Chapter 1: Patient Safety and Medication Errors (Mandatory)

2 Contact Hours

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Author Disclosure: Bradley Gillespie and Elite do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0761-9999-16-132-H05-P
Activity Type: Knowledge-based
Initial Release Date: June 1, 2016
Expiration Date: June 1, 2018
Target Audience: Pharmacist in a community-based setting.

To Obtain Credit: A minimum test score of 70 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at Pharmacy.EliteCME.com.

Learning objectives

At the conclusion of this knowledge-based learning activity, the pharmacist will be able to:

• Describe the significance of the Institute of Medicine’s 1999 and 2006 report on medication errors.
• Define and distinguish between the following terms: safe medication, drug safety, quality issues, medication errors and adverse drug events.
• List each of the governing bodies involved in medication safety (FDA, AHRQ, IOM, USP, NCC, ISMP, JCAHO).
• Identify the types of medication errors made by pharmacists.
• Discuss additional reasons that pharmacists may cause a medication error, as defined by the Food and Drug Administration.

• Identify the ways a patient may be responsible for initiating a medication error.
• Discuss the format for reporting a medication error.
• Discuss Florida’s law for the Pharmacy Continuous Improvement Program.
• Identify ways to promote medication safety for patients.
• Identify the six medication “rights” to improve patient safety.
• Discuss recommendations to improve patient safety during the distribution phase of drug administration.
• Identify the consumer’s role in improving medication safety.

Pre-assessment questions

Prior to beginning work on this activity, test your baseline knowledge by answering the following questions. These questions may be repeated in the final examination.

1. Which of the following is not a component of a safe medication system?
   a. Administration of the drug.
   b. Preparation and dispensation of the drug.
   c. Selecting the generic equivalent that provides the best profit margin.
   d. Selection and procurement of the drug by a pharmacy.

2. Many Internet pharmacies try to alleviate patient anxiety by noting that they are ordering their prescriptions under the concept of “responsible self-treatment.” Which of the following are components of responsible self-treatment?
   a. There are no medications with guaranteed efficacy.
   b. Most medications are safe.
   c. The Internet pharmacy takes full responsibility for the patient’s safety.
   d. All medications act independent of each other.

3. FDA has determined that it is always safe to purchase medications from Internet pharmacies.
   a. True
   b. False

Introduction

Over the past decade, medication safety has been a big concern for pharmacists who dispense or administer medications to patients. The Institute of Medicine (IOM) states that even though medication errors can occur anywhere within a safe medication system, it occurs more frequently in the prescription and administration processes. Pharmacists need to be especially concerned with the prevention of errors during the process of preparing and dispensing medications.

In 1999, the public learned about medication errors when the Institute of Medicine (IOM) released a report, “To Err is Human: Building a Safer Health System.” The IOM report disclosed that an estimated 44,000 to 98,000 deaths result from medical errors in hospitals alone, with 7,000 of the deaths related to medications. The report was a revelation to patients, families and the entire health care team.
As pharmacists, it is imperative to understand the legalities, responsibilities and accountability that we have to patients while participating in any component of the medication administration process.

In 2004, the Food and Drug Administration (FDA) reported alarming data provided by the Slone Epidemiology Center at Boston University, showing that in a given week, half of U.S. adults will use prescription drugs, and 10 percent will take at least five different medications. In 2006, the IOM reiterated the data, as it estimated that in any given week, four out of every five adults will use a prescription medicine, over-the-counter (OTC) drug, or dietary supplement, and nearly one-third of adults will ingest five or more different medications.

In 2001, Ernst and Grizzle estimated that the total cost of drug-related morbidity and mortality in the ambulatory care setting was more than $177 billion, which is greater than the cost of the medications themselves.

To avoid even unintentional harm to patients, health care professionals must understand and abide by the expectations bestowed upon them. Patients and their families put their trust in health care professionals each time they enter a health care facility. It is our duty as pharmacists to serve and protect each patient by appreciating the power of each drug before dispensing any medication to a patient.

### Definitions related to the safety of medications

The FDA defines “safe” medication as one whose benefits outweigh the risks for patients. The IOM uses the terms “drug safety” and “quality issues” in discussion of the safe, effective, appropriate and efficient use of medications. There are five components in a safe medication system:

1. Selection and procurement of the drug by a pharmacy.
2. Prescription and selection of the drug for the patient.
3. Preparation and dispensation of the drug.
4. Administration of the drug.
5. Monitoring of the patient for its effect.

Although all of these items are not always under the watchful purview of the pharmacist, he or she should be at least mindful, if not fully responsible, for all of these critical points.

A medication error is defined by the National Coordinating Council (NCC) as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.”

