coupled and interdependent. The High Reliability Organization Theory recognizes that errors will occur, but that the frequency and the consequences of error can be reduced by organizational systems and culture.

The “Swiss cheese” model (Figure 1-2) is useful for describing the Normal Accident Theory conceptual relationship between continuously and commonly occurring medication use system process errors and the relatively less frequent, but apparently random and unpredictable production of patient harm. The Swiss cheese model conceptualizes health care as a complex multistep system in which errors commonly occur at each step, but which also are averted by common defenses and safety nets. Errors only reach the patient when all of the defenses fail simultaneously or sequentially, and the error penetrates through “holes” in the slices of safety nets. This model is a useful conceptual framework with which to understand how errors in care may or may not result in patient harm within a complex health care system. This model also illustrates how High Reliability Organization Theory methods to both reduce the occurrence of errors in medication use system processes (fewer errors bombarding the defenses) and improve the system of safety defenses (fewer and smaller holes in the defenses, or more layers of defenses) will reduce the likelihood of errors reaching the patient and causing harm. The High Reliability Organization Theory provides the foundation for most recommendations

regarding effective and safe functioning within complex organizations such as health care.

**Why do Errors Occur?**

Errors are part of the human condition; humans are fallible by nature and design. Drug errors that injure patients occur as a result of fallible and poorly trained humans functioning in poorly designed and complex systems with inadequate safety controls. The model of accident causation (Figure 1-1) provides a useful framework for understanding the interaction of human performance with the systems used to provide patient care and potential patient injury. Latent conditions are those that either produce errors or allow errors to occur either continuously or under certain circumstances. Latent conditions commonly are because of deficiencies in some aspect of design or performance of the care system. Examples include system processes, policies and procedures, reliability of adherence to procedures, available technologies, staff levels, and training. Error-producing conditions are those for which the chance of error is increased because of the introduction of factors that stress the system. Examples of stressors include reduced staffing, increased acuity of care, and introduction of new drugs with look-alike packaging. Error-producing conditions involve circumstances in which either error is more likely, violations of safety processes are more likely, or both. Active failures are errors in caregiver performance or violations of standards of care (or both) that are allowed within the system and environment. Safety systems and processes are

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Manasse HR. Not too perfect. Hard lessons and small victories in patient safety. *Am J Health-Syst Pharm* 2003;60:780–7.

Reason JT. Human error: models and management. *BMJ* 2000;320:768–70.

**Table 1-3. Problem-prone Medication Use Processes and Practices**

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**Common Individual Performances and Tasks**

- Drug history taking
- Assessment of appropriateness of patient drug regimen
- Documentation of medication use and history
- Calculation skills
- Development of drug therapy plan
- Prescription writing
- Accuracy and technique of drug selection and preparation

**Communications and Team Functioning**

- Communication of drug therapy plan to patient and other caregivers
- Problem identification and solving
- Use of verbal orders or telephone orders
- Illegible handwriting
- Inaccurate, ambiguous, and incomplete prescription writing
- Drug reconciliation as patient progresses through medical system
- Use of abbreviations, acronyms, and medical nomenclature in drug orders and documentation
- Authority gradient among caregivers or intimidating or abusive behavior

**Medication Use System Processes**

- Accessing or finding critical information
- Reconciling drugs at various stages of the care process
- Computer order entry
- Conversion between units of measure (e.g., apothecary to metric and mcg to mg)
- Requirement to perform calculations
- Expressing doses and administration rates
- Product labeling
- Placement of zeroes and decimal points
- Converting routes of drug administration, use of dose equations to calculate or express doses
- Drug measurement, determining volume of drug to provide a desired dose
- Drug preparation technique
- Changing routes of administration
- Setting of infusion pumps to provide a desired drug dose
- Drug administration in patients with multiple lines and tubes
- Selecting drugs from stock supplies
- Patient identification
- Checking processes
- Drug control processes
- Correct timing of drug administration
- Appropriately monitoring patient response and appropriately adjusting therapy

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**Table 1-4. Characteristics of Drugs and Drug Administration Processes that have been Associated with an Increased Risk Error**

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- Similar, look-alike, or soundalike names
- Similar packaging
- Multiple dosage forms
- Complex preparation procedures
- Multiple possible routes of administration
- Wide dosage ranges
- Doses expressed in variable ways (mcg. vs. mg and ml vs. teaspoonful)
- Major dose variations when administered by different administration routes
- Unusual dose frequency (e.g., weekly)
- Unusual administration routes
- Complex dosage regimens
- Combination drug products
- Doses must be calculated
- Unusual administration processes
- Multiple drug-drug or drug-food interactions
- Multiple significant contraindications for use
- Alterations of doses in select patient populations (e.g., renal impairment, or the elderly)
- Liquid drugs
- Variable doses over time
- Proscribed therapy duration
- Maximum daily or total therapy dose maximums
- Complex laboratory monitoring processes

---

the defenses (safety nets, and checks and balances) that prevent errors because of active failures from reaching the patient; or if they reach the patient, defenses provide appropriate amelioration of the harm to limit harmful consequences. Improving medication safety requires an understanding of human factors that affect performance, and how systems create or allow latent and error-producing conditions. Understanding how errors occur is critical to preventing the initiating events that eventually may lead to patient harm. The tracking of errors from the point of initiation through the rest of the medication use process provides understanding of how errors are propagated or averted by the system before reaching the patient. The idea of evaluation of error initiation and propagation within an entire medication use system is used in error evaluation techniques such as root cause analysis (RCA) and failure mode effect analysis (FMEA).

#### Human Performance Factors Leading to Errors

By nature, humans are prone to commit errors. Human cognitive functioning is variable, faulty, and easily disrupted and, therefore, not well suited to perform reliably many of the functions necessary to provide safe medical care. Humans continuously function in two parallel cognitive modes: an automatic mode and a problem-solving mode, with errors possible in both. Human cognitive function is

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Schneider PJ. Applying human factors in improving medication-use safety. *Am J Health-Syst Pharm* 2002;59:1155–9.

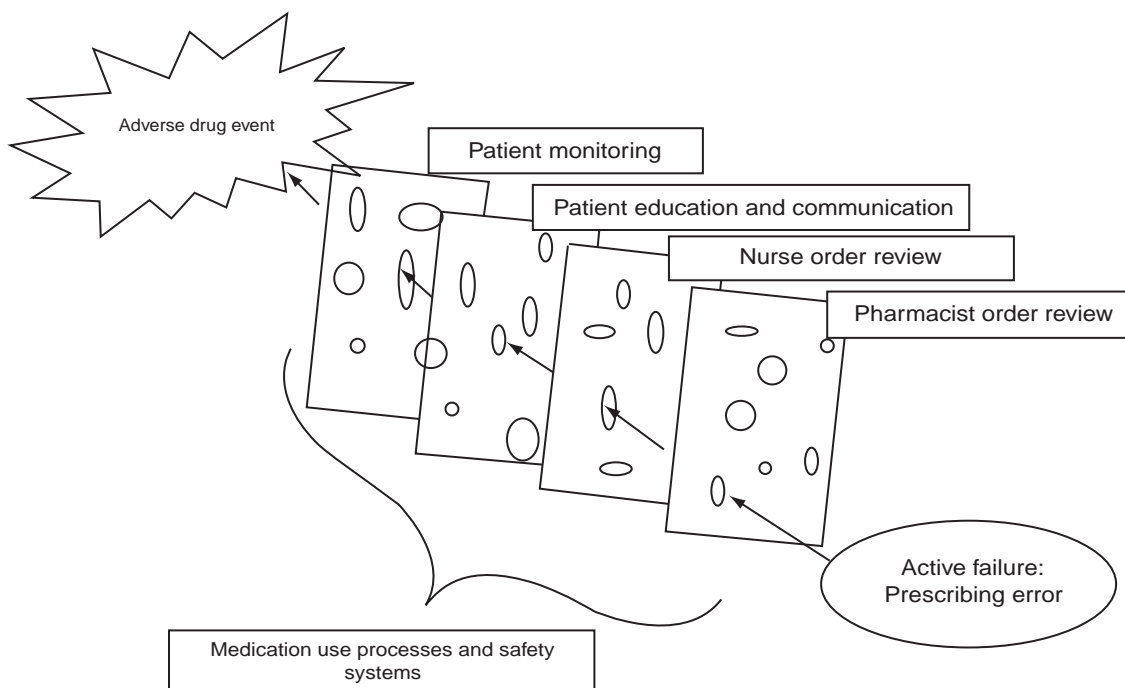


Figure 1-2. Reason's "Swiss cheese" model of organizational error applied to medication safety. In this example, the active failure is a common prescribing error, but due to sequential or simultaneous failure in the multiple organizational processes that usually avert the same error, it is not prevented. When the error reaches a susceptible patient, an adverse drug event occurs.

Adapted with permission from BMJ Publishing Group. Reason J. Human errors. Models and management. *BMJ* 2000;320:768–70.

primarily in the automatic mode. It occurs rapidly, with minimal to no effort, and little conscious awareness. The automatic mode is an inherent or learned process active for routine minor (breathing) to highly complex (touch-typing) activities.

The problem-solving cognitive mode is a much slower, conscious, demanding process that requires information-gathering and processing, use of memory, and application of decision-making rules. The problem-solving mode is difficult for humans to sustain and once learning occurs, the automatic mode often takes over some or most of performance functions that initially required cognition in the problem-solving mode. The human performance errors that occur in the automatic mode differ from those that occur in the problem-solving mode.

Cognitive errors occurring in the automatic mode usually are called slips. Cognitive slips include capture errors in which a more familiar routine task is performed rather than the intended similar, but different, action (e.g., a person driving past the store he or she meant to stop at on the way home from work). Description errors occur when the correct action is applied to the wrong object or in the wrong situation. Look-alike and soundalike errors often are the result of description errors. An association-activation error occurs when a familiar action triggers a commonly performed, but wrong, subsequent action. Another common slip is loss of activation (starting to take an action), but then forgetting the intention of the action. Errors in the automatic mode occur more commonly when individuals are fatigued, disrupted, or stressed. Evaluation of errors

during common medication use system tasks often reveals these types of errors.

Lapses are temporary failures of memory or attention that are likely to play an important part in error when important facts must be provided by an individual's memory. In such cases, the individual possesses such knowledge as memories, but the facts are not extracted from memory and used when needed. An example is the need to check for renal function when prescribing a renally excreted drug. Errors because of common memory lapses may be particularly amenable to effective prompts and reminders.

Cognitive errors occurring in the problem-solving mode are called mistakes. Knowledge-based mistakes occur when an individual does not possess adequate information to assess or solve a problem correctly or to safely perform a task. Such knowledge-based mistakes are obviously more common when the role of knowledge is paramount. Inadequate drug therapy knowledge is likely to be a major contributor to knowledge-dependent activities, such as planning and assessing drug therapies. Humans also solve problems through pattern matching based on prior experiences and knowledge. Faulty pattern matching and subsequent decision-making occurs because of the way humans generalize, categorize, and standardize information, leading to bias when information is recalled through memory. Mistakes that are rule-based involve application of the wrong rule to solve a problem or misapplication of a rule because of errant assessment of the problem to which the rule is applied. Another type of problem-solving cognition error is the "availability heuristic" in which the first solution, even if incorrect, is applied to a problem. Other

problem-solving errors include biased memory decision-making, in which decisions are based on experience of the commonplace rather than effectively judging new data regarding a new problem. Overemphasis on the discrepant occurs when decisions are based on less common discrepancies in data rather than assessing information to arrive at a more logical conclusion. Confirmation bias is faulty decision-making resulting from giving excess weight to evidence that supports a hypotheses and ignores information that contradicts it. Many errors in decision-making occur because of overconfidence (i.e., the propensity for a person to be overconfident in his or her chosen problem solution while refuting contrary evidence). Humans under stress have a tendency to revert to dependence on previous problem solutions rather than making appropriate decisions based on available evidence. In some situations, humans will make faulty decisions because they focus attention on a single or limited item, but ignore equally important information, thereby missing important evidence or occurrences. Mistakes, like slips, occur more commonly under conditions of fatigue, stress, and distraction. Clearly, many errors and deficiencies in the medication use process result from one or more types of problem-solving errors.

Intentional human performance failures that lead to medication safety deficiencies include conscious violations of established care processes or standards and willful behaviors leading to poor communication and team functioning. Caregivers violate safety processes on an extremely common and often routine basis. This occurs for many reasons, including a lack of appreciation for the importance of a safety process, a competing interest such as efficiency, or the perception that they can practice safely without the safety process in place. The fact that the vast majority of medication use process errors never lead to patient harm creates a perception that important safety practices are simply inconvenient and prevent caregivers from efficiently taking care of patients. Caregivers whose behaviors create poor team functioning may create error-producing conditions and reduce the effectiveness of established defenses designed to avert errors once they have occurred. These intentional human performance deficits often are the result of the traditional training and hierarchal culture of medical education and care. The nature of medical systems involves important interactions and communications between individuals and groups. Individuals unwilling to function as part of a larger organization create error-producing conditions by disrupting effective team function, increase the risk of errors during work hand-offs, information exchange, and problem-identification and problem-solving.

The nature of drug errors and the impact of medication safety deficiencies on patients, the health care system, and society are beginning to be understood and appreciated. With this knowledge, improvements in patient safety can and must be undertaken. Truly improving patient safety requires that changes made in care processes produce desired results and do not create substantial new safety risks. The pharmacist should have a sound understanding of medication safety improvement principles, strategies, practices, and implementation methods.

## Improving Medication Safety

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### The Systems Approach to Medication Safety

Medication safety cannot be consistently ensured when outcomes rely solely on the limitations and variability of individual human performance. Rather, safety in patient care must be based on the entire organization's commitment to safety and the design and function of the medication use system. Traditionally, error in medical care has been viewed, and dealt with, as a personal problem. If an error was made, it was assumed that it was an isolated event and that the caregiver failed because of forgetfulness, lack of attention, incompetence, moral weakness, a lack of knowledge, or a lack of effort. The role the system played in allowing or producing an error was not appreciated; the importance of systems in preventing errors was not appreciated either. Error prevention primarily focused on expecting perfect human performance and improving individual performance when deficiencies were found and punishing those who made errors. Changes in the caregiver's actions and behaviors were expected to prevent the error from occurring again. However, this approach fails to correct underlying problems in the system of care that create the environment in which an error may occur (latent conditions). The approach also does not address conditions in which error is more likely (error-producing conditions), conditions that allow active errors and violations to occur, and for defenses and error recovery processes to fail (Figure 1-1).

A systems approach to error evaluation and prevention focuses more on the conditions in which individuals work, attempting to reduce the chances that an error can occur, increasing the chances errors are averted before reaching the patient, and providing mechanisms to ameliorate errors that do reach the patient. In a systems approach, work environments and processes are proactively designed and revised to support caregivers and depend less on individual performance to ensure proper outcomes. When errors or deficiencies are detected, they are viewed primarily as a systems problem, likely to occur again, involving different individuals, rather than a problem with a caregiver. Errors are always learned from and prompt organizational changes, which are designed to prevent similar errors in the future. A systems approach to quality and safety has been used for some time by industry and institutionalized in large, complex high-reliability organizations, such as the airline industry, nuclear energy industry, and the military. Safety principles used by these organizations largely are applicable to medical care, an even more complex and dynamic process. The change in thinking about medical errors from primarily a caregiver problem to that in which systems play a major role was a major breakthrough in the patient and medication safety movement of the 1990s.