In 1996, the NCC classified a medication error based upon the severity of the outcome to ensure that all health care professionals use the same terminology and to track errors in a consistent, systematic manner. In July 2006, the National Academies of the IOM released a report that claimed 1.5 million people are harmed annually by medication errors, which cost more than $3.5 billion a year. This figure alone should be adequate to get the attention of all practicing pharmacists. Further, in 2006, a study showed that the most common medical errors are related to medications.

Adverse drug events are defined as “any response to a drug which is noxious or unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease.” According to the Agency for Healthcare Research and Quality (AHRQ), more than 770,000 people are injured or die each year in hospitals from adverse drug events, which may cost up to $5.6 million each year per hospital, depending on hospital size.

Although the data is alarming, this estimate did not include the effect of adverse drug events on the length of the admission, malpractice and litigation costs, or the costs of injuries to patients. The AHRQ estimates that the cost to U.S. hospitals to treat patients who suffer adverse drug events during hospitalization is between $1.56 and $5.6 billion annually.

According to the IOM, although adverse drug events are rising and considered preventable, it is difficult to obtain an accurate measurement of how often preventable adverse drug events occur in the various phases of the drug use process. The IOM alludes to studies over the past few years estimating that anywhere from 380,000 to 800,000 preventable adverse drug events occur annually – however, the committees believe that these are underestimates. According to the IOM committee, although the data varies depending on the study, it is estimated that 1.5 million preventable adverse drug events occur in the U.S. annually.

### Governing bodies

To have a better understanding of medication safety, it is important to understand that there are many agencies and organizations eager to promote the safety of medications for patients and health care professionals alike. Each is geared toward monitoring the efficacy of every medication on the market, and providing education to the public and health care professionals. Below are a few of the agencies and organizations that monitor adverse drug events and medication errors every year.

**HHS:** The U.S. Department of Health and Human Services (HHS) is the government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS encompasses more than 300 programs related to the health of Americans, including safe monitoring and administration of medications.

For fiscal year 2014, the HHS budget is approximately $967.3 billion. There are two U.S. public health agencies under the HHS responsible for the efficacy encompassing medications, the Food and Drug Administration and the Agency for Healthcare Research and Quality.

**FDA:** The Food and Drug Administration (FDA) is well known to the public and health care professionals. The FDA began as a single agency with a single chemist in 1862. In 1906, the Federal Food and Drug act was passed, but the FDA did not get its name until July 1930. The FDA’s mission is to protect public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the nation’s food supply, cosmetics and products that emit radiation.

While FDA regulates and approves all medications, it does not usually conduct the research supporting these approvals. Within the FDA, there are numerous groups responsible for ensuring patient safety, public knowledge and the prevention of medication errors. FDA has collaborated with other agencies to establish a standard framework to electronically share important data about medications to promote efficiency and safety. FDA has a subsidiary component, called MedWatch, that is responsible for safety information and adverse event reporting.

**AHRQ:** The Agency for Healthcare Research and Quality (AHRQ) was established in 1989 as the Agency for Health Care Policy and Research. Reauthorizing legislation passed in November 1999 established AHRQ as the lead federal agency on health care quality...
research. AHRQ, part of the U.S. Department of Health and Human Services, is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ has completed a vast amount of research on medication errors, medication safety and the effect on patients.20

The National Academy of Sciences is an adviser on scientific and technological matters. It was chartered by the U.S. government under the auspices of President Abraham Lincoln in 1863. In 1970, the Institutes of Medicine (IOM) was founded as an independent, nonprofit organization that provides unbiased and highly authoritative information needed to guide government decision makers and the public. Although the IOM is independent and works outside of the government, it serves as the health arm of the National Academy of Sciences.21 The unique component of the IOM is that researchers and scientists are unpaid volunteer experts, dedicated to promoting safe medication practices.

IOM: The Institute of Medicine (IOM) encompasses experts and scientists tasked with improving the lives of millions of people around the world using evidenced-based practice.22 The IOM is mandated by Congress, through the Medicare Modernization Act of 2003 (Section 107 (c)), to “carry out a comprehensive study of drug safety and quality issues in order to provide a blueprint for system-wide change.”23

One of the committees involved in promoting medication safety within the IOM is formed from within the Center for Drug Evaluation and Research (CDER) at FDA. CDER’s goal is to review the drug information, safety surveillances and key aspects of the contributions of the pharmaceutical industry, academic research, Congress and patients using medications.24

For-profit organizations

USP: The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements and other health care products manufactured and sold in the United States. USP sets standards for the quality of these products, and works with health care providers to achieve those standards. The USP standards are also recognized and used in more than 130 countries. It has helped ensure the manufacture of high quality pharmaceuticals, as well as reliable pharmaceutical care, for people throughout the world, for more than 185 years.25

NCC: In 1995, the National Coordinating Council (NCC) was established to promote the safe use of medications. The mission of the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) is to maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting, and promotion of medication error prevention strategies.26 The NCC-MERP helps to heighten awareness of medication reports within the health care system and provides education on medication errors for consumers and health care professionals. Further to that, NCC-MERP develops comprehensive literature reviews, describing the safe use of medications. Its goal is to protect patients by not allowing any patient to be harmed by a medication error.27

Nonprofit organizations promoting patient safety

ISMP: The Institute for Safe Medication Practices (ISMP) began in 1975 as a nonprofit organization that receives no advertising revenue and is devoted entirely to medication error prevention and safe medication use.28 The ISMP took over management of the United States Pharmacopeia-developed Medication Errors Reporting Program (USP-MERP) in late 2008, re-branding it as ISMP MERP.

ISMP MERP is designed for reporting the cause of medication errors and provides recommendations for preventing future errors, always identifying the erroneously used medication. In addition, the ISMP reports to the appropriate regulatory agency and the manufacturer of the company. To assess whether any medication has been incorrectly listed anywhere, the Institute for Safe Medication Practices continuously updates its website, noting any incorrect data published in textbooks and publications.29

JCAHO: Joint Commission on Accreditation of Healthcare (JCAHO) is a nonprofit organization that has been affiliated with monitoring patients in some capacity since 1910. In 1965, Congress passed the Social Security amendment that incorporated a provision in which each hospital needs to be JCAHO-accredited to receive reimbursement for patient care from Medicare or Medicaid.30 The goal of JCAHO is to improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

Background

As pharmacists, we enter the profession so that we may care for others, and to ensure that no harm comes as a result of this care. Although one’s intentions may be good while caring for a patient, medication errors do occur on a daily basis, often at the expense of the patient.

Regardless of the circumstances, while caring for another, it is important to remember: “I am here to care for this patient and family; they have put their trust in me.” We must remember to treat each patient as we would want our loved ones to be cared for while in the hands and at the mercy of the health care system.

Throughout our health care system, with today’s economic realities, professionals encounter shortages in their departments. Although it may induce more stress in the workplace, that should not affect safe medication practices and pharmaceutical care.

To bring change to the system, it is imperative to recognize the components that contribute to medication errors. According to McLeod (2007), the Joint Commission Journal on Quality and Patient Safety has said that nearly 5 percent of errors reported to the national database for medication errors from 2004 to 2006 involved medication abbreviations, and the majority (81 percent) occurred during the prescribing phase.31

Based upon the study of nearly 30,000 abbreviation-related medication errors, JCAHO in 2005 initiated the “Official Do Not Use List” that was implemented in the hospitals nationwide (See Table 1).32 Of the common abbreviations used by many experienced health care professionals, “QD” for “once daily” was associated with more errors than any other abbreviation, followed by “U” for units (13.1 percent), “cc” for milliliters (12.6 percent) and “MS” or “MS” for morphine sulfate (9.7 percent).33 The “Official Do Not Use List” is being used by health care professionals nationwide, and it was also incorporated into JCAHO’s patient safety goals.34

The ISMP recommends that health care professionals do not stop at the minimum guidelines of JCAHO standards on abbreviations to avoid preventing medication errors. Since 2006, the ISMP has offered a more comprehensive list that can be accessed on the Internet.35
Florida Law and the Continuous Quality Improvement Program

The Institute of Medicine’s 1999 groundbreaking report on medical errors has led to some state boards, including Florida, to examine ways to reduce these errors. Florida Law states in Sec. 64B16-27.300 of the Florida Standards for Practice for pharmacists that each pharmacy shall establish a Continuous Quality Improvement (CQI) Program and that the program shall be described in the pharmacy’s policy and procedure manual. The Continuous Quality Improvement Program is a system of standards and procedures to document quality-related events and improve patient care. A “Quality-Related Event” means the inappropriate dispensing or administration of a prescribed medication including:

A. A variation from the prescriber’s prescription order, including, but not limited to:
   - Incorrect drug;
   - Incorrect drug strength;
   - Incorrect dosage form;
   - Incorrect patient;
   - Inadequate or incorrect packaging, labeling, or directions.

B. A failure to identify and manage:
   - Over-utilization or under-utilization;
   - Therapeutic duplication;
   - Drug-disease contraindications;
   - Drug-drug interactions;
   - Incorrect drug dosage or duration of drug treatment;
   - Drug-allergy interactions; or
   - Clinical abuse/misuse.

At a minimum the pharmacy’s CQI Program shall contain provisions for a Continuous Quality Improvement Committee, provisions to ensure that the committee conducts a review of the Quality Related Events at least every three months, a planned process to record, measure, assess, and improve the quality of patient care and the procedure for reviewing Quality Related Events.

Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. Documentation of a Quality-Related Event shall include a description of the event and Pharmacists shall maintain the records at least until the event has been considered by the committee and incorporated in the summary required by Florida law. Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential.

Types of medication errors involving health care professionals

According to FDA, medication errors contribute to at least one death every day, and injure approximately 1.3 million people annually in the United States. Between 1993 and 1998, the FDA completed a study in which it found that the most common medication errors were the following:

- Administration of an improper dose of medicine, accounting for 41 percent of fatal medication errors.
- Administration of the wrong drug, accounting for 16 percent of fatal medication errors.
- Administration of medicine using the wrong route of administration, accounting for 16 percent of fatal medication errors.

Almost half of the fatal medication errors occurred in people over the age of 60. Older people may be at greatest risk for medication errors because they often take multiple prescription medications. With the pharmacist’s combination of training and experience, we are often in an ideal position to identify and correct these types of errors and have a favorable impact on overall patient well-being.

The FDA has stated that a medication error can occur during any of the following components of the drug-use process:

- Prescribing.
- Repackaging.
- Dispensing.
- Monitoring the patient for side effects and adverse drug events.
- Administering.
- Poor communication between doctors, nurse practitioners, nurses or pharmacists.
- Ambiguities in the product name, directions for use, medical abbreviations or the legibility of the writing.
- Professional training and techniques.
- Poor procedures and techniques.
- Clinical abuse/misuse.
- Drug-allergy interactions;
- Drug-drug interactions;
- Drug-disease contraindications;
- Drug-disease contraindications; or
- Drug-drug interactions.

Additionally, FDA has provided other common causes of medication errors:

- Monitoring the patient for side effects and adverse drug events.
- Administering.
- Poor communication between doctors, nurse practitioners, nurses or pharmacists.
- Ambiguities in the product name, directions for use, medical abbreviations or the legibility of the writing.
- Poor procedures and techniques.
- Clinical abuse/misuse.
- Drug-allergy interactions;
- Drug-drug interactions;
- Drug-disease contraindications;
- Drug-disease contraindications; or
- Drug-drug interactions.

Types of medication errors initiated by a patient

Although health care professionals have made many medication errors over the years, an error can also be committed intentionally or unintentionally by the patient. The first potential problem as noted by the IOM in 2006 is that 50 percent of patients do not take their medications as prescribed. As pharmacists, we have to change the way that we communicate with our patients, sharing our education and knowledge in the hope that they will take their medications as prescribed, safely.

Patients may perceive that a medication is simply a “quick fix” to a problem; as pharmacists, we need to teach them about each medication’s purpose, potential side effects, drug-drug interactions, drug-food interactions and safety concerns. Patients should also be reminded that before using any OTC medication or herbal product, they should check with their doctor or health care practitioner because those products may interact with current medications and health conditions in the same manner as other medications.

Another potential problem is drug abuse. In 1999, the National Institute on Drug Abuse (NIDA) reported that 4 million Americans 12 years or older had used a prescription medication for non-medical reasons. Therefore, it is incumbent on the pharmacist to be aware of this fact and assess each patient who may abuse a prescriptive or non-prescriptive medication provided to them.

A third potential medication error initiated by a patient is purchasing a medication, with or without a prescription, on the Internet. A patient may have a preconceived notion that he or she wants or needs to be on a certain medication after reading or hearing an advertisement from
a pharmaceutical company. If the patient’s primary care physician refuses to write a prescription, a patient often can purchase the medication online without a prescription. In other cases, Internet pharmacies are abused by patients who have tendencies towards self-medication, not believing that they need the guidance of a qualified prescriber.

Some websites and companies attempt to alleviate patients’ concerns about the practice by noting that they are ordering under the concept of “responsible self-treatment”:
- The term “self-treatment” means that the patient takes responsibility for the results obtained by controlling their own access to medication. Responsible self-treatment assumes that the patient owns the information on an accepted preparation, and realizes the following:
  - There is no such thing as an absolutely safe medicine.
  - There are no medicines with guaranteed efficacy.
  - Any medicines accepted simultaneously can interact positively or negatively with each other.

According to the World Health Organization (WHO), responsible self-medication is a practice where patients can treat their conditions and ailments using medicines that are approved and available in their region without a prescription. Further, these medications must be proven to be safe and effective. This WHO definition does not seem to align with the message inferred by Internet pharmacies promoting this practice. If a medication error should occur in any format, as a registered pharmacist, you have a professional, ethical and legal obligation to report it to the appropriate authorities. Within the United States, the Medication Error Reporting program (MER) and the FDA work in conjunction to monitor the efficacy of each medication to prevent future medication errors. Since March 13, 2003, the FDA has required that all actual and potential medication errors must be submitted to the agency within 15 calendar days. Additionally, FDA reviews medication error reports that come from drug manufacturers using the MedWatch reporting system and ISMP MERP.