The systems approach is highly applicable to medical care but does appear to run counter to the pervading training, culture, and traditions of medical care. However, a systems approach does not absolve caregivers from taking responsibility for ensuring their competency and fitness to

**Table 1-5. Medication Safety Resources on the Internet**

Agency for Healthcare Quality and Research (AHRQ)	<a href="http://www.ahrq.gov">www.ahrq.gov</a>
AHRQ Morbidity and Mortality Rounds on the Web	<a href="http://www.webmm.ahrq.gov">www.webmm.ahrq.gov</a>
American Hospital Association (AHA)	<a href="http://www.aha.org">www.aha.org</a>
Healthcare Research and Education Trust (HRET)	<a href="http://www.hospitalconnect.com">www.hospitalconnect.com</a>
American Pharmacy Association (formerly American Pharmaceutical Association)	<a href="http://www.apha.org">www.apha.org</a>
American Society of Consultant Pharmacists (ASCP)	<a href="http://www.ascp.com">www.ascp.com</a>
American Academy of Pediatrics (AAP)	<a href="http://www.aap.org">www.aap.org</a>
American Society for Parenteral and Enteral Nutrition (ASPEN)	<a href="http://www.aspen.org">www.aspen.org</a>
American Society of Health-Systems Pharmacists (ASHP)	<a href="http://www.ashp.org">www.ashp.org</a>
California Institute for Health Systems Performance (CIHSP)	<a href="http://www.cihsp.org">www.cihsp.org</a>
Center for Drug Evaluation and Research (CDER)	<a href="http://www.fda.gov/cder">www.fda.gov/cder</a>
Food and Drug Administration (FDA)	<a href="http://www.fda.gov">www.fda.gov</a>
Institute for Healthcare Improvement (IHI)	<a href="http://www.ihl.org">www.ihl.org</a>
Institute for Safe Medication Practices (ISMP)	<a href="http://www.ismp.org">www.ismp.org</a>
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)	<a href="http://www.jcaho.org">www.jcaho.org</a>
Leapfrog Group	<a href="http://www.leapfroggroup.org">www.leapfroggroup.org</a>
Massachusetts Coalition for the Prevention of Medical Error	<a href="http://www.macoalition.org">www.macoalition.org</a>
National Coordinating Council for Medication Error Reporting Program (NCC MERP)	<a href="http://www.nccmerp.org">www.nccmerp.org</a>
National Council on Patient Information and Education	<a href="http://www.talkaboutrx.org">www.talkaboutrx.org</a>
National Patient Safety Foundation (NPSF)	<a href="http://www.npsf.org">www.npsf.org</a>
National Quality Forum (NQF)	<a href="http://www.qualityforum.org">www.qualityforum.org</a>
Partnership for Patient Safety	<a href="http://www.p4ps.org">www.p4ps.org</a>
Pediatric Pharmacy Advocacy Group (PPAG)	<a href="http://www.ppag.org">www.ppag.org</a>
QualityHealthCare.org	<a href="http://www.qualityhealthcare.org">www.qualityhealthcare.org</a>
United States Pharmacopeia (USP)	<a href="http://www.usp.org">www.usp.org</a>
Veterans Affairs National Center for Patient Safety	<a href="http://www.patientsafety.gov">www.patientsafety.gov</a>

work, maintenance of their skills, complying with all standards of care, and effectively functioning as part of the system. With a systems approach, the organization accepts a shared responsibility to assist caregivers in maintaining competency and creating a safe work environment.

Comprehensive recommendations for improving medication safety and reducing patient risk are available. All organizations recommend a systems approach to improving safety and promote the implementation of similar medication use process improvements (Table 1-5). Improving medication safety involves effective leadership, developing a culture of safety with a just or nonpunitive error reporting and learning environment, and implementing effective medication safety processes.

#### Leadership for Safety and Quality

Organizational leadership must establish the framework and resources to produce improvements within an organization. Health care organizations should ensure that there is clear and effective executive leadership and accountability related to medication safety. The organization must clearly communicate a vision that patient safety is everyone's primary responsibility and clearly define how the organization strives to attain this goal. Leadership responsibilities include providing appropriate resources, establishing goals, assigning responsibility, and providing appropriate authority to individuals and groups. A detailed description of leadership responsibilities and a

work plan for safety can be found in the American Hospital Association's (AHA) Pathways for Medication Safety: Leading a Strategic Planning Effort (available at [www.medpathways.info](http://www.medpathways.info)), and in the ISMP Medication Safety Self-Assessments (available at [www.ismp.org](http://www.ismp.org)). A useful tool for leadership to understand and fulfill this responsibility can be found in the Medication-Use System Safety Strategy (MS3) developed by the American Society of Health-System Pharmacists (ASHP). The MS3 provides a detailed listing of tasks oriented toward implementing safety processes. Key leadership groups in improving medication safety in hospitals include the pharmacy, nursing, and medical staff leadership; risk management and quality improvement; and the pharmacy and therapeutics (P&T) committee. Establishment of a medication use and safety team should be considered if one is not already in place. Medication safety officers lead and coordinate medication safety improvement efforts within many large health care organizations. In community pharmacies, long-term care facilities, home infusion, and mail-order pharmacies, an appropriate leadership structure should be established based on specific characteristics of the practice, organizational, or corporate structure.

#### Developing a Culture of Safety and Quality

A critical factor in improving medication safety is the establishment of a culture of safety and quality among all individuals, and as a core characteristic of the organization

as a whole. Culture can be defined as the framework of attitudes and values within which groups and individuals function. Organizations with a high level of quality and safety (high-reliability organizations) develop and foster cultures with the following characteristics:

- Safety is a primary priority of the organization and seen as everyone's responsibility.
- Safety concerns are not secondary to efficiency or cost considerations.
- Resources and incentives for staff are provided to ensure maximum safety.
- All organizational components apply safety principles in their work and in a coordinated fashion when interacting with those outside their individual areas.
- Errors and problems consistently are reported, fairly and openly discussed, and learned from in a nonpunitive manner.
- Error risk consistently is assessed and reported by all staff without fear of retribution.
- Team work and communication, regardless of hierarchy, are actively promoted and rewarded.
- Those in position to make the best decisions regarding safety are empowered, regardless of hierarchy.
- Safety is objectively monitored and appropriate change is implemented.

Currently, the culture of most, if not all, patient-care organizations, is not adequately safety oriented. Fostering such a culture of safety is time-consuming, difficult, and progresses slowly. A culture of safety will be developed only if actively and aggressively promoted by leadership at all organizational levels. It should be promoted continuously as organizations work to implement known medication use safety processes. Concurrently working to develop a safety culture while making improvements will not only increase the likelihood that safety practices will be successfully implemented and adhered to, but also produce an environment in which further safety improvements are likely to occur. Without a culture of safety and quality, even well-designed improvements in medication use processes are less likely to be successful in reducing risks to patients. A culture of safety and quality is important in that the provision of health care is, and will continue to be, highly reliant on the skills and actions of individuals. Guidance on creating, communicating, and measuring a culture of safety and quality is available from several sources, including the Pathways for Medication Safety: Leading a Strategic Planning Effort, The Institute for Healthcare Improvement's (IHI) Safety Climate Tool (available at [www.qualityhealthcare.org](http://www.qualityhealthcare.org)), and ASHP's Medication Safety Issue Brief: Creating a Culture of Safety.

### Safe Medication Use System Processes *General Systems Safety Strategies and Design Principles*

General strategies and principles for improving patient safety through process and practice design have been

delineated by IOM and other organizations and are as follows:

- Increase visibility of processes so users can see what and how things need to be done and what happens if a step is not completed.
- Simplify tasks to reduce reliance on individual performance skills (planning, memory, vigilance, and problem-solving).
- Apply design principles with affordances for error, and design of processes and equipment that communicate how they work to the user and then lead to desired outcomes.
- Use forcing functions (i.e., design processes such that action is "forced" to occur in the desired manner) and constraints to guide individuals to correctly perform functions and to be less likely to take the wrong action.
- Establish error recovery processes that make it easy to recover or back out if a wrong action is taken.
- Implement standardization with resultant simplification and consistency of processes. Standardization will have inherent forcing function effects as well.
- Respect human limits by applying knowledge about human factors in process design
- Promote effective team functioning.
- Anticipate the unexpected. Plan to monitor all changes carefully for their effectiveness and unanticipated consequences.
- Create a learning environment in which detection of process deficiencies and failures is seen as an opportunity for improvement.

The medication use process is a complex multistep process with numerous interacting components. Current processes that deliver drug therapy place a high level of reliance on the performance of caregivers and patients. The work processes required to deliver drug therapy can be designed to reduce the risk for error by applying known safety strategies. Technological advances improve patient safety by reducing the reliance on, while enhancing, human performance. However, these technologies are not available in most health care environments today, and in many environments in which they exist, the systems are not comprehensive. Even when available, individual performance continues to be a crucial component of the medication use process. As previously discussed, effective application of these strategies requires that appropriate leadership, culture, expertise, and resources are in place.

### *Specific Medication Use Processes Safety Strategies and Best Practice Recommendations*

The key to an effective safe medication use system is the consistent application of standardized system processes. System process strategies to improve medication safety are based on identified deficiencies in care, leading to error and patient harm, methods shown to prevent care deficiencies, and processes that allow recovery and amelioration of errors once they do occur. Many medication safety strategies are

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Bagian J, Lee C, Gosbee J, et al. Developing and deploying a patient safety program in a large health delivery system: you can't fix what you don't know about. *Jt Comm J Qual Improv* 2001;27:527-32.

**Table 1-6. Institute for Safe Medication Practices Medication Safety Self-Assessment Core Distinguishing Characteristics**

1. Essential patient information is obtained, readily available, in a useful form, and considered when prescribing, dispensing, and administering medications.
2. Essential drug information is readily available in a useful form and considered when ordering, dispensing, and administering medications.
3. A closed drug formulary system is established to limit choice to essential drugs, minimize the number of drugs with which practitioners must be familiar, and provide adequate time for designing safe processes for the use of drugs added to the formulary.
4. Methods of communicating drug orders and other information are standardized and automated to minimize the risk for error.
5. Strategies are undertaken to minimize the possibility of errors with drug products that have similar or confusing manufacturer labeling/packaging and/or names that look and sound alike.
6. Readable labels that identify drugs clearly are on all drug containers, and drugs remain labeled up to the point of actual drug administration.
7. Intravenous solutions, drug concentrations, doses, and administration times are standardized whenever possible.
8. Medications are delivered to patient care units in a safe and secure manner and available for administration within a time frame that meets essential patient needs.
9. Unit-based floor stock is restricted.
10. Hazardous chemicals are safely sequestered from patients and not accessible in drug preparation areas.
11. The potential for human error is mitigated through careful procurement, maintenance, use, and standardization of medication delivery devices.
12. Medications are prescribed, transcribed, prepared, dispensed, and administered in a physical environment that offers adequate space and lighting and allows practitioners to remain focused on medication use without distractions.
13. The compliment of qualified, well-rested practitioners matches the clinical workload without compromising patient safety.
14. Practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices.
15. Practitioners involved in medication use are provided with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused.
16. Patients are included as active partners in their care through education about their medications and ways to avert errors.
17. A nonpunitive, system-based approach to error reduction is in place and supported by senior administration and the board of trustees/directors.
18. Practitioners are stimulated to detect and report errors, and multidisciplinary teams regularly analyze errors that have occurred within the organization and in other organizations for the purpose of redesigning systems to best support safe practitioner performance.
19. Simple redundancies that support a system of independent double-checks or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients.
20. Proven infection control practices are followed when storing, preparing, and administering medications.

Adapted with permission from the Institute for Safe Medication Practices. ISMP. Medication Safety Self-Assessment, March 2000. Available at [www.ismp.org](http://www.ismp.org). Accessed July 2003.

based on experience and common sense. Few are based on controlled trials. Hence, the evidence base for most commonly used and recommended medication safety strategies is lacking. This is not surprising given the complex nature of drug error causation and prevention that cannot readily be studied in a manner similar to that commonly used in medicine. The Agency for Healthcare Research and Quality (AHRQ) commissioned a systematic review of the evidence available supporting patient safety practices. The science of patient safety is in its infancy. It is necessary to develop appropriate research techniques to evaluate the effectiveness of major and costly patient safety processes before they are recommended for universal implementation. Despite the lack of high levels of evidence of effectiveness for specific safety strategies, considerable improvement in safety has occurred by applying historic and

common sense strategies based on critical event analysis, RCA, and experiences of nonmedical industries.

Specific strategies for improving medication safety have been promulgated by many organizations. A comprehensive list of recommendations are available from the ISMP in its Medication Safety Self-Assessments and its biweekly publication ISMP Medication Safety Alert! (available in both Acute Care and Ambulatory Care editions). The 20 core characteristics of a safe drug use process in hospitals recommended by ISMP are listed in Table 1-6. Within these 20 core characteristics, ISMP provides more than 190 specific representative characteristics of a safe medication use system. A similar listing is available for community pharmacy practices. Resources for additional best practices recommendations for improving medication safety are provided in Table 1-5. A

Shojania KC, Duncan BW, McDonald KM, Wachter R, eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality, 2001. Available at <http://www.ahrq.gov/clinic/ptsafety/>.

Shojania KG, Duncan BW, McDonald KM, Wachter RM. Safe but sound: patient safety meets evidence-based medicine. JAMA 2002;288:508-13.

Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Patient safety meets evidence-based medicine. JAMA 2002;288:501-7.

listing of commonly recommended best practices is provided in Table 1-7. Although these best practice recommendations often address improvement as isolated medication use processes, the most effective changes address the steps and individuals throughout the medication use system. Almost all recommended specific medication use system safety strategies can be categorized into one of the following overlapping and interdependent areas.

### Leadership

Leadership at all levels within an organization is critical to create and maintain a culture of safety and reliability. This leadership must extend throughout the organization to the point of patient care. Implementing medication safety procedures involves many individuals from multiple disciplines, departments, and committees. Clearly, pharmacy department leadership and staff must play a central and active role. Pharmacists have the greatest understanding of the medication use process, drug therapy, and safety processes and, therefore, should assume primary responsibility for aggressively promoting and implementing medication safety within an organization. This involves working in a coordinated fashion with, and through, the many other organizational components involved in the process. These components include the medical, nursing, and other caregiver staffs and their internal organizational structures, laboratory services, all levels of management, risk management, quality improvement, biomedical engineering, information services, public relations, and patient information services (medical records). Of importance, pharmacists must be actively involved with the various organizational groups and committees involved directly and indirectly with medication use, in particular the P&T committee or medication use/safety groups. Including safety considerations in the formulary policies, processes, and decisions is necessary. Formulary deliberation and decisions should center as much, or more, around safety and appropriate medication use issues as therapeutic issues. Safety-based drug use controls, restrictions, and forcing functions, such as mandatory order sheets or protocols, should be made part of the formulary policies. The P&T committee or other designated medication safety groups should develop, promote, coordinate, and implement safety procedures within the organization. As many safety processes involve restrictions and limitations on access to, and use of, drugs, the group responsible for medication safety should be given the proper level of authority and support. Effective input from and communication to staff, in particular physicians and nurses, regarding the rationale for and nature of safety-based processes are necessary for success.

Successful implementation of safety processes requires a consistent and coordinated approach from all system components. Coordinated efforts routinely involve risk management and quality improvement departments in reporting and evaluating error reports as well as in implementing improvements. All managers and supervisors should be appropriately oriented to a systems-based approach to safety, and the importance of supporting and fostering a nonpunitive reporting process in their day-to-day management activities.