The following organizations are obligated to track medication errors:
- FDA – Accepts reports from consumers, health professionals and drug companies about products regulated by FDA, including drugs and medical devices, through MedWatch, the FDA’s safety information and adverse event reporting program.
- Institute for Safe Medication Practices MERP – Accepts reports from consumers and health professionals on medications and publishes Safe Medicine, a consumer newsletter on medication errors.
- Quantros – MedMARX is an anonymous medication error reporting program used by hospitals that was developed by USP but managed by Quantros since late 2008.

According to the ISMP MERP program, all health care professionals should report actual or potential medication errors that occur due to any of the following reasons:
- Errors in the prescribing, transcribing, dispensing, administering and monitoring of medications and vaccines.
- Wrong drug, wrong strength, or wrong dose.
- Wrong patient.
- Confusion over look-alike/sound-alike drugs or similar packaging.
- Wrong route of administration.
- Calculation or preparation errors.
- Misuse of medical equipment.

It should be noted that a potential medication error is considered a “near-miss.” Consider this example:

An order for a fourth dose of medication to be administered to a patient is listed on a medication administration record (MAR). Prior to administration, the pharmacist reviews the chart and notes that the medication was supposed to be discontinued after the third dose. Based on the pharmacist’s vigilance, the mistake is averted. This potential dosing error would be considered a near-miss, because the potential was present for an error but it did not occur and the patient did not receive the incorrect medication.
It is recommended that pharmacists adhere to the following reporting methods for an actual or potential medication error in a confidential and anonymous format:45

- U.S. Food and Drug Administration’s MedWatch Reporting Program: 800-FDA-1088 or https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

Once a medication error has been reported, the FDA’s Office of Post Marketing Drug Risk Assessment (OPDRA) will review and classify the taxonomy of the medication error using a system developed by National Coordinating Council for Medication Errors Reporting and Prevention (NCC-MERP).46 It is important to understand that the FDA receives an abundance of reports on cases and therefore will only review reports that are properly completed. Between 2000 and 2008, the FDA received in excess of 95,000 reports of actual or potential medication errors.47 FDA defines serious as any adverse event that is fatal, life-threatening, or associated with a disability, hospitalization or congenital anomaly.48 The ISMP reports medication errors through a variety of newsletters to ensure that all health care professionals are properly targeted, regardless of their practice setting.49

In addition, it is imperative to thoroughly complete all reporting forms to ensure the provision of appropriate data to FDA. Failure to do so may lead to a delay in the investigation of the medication involved and the reasons why the problem occurred, impeding the agency’s ability to warn and prevent future episodes. See Table 2 for recent examples of drug safety communication advisories from FDA.49

### Promoting medication safety

The IOM is the innovative leader in eliciting change in America’s medication safety guidelines. Since the IOM released data in 1999 to health care professionals and the public, government agencies such as FDA have collaborated with the IOM to promote change. After the 1999 report, FDA encouraged the IOM to review the current data and provide factual, concrete suggestions to promote medication safety for all Americans. Because errors are preventable, all pharmacists should take responsibility and accountability for all of their actions to ensure medication safety.

In 2006, an IOM report requested that U.S. government agencies take the lead in implementing steps to reduce medication errors, with precise deadlines and recommendations. The IOM estimated that the government should expect to spend $100 million annually to research the most useful and cost-effective ways to reduce medication errors.36

The 2006 IOM recommendations (and response to them, where applicable) were:

- FDA and the Agency for Healthcare Research and Quality should be charged with working with the pharmaceutical industry to address problems with drug labels and packaging by the end of 2007 and possibly implement standardized drug names and labels.
  - FDA acted on this in 2008, shifting increased responsibility to the Office of Surveillance and Epidemiology.50
- By 2008, all health care providers were to develop a plan to transition to electronic prescribing systems.
  - A report from Office of the National Coordinator for Health IT (June 2012) estimated that 45 percent of new and renewal prescriptions were sent electronically in 2012.51
- By 2010, all health care providers were to begin using electronic prescribing systems.
  - The same report noted that 48 percent of U.S. physicians now use electronic prescribing systems, compared to only 7 percent in December 2008.51
- The National Library of Medicine should create a central online database for consumers to find information on medications and work with FDA and CMS to consider creation of a nationwide telephone hotline for patients who cannot read printed information.
  - The National Library of Medicine manages a suite of drug information portals to provide consumers with information on drugs, herbs and supplements.52 Patients can call the FDA Division of Drug Information (DDI) for drug information by telephone at 855-543-3784 or 301-796-3400.53
- All health care providers should report medication errors to patients and family members, regardless of whether harm occurred.
- Pharmaceutical companies should disclose all clinical trial results and limit the practice of providing physicians with free samples of medications because the samples are poorly regulated.