Because of the central role of pharmacy in medication use, pharmacists are best equipped to provide the necessary skills and understanding to coordinate the process as part of a multidisciplinary team. Many organizations established such medication safety teams to undertake the numerous tasks required. Some organizations have created medication safety officers to provide a dedicated resource for the task. Leadership should delineate the expectation that all caregivers view themselves as part of the system and recognize the critical role their performance plays in safety. Establishing and consistently applying individual practices that enhance patient safety is each caregiver's responsibility. Recommended best practices for prescribers, pharmacists, nurses, and patients are provided by many organizations listed in Table 1-5.

### Information Availability, Transfer, and Use

Major improvements in medication safety can be achieved by making information more accessible to, and appropriately applied by, caregivers, such as readily available information regarding the patient and drug therapy and the availability of staff who have the skills and resources to use the information effectively. Strategies to improve the availability and use of information encompass many interrelated functions, including technologies, staff competency, teamwork, staff deployment, communications, formulary policies, documentation practices, organizational processes and structure, culture, workload, and environmental factors. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards require that organizations define a minimum set of patient information items (e.g., age, weight, height, sex, pregnancy status, breastfeeding status, major disease states, and drugs) that is readily available to caregivers. The deployment of unit-based pharmacists has enhanced their ability to provide decision support to other caregivers and to prevent drug errors. It is estimated that unit-based pharmacists have the potential to detect and prevent more than 75% of preventable ADEs in hospital settings. This effective error prevention is largely because of the improved communications, teamwork, access to patients and families, information available to the pharmacists, and subsequent effectiveness of decision support provided by pharmacists.

### Drug Standardization, Task Simplification, and Control

Control of drug availability, distribution, and preparation is a fundamental method of reducing risk to patients for drug errors. By controlling accessibility, standardizing processes, and reducing variability, the opportunity for error is reduced. Drug standardization and control involves all components and individuals involved in the process. Reduction of patient risk for error through drug control processes involves the limitation of ready accessibility of drugs to caregivers and restrictions on individual variability in practice. These limitations may produce delays and less efficient (but safer) workflow processes. To accomplish improved drug controls and standardization, workload shifts to the pharmacy department and appropriate resources are necessary. Successful implementation requires organizations to address these issues in process design and resource allocation. An organization's formulary

**Table 1-7. Selected Specific “Best Practices” Recommendations for Safe Medication Use Systems**

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**Active Front-line Leadership and Oversight**

- Front-line managers and other “leaders” actively promote and pursue medication safety
- Participation of staff in patient safety improvement is actively encouraged and fostered
- Medication error reporting is actively promoted
- Medication errors are handled discreetly and justly
- Medication safety deficiencies are openly discussed
- Unsafe conditions are eliminated or controlled appropriately and in a timely fashion
- Unsafe behaviors and interpersonal interactions are actively discouraged and managed
- Staff are supported and empowered to make decisions and take actions in unsafe situations to protect patients

**Information Availability, Transfer, and Use**

- Important patient and drug information is readily available to all caregivers and effectively used in care. Minimally, patient information includes patient age, weight, height, medications, disease states, pregnancy status, breastfeeding status, and important laboratory data such as serum creatinine
- Drug information is readily available to all caregivers and used at the point of care
- Medication pocket guides, intravenous medication guideline particularly for high-alert medications, and intravenous compatibility guides are readily available
- Appropriate information regarding new medications or uses is disseminated
- Laboratory computer interfaces with pharmacy computer and provides automatic alerts
- Pharmacists are readily available to patients and other care providers and review the patient’s medication profile whenever new prescriptions or medication orders are written
- Pharmacy computers have appropriate decision support tools, and alerts, and warnings
- Computerized medical record and computerized physician order entry (CPOE) systems are used and have appropriate decision support and alerts and warnings
- Pharmacy-generated computerized medication administration records (MARs) are used
- Patient medication history and current medications are accurately recorded
- Patient medications are reconciled at multiple stages in their care
- Prescribers provide indication for use, appropriate monitoring parameters and any special instructions are provided with prescriptions for medications including clear and unambiguous parameters for administering, holding, or discontinuing a medication
- Medication-related issues are communicated clearly and documented in the patient record

**Improving Identification, Verification, Checking, Reconciliation, Warnings, and Alerts**

- Abbreviations and acronyms are defined and used sparingly and only when risk of misinterpretation is remote
  - Pharmacy computer profile includes all pertinent information to evaluate drug therapy
  - Medication orders are clear and unambiguous
  - Verbal orders are not accepted for chemotherapy
  - Illegible orders are always clarified and the prescriber informed of need to improve clarity of writing
  - Automatic drug interaction and duplicate drug therapy screening is used either by the pharmacist or prescriber or both
  - Laboratory computer interfaces with pharmacy computer and provides automatic alerts
  - Display laboratory results related to medication use in graphical format
  - Establish dose limits, implement automated dose checking
  - The pharmacist resolves all concerns regarding a prescription before to dispensing
  - Medication administration records are routinely compared to the pharmacy computer profile
  - Pharmacy provides all drug preparation, compounding, and manipulation services
  - Unit dose system is used
  - Limit and control access to medication stocks and automated dispensing cabinets (ADCs)
  - Establish and enforce clear procedures for use of ADCs
  - Use ADCs that allow access to only one item per transaction
  - Do not allow returns to ADCs to be returned to drawers, designate a “return bin” for refilling by pharmacy
  - Provide timely delivery of medications
  - Provide standardized protocols for medication use
  - Machine-readable (bar code) identification is used in drug preparation, dispensing, and administration
-

**Table 1-7. Selected Specific “Best Practices” Recommendations for Safe Medication Use Systems (Continued)**

**Improving Identification, Verification, Checking, Reconciliation, Warnings, and Alerts (Continued)**

- Machine-readable (bar code) identification is used to identify patients
- Implement automated dispensing technologies
- Delineate expected safety procedures for the medication administration process
- Two patient identifiers are used before to drug administration or dispensing
- Establish standard dose administration times
- Double-checks are used at bedside for chemotherapy, epidural medications, or intraspinal medications
- Label distal end of all lines and tubes
- Medications should remain in packaging until just before administration
- Routinely check patient allergies before all medication administrations
- Documentation of medication administration is clear, consistent, and easy to find
- Immediately document medication administration in medical record
- Use electronic entry/bar code scanning for medication administration documentation
- Warnings and processes are in place to limit risk for soundalike or look-alike errors
- Independent double-check processes are built into workflow and involve multiple individuals in workflow to provide increased opportunity for error detection
- Medications are not compounded if suitable manufactured products can be used
- The original, copy, or digital copy of the prescription is referenced while preparing, filling, or dispensing medications
- Filled medication vial content is compared to a digital photo of medication
- Policies and procedures delineate and reinforce safety processes
- Medications with look-alike packaging are not stored next to each other, and warnings and labels are used to prevent look-alike and soundalike errors
- Medications are always clearly and appropriately labeled, and warning labels or special packaging are used for high-alert medications
- When medication dose equations are used, the prescriber should include the dose equation being used and final calculated dose in the order
- Leading zeroes are always used before a decimal point and trailing zeroes are never used in written or printed materials
- The metric system is used
- Doses are expressed in mass amounts (e.g., microgram or gram) and not volume, unless volume is convention (i.e., antacid suspension)
- Medication administration record is routinely compared to the pharmacy computer profile
- Warnings and alerts regarding drug therapy initiated by the pharmacist are communicated effectively and carefully considered by the prescriber
- Automated warnings and alerts are clear and consistently considered
- Use only ballpoint pens for handwriting prescriptions
- Ensure carbon and facsimile copies of prescriptions and other medication-related documents are legible

**Medication Standardization, Task Simplification, and Control**

- Organizations should limit available products through a formulary system
- Safety concerns are considered in formulary decisions
- Provide standardized protocols for medication use
- High-alert medications are strictly controlled, standardized, and defined
- Medication preparation processes are pre-planned whenever possible
- Use of calculations in drug prescribing and preparation is minimized
- Standard pre-planned concentrations, solutions, and volumes are used
- Pharmacy performs all drug preparation
- Medication access is carefully controlled
- Standardized order sets are used whenever appropriate, particularly for complicated drug therapy regimens
- Pharmacists review all medication orders before drug administration except in emergency situations
- Medications are not released from automated dispensing machines until pharmacist order review and approval occurs
- Medications are not compounded if suitable manufactured products can be used
- Dangerous chemicals are not stored in pharmacy or other care areas
- Establish and enforce strict policies regarding medication stock in patient care areas
- Documentation of medication administration is clear, consistent, and easy to find

**Table 1-7. Selected Specific “Best Practices” Recommendations for Safe Medication Use Systems (Continued)**

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**Communication and Teamwork**

- Verbal and telephone orders are limited and always read back after transcription for confirmation
- Care team trains and works together as a team
- Communications among caregivers regarding medications are clear and professional
- Establish defined simplified and consistent workflow processes
- Pharmacists are readily available to patients and other care providers
- Intimidating or other inappropriate behaviors are not tolerated and do not prompt caregivers to proceed with actions they have concerns about
- Illegible orders are always clarified and the prescriber is informed of the need to improve clarity of writing
- Use preprinted forms with appropriate prompts and information order sheets whenever possible, and preprinted order sheets are carefully reviewed for clarity

**Staffing and Competency**

- Have effective process for orienting all caregivers to the medication use system
- Use academic detailing to improve medication use
- Provide ongoing education regarding medications and medication safety
- Distribute and post information and newsletters regarding medication safety
- Publicize (anonymous) examples of common medication errors
- Instruct staff in appropriate methods and importance of double-checks
- Staff performing particularly hazardous or specialized process, such as chemotherapy administration, are trained appropriately and competency regularly assessed
- Competency of all staff is regularly assessed
- Implement targeted education related to identified deficiencies in the medication use process
- Regularly communicate changes and issues regarding the medication use system
- Staff are trained on the equipment and devices they will use

**Environment and Equipment**

- Adequate workspace is provided
- Work areas are adequately lighted and uncluttered
- Distractions and disruptions are minimized
- Provide magnification in appropriate areas
- Limit traffic through critical work areas
- Provide comfortable temperatures in work areas
- Provide appropriate equipment
- Control and limit types of equipment available
- Use only free-flow protected and “smart” pumps
- Use only oral syringes for oral medications
- Maintain all equipment
- Perform risk assessment of all equipment using human factor analysis techniques
- New technologies, such as CPOE and bar code identification, are carefully assessed before implementation, and they are implemented in such a way so as to minimize risk
- Errors related to the implementation of new technologies are closely monitored and managed

**Monitoring of Safety**

- Medication errors and deficiencies are reported and reviewed
  - Multiple methods of monitoring medication use system safety are in place
  - Practitioner interventions to prevent errors are collected and reviewed
  - All adverse drug events and errors are reviewed for opportunities for improvement
  - Monitor alert overrides and ADC overrides
  - Monitor use of antidotes and other trigger medications
  - Implement computer-based expert knowledge systems to monitor medication use
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**Table 1-7. Selected Specific “Best Practices” Recommendations for Safe Medication Use Systems (Continued)**

**Monitoring of Safety (Continued)**

- Implement ongoing quality monitoring for dispensing processes
- Actively solicit feedback regarding safety issues from staff

**Patient Involvement**

- Establish effective lines of communication and encourage questions
- Listen carefully to patient requests, complaints, and thoughts
- Reconcile any patient issues with medications
- Provide patient and family education regarding medications and disease states
- Provide written patient-specific information regarding medications and diseases states
- Educate patients about proper medication use
- Implement method to improve patient adherence to medications
- Educate patient and families about ways to reduce risk for errors
- Ask the patient and family to be partners in safety
- Involve patient and family in patient identification and medication verification processes
- Inform patients of every medication being administered and its intended use every time a drug is administered
- Provide patient/family with written tips on avoiding medication errors
- Refer patients to useful information sources such as Web sites

policies should support and integrate principles of drug control, standardization, and limited accessibility. The JCAHO standards require organizations to use standardized parenteral products prepared by the pharmacy whenever possible.

**Improving Identification, Verification, Checking, Reconciliation, Warnings, and Alerts**

Processes to improve patient and drug identification, establish effective double-checking and verification processes, along with appropriate warnings and alerts, assist caregivers in performing common routine tasks, as well as guiding care in uncommon or unfamiliar situations. These strategies reduce errors such as those involving drug administration to the wrong patient; selection of the wrong drug, dose, and route of administration; pump-setting errors; and wrong administration time. In particular, problems related to dose calculations, drug preparation errors, and look-alike and soundalike drugs are reduced. Implementing a process in which a second individual independently double-checks the work of another is effective in that such checks may detect up to 95% of errors made by another individual. Prudent use of color-coding, warning labels, and special packaging to increase visibility also are useful error prevention methods. Technologies, such as machine-readable (bar code) verification during patient identification, drug dispensing, and administration, are particularly effective. Computer-generated drug administration records (MARs) provide a greater opportunity for clear communications and more accurate drug and dose verification.

**Communication and Teamwork**

Fostering effective communication and teamwork among all participants in the medication use process is critical. Broad organization communications as well as caregiver to caregiver communications should be addressed.

Organizations should define the appropriate standards for written and verbal communications. Limitations on the use of abbreviations and acronyms should be developed and legibility problems addressed. Expectations for, and training in, interpersonal communications and behaviors need to be established and promoted. The medication use process is interdisciplinary and depends on teamwork and effective communications and interpersonal interactions. Deploying pharmacists to patient care units substantially improves communication and effectiveness of pharmacist decision support to prescribers and nurses. Caregivers should be aware of the components of the process, their functions, and interrelationships. Staff members who work together in a medication use process should train together. When properly implemented, technologies, such as electronic mail, computerized physician order entry (CPOE) and organizationwide computer systems, can improve communications.

**Staffing and Competency**

Given the dependence of the medication use system on individual performance, ensuring the availability of a competent staff is critical. Staff should be competent in drug therapy knowledge and in how to function safely and effectively within the medication use system by adhering to policies and procedures, fostering team work and communications, and consistently using decision-support tools. Organizations must have effective processes to ensure their staffs are competent to use devices and equipment when caring for patients. Staffing must be appropriate for the workload, and work hours should be limited to safe levels. The well-documented value and cost-effectiveness of pharmacists in reducing patient risk for ADEs should be considered in organizational decisions regarding pharmacy staffing levels. Routine constructive assessment of staff competency and performance is critical.

## Environment and Equipment

Establishing and maintaining an environment that supports staff performance can enhance patient safety. This includes proper space and lighting, minimal clutter, proper temperature, low noise levels, and a minimum number of distractions and interruptions. Medical equipment should be assessed, controlled, distributed, and maintained with safety as a primary priority.

## Monitoring of Safety

An effective medication safety monitoring and reporting process is necessary for an organization to provide safe drug therapy. Information from an effective monitoring process will promote continued improvements within an organization and help create a culture of safety (see the Reporting, Assessment, Measuring, and Monitoring section).

## Patient Involvement

Patients and their families are critical components of a safe medication use system. Effective education and continued engagement of patients in their care results in improved medication use, fewer errors, and earlier detection of problems. Patients should be educated regarding medication safety and instructed to actively participate in their care and error prevention activities.

## *Technologies to Improve Medication Safety*

Many technologies have been implemented to improve medication safety, and many hold promise to be extremely useful tools to improve medication safety. Despite the increasing use of technologies, only limited information regarding impact of patient safety is available. Application of computer and other technologies in the medication use process provides promise for improved information in many areas, including real-time transfer and provision of critical patient and drug information and decision support; support for teamwork and communication among caregivers; provide more effective means of drug and patient identification and verification; and improve patient monitoring through automated alerts and information feedback. A long-term benefit of information technology is improved data for measuring and monitoring medication use processes and outcomes. Introducing technology requires careful planning that includes all involved in the process, careful risk assessment, effective staff training, establishing and measuring baseline measures, and ongoing monitoring. Introducing technology into medication use historically has been isolated to specific functions related to the preparation and dispensing of drugs. More recently, technologies are being used during the prescribing, drug administration, and patient monitoring steps of the process. Technologies for safety will be most effective when fully integrated into care

and connected to create a closed loop throughout the medication use system.