- Many scientific journals require the posting of all clinical trials prospectively (as well as results, when available) as a condition for publication. The value of this transparency should strengthen the science and preserve the integrity of the medical literature.54 Although some new limitations are in place, pharmaceutical companies still distribute samples.
- Pharmaceutical companies should package pills in blister packs to simplify identification and make it easier for consumers to remember whether they took a dose.
  - Although some medications are contained in blister packages, this is the exception, not the norm.
- Patients should maintain a list of all prescription and nonprescription treatments that they take and review the document with their health care providers to ensure that there are no potential drug interactions.
- Patients need to become responsible for reading, understanding and abiding by the medication instructions.50

Although the IOM has provided many recommendations for U.S. government agencies to implement, the first step in promoting medication safety is to allow and encourage each patient to take a more active role in his or her own medical care. In the past, many patients and their families thought they would be perceived as disrespectful or rude if they questioned their health care practitioner. However, a new way of thinking, according to the IOM 2006 brief report, is to promote a partnership between the health care provider and the patient.

To initiate and implement this paradigm shift, doctors, nurses, and pharmacists need to communicate with patients by listening, consulting and educating them appropriately about each of their medications at various stages of their care.57

It is a wonderful idea, but many practitioners argue that restrictive reimbursement by insurance companies, Medicaid and Medicare make it difficult to spend a large amount of time with each patient. Many times, these professionals assume that another professional will spend the quality time that each patient deserves. It is a vicious cycle, but pharmacists can be the leaders in turning it around by promoting quality communication.

The governing agencies encourage health care professionals to keep up-to-date on the latest information on available technological advances. For instance, the IOM states in its 2006 brief report that it is impossible to remember every detail about a medication; therefore, it recommends health care professionals use a point-of-care reference to assess components of the desired medication.57

As a result of the IOM recommendations, there have been numerous positive outcomes designed to enhance patient safety. Some examples include:

- The Center for Quality Improvement and Patient Safety (CQuIPS) has been established at AHRQ to integrate patient safety into the
broader quality framework, conduct research on how to reduce medical errors, and educate patients about their safety.

- National summits have been conducted, including AHRQ’s Patient Safety Research and Practices Summit (September 2000), the Food and Drug Administration’s Drug and Device Safety Summit (throughout 2001), and the Department of Veterans Affairs’ (VA) Patient Safety Practices (September 2001).
- The Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services [CMS]) is considering regulations requiring hospitals participating in Medicare to have ongoing medical error programs in place.
- The Office of Personnel Management (OPM) will require all plans in the federal employee health benefits program to seek accreditation that includes the evaluation of patient safety and programs to reduce errors.
- The VA and Department of Defense (DOD) are leaders in computer order entry systems.55

**Recommendations for improving medication safety during the dispensing phase**

It is imperative that pharmacists adhere to the recommendations and guidelines of our governing agencies to improve our medication practices. This can ensure that pharmacists are more conscious about their actions before they dispense a medication to a patient.

All pharmacist programs emphasize the six medication “rights” before administering any medication:
- The right patient.
- The right medication.
- The right dose.
- The right route.
- The right time.

**The right documentation.** Before dispensing any medication, one of the first precautionary steps to take is to always check the physician’s orders against what is known about the patient: What is the disease? are there any concomitant medications that could lead to a drug-drug interaction; does the patient have any co-morbidities that could complicate the use of the medication?

Second, the pharmacist is responsible for verifying that the prescriber has ordered the correct medication at the correct dose, to be administered at an appropriate frequency. Even though there are technologies in place to assess and scrutinize the prescriber’s orders, never assume that the available systems will detect a problem or that another colleague verified the order. It is better and safer to check and re-check the order.

Once the medication on the record matches the correct, safe dose that the prescriber ordered, the pharmacist is responsible for ensuring that the correct quantity of the correct medication at the correct dose is accurately provided to the patient at the correct time.

If the pharmacist is not familiar with a medication, he or she should look it up in a drug reference before beginning the process of dispensing the medication. The pharmacist must never assume that the prescriber is fully aware of the medication classification, use, safe dose, side effects, drug-drug interactions, drug-food interactions and other implications. There are so many medications on the market that it is impossible for anyone to fully understand the implications of all drugs that might be prescribed to a patient.