The pharmacy computer was the first widely used technology in the medication use system. Pharmacy computers provide pharmacists with decision support during the prescription review/dispensing process. The computers provide information regarding drug-drug interaction and maximum dose alerts, up-to-date drug information and patient-specific information. The addition of improved connectivity of pharmacy computers with other sources of information about patients, such as laboratory results and medical records, and drug information resources provides greater decision support for pharmacists. Drug preparation and dispensing technologies include automated total parenteral nutrition and other complex parenteral solution compounders, robotic syringe preparation, robotic dispensing machines, and ADCs. The use of bar code drug verification with or without companion automated dispensing systems are designed to improve the accuracy of dispensing.

At the drug administration step, computer-generated MARs reduce transcription errors, improve transfer of important information, and improve coordination between pharmacy and nursing during drug administration. The use of bedside computers for information delivery and transfer, and bar code technology for verifying drug and patient identification, have the potential to reduce errors during drug administration. Newer drug infusion devices with improved safety engineering design allow bar code verification, dose and infusion rate checking and controls, promote standardization, and provide effective alarming and warning processes.

The use of CPOE and electronic medical records produces substantial improvements in medication safety through improved decision support, communication, standardization, and information transfer. Implementing effective CPOE systems can substantially reduced medication use system process errors and potential ADEs.

The greatest improvements in medication safety will be achieved when technologies are used throughout the entire medication use process from completely computerized patient medical records with CPOE to robotic drug preparation and dispensing, computerized MAR to drug and patient bar code reconciliation before drug administration and electronic administration documentation. Hospitals across the United States are evaluating or adopting technologies such as CPOE and bar coding; however, in 2004, less than 10% of hospitals had fully implemented such systems. Implementing technologies involves considerable costs and can be time-consuming. Failures in implementation of CPOE have occurred. Although technologies promise substantial improvements in medication safety, many issues, including the need for establishment of standards for decision support and terminology, and determination of how and when

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Bates DW, Gawanda AA. Improving patient safety with information technology. *N Engl J Med* 2003;348:2526–34.

Neuenschwander M, Cohen MR, Vaida AJ, Patchett JA, Kelly J, Trohimovich B. Practical guide to bar coding for patient medication safety. *Am J Health-Syst Pharm* 2003;60:768–79.

Kuperman GJ, Gibson R. Computer physician order entry: benefits, costs, and issues. *Ann Intern Med* 2003;139:31–9.

technologies fail to reduce errors or introduce new errors into the system, have arisen. Just having a specific technology, in place will not provide improved safety; as with all tools, the effectiveness of technologies depend on appropriate implementation and use. In the complex medical care environment, managing the human-technology interface is critical to maximizing the value of technologies as tools to improve medication safety.

### *Medication Safety Process Implementation Strategies*

Opportunities to improve medication safety exist in all phases of the medication use process and all involved individuals. Optimally, improvements should address safety deficiencies identified through ongoing assessment of medication use processes within an organization (see the Measuring and Monitoring Medication Safety section). All improvements should be carefully designed and planned using a systems approach and applying human factors research. Successful programs for improving patient safety are those that make multiple small changes in critical components of specific processes rather than attempting to change entire systems. Improving the safety of medication use systems typically consists of a continuously ongoing process of multiple changes in multiple components and functions of the system. Methods for implementing safety improvements vary from organization to organization as does the specific process targeted for improvement.

Medication safety improvements are always best implemented by a team that is collectively knowledgeable about all aspects of the process being targeted. For most medication use process improvements, this involves a multidisciplinary team. Because of the complex medication use process, many improvement teams may be working simultaneously on different problems within an organization. The efforts of teams should be coordinated, and progress reported to a safety oversight body or individual. However, organizations should foster a standard approach to process improvement. One successful method of implementing improvements in medication safety, the Model for Improvement (available at [www.qualityhealthcare.org](http://www.qualityhealthcare.org)), was developed by the Associates in Process Improvement and has been used by the IHI and others. This model involves setting goals for the group, establishing measures to determine if improvements have been made, and determining what changes could be made to improve a process. The team chooses the changes to be implemented and tests those changes on a small scale to determine their effectiveness, and issues associated with the change before wider application of the change.

Implementing small changes that are tested by the rapid Plan-Do-Check-Act (PDCA) cycle is recommended in the Model for Improvement. Using the PDCA approach, proposed changes (Plan) are implemented on a small scale (Do) and assessed (Check) with subsequent changes made based on findings (Act). Small changes in processes that are

implemented using the PDCA model may occur in linked sequence or concurrently. By performing repeated PDCA cycles, considerable improvements in the medication use process can be implemented. The PDCA process is particularly applicable to the medication use process, as it consists of multiple interdependent subcomponents and multiple individuals.

## **Reporting, Assessing, Monitoring, and Measuring**

Effective reporting, assessment, and detection of deficiencies in the medication use process are essential to implementing and maintaining safe drug practices. On an immediate basis, error reporting can provide the opportunity to improve the care of the patient involved, reduce imminent risk to others, facilitate the rapid provision of any needed legal and psychological services, and provide a more accurate record of events. In the longer term, robust detection and reporting processes provide the opportunity to learn about medication safety deficiencies within the organization, their causes, prevention strategies, and error defenses.

The awakening of health care in the late 1990s to the problem of medical errors was largely because of the availability of publications that found much higher ADR rates and errors than typically perceived. There remains considerable controversy and disagreement regarding the true frequency and patient impact of medical errors among both the public at large and health care providers. This lack of consensus regarding the importance of medical safety procedures results from the invisibility of medical care deficiencies and their impact on patient outcomes to most caregivers. Despite numerous well-designed and systematic studies consistently demonstrating a high frequency of errors in care and serious patient harm, these findings are not consistent with caregivers' own perceptions that are formed by the invisibility of errors. This failure to recognize deficiencies in care, or that such deficiencies result in patient harm, is a product of the nature of medical errors and their often delayed or subtle impact on patients. In addition, the culture of health care is one in which error reporting, discussing, and learning often are ineffective or actively discouraged. Failure to truly convince caregivers that medication safety is a serious patient care problem and that their every day actions and behaviors play an important part in safety is responsible for much of the lack of cultural change, inertia, and controversy within health care, related to implementation of, and compliance to, medication safety processes. Many changes in the perceptions, attitudes, behaviors, and actions of caregivers that will improve medication safety can result from effective error reporting and assessment processes. These effective reporting and assessment processes provide organizations with the raw

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Kelly K, Cohen M, Smetzer J. Optimizing Computer Systems for Medication Safety. ISMP Medication Safety Alert Newsletter. Community/ambulatory care edition. 2003;2(7):1-2. Available at [www.ismp.org](http://www.ismp.org).

Leape LL. Reporting of adverse events. *N Engl J Med* 2002;347:1633-8.

materials and motivation with which they can create a learning culture and environment. Such an environment greatly increases the likelihood that significant improvements in safety processes will occur. Effective error reporting also allows the ongoing monitoring of medication use systems and the impact of revisions to those systems on patient safety. External reporting of errors to governmental bodies and accreditation bodies (usually errors with fatal or severe patient harm) may be mandatory in defined circumstances.

Experience has demonstrated that successful error reporting programs are safe, simple, and worthwhile, with the following critical components:

- The reporting system is nonpunitive in nature (i.e., there is no punishment from others for reporting errors).
- The system is confidential. The name of the patient, reporter, and caregiver(s) involved are protected from third parties.
- The system is independent of bodies with the authority to punish the reporter.
- The reports are analyzed by individuals with expertise in clinical and operational circumstances and they are able to recognize contributing systems causes of error.
- Reports are evaluated in a timely fashion and recommendations for improvement rapidly distributed.
- A systems-oriented approach is used in which causes of errors and preventing them in the future are viewed as a function of the system rather than individuals.
- Those responsible for gathering reports are capable of making recommendations for improvement, and the organization is willing to make appropriate changes whenever possible.

Implementing effective medication safety reporting processes within an organization serves many critical functions in improving medication safety. It is a critical component of medication safety.

### **Internal Drug Error Reporting**

Most health care organizations coordinate or incorporate drug error reporting into their risk management processes. The methods used to detect, record, report, and assess drug errors vary from organization to organization. Whatever the processes used, pharmacists should play a significant role because of their knowledge of drugs and their broad understanding of the medication use system. Medication safety reporting systems should incorporate not only reports of drug errors and deficiencies but also organizational reports of ADRs. As previously discussed, a large proportion of ADRs, particularly severe ADRs (the type more likely to be reported), are preventable in that some deficiency in care occurred. Inclusion of ADR reports in the medication safety reporting system allows for a search for care deficiencies leading up to ADRs. When such care process deficiencies are discovered and linked to an actual ADR, the likelihood that an organization will be motivated to improve safety is greatly increased.

Internal reporting systems should incorporate the safe, simple, and worthwhile components of successful reporting systems previously discussed. Internal reporting systems also must provide for data collection required for any

mandatory reporting requirements (such as state-reportable incidents and the JCAHO sentinel events). Internal error reporting should include a clear delineation of the purpose of error reporting within the organization and responsibilities of all staff to report. Internal error reporting processes provide two main purposes: to detect deficiencies in the safety process of medication use systems (which will most benefit patients) and to identify individuals with performance deficiencies. Given the inadequacies of reporting processes, spontaneous voluntary error reporting must be used only as part (and recognized as an extremely limited part) of a multifaceted evaluation of individual caregiver performance.

In general, the person who discovers an error is the one who reports it. This may or may not be the individual who has made the error. The reporting individual may or may not know who made the error, or how and why the error occurred. The most valuable information from an error or ADE report is a clear and factual summary (story) of the occurrence. The anonymity of reporter and individual(s) involved also should be defined. The meaning of anonymous should be delineated. Organizations may require the name of the reporting individual and the names of caregivers thought to be involved, but organizations may take steps to ensure that names are not divulged outside established risk management processes. Other organizations may choose to make the provision of names optional, or not even request such information. Issues with anonymous reporting systems include the inability to obtain additional facts regarding errors from those involved and the perception that anonymous reporting systems absolve caregivers of their professional and ethical responsibilities. Anonymous reporting of errors does not mean that individuals involved in errors can or should avoid disciplinary actions or legal proceedings when such actions are appropriate. Anonymous reporting processes do not take away any rights of injured patients. Organizations must balance the competing needs of improving future medication safety through increased reporting with those of complete understanding and documentation of errors, individual caregiver performance review, and patient rights.

### **Internal Error Reporting Processes and Mechanisms**

Clear and simple processes and mechanisms for reporting errors and safety deficiencies need to be established within an organization. The organization should delineate the errors, deficiencies, occurrences, incidents, or situations that are to be reported. Caregiver definitions of what constitutes an error vary widely and should be clearly defined and communicated to staff and patients. A time frame for error reporting should be established. Any care deficiencies that alter patient care (errors that reach the patient) must be reported immediately. The patient's caregivers are to be informed immediately of an error that reaches the patient so that patient assessment and any needed care can be provided. The unit manager should be informed immediately of any significant errors, so he or she can assess further patient risks. Of importance, patients and/or their family should be informed of the facts of the error and what is being done. A planned process for dealing with serious patient harm because of an error should be

established. The plan should involve disclosure processes to the patient/family, and involve physicians and other caregivers, administration, management, risk management, legal, pastoral care, employee assistance program, and public relations. For most detected drug errors that reach the patient and cause no or minor/reversible patient harm, reports do not need to be immediately reviewed by risk management or other bodies as long as appropriate care is being provided.

To maximize the opportunity to learn from an error, organizations should use near miss (errors averted before reaching the patient) and no patient harm drug errors along with errors that cause patient injury in their drug error reporting processes. Reporting drug errors that were averted before reaching the patient also should be included in an organization's drug error reporting process. Averted errors, often referred to as near misses or close calls, are extremely common in the medication use system, but they are not dissimilar to causes and common components of error scenarios that, under slightly different circumstances, cause patient harm. Reporting and using near miss information is used widely in nonmedical industries to evaluate and improve safety systems. The evaluation of cases involving preventable adverse patient outcomes from medication safety deficiencies always involves some error or set of errors in processes or defenses, even if a direct relationship between an error at a single point in the process and eventual patient harm cannot be established. However, establishing a cause-and-effect relationship is not necessary to learn from all detected errors and deficiencies. If a cause-and-effect relationship is unclear, changes implemented to reduce detected process errors will not necessarily prevent similar future patient harm, and do carry a risk of introducing new errors. Nonetheless, including probable errors and near misses in medication safety incident reporting programs can provide substantial information about the quality and safety of the various components of an organization's medication use system. Some advantages of near miss reporting programs include a much higher frequency of reports with possible quantitative evaluation, easier reporting and data collection, and limited liability concerns. Individual or multiple steps in the medication use system can be evaluated using near miss reports. Knowledge gained from such near miss reports is highly useful in failure mode analysis (FMA). Evaluation and use of both error (near miss and no patient harm error reporting) and patient injury (reports of patient harm from errors) reports provide complementary perspectives of medication safety systems.

Detected errors are recorded and reported by a paper form, telephone (or voice mail), electronic mail, personal digital assistants (PDAs), internal computer system (intranet), or verbally to trained staff such as pharmacists, risk management specialists, or quality specialists. Many commercial Web-based reporting systems are available. Information regarding an error that is written in the patient's medical record should be delineated—the facts of the error, who was informed, and subsequent actions. But assessment of "cause and effect" of subsequent patient outcomes are not to be included because this involves assumption. It is worthwhile to design a reporting process that is as clear, concise, and unambiguous as possible. The report should

stress the reporting of a factual account of the error and its observed consequences, and allow communication of any error-producing conditions and perceptions of the causes of the error. This is best done through teaching the staff to provide a narrative describing pertinent facts and details. Unambiguous prompts for information should be provided. Requiring the reporter to classify the error or outcome, classify the drugs involved, determine steps in the medication use process, and list causes is not usually particularly helpful, and it may produce bias in cumulative data. Classification is best performed by a limited number of individuals using standardized definitions and guidelines (see the Error Evaluation section). In addition to reporting errors noted in daily care functions, providers should routinely document their activities related to preventing drug errors and improving drug therapy. The reporting of these caregiver interventions provides a large amount of data useful in assessing system performance and safety. No matter what the mechanism for recording and reporting errors, the information gathered should provide enough information to meet the reporting system objectives. At a minimum, information should include patient name and a second unique identifier (most commonly date of birth or medical record number), date, time, location of incident (if not obvious), reporter name (may be voluntary), narrative description of events (should include name of drug(s) and what deficiency in care occurred), any observed patient outcomes, subsequent requirements for increased monitoring or treatment, and who was informed of the error. Instructions of how and to whom the reporter is to submit the report should be provided. The information should be handled as confidential by all involved, with clearly defined distribution and communication processes (i.e., who gets the error report and when) that ensures that proper patient assessment and medical care are provided.

#### Patient Disclosure of Errors

Patients should be involved in their care as much as possible, and involving patients in their drug therapy improves medication safety. The public is well aware of the potential for errors to occur, as many have experienced errors in the past. The public also expects that individual health care providers and organizations accept responsibility for their performance, and be honest and forthcoming. Traditionally, caregivers and health care organizations have failed to fully disclose medical errors to patients for reasons that include paternalism, shame, fear of litigation, loss of reputation, and deterioration of their relationship with patients. However, failure to fully disclose errors may result in even greater loss of patient confidence and trust in caregivers and organizations, reduced satisfaction with care, and may actually increase the likelihood of litigation. Disclosure of errors that alter the planned delivery of care should be divulged to the patient whenever possible. The potential negative effects should be discussed, as should the plan to monitor for and ameliorate any potential harmful effects. Patients should be told the facts of the occurrence and, if asked, the individuals involved. If facts are unknown or unclear, the patient should be informed of this and told that an active process is in place to determine what happened and why. An explanation of how the error

occurred, without making excuses, can help the patient understand why things did not go as planned. Do not minimize the nature or potential for harm from the error. Of importance, an apology should be offered and complete acceptance of responsibility by the organization. Most important, patients and families want to know that something is being done to prevent the same or similar errors in the future. Fear of litigation should not influence behaviors toward, or information provided to, the patient or family.

### Promoting Caregiver Reporting of Drug Errors and Safety Deficiencies

Reporting of drug errors and deficiencies is considered a professional and ethical responsibility of all health care providers. Individuals and organizations must incorporate detection and reporting of safety deficiencies in their daily routine. The purpose of error reporting as a means of improving patient safety should be promoted and known to caregivers. The expectations for reporting by caregivers must be delineated, and clear and consistent processes related to reporting must be established. Tangible patient safety improvements resulting from reporting should be demonstrated to caregivers so that reporting is seen as worthwhile.

There are many significant knowledge, motivational, and cultural barriers to successful medical error reporting programs. Poor caregiver recognition and understanding of safety deficiencies and unsafe behaviors and their significance are common. Although preventable ADEs are common, recognition of adverse patient outcomes resulting from routine medication use system process errors is poor. Preventable ADEs seldom occur because of the exact same set of circumstances, and appear to front-line caregivers as an individual performance failure and a chance set of circumstances rather than the recognizable and alterable underlying latent and error-producing conditions. Staff education regarding the frequency and nature of medical errors and their role in reducing risk through reporting errors should be ongoing within the organization. Specific standards of care should be defined whenever possible to establish safe practices and “norms” and to minimize variability. Compliance with care and safety standards should be promoted at all levels of the organization and monitored. Organizations should define what occurrences and conditions are expected to be reported rather than leaving it up to caregivers to decide.

Caregivers must be appropriately motivated to spend time and effort reporting errors. Reporting of errors and safety deficiencies needs to be as simple and efficient as possible to minimize time taken away from other functions. Motivating caregivers by promoting error reporting as an important and positive approach to safe patient care creates the proper cultural environment. When improvements are made, the role of reporting in prompting the process improvement change and its design should be communicated. Such communication demonstrates the positive impact reporting can have on patient safety.

Addressing the deep-seated cultural barriers to reporting medical errors is more difficult. Cultural barriers will be reduced through proper leadership behaviors and actions at all levels of leadership, communication and interactions with staff and patients, and through the establishment of a just and nonpunitive error reporting system.

### Just and Nonpunitive Responses to Drug Errors

Responses to, and assessment of, error reports must be perceived and executed as fair, just, and nonpunitive to the individuals involved and the reporter. The culture of medical care is based on the concept of perfect individual performance. Responsible caregivers do not intend to commit errors or engage in actions or behaviors that they believe will result in patient harm. Nonetheless, when errors do occur, the responses primarily focus on the caregivers involved. Internally, a caregiver’s response to errors in which he or she is involved include anguish, anxiety, guilt, loss of confidence, personal disappointment, and fear of professional, social, personal, and legal repercussions. The response often is significant, producing anxiety, sleeplessness, and difficulty concentrating. Processes must be established to help caregivers involved in errors cope with the psychological impact they impart. Organizations that use the person approach to errors typically address only the caregivers involved through corrective action procedures, which are inherently punitive in nature. Such subtle, overt, delineated, or inferred punitive responses by the organization or its caregivers greatly reduce the likelihood that future errors will be reported and learned from. More important, it fails to result in broader and longer lasting improvements in patient care. Thus, it is critical that a nonpunitive approach to error reporting and assessment is established within health care organizations, and this approach is mandated by the JCAHO.

Effective nonpunitive error reporting and assessment stress the systems nature of medical error and its prevention and organizational learning from the error, and also recognize the need for individual and care team learning to occur. Because fewer positive changes in individual behavior occur when a person ascribes errors to causes outside him or herself (external), nonpunitive or blame-free systems should fully recognize the individual’s role and his or her actions in an error and expect the individual to learn from the error. Similarly, a nonpunitive environment allows learning from errors to be extended to the larger caregiver team. In a nonpunitive environment, errors committed by others are more likely to be reported by colleagues, discussed constructively, learned from, and produce positive changes made beyond those caregivers directly involved. Organizations must clearly delineate the role of error reports (if any) in individual performance assessments. Use of error reports in performance assessment automatically creates a potentially punitive environment and should be carefully considered. Given inequities, inaccuracies, and confounding interpersonal and cultural variables in current error reporting programs, routine use of error reports as an

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important determining part of individual performance evaluation typically is inadvisable and will result in an environment in which error reporting is seen as punitive. However, reports in which caregivers act in a reckless or grossly negligent manner should prompt appropriate and fair responses from managers. Clearly, error reports cannot be ignored in the management and supervision of caregivers. However, error reports should not be used as comparators of performance, but rather considered one set of information in the larger context of job responsibilities and performance. Repeated error reports should prompt an appropriate and fair investigation into the errors, the role of the caregiver, and the role of the system. Useful models exist for determination of system and caregiver culpability that can be applied to drug errors. Properly performed evaluations typically will reveal both system deficiencies and/or performance deficiencies common to many caregivers performing the same function, rather than any one caregiver. This evaluation should lead to implementation of systems that reduce chance of error and assist all staff in performing their job functions. Seldom will proper evaluation reveal a situation in which the error was solely because of individual incompetence, gross negligence, or recklessness.

#### Assessing Internal Drug Error and Safety Deficiency Reports

The purpose of error reporting is to provide information to an organization so that it can learn how to improve patient safety. Effective evaluation and analysis of error reports plays a critical role in identifying opportunities for improvement and the design and implementation of safety improvements. Ineffective error report evaluation and analysis may result in the failure to recognize or understand care deficiencies, and implementation of less than optimal or ineffective error prevention processes, or even ones that actually increase patient risk. To best improve patient safety, error reports must be collected, investigated, reviewed, and analyzed in a planned and organized fashion by trained, experienced, knowledgeable individuals.

#### Evaluating Error Reports

An effective ADE and error reporting system will generate many reports. Even suboptimal systems will receive more reports than can, or need to be, fully investigated. Resources required for full evaluation of all reports would be excessive and of diminishing added value. Priority should be given to reports of serious patient harm or potential harm because of medical error, and all such reports should be fully investigated. Other reports that point to conditions with a high likelihood for significant patient harm should be systematically reviewed. Priority is given to such reports as they may demonstrate conditions of impending patient harm that may be preventable or

ameliorated. Although each report should be valued, many error reports do not require an in-depth evaluation; however, these reports should be processed and evaluated to provide for maximal learning. This process should include a rapid review and evaluation, severity rating, and coding by trained staff, with feedback to caregivers and managers. Systematic and standardized evaluation of all reports by a limited number of individuals provides consistency and the increased potential for recognition of trends across an institution. A pharmacist should review all error reports involving drugs reported within an organization. Consistent evaluation, abstracting, and coding allow error report summaries to be placed in an electronic relational database for trend tracking and future data extraction. Such an evaluation process allows identification of common errors and deficiencies reported over time through evaluator recognition and error report database queries. Common components of an error report database include patient identifier, date of occurrence, time of incident, location, narrative describing the incident, patient outcomes, severity rating, name of drug(s) and drug class(es), types of error(s), medication use process step(s), type of service, and contributing factors and conditions. The NCC MERP developed a taxonomy of drug errors and a standard index for rating drug errors. This index categorizes errors into one of nine categories based on whether the error reached the patient and the potential for, or actual, patient harm. The United States Pharmacopeia (USP) MEDMARX system and the ANALYZE-ERR system of ISMP Canada (available at [www.ismpcanada.org](http://www.ismpcanada.org)) are examples of useful tools providing structured formats for error evaluation.

Complete and formal review of drug errors and safety deficiencies may be prompted by a single report or as a result of repeated reports of similar errors, errors involving specific drugs or treatments, errors in specific clinical situations or environments, and reports of errors in specific steps of the medication use process. The use of an error database greatly facilitates identifying opportunities for improvement over time and across an organization. Review of individual error reports or of a series of similar errors should follow a defined process to ensure a complete and efficient evaluation resulting in appropriate and useful outcomes. This process commonly follows the RCA format. An RCA is a retrospective, blame-free, systems-based evaluation of events surrounding errors that attempts to define any and all contributing causes to the outcome (e.g., latent and error-producing conditions, performance or active failures, and the reasons defenses failed). The process involves a multidisciplinary team led by an individual trained in the process. Team members should include caregivers who have first-hand knowledge of the processes being evaluated and organizational leadership. Caregivers who were directly involved in the error should be included to provide first-hand information. All team

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members should receive orientation to the RCA processes and goals. There are many variations on the specific processes used in RCA of medical errors. The six common components of RCA include the following:

- Determine the actual sequence of events leading up to, during, and after the event. The sequence of events should be based on staff interview, record review, and all other useful information sources. Human factors and conditions proximal to the incident, as well as processes and systems related to the event, should be identified. Identify error amelioration defenses that worked and those that failed. Flow charts and diagrams are used in this process to identify the sequence of events and interrelationships between functions and processes.
- Determine all events and conditions that contributed in any way to the outcome.
- Evaluate underlying causes of ADEs by asking “why” multiple times in series (e.g., Why did the patient receive an overdose of morphine? Why did the nurse measure the wrong amount? Why did the nurse have to do calculations to measure at all? Why was the drug not provided in unit dose?). This type of evaluation identifies systems causes of error and targets for systems improvements. To provide a comprehensive analysis, all pertinent events, processes, and areas involved in the error should be evaluated.
- Identify areas of risk and their contribution to outcome or potential for adverse outcomes.
- Identify areas in which process improvements are possible to reduce risk in the future as well as improve defenses against patient harm.
- Develop a plan of improvement to reduce risk of future error that includes an error reduction strategy, leadership oversight, individual responsibilities, time lines, evaluation method, and follow-up.

Root cause analysis typically addresses and evaluates errors that have occurred. Failure mode analysis techniques are useful methods for evaluation of error prone drug processes. Failure mode analysis provides a broader approach to evaluating deficiencies in processes beyond the findings surrounding a single event, and in designing and implementing improvements. When error reports, quality monitors, or an RCA demonstrate multiple ongoing problems or poor outcomes in the many subprocesses within a medication use process step, but specific causative errors cannot be determined, failure modes may be more useful in identifying components to improve overall processes. Failure mode analysis attempts to identify all the ways a process, products, and processes may fail, why they fail, and the effects of failure. This process of analysis has been applied widely to nonmedical systems for more than 30 years, and only recently has been used widely to reduce risk for medical error. Similarly, FMEA evaluates all of the ways (modes) failures could occur, what the effects of those failures could be, what the likelihood of failure is, what the effectiveness of

mechanisms of failure prevention or recovery are, and what the severity of harm would be from the failure. Human error mode and effects analysis (HEMEA) attempts to identify what ways a human could make an error within a system or process, and what the effect of that error would be. The HEMEA incorporates known human factors into evaluation of errors or predicting errors and their effects. The HEMEA technique is particularly useful in identifying potential errors or evaluating errors that involve human actions (e.g., prescriber writing a drug order), human-product interactions, reading or interpreting instructions, physically using a product (i.e., pharmacist preparing a drug), and human-machine interface (e.g., pharmacist order entry into a computer and intravenous pump setting). Specific techniques for FMAs vary, but the usual seven steps of an FMA are the following:

- Define the topic.
- Assemble a multidisciplinary team similar to that described for RCA, with caregivers highly knowledgeable of processes being examined, as well as caregivers more remote to the process. Multiple pharmacists with different experiences, perspectives, and job functions should be included.
- Graphically describe the actual function being analyzed, identifying each major step and each problem-prone step.
- Identify a specific step or steps to be analyzed to limit the scope of the analysis.
- Identify and diagram all subprocesses within each step.
- Determine all possible or potential failure modes for each subprocess, and severity and potential for harm for each failure mode. Standardized rating/scoring scales are available. Based on the score determined by this process, identify those failure modes that need to be improved.
- Identify strategies to reduce risk from identified “high-hazard” failure modes and what outcome measures should be used to measure impact of improvements. Obtain leadership approval and support and identify individuals responsible to implement improvement strategies.

Root cause analysis and FMEA are best performed using a common framework or protocol. This assists in attaining complete and useful error report evaluation and risk assessment by multidisciplinary groups. The AHA Pathways for Medication Safety: Looking Collectively at Risk uses the ISMP Medication Safety Self-Assessments to provide useful frameworks. These tools provide a comprehensive framework of ideal characteristics of safe medication use systems with which errors, their causes, and defenses can be evaluated.

A protocol based on models of organizational accidents (Figure 1-1) has been successfully used to investigate and analyze medical error reports, and it has been effective when applied to drug error reports. This protocol evaluates leadership, institutional, organizational, management, work environment, team factors, individual caregiver, task (job/function) factors, and patient factors and their

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relationship to the harmful outcome. Other concepts and methods to evaluate medical error have been useful, particularly in evaluating errors with complex and poorly defined causes and include an “injury prevention” model based on injury prevention outside of medical care and a public health approach to assessment of harmful outcomes and their prevention. These models focus on actual poor patient outcomes rather than individual errors in processes, and then identify the weakest link in the chain of injury causation that could be: the drug as the agent of injury, patient conditions/factors, method of drug delivery, and environmental factors. The chance for future injury is reduced through intervention at the identified weakest points of causation. This approach often produces engineering solutions, such as free-flow protection on infusion pumps.

Methods of incident evaluation are based on attempting to prevent injury through identifying errors in processes in the domains of human, technological, and organizational function to reduce the chance of errors occurring and/or improving recovery from them. Although many times systems improvements involve technological and organizational changes, outcomes of medical care today remain, in large part, a product of individual caregiver performance. The importance of medical injury prevention through improving performance, knowledge, skill, and teamwork should not be minimized or avoided when looking for systems causes and solutions. Though often unreliable as a method of improving care, education and training of caregivers remains an important system through which patient safety can be improved.

### Use of External Drug Error Reports

Despite the variability in the structure and processes of medication use systems, many commonalities exist that allow learning from other health care organizations. Medication safety deficiencies and errors commonly are reported in the lay press, medical publications, and by organizations such as the ISMP, Food and Drug Administration (FDA) and its Center for Drug Evaluation and Research (CDER), USP, NCC MERP, and JCAHO. Published reports of studies examining ADEs and drug errors also provide information that is highly applicable to most health care organizations. These external reports should be used in a similar manner to those detected through an internal reporting system. Such reports typically identify errors with significant potential for patient harm and with underlying conditions and causes common to most health care settings. Even if an organization has not experienced similar errors, these external reports should prompt a review of internal processes to assess risk for similar errors. Organizational learning occurs when important, and particularly applicable, external reports are widely disseminated within an organization. Health care organizations accredited by JCAHO are required to evaluate

and respond to reports of errors in the JCAHO Sentinel Event Alert as a condition for accreditation. The removal of concentrated potassium from patient care units in most United States hospitals is one example of safety improvements resulting from external reporting. An advantage of using external reports of deficiencies is the lack of emotional and biased thinking commonly found when organizations deal with internal reports, whereas a disadvantage is the lowered level of motivation to respond to errors occurring outside an organization.