In November 2005, the FDA mandated that all prescription drug information had to be submitted in a searchable electronic format database to provide information for healthcare professionals and the public.48

In January 2006, the FDA revised the format in which prescription drug inserts were to be written and laid out. During that time, the FDA mandated that inserts be written in a clear, concise manner to provide each healthcare professional the most up-to-date and easy-to-read information to best promote patient safety.42

Every year, JCAHO releases the updated National Patient Safety Goals, customized to various inpatient and outpatient settings, to which hospitals and clinics must abide by for accreditation. In June 2007, the board of commissioners at JCAHO approved the 2008 National Patient Safety goals. The third goal involves the safety of medications:
- Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used by the organization, and take action to prevent errors involving the interchange of these drugs.
- Label all medications, medication containers (for example, syringes, medicine cups, basins) or other solutions on and off the sterile field.
- Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.56

**Bar code label rule**

In February 2004, the FDA issued a final rule requiring bar codes on certain drugs, biologicals and blood product labels.57 According to 21 CFR 201.25, “manufacturers, repackers, relabelers, and private label distributors of human prescription drug products, biological products, and over-the-counter (OTC) drug products that are dispensed pursuant to an order and are commonly used in hospitals are subject to the bar code requirement, regardless of the method they use to distribute their drug products.”58

After the initiation of bar codes, the FDA estimated that their implementation would help prevent nearly 500,000 adverse events and transfusion errors, while saving $93 billion in health costs over 20 years.59

With the advances in technology, the governing bodies also recommended that facilities incorporate electronic prescriptions by 2010 to avoid mistakes with handwritten prescriptions. Over the years, many pharmacists have complained that physicians’ handwriting can be illegible. Pharmacists are trained to verify the medication with the ordering physician instead of making educated guesses about what the doctor meant. The IOM promotes e-prescription software programs because they can also help by assessing for drug allergies, drug-drug interactions and overly high doses during the writing phase to prevent potential medication errors.37

According to the Health Care Quality Modernization, Cost Reduction, and Quality Improvement Act, prescribing errors were reduced by 95 percent and hospital costs lowered by 13 percent with automated prescribing. The government has also included e-prescribing adoption in the Medicare Prescription Drug Improvement and Modernization Act of 2003, and many payors are sponsoring e-prescribing initiatives for their providers. E-prescribing can increase patient safety by preventing errors, improving continuity of care, and by tracking and providing feedback about adverse events.60
Drug name confusion

FDA collaborates with the ISMP to assess and review potential medications that look alike, sound alike and have labels that could cause a medication error. FDA is adamant about eliminating potential confusion because of the name, appearance or sound of the medication. The goal is to prevent errors during the procurement of a medication.

The last time a medication name was changed was in 1994: Levoxine, used to treat hypothyroidism, was often confused with the heart medication Lanoxin. Therefore, FDA recommended a name change. Subsequent to this request, Levoxine was changed to Levoxyl.

It should be noted that after drugs are approved, FDA monitors each medication for errors caused by name confusion. If errors or confusion are noted, FDA informs health care professionals about it in an effort to avoid additional problems. For example, FDA has reported errors involving the administration of methadone instead of the prescribed Metadate ER, (methylphenidate) for the treatment of attention deficit/hyperactivity disorder (ADHD). Unfortunately, there was a case reported where an 8-year-old boy died because the pharmacist filled the opiate, methadone, rather than the intended methylphenidate.

As a pharmacist, it is imperative to recognize the vast array of potential errors from drug name confusion: the data is staggering. In addition, according to Meadows, other examples of drug name confusion reported to FDA include:

- Serzone (nefazodone) for depression and Seroquel (quetiapine) for schizophrenia.
- Lamictal (lamotrigine) for epilepsy, Lamisil (terbinafine) for nail infections, Ludiomil (maprotiline) for depression and Lomotil (diphenoxylate) for diarrhea.
- Taxotere (docetaxel) and Taxol (paclitaxel), both for chemotherapy.
- Zantac (ranitidine) for heartburn, Zyrtec (cetirizine) for allergies and Zyprexa (olanzapine) for mental conditions.
- Celebrex (celecoxib) for arthritis and Celaexa (citalopram) for depression.

Drug labeling

In January 2002, a study found that consumers tend to overlook important label information on OTC drugs. Four months later, in May 2002, FDA mandated a standardized “drug facts” label on foods and medications to ensure that consumers have the appropriate information on the product’s ingredients, uses, warnings, dosage, directions and proper storage.

For example, during the fall of 2007, news media reports claiming that parents were overdosing their children led many people to believe that cough medications were no longer safer to administer to children under 6 years of age. Pharmaceutical companies responded by changing the labels on all cough medications, telling parents to consult with their doctor before giving a child under 6 years of age the medicine.

In 2000, the FDA proposed a new package insert that was more user-friendly and highlighted the critical information needed for physicians prescribing products. In January 2006, the FDA initiated new changes in the format for the labeling of prescription drugs to provide health care professionals clear and concise prescribing information. The IOM committee recommends that the drug industry and the appropriate federal agencies work together to improve nomenclature, which encompasses drug names, abbreviations and acronyms. It is also critical to teach patients to recognize that if the medication does not look right based upon its color or shape, they should never assume it is the correct, prescribed medication.