### Systematic Methods for Internal ADE and Error Detection

Underreporting in internal voluntary systems limits the value of such systems in assessing medication safety within an organization. The number of reports to a voluntary reporting system should not be used as an accurate measure of error or ADE rates, and the NCC MERP has stated specifically that benchmarks or comparisons of error rates between organizations is not appropriate. Improved, but still imperfect, methods for detecting ADEs and medication safety deficiencies have been developed. The ability to consistently measure medication safety accurately is not presently possible; however, improved measurement techniques should be considered (see *Measuring Medication Safety* available at [www.latiolais.org](http://www.latiolais.org)). These enhanced methods produce significantly more useful information but are sometimes significantly more labor-intensive.

### Medical Record Review

Medical record review can detect ADEs as well as errors and deficiencies in care in the patient assessment, prescribing, transcribing, dispensing, administering, and monitoring steps of the drug process. In addition, this method provides an opportunity to assess the systems-based causes of errors and their defenses. Standard medical record review for ADE documentation of errors is usually a component of retrospective case reviews and hospital medical information services. This method provides improved but limited increased error detection compared with voluntary reporting. The value of medical record review is enhanced greatly by using trained reviewers, computerized monitoring, and solicited and voluntary caregiver reporting. Record review that incorporates systematic record review to identify triggers of potential ADEs and errors is a more effective and efficient way of identifying potential problems. Adverse drug event triggers include readily identifiable items, such as a sudden change in patient condition, orders for antidotes, and report of patient events commonly because of an ADE (rash and diarrhea). The IHI-developed medical record review method for detecting ADEs based on triggers is applicable widely in the hospital setting (Idealized Design of the Medication System Design Group. Adverse Drug Event Measurement Kit [version 3]; available at [www.ihl.org](http://www.ihl.org)). A

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standard process performs data extraction and identifies errors, ADEs, or triggers signifying the possible occurrence of an ADE during a short medical record review. If errors, ADEs, or triggers are found, the ADE and error are categorized using the NCC MERP categorizations and further case review is undertaken. Adding ongoing solicitation and prompting of reports from caregivers and patients regarding ADEs and errors further improves detection rates. When computerized processes and records are available, information suggesting that an ADE or error has occurred often can be extracted efficiently. These enhanced medical record review processes have been extremely useful in providing important information regarding the frequency, nature, and causes of errors and ADEs. Enhanced medical record review studies demonstrated ADE rates of 6–20% in hospitalized patients (30–50% of which are preventable) and ADE rates between 5% and 25% in ambulatory patients (25% or more of which are preventable).

Limited scope record reviews can identify errors in select medication use processes targeted for assessment or improvement. Examples of useful limited scope record reviews include comparison of pharmacy computer order entry versus original prescription; review of prescriptions for errors and subsequent detection and correction by the pharmacist; and comparison of the MAR with the original prescription.

### Adverse Drug Events and Error Finding through Drug Use and Laboratory Triggers

A less comprehensive approach to increased detection of ADEs and errors using triggers to identify various potential drug use and laboratory also can be implemented. These approaches identify potential ADEs or errors based on drugs dispensed by pharmacy (e.g., antidotes, antihistamines, sodium polystyrene sulfonate, and vitamin K), types of drug orders (orders to start or stop certain drugs), and unadministered drugs returned to the pharmacy. Requiring justification for withdrawal of select trigger drugs from automated dispensing machines also is used to prompt further investigation for a potential ADE. Laboratory results, tests, or orders also can provide a method by which ADE detection can be improved. Examples of laboratory results that may signal an ADE include serum drug concentrations above a defined concentration, high serum potassium concentration, request for *Clostridium difficile* assay, hypoglycemia, thrombocytopenia, neutropenia, elevated international normalized ratio (INR), and new elevations in serum creatinine.

### Observation Technique

The observation technique, developed by Kenneth Barker and colleagues in the 1960s, evaluates error rates in drug dispensing, preparation, and administration. This methodology is proscribed by the Centers for Medicare and Medicaid Services (CMS) for monitoring of drug administration in long-term care facilities as a condition of

participation, and an extension of this requirement to hospitals has been proposed. The observation technique uses a trained observer witnessing and systematically recording data about drug preparation, dispensing, or administration, and then compares the action with original prescribed orders. Any discrepancy between the two is considered an error. Additional data also can be collected regarding conditions (e.g., illumination, sound, and disruptions) to assess their impact on error rates. This technique detects errors at rates of more than 1000 times that of spontaneous voluntary reporting programs and 50 times that of standard medical record document review. When compared in the same institution, observation methods detected a drug administration error rate of 17.9%, chart review 1.3%, and spontaneous incident reporting 0.04% (the detection of wrong time errors accounts for a large proportion of the difference). An individual organization can use the observational technique to study closely the specific medication use process steps of dispensing and administration. This technique detects specific errors quickly and accurately, such that it can be used for short time periods in targeted processes and areas to determine underlying error frequency, and to monitor the impact of process changes on error rates.

### Practitioner Interventions

Caregivers commonly detect and correct errors and other deficiencies in care during their daily duties. This is particularly true of pharmacist review of physician prescriptions and checking processes during dispensing, and the checking of dispensed drugs versus the MAR. The frequency of reporting these types of near miss errors often is low, with a perception that such errors are harmless or part of the normal routine of patient care. Experience and comparison with studies reporting the causes of preventable ADEs demonstrate that errors averted through practitioner intervention mimic errors that reach the patient. Root cause analysis of errors often demonstrates that routinely averted errors are major contributors to patient harm. As demonstrated in nonmedical industries, near misses provide organizations with considerable opportunity to learn about the safety of their systems. Many institutions do not routinely collect information regarding practitioner interventions as part of their medication safety programs even when such data are sometimes readily available. Most information on practitioner interventions is available from programs focusing on pharmacy interventions. Implementing a simple and systematic process to record and report practitioner interventions related to medication safety provides important information regarding the frequency and nature of errors in specific steps of the system, usually the prescribing (pharmacist interventions) and dispensing processes (nursing interventions), as well as the effectiveness of system defenses to avert errors.

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Schiff GD, Klass D, Peterson J, et al. Linking laboratory and pharmacy. Opportunities for reducing errors and improving care. Arch Intern Med 2003;163:893–900.

## Technology-based Error and ADE Detection

Technology offers an opportunity to quickly, efficiently, and, in some cases, more effectively identify ADEs and medication safety deficiencies. Laboratory and pharmacy computers; electronic medical records; automated dispensing technologies; and point-of-care technologies, such as bar code reconciliation and “smart” infusion pumps, provide information that can enhance ADE and medication safety deficiency detection. Pharmacy order entry and CPOE systems can report warnings and overrides, the ordering of drugs (e.g., antidotes), and certain types of orders. Computerized dispensing technologies can provide alerts when drugs are returned to the pharmacy that should have been administered. Automated dispensing machines can provide information about dispensing of certain drugs and the use of overrides. Technologies used at the point of care can record and report attempts to administer the wrong drug or dose, the wrong patient, wrong time, and omitted doses. Computerized laboratory results reporting can identify results potentially related to ADE or drug therapy monitoring. Electronic medical records provide a wealth of extractable information that can be efficiently searched. Processes for automated data mining of electronic medical records are now available that can identify high-risk ADE situations, potential and actual ADEs, and medical errors rapidly and on an ongoing basis. All of these information sources can assess risk and design system improvements.

## Focused Monitoring

Focused quality evaluations of specific aspects of an organization’s medication use system can provide valuable information to assess and improve a medication use system. Such focused evaluations may measure the frequency of an error within a specific medication use process (such as accuracy of pharmacist computer order entry or accuracy of drug dosing in pediatrics), deficiency in the delivery of care (timing of antibiotic surgical prophylaxis or use of  $\beta$ -blocker in patients with myocardial infarction), and patient outcomes known to be related to provision of appropriate care (frequency of contrast dye-associated nephropathy and adequacy of preprocedure hydration). The value of this information will be greatest when standardized criteria are used and all concerned parties are involved. Targets of successful focused quality evaluations usually are based on significant problems identified through internal reporting processes, observations, and concerns that established standards of care may not be consistently provided. When well designed, these types of focused quality evaluations can provide valuable information with which changes in the system of care can be designed, and their impact accurately evaluated with pre- and postimplementation studies.

## Evaluating Medication Safety Processes through Comparison with “Best Practices”

Organizations must assess their medication use process using other means because of the limitations of information

provided through presently available internal medication safety deficiency reporting programs. Medication safety systems can be assessed by comparing the organizations medication use processes to widely recognized professional and organizational standards and recommended best practices. These standards and best practices define medical errors broadly, addressing the quality of care, the safety with which it is provided, and whether it is provided in the most cost-effective manner. This broad definition of patient safety recognizes that failure to appropriately treat patients (care omissions) produces as much as or more harm than errors in care delivery, and that wasteful expenditure of limited health care resources will impair access to needed care. As such, available practice guidelines define both *what* care should be administered and *how* care is best provided. No controlled, clinical trials have demonstrated the effectiveness of many standards and best practices in improving medication safety. Many experts do not believe that a medical model of establishing an evidence base for effectiveness is necessarily an appropriate method for evaluating medication safety processes given the nature of errors, the integral role of human factors, and the difficulty of measuring the effect of interventions on outcomes. In addition, requiring studies to prove the value of widely implemented and accepted safety practices would be time-consuming, expensive, and provide minimal value. Although practices to improve patient safety and outcomes should be based on the best available evidence and information, expecting a strong scientific evidence base for all safety practices is not realistic and prevents rapid implementation of effective processes. Most recommendations are based on long-standing experience and common sense approaches to reducing patient risk learned through systems-based error and risk analysis. Best practices recommendations are available from many sources and continually are updated and expanded. The type and scope of best practices recommendations vary based on the recommending organization’s focus and purpose. Recommendations are available for many processes in the medication use system, specific patient populations, specific care environments, and common therapeutic interventions. Many states have mandated specific practices for select medication use processes. The JCAHO proscribes many safety-based medication use practices as a condition of accreditation. These practices are delineated in the Medication Management, other accreditation standards, the JCAHO Patient Safety Goals, and the JCAHO Sentinel Event Alerts (all available at [www.jcaho.org](http://www.jcaho.org)). The ISMP developed tools for comprehensive evaluation of the safety of medication use systems in hospitals and in community pharmacies. The ISMP also provides best practices recommendations in its biweekly newsletters. The ASHP publishes practice standards for pharmacies in health care organizations, and recently released a self-assessment tool for organizations to measure compliance with these care standards. The National Quality Forum (NQF) has developed a list of quality standards, many which are related

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Hieb B, Stumpf J. Improving Patient Safety Through Expert Knowledge and Critical Knowledge and Critical Health Care Decision Support. Available at [www.misys.com](http://www.misys.com). Accessed July 15, 2003.

to medication use. A partial listing of organizations providing best practices recommendations is provided in Table 1-5. Best practices recommendations commonly are found in medication safety-related publications, and are contained within consensus treatment guidelines. Organizations should evaluate the relevancy of a best practice to their care environment and determine if internal systems and processes are consistent with the recommendations, or if alternative processes are in place to address the safety and effectiveness of the care process(es) being addressed. Information obtained from internal medication safety reporting programs can identify problem-prone processes and prioritize the implementation of recommended best practices.

### External Error Reporting Programs

Reporting ADEs, drug errors, and safety deficiencies to external organizations provides an additional opportunity for organizations and individuals to contribute to the medication safety of their patients. External reporting to central databases allows rapid and/or improved recognition of new or infrequent ADEs and drug errors, identification of trends in risks to patients, and development of best practice recommendations. Common concerns regarding reporting to external programs include potential loss of anonymity, and unauthorized or inappropriate use of divulged information. External reporting programs may be voluntary or mandatory. Like internal reporting programs, the most successful will be safe, simple, and worthwhile.

The 1999 IOM report recommended the development of a mandatory reporting system for serious medical errors as a method to ensure accountability and to help drive safety improvements. Considerable divergence of opinion exists between the public and health care regarding the need and value of mandatory reporting systems. The public considers mandatory disclosure as fulfilling the obligation of health care to ensure accountability of providers to those who are harmed, provide oversight of health care organizations and providers, and a method to promote improvements in care. On the other hand, health care systems and providers consider mandatory reporting to be inherently punitive in nature, thereby reducing reporting and subsequent open discussion and learning from errors, as well as increasing the potential for litigation and loss of reputation, public trust, and economic disadvantage from loss of business. Despite considerable discussion and debate, no national mandatory reporting program has been established.

Mandatory reporting of drug errors is required by JCAHO and at least 20 state health departments. The JCAHO requires the reporting of defined serious patient safety deficiencies to its Sentinel Events Reporting Program. Sentinel events are defined by JCAHO as "... an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function ...". Drug-related sentinel events include serious errors and ADEs. Events considered reportable by JCAHO are those that "... resulted in the unanticipated death or major permanent loss of function, not related to the natural course of the patient's underlying illness or condition." The JCAHO evaluates the organization's response to the error

both in terms of analysis of underlying causes using RCA and corrective actions taken. State-based mandatory reporting systems vary widely as to which types of occurrences must be reported and how those reports are handled. Most information remains confidential, with some states providing summary reports to the public, as well as occasional alerts regarding specific issues identified. Both JCAHO and state reporting programs appear to receive reports of only a small fraction of significant errors. This is not surprising, considering the complexity and disincentives to reporting. Pharmacists should be familiar with the mandatory reporting requirements to JCAHO, the state in which they practice, and any other organization requiring reporting.

Voluntary reporting programs for ADEs and drug errors include the MERP coordinated by USP, the MEDMARX program of the USP, and the MedWatch program of the FDA. Reports to MERP are shared with ISMP, FDA, and drug manufacturers. Error reports are used by ISMP and USP to track and trend error frequency and to develop recommendations for their prevention. The Pediatric Pharmacy Advocacy Group (PPAG) provides a system for reporting ADEs in children (Pediatric Adverse Drug Reaction Reporting System available at [www.ppag.org](http://www.ppag.org)). The MEDMARX system, a subscription-based national reporting system operated by USP, is an Internet-based program that allows subscribers to submit reports with a standard set of information. More than 600 hospitals and governmental health agencies participate in MEDMARX. Most participants submit all drug errors reported in their internal reporting system, further emphasizing the importance of developing an effective internal process. The data in summary and comparative reports provided by the MEDMARX program will reflect the wide variability of the nature and frequency of reporting among organizations. The data set submitted to MEDMARX includes factors related to the error, harm that occurred (using the NCC MERP categorization), and actions taken. The large MEDMARX database allows identification of error-prone drugs, processes, and environments and the development of appropriate recommendations for risk reduction.

The FDA provides the voluntary and confidential MedWatch program for reports of serious ADEs, errors, and other problems with drugs and medical devices. The FDA also manages the Vaccine Adverse Event Reporting System (VAERS) for reporting vaccine-related serious ADEs. Evaluation of ADE reports may prompt changes in product labeling, packaging, and alerts to consumers and caregivers through their Web sites and publications, such as the FDA Medical Bulletin and MedWatch Update. The MedWatch system also disseminates information through communications to MedWatch Partners, a large group of organizations that also includes some major pharmacy chains. Information is relayed to members through meetings, newsletters, journals, and electronic communications.

The JCAHO Sentinel Event Reporting Program is a mandatory system but also accepts all reports on a voluntary basis; however, failure to report certain defined serious errors may compromise accreditation. The JCAHO compiles reports of errors and publishes alerts in its Sentinel

Event Alert on an ongoing basis on its Web site, along with recommendations to prevent future errors. This publication, and medication use-related recommendations contained therein, should be routinely reviewed by pharmacies and incorporated into the assessment and process improvement programs for organizations' medication use processes. The JCAHO requests documentation that an organization applying for accreditation has reviewed the sentinel event report and taken appropriate action when necessary.

None of the mandatory and voluntary ADE and drug error reporting programs is ideal. Many capture only a small fraction of errors that occur and those are probably not representative of errors seen within any single health care setting. Nonetheless, the value of reporting is substantial and all health care providers should contribute reports. The information about errors and methods of improving the safety of drug therapy derived from these programs benefit all care providers and their patients.

## Health Care System Stakeholders and Medication Safety

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### Public-at-large, Patients, Families, and Patient Advocacy Groups

Health care consumers can impact the advancement of quality in the organizations from which they receive care. Health care providers are highly motivated by public opinion. The public availability of comparative information on quality of care outcomes drives organizations to take substantive steps to improve, even if it is only in the specific areas being reported. By increasing the demand for the public disclosure of such quality "report cards", the general populations within geographic areas can positively influence health care available to them.

Patients and their families are at the center of medication use safety and quality. Optimum outcomes depend on the pivotal role the patient and family play in the medication use process. Most patients need considerable education, counseling, and encouragement to actively participate in their care. Many organizations provide useful resources for patients regarding medication use and safety (Table 1-5). It is the caregiver's responsibility to actively involve patients as partners in their care and incorporate their concerns and perspectives. This responsibility can be fulfilled by routinely incorporating practices into care processes that promote and encourage participation by patients and their families.

### Health Care Organization and Providers

This chapter has focused on the role of health care organizations and providers in medication use safety and quality. A fundamental change must occur for health care to become a high reliability industry. These critical changes reach to all levels and components of health care, in

particular to the individual caregiver's skills and behaviors. Creating a safer care system with a culture of safety and quality can be accomplished by implementing the many principles, strategies, and recommendations discussed in this chapter.

### The Role of the Pharmacist

The pharmacist is the health care professional best-suited and positioned to lead improvements in medication safety. Pharmacists should fully understand that knowledge of medication safety has always been, and will continue to be, a fundamental skill of the profession. Knowledge of medication safety should be integrated with drug therapy, drug preparation and distribution, and patient education activities. Pharmacist training should include the basics of drug and general patient safety as an explicit part of the curriculum. Pharmacists should be medication safety advocates within the organizations in which they practice and in the community as a whole.

### Health Care Accreditation Bodies

Patient safety is a major focus of health care accreditation. The JCAHO, the most prominent accrediting organization for hospitals in the United States, incorporates promotion and assessment of medication safety in its processes. The JCAHO standards for accreditation address organizational leadership, quality management, risk management, characteristics of medication use processes, and staff competency. These standards are based on an industrial model of defined best practices; however, the relationship between accreditation and quality of care provided has not been clearly demonstrated. The organization distributes Sentinel Event Alerts to alert health care organizations of safety threats detected through its Sentinel Event Reporting Program. Organizations are expected to assess themselves for similar safety deficiencies and incorporate improvements as needed. Starting in 2003, JCAHO established highly specific safety goals that organizations must meet as a condition of accreditation. Many resources to assist health care organizations implement improved medication safety are available from JCAHO. The National Committee for Quality Assurance (NCQA; available at [www.ncqa.org](http://www.ncqa.org)) is the primary accrediting body for managed health care organizations. In addition to accreditation surveys, NCQA evaluates health care through the Health Plan Employer Data and Information Set (HEDIS) that measures performance in key clinical areas and through a survey of patient satisfaction.

### Governmental Role in Medication Safety

Federal and state governments are involved in multiple facets of patient and medication safety. Their roles include oversight and governing functions, public advocacy, as a provider of health care, and as a major purchaser of health care services. Federal efforts to improve medication safety are coordinated through the Quality Interagency Coordinating (QuIC) Task Force, with AHRQ as the lead agency on quality for the federal government. The AHRQ

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Shaller D, Sofaer S, Findlay SD, Hibbard JH, Lansky D, Delbanco S. Consumer and quality driven health care: a call to action. *Health Aff* 2003;22:95-101.

funds research on medical errors, methods to reduce errors and improve quality of medical care, and to disseminate information regarding improvement strategies to the health care system. A systematic analysis of the evidence basis for patient safety practices has been published by AHRQ and a list of patient safety indicators to use as a screen for adverse patient events (available at <http://www.qualityindicators.ahrq.gov/>) has been developed by the agency. The AHRQ provides medication safety resources and information on an online newsletter and morbidity and mortality case discussions (available at [www.ahrq.gov](http://www.ahrq.gov) and <http://webMM.ahrq.gov>, respectively).

The NQF is a private sector public benefit organization established by the federal government as a broadly representative body to establish standard quality measurement tools. More than 170 public and private organizations participate in the NQF. The measurement tools developed by the NQF include many medication use criteria and they are designed to help government, providers, purchasers, and consumers evaluate the quality of health care delivery (available at [www.qualityforum.org](http://www.qualityforum.org)).

The CMS operates through contract peer-review organizations (PROs) to measure, monitor, and improve quality of care in organizations participating in CMS programs. The CMS also requires that organizations establish appropriate quality improvements as a condition for participation, and it is evaluating specific requirements for error monitoring and reporting in acute care settings. The use and reporting of specific quality indicators has been proposed as a condition for participation in CMS programs.

The Department of Defense and Department of Veterans Affairs (VA) have taken leadership positions in improving medication safety. The VA has established the National Center for Patient Safety (available at [www.patientsafety.gov](http://www.patientsafety.gov)) to coordinate safety efforts in the VA and the Patient Safety Reporting System (PSRS), a medical error reporting system modeled after the successful nonpunitive reporting process used in aviation. The use of CPOE and bedside bar code drug reconciliation have been widely implemented throughout the VA system.

The FDA is addressing the problem of medication safety through many initiatives. A primary function of the FDA is to assess the efficacy and safety of drugs. The FDA provides drug-risk assessment and error prevention efforts, error and product problem reporting (MedWatch program), risk reduction research, and numerous and varied processes for risk management communication to the consumer and health care provider. The FDA works with the pharmaceutical industry, patient safety groups, and organizations to improve drug labeling, packaging and drug names, and in promoting medication safety. Recently, the FDA mandated the use of machine-readable labeling (bar code) on all pharmaceuticals.

The FDA's CDER is responsible for establishing and enforcing quality standards of marketed products, providing premarketing risk assessment and postmarketing monitoring of safety issues related to pharmaceuticals. Postmarketing risk assessment obtains information from voluntary practitioner reports and mandatory reporting by pharmaceutical manufacturers. The process focuses on ADEs that result from drug use outside those which were

originally anticipated and the identification of events and problems not recognized during premarketing risk assessment. The CDER has an Office of Drug Safety (available at [www.fda.gov/cder/offices/ODS](http://www.fda.gov/cder/offices/ODS)).

State government agencies, such as health departments, professional licensing bodies, and health care purchasing agencies, promote medication safety in many ways. State regulations define specific minimum standards for the operation of health care facilities and professional practices that are monitored and enforced by various regulatory and licensing agencies. About 20 states have mandatory reporting processes, most require quality improvement processes within health care organizations, and some require hospitals to assign a "patient safety officer". Many states are requiring that specific safety practices be adopted. Some states now require that pharmacists attend continuing education programs related to medication safety.

### **The Pharmaceutical Industry**

The pharmaceutical industry has an obvious stake in the safe and effective use of its products. However, the primary objectives of the medical research, educational efforts, and marketing strategies of pharmaceutical firms are compliance with regulatory requirements and promotion of their products. From the pharmaceutical manufacturer's point of view, patient safety considerations are not as much of a priority as economic considerations are. Most research on drugs demonstrates the greatest benefit and lowest risk, rather than evaluates use in high-risk populations and circumstances. Unfavorable research about drugs is less likely to be published, and certainly less likely to be made available to caregivers during marketing of the drug. Similarly, promotion of drugs stress the possible benefits and downplays potential ADEs or other problems, leading caregivers and patients to underappreciate the potential risks of medication use. Safety considerations in drug branding and packaging decisions are not adequately considered. Notable exceptions in which pharmaceutical manufacturers have implemented changes because of safety concerns have occurred when specific problems have been identified. The pharmaceutical industry, in partnership with the FDA recently has started to more systematically address medication safety in the regulatory process. Incorporating more safety considerations into pharmaceutical development, research, branding, labeling, packaging, and marketing would be beneficial.

### **Professional and Other Health Care Industry Organizations**

Many local and national professional organizations, quality improvement groups, and health care industry-related organizations have developed programs and resources related to improving medication safety. Many of these organizations have promulgated recommendations and statements related to improving medication safety and have established groups and foundations specifically to address patient safety or quality issues. A partial listing of organizations is provided in Table 1-5. Most group purchasing organizations have incorporated medication safety initiatives and resources into their member services.

Many national organizations have played an important role in improving and increasing the awareness of medication safety. The ISMP's primary mission is improving medication safety. It provides a drug error reporting process and large number of useful resources, products, and services dedicated to improving medication safety. Both organizations frequently publish warnings and recommendations related to medication safety, and lobby governmental agencies and pharmaceutical companies to improve medication safety.

The NCC MERP is a coordinating body of a broadly representative group of organizations involved in medication use and safety. The NCC MERP has developed a well-recognized process for evaluating and categorizing drug error reports, and taxonomy for drug errors. The group promotes error reporting, understanding of errors, and methods of improving medication safety.

### Health Care Payers and Purchasers

Purchasers of health care, both public and private, have an obvious stake in making patient care safer. In response to the problems identified in the IOM report, the Business Round Table formed The Leapfrog Group. This organization of more than 130 private and public health care purchasers promotes and leverages major improvements in patient safety using its members' purchasing and the public-at-large. The group promotes improvements in safety by making decisions to purchase health care services from organizations that implement specified patient safety processes that have demonstrated a major impact on safety. Among the first initiatives of The Leapfrog Group is promotion of the widespread implementation of CPOE.

### Challenges and Opportunities

Despite the general recognition of medication safety deficiencies as a major public health problem, adoption of accepted safety practices has occurred slowly or not at all. Many barriers appear to be responsible. Although the problem of drug errors is well described, health care providers often do not appreciate the risk to patients. The nature of drug errors and their consequences results in the problem being invisible to practitioners in their everyday experiences. The traditional medical culture of individualism and the punitive approach used to address errors in health care contribute to the invisibility of the problem. This failure to appreciate the problem combined with the inconveniences and restrictions that many medication safety procedures place on practitioners commonly result in resistance to the adoption of safe practices. Thus, the present health care environment's culture of safety is not optimal to support adoption of the necessary changes. Other important implementation barriers include lack of available resources and competing priorities. The incidence and cost of drug errors usually are not visible, and leadership often is hesitant to dedicate resources to address an issue that cannot be quantified. In addition, the task of improving medication safety in a

comprehensive way has proven to be a much larger, more complex, and more difficult task than many organizations initially thought. Safety also is a moving target as the number of drugs available and processes of care continually expand and change. The knowledge and skills of caregivers often is inadequate to provide safe and effective drug therapy to patients. Implementing technological tools that promise to reduce drug errors is a costly, slow, and difficult undertaking, and it introduces new types of errors and problems. The lack of empiric evidence for improved safety resulting from recommended safety strategies further hinders wide acceptance of many safety strategies. Given the cost and effort required to universally implement major safety strategies, such as CPOE, obtaining evidence of effectiveness should be considered a priority. Despite these many barriers, substantial improvement is being made. The success of health care organizations, such as the VA system, Brigham and Women's Hospital in Boston, and others in implementing many principles discussed in this chapter demonstrates that improved patient safety is possible.

Many recent developments will help providers meet the challenges of establishing cultures of safety and quality, increasing understanding of methods to improve medication safety, and improving availability of resources. Introduction of technologies to the medication use process has improved safety in select settings, but the high costs, limitations, and potential to introduce new errors has been recognized. As these technologies improve, they hold great promise in improving patient safety. Increasing patient awareness of medication safety and increased involvement in the patient's care creates opportunity for improving patient outcomes. Efforts by governmental agencies, and public and private organizations will help institutionalize safety concepts as standards of care.

## Summary

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Deficiencies and errors in the use of drugs are responsible for a considerable proportion of ADEs, most of which could be avoided with improved medication safety processes. The concept of medication safety encompasses the entire medication use process and all individuals involved in the process. Although medical care usually is provided by caregivers, the quality and safety of care is an end product of the many processes that comprise the drug use system. All present recommendations related to improving medication safety embrace a systems approach to preventing errors and their consequences. Key components to improving medication safety include effective leadership, creation of a culture of safety and quality, implementation of safe drug practices, and an effective error and deficiency reporting process. Pharmacists in all care settings should provide expertise and leadership in improving medication safety.

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Silverman JB, Stapinski CD, Churchill WW, Nepl C, Bates DW, Gandhi TK. Multifaceted approach to reducing preventable adverse drug events. *Am J Health Syst-Pharm* 2003;60(6):582-6.

# Annotated Bibliography

1. Institute of Medicine. Committee on Quality of Health Care in America. In: Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academies Press, 1999.

This landmark report produced by the Institute of Medicine (IOM) Committee on Quality of Health Care in America set the current patient safety movement in motion. The report was the first of four important reports on the quality of medical care from the IOM. The evidence base for the report's findings and recommendations is the first comprehensive review of available patient safety information and publications in the United States. Based on the Committee's findings, the report estimated 44,000–98,000 Americans die annually as a result of medical error, more than 7000 of which are related to drug errors. Although controversial, the estimated number of unnecessary deaths caught the attention of the public, press, medical purchasers, payers, and the government. The report includes an excellent discussion of how errors occur and a specific focus on the problem of drug safety. Of importance, the report provides specific improvement agendas for various stakeholders, implementation strategies, and a broad set of specific recommendations for improvements. The necessity of establishing effective error reporting and using a systems approach to improve patient safety is prioritized. The report remains a primary resource for health care professionals seeking information related to patient and drug safety. Any pharmacist with major patient safety responsibilities should read the report.

2. Cohen MR, ed. *Medication Errors*. Washington, D.C.: American Pharmaceutical Association, 1999.

This excellent text provides a comprehensive review of the problem of drug errors, their evaluation, and recommendations for prevention. Pioneers in the drug safety movement author many of the chapters. The text discusses common drug error problems in a clear and practical fashion. Chapters dedicated to errors involving specific populations, types of drugs, and the various steps of the drug use process are included. The book provides numerous examples of instructive drug errors and easy-to-implement recommendations for risk reduction. The contents of this text are complemented and updated by the biweekly newsletter Institute of Safe Medication Practices (ISMP) Medication Safety Alert! ([www.ismp.org](http://www.ismp.org)). Information provided in this book provides the reader with a sound foundation of knowledge in regard to drug safety.

3. Barker KN, Flynn EA, Pepper G, et al. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002;162:1897–903.

This study provides important information regarding the frequency and nature of errors in drug administration in hospitals and long-term care facilities. The investigators use the observational method, the most effective methodology for detecting errors in drug administration. The observation method is applicable to other specific drug use steps and has been used to determine the frequency of error in drug preparation and dispensing. Observational studies provide a relatively accurate picture of the frequency of errors in these processes. This particular study demonstrated an overall error rate of 20%. Half of these errors were because of errors other than wrong administration time, demonstrating that one in

10 drug administrations involved errors with some potential for patient harm—an alarming frequency. The large number and varieties of health care organizations included in the study and the methods used provide strong evidence that drug administration errors occur at a much higher rate than most caregivers would estimate. The observational studies also demonstrate that the frequency of spontaneous voluntary reporting is not useful as measures of drug safety. Because these investigators studied discrete and common drug use processes in multiple institutions, the findings should be considered applicable to most hospitals, long-term care facilities, and pharmacies.

4. Ghandi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N Engl J Med* 2003;348:1556–64.

This study is one selection from a remarkable series of publications by the Boston-based research group regarding adverse drug event (ADE) frequency and ADE preventability in common patient care settings. In this study, the authors used chart review and patient interviews to identify potential ADE. The findings demonstrate that ADEs occur in 25% of patients given a prescription. The study is important because it provides a broad population-based estimate of ADEs in a real-life setting. Almost all other information regarding baseline ADE frequency in ambulatory patients comes from drug trials, in which patients are carefully selected, and typically have fewer concurrent disease states or drugs. The authors determined which ADEs could have been prevented or ameliorated with proper care or application of recommended safety strategies. The authors determined that 11% of detected ADE are preventable and 28% ameliorable. The results of this study and others by the group provide substantial evidence and specific information regarding the high frequency and nature of ADEs and their causes. These results have important implications for pharmacists and their care of patients. An important finding of the study was the frequency of ADEs because of failure of caregiver-patient communication, a point to be considered whenever pharmacists are caring for patients.

5. Vincent C. Understanding and responding to adverse events. *N Engl J Med* 2003;48:1051–6.

In this article, the author reviews many important aspects of analysis of medical errors that are applicable to pharmacy practice. The article provides a succinct discussion of the nature of errors and the importance of error analysis in learning from error. A step-by-step methodology for critical incident review is described. This method has been successfully applied to many types of patient safety deficiencies, including studies focusing specifically on drug errors. The method is particularly effective at identifying systems-related deficiencies. The discussion on effect of error on patients and families and on managing patients when harm occurs is particularly useful. The reference also provides important guidance on managing caregiver staff that has been involved in a serious medical error. The article should be reviewed by all pharmacists with responsibilities that could include dealing with the aftermath of a serious drug error. The article should be made available as a guide to all involved if a serious drug error does occur.



# SELF-ASSESSMENT QUESTIONS

## Questions 1–25 pertain to the following case.

M.E. is an 82-year-old woman in the coronary care unit of a 400-bed hospital. She has renal impairment and is unable to take oral drugs. Digoxin 0.0625 mg (half of a 0.125 mg tablet) orally 1 time/day is one of the many maintenance drugs she was taking and or given prescriptions for when admitted. The physician gives a telephone order to the nurse that is heard as, and transcribed in the medical record, as “0.625 mg/day intravenous digoxin while nothing by mouth”. The order is transcribed “as written by the prescriber” into the drug administration record by the nurse. The nurse obtains injectable digoxin from the automated dispensing cabinet (ADC). The digoxin, like all other drugs in the coronary care unit ADC, is made accessible before pharmacy order review (no “lock-out”) because the organization policy allows all drugs in intensive care units (ICUs) to be available without “lock-out”. Despite written policies that drugs should not be obtained from ADC before pharmacy review in nonemergent situations, this had become the routine practice in the ICUs and emergency department of the hospital, and was known to managers. Similarly, despite a written policy requiring that all orders be sent immediately by facsimile to pharmacy for review, the nurses frequently failed to send copies of drug orders they could obtain themselves from the ADC. The pharmacy was aware of this situation, but did not routinely review ADC use and withdrawals against drug orders. The patient received digoxin 0.625 mg intravenous for three doses. The patient was awake and oriented throughout the hospitalization. The patient is transferred out of the coronary care unit 2 hours after the third dose is given. Later that evening, the patient is noted to be symptomatically bradycardic with a pulse of 41 beats/minute and is transferred back to the coronary care unit. Her bradycardia was managed supportively. Digoxin level was 4.4 ng/ml (usual therapeutic range 0.5–2 ng/ml). The 10-fold dosage error is noted and digoxin is held until serum levels are within the therapeutic range. The patient

recovers and is eventually discharged without further complications. The patient and her family are told that the patient had a “reaction” to one of her drugs but is not informed of the dosage error. Even though the medical and nurse managers of the unit and the director of pharmacy are aware of the error, no report of the incident is sent to risk management. The prescriber is informed of the events, and the nurse reminded of the necessity of checking orders carefully. The case is not discussed in any other quality forum and no changes are made in policies and procedures regarding accessibility of drugs from the ADCs.

1. The drug safety and care deficiencies leading to the adverse drug event (ADE) in this case can best be described by which one of the following statements?
  - A. The ADE can be primarily attributed to the isolated performance failure of the nurse to correctly hear the prescriber’s order.
  - B. The prescriber played little part in initiating or propagating the error.
  - C. Many contributing latent error-producing conditions were present.
  - D. The case is unusual in that the ADE was a result of a sequence of safety deficiencies.
2. Which one of the following statements describes the least important risk factor for the ADE to occur in this case?
  - A. The patient had only limited familiarity with the drugs she was receiving.
  - B. The patient was elderly and in an ICU.
  - C. The nurse was unfamiliar with digoxin therapeutics.
  - D. The patient was not able to take oral drugs.

3. Which one of the following characteristics of the hospital's drug use system processes was the major contributor to the preventable ADE?
  - A. Failure to have clear policies regarding the use of leading and trailing zeroes in drug doses.
  - B. Inadequate knowledge and training of staff regarding proper dosing when switching routes of administration.
  - C. Failure to have adequate safety controls and limited access to high-alert drugs, such as digoxin.
  - D. Failure to have standardized monitoring processes for patients on digoxin.
4. Which one of the following statements regarding this ADE is most accurate?
  - A. Serious and life-threatening ADEs, such as the one discussed in the case, are more commonly preventable than less serious ADEs.
  - B. It is unlikely that previous errors involving decimal point confusion or misplacement with digoxin had occurred before the case.
  - C. Like most preventable ADEs, the ADE in this case primarily resulted from serious errors in cognitive decision-making by caregivers.
  - D. The chance that the patient would experience any ADE during her hospitalization was extremely remote.
5. Which one of the following statements regarding the causes and contributors to preventable ADEs is most accurate?
  - A. Mental slips and lapses by individual caregivers are the underlying cause of most serious ADEs.
  - B. Drug names and packaging lead to the majority of drug errors.
  - C. Deficiencies in caregiver knowledge and use of information contribute to a minority of preventable ADEs.
  - D. The majority of preventable ADEs in hospitals could be prevented or avoided by pharmacists.
6. Which one of the following statements regarding ADEs and drug errors is most accurate?
  - A. When an ADE occurs, the chance that a deficiency or error in care caused or contributed to the event is remote.
  - B. An isolated error or deficiency in the drug use process is highly likely to produce an ADE.
  - C. The cause-and-effect relationship between drug use process errors and an ADE is usually obvious to caregivers.
  - D. Deficiencies and errors in the prescribing process contribute to the majority of preventable ADEs.
7. Which one of the following statements regarding the relationship between errors and preventable ADEs is most accurate?
  - A. Errors that occur in the earlier steps of the drug use process, such as prescribing, are less likely to be detected and averted than those occurring later in the process.
  - B. Most errors that reach the patient and alter the planned care produce an ADE obvious to the patient and caregiver.
  - C. Once an error has occurred, the severity and impact of the ADE often is not ameliorable.
  - D. Errors in drug choice and dosing are the most common types of errors causing preventable ADEs.
8. Which one of the following statements regarding the discharge of M.E. to home is most accurate?
  - A. Errors and deficiencies in drug use are common when patients transfer from one care environment to another.
  - B. M.E. will be at a low risk for a preventable ADEs in the few weeks after discharge.
  - C. The hospital's processes are likely to adequately involve patients in ensuring drug safety.
  - D. Communication between patient and caregivers can be relied on to be an effective monitor for any ADE that might occur.
9. M.E.'s physician provides her with prescriptions to be filled after discharge. Which one of the following statements regarding drug safety in the community is most accurate?
  - A. Errors in prescriptions dispensed from pharmacies are extremely rare and unlikely to be encountered by most pharmacists.
  - B. Many ADEs in community-dwelling patients could be avoided or ameliorated with improved patient-caregiver communication.
  - C. Patient adherence to drug therapies and instructions plays only a minor role in producing preventable ADEs.
  - D. M.E. or her family is highly likely to ask for information or help in using her drugs.
10. Which one of the following statements regarding direct and indirect avoidable costs of the drug error in this case is most accurate?
  - A. Additional time in the coronary care unit is not a true additional cost as the facility and staff costs are fixed costs.
  - B. Additional length of hospital stay could not be clearly attributed to the error, and is usually an insignificant contributor to overall cost of care anyway.
  - C. The cost of errors and adverse events has been demonstrated to be minimal and should be considered the cost of doing business.
  - D. The cost of adverse events and errors contribute considerably to increased health insurance costs.
11. Which one of the following statements best describes the likely impact of preventable ADEs (such as the one discussed in this case) on the hospital?
  - A. Errors that occur in the earlier steps of the drug use process, such as prescribing, are less likely to be detected and averted than those occurring later in the process.
  - B. Most errors that reach the patient and alter the planned care produce an ADE obvious to the patient and caregiver.
  - C. Once an error has occurred, the severity and impact of the ADE often is not ameliorable.
  - D. Errors in drug choice and dosing are the most common types of errors causing preventable ADEs.

- A. Reduced likelihood that the patient and family will recommend the hospital to others.  
 B. Increased malpractice insurance costs.  
 C. Unnecessary expenditures of limited resource.  
 D. Reduced reimbursement from health care purchasers.
12. Which one of the following regarding the societal costs and impact of preventable ADEs is most accurate?  
 A. The overall costs of ADEs to the United States economy is inconsequential and does not impact overall costs of patient care.  
 B. Adverse drug events are thought to be a common cause of death in the United States.  
 C. Patients consider the reduction of medical error to be among the highest priorities for health care today.  
 D. The recognition of the impact of ADEs has produced dramatic practice changes in most areas of the United States health care industry.
13. Which one of the following deficiencies that allowed the digoxin overdose to occur is least likely to be improved by “organizational system” changes?  
 A. Inadequate nurse education regarding digoxin pharmacokinetics.  
 B. Drugs made available from ADCs in nonurgent situations without “lock-out” before pharmacy order review.  
 C. Routine failure of nurses to send orders to pharmacy for drugs available in the ADC without “lock-out”.  
 D. No requirement for independent “double check” of potentially toxic (high-alert) drugs when removed from an ADC.
14. The primary deficiencies in leadership that contribute to errors, such as the one discussed in this case, include which one of the following?  
 A. Failure to provide adequate staffing levels.  
 B. Failure to ensure competency of caregivers.  
 C. Failure to provide adequate resources for computerized prescriber order entry.  
 D. Failure to promote and monitor adherence to standard safety processes.
15. Which one of the following statements best describes caregiver drug safety practices?  
 A. Most caregivers closely adhere to all routine drug safety processes.  
 B. Most caregivers routinely fail to report common drug safety deficiencies and errors.  
 C. Most caregivers would agree that routine safety procedures are critical safety measures in their everyday work.  
 D. Most caregivers would agree that common and routine drug safety procedures always take priority over efficiency and convenience in routine patient care.
16. Which one of the following organizational responses to the described events is most likely to reduce the chance for similar errors in the future?  
 A. Greater disciplinary action, such as suspension, when individuals make errors.  
 B. Required reeducation sessions for the nurse and doctor involved.  
 C. System which ties merit raises and promotion to the number of errors made by each caregiver.  
 D. Establish a process for evaluation of lessons learned from the error to improving policies and procedures.
17. Which one of the following actions is likely to provide the most useful information regarding the care deficiencies surrounding this case’s ADE and possible strategies to reduce similar risks in the future?  
 A. Review of patient’s medical record.  
 B. Interview of involved prescriber and nurses.  
 C. Multidisciplinary root cause analysis.  
 D. Discussion with the patient and his or her family.
18. Which one of the following strategies would most likely prevent similar avoidable ADEs in the future?  
 A. Require pharmacy review of order before release of drugs from the dispensing cabinet.  
 B. Establish a policy that digoxin injection doses be double-checked by nursing before administration.  
 C. Establish a policy to allow verbal or telephone orders only in emergencies.  
 D. Require that staff immediately record any verbal or telephone order and read the order back to the prescriber for verification.
19. Which one of the following strategies is least likely to improve the type of drug safety deficiencies discussed in the case?  
 A. Incorporating training regarding drug safety strategies for high-alert drugs in staff orientation and ongoing education.  
 B. Providing education regarding intravenous digoxin therapeutics for all staff using the drug.  
 C. Implementing computerized prescriber order entry.  
 D. Establishing control and standardization process for all high-alert drugs.
20. The risk management department of this hospital receives reports of 20–30 errors involving drug use each month. The hospital recently has gone through a successful accreditation survey. The assessment of the drug quality team is that the hospital has excellent drug use systems with few drug errors and few cases of patient harm from drug errors. Which one of the following statements most strongly supports this assessment?  
 A. The hospital had an easily recognizable culture of safety.  
 B. The hospital had no recent lawsuits involving drugs.

- C. Accreditation survey results may provide some measure of the safety processes of the hospital.
- D. The rate of drug errors reported to risk management is within the range of errors to be expected in the hospital.
21. Establishing which one of the following characteristics of a culture of drug safety among the staff caregivers would be most effective in preventing similar errors in the future?
- A. Staff consistently follows delineated safety procedures even at the expense of efficiency.
- B. Environment in which staff will not tolerate clearly negligent and unsafe behaviors.
- C. Caregivers establish individual behaviors and practices that they feel will ensure the best patient outcomes.
- D. High frequency of error reporting within the hospital.
22. Which one of the following methods of measuring the organization's drug safety practices is likely to be most effective to specifically monitor safety deficiencies, such as those involved in this case?
- A. Comparison of the organization's policies and procedures to established "best practices".
- B. Observational methods.
- C. Review of spontaneous voluntary drug error reports.
- D. Review of medical record coding for ADEs involving digoxin.
23. Which one of the following strategies is likely to be the most successful method for promoting the reporting of drug safety deficiencies by the staff of this hospital?
- A. Simplify the required process for reporting.
- B. Establish clear reporting process and guidelines.
- C. Establish a policy in which failure to report will result in disciplinary actions.
- D. Establish feedback to staff regarding positive improvements implemented as a result of error reporting.
24. Which one of the following statements reflects the usual expectations of patients and families regarding disclosure of the problem and expectations for corrective actions associated with errors?
- A. Patients and families prefer not to be informed of mistakes and deficiencies in their care unless serious long-term negative outcomes result.
- B. Patients and families expect that individuals who make errors should be appropriately reprimanded, penalized, or punished.
- C. Patients and families usually expect individuals directly and indirectly involved and the hospital as a whole to take responsibility for the error and apologize.
- D. Patients and families are not primarily concerned about how similar errors can be prevented in the future.
25. Which one of the following statements regarding the roles and activities of various drug safety stakeholders is most accurate?
- A. The Leapfrog Group has been established to lobby the federal government for the establishment of drug safety standards, in particular mandatory use of CPOE.
- B. The National Quality Forum is the lead federal government agency responsible for monitoring safety and quality in health care.
- C. By law, the Food and Drug Administration must restrict its drug risk assessment to premarketing evaluations.
- D. The Joint Commission on Accreditation of Healthcare Organizations has established specific drug safety goals and criteria as a condition for accreditation.