FDA recommendations to improve medication safety

On January 30, 2007, the FDA announced 41 initiatives to improve drug safety based on the recommendations of the IOM. Among them were:

- List all products by generic name.
- Do not include the salt of the chemical when expressing a generic name unless there are multiple salts available (i.e., hydroxyzine hydrochloride and hydroxyzine pamoate).
- Use brand names in upper case letters (i.e., LANOXIN, LASIX) to differentiate them from their generic cohort.
- Express suffixes that are part of the brand name (i.e., SR, SA, CR) within both the generic name field and the brand name (i.e., diltiazem XR).
- Avoid the use of all potentially dangerous abbreviations and dose expressions. (See Table 1 – The Do Not Use list.)
- Do not use trailing zeros (5 mg, never 5.0 mg).
- Use leading zeros for doses that are less than 1 (0.3 mg, never .3 mg).
- Spell out the word “units.”
- Use the proper, approved standard abbreviations for dosage units.
- Do not abbreviate names (do not use Mso4 for morphine).
- Use upper case and lower case letters (i.e., HydroXYzine and hydrALAZINE) to help distinguish look-alike products.
- When the drug name, strength, dosage form and dosage units appear together, avoid confusion by listing the generic name first and provide a space between them.

Additional recommendations for pharmacists to improve medication safety

In addition to ensuring that the previous recommendations are implemented, pharmacists may be able to participate in implementing the following guidelines to promote patient safety, as incorporated in JCAHO’s national safety goal.

In 2006, JCAHO initiated the medication reconciliation form to help prevent medication errors. The medication reconciliation form is implemented upon admission, transfer to another unit, and discharge from the facility to ensure that all home medications and discharge medications are clearly stated to avoid an overlap or drug-drug interactions. The requirements for JCAHO’s national safety goals include:

- Implement a process for obtaining and documenting a complete list of the patient’s current medications upon the patient’s admission to the organization, with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list. (Note: While this safety goal does not require a separate form for the medication list, many organizations have found it useful to develop and use one or more forms to support the medication reconciliation process.)
- Ensure that a complete list of the patient’s medications is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization.

In the second national standard, JCAHO recommended the following to prevent a medication error during the communication phase.
Pharmacists are often required to take verbal orders from a doctor or other prescriber or their representative over the telephone, or sometimes, even in person. Before taking a verbal order over the telephone, the pharmacist should gather all available data about the patient. When given a verbal order, the pharmacist must repeat each component of the order back to the caller, which includes verbalizing the medication and spelling it (if appropriate), reiterating the dose and the frequency of the medication.

**Consumers’ role to improve medication safety**

FDA has been diligently attempting to eradicate or reduce medication errors for patients in a very complex medical system. To promote medication safety, FDA recommends that consumers collaborate with their health care providers to reduce errors. FDA urges consumers to take the following steps:  
- As a patient, know the most common type of medication errors that occur. The most vulnerable populations are children and elderly patients over 60 years of age. According to another report in 2007 by FDA, more than 700,000 people go to emergency rooms every year because of a medication interaction. In the same consumer health information form, the FDA said that the most commonly implicated drug causing unexpected medical problems for patients is Coumadin (warfarin).
- Know the name of your medication and its purpose. FDA reiterates that the patient should never take a medication just because “the doctor said so.”
- Always read and understand the directions for taking each medication safely and properly as prescribed. According to Weiss (2006), more than 50 percent of patients do not take their medications as prescribed.

**Goals for the future**

Although progress has been made, more providers need to begin using e-prescribing systems, and all pharmacies should be able to receive prescriptions electronically. The Agency for Healthcare Research and Quality (AHRQ) should take the lead in fostering improvements in IT systems used in ordering, administering and monitoring drug usage.

**Conclusion**

Although there are many variables that lead to medication errors in our complex medical system, there are multiple actions that we can take as pharmacists to promote patient safety. It is imperative to understand the legal responsibilities and obligations that you have to patients you care for directly or indirectly on a daily basis.

Each health care professional can take the initiative and rise above the shortcomings within our health care system to promote patient safety. The governing bodies have provided an abundance of research and evidence-based practice recommendations to prevent and help eradicate the risk of medication errors.

No one ever wants to be a party in a medication error, especially knowing that the errors can be disabling to a patient or even cause death. It takes just a few extra minutes to ensure that each medication is safely prescribed, dispensed and administered to the patient.

Remember: Each patient is an individual who has a story and a family; do not jeopardize his or her safety and life. The next time, it could be your loved one who is the patient.

**TABLE 1**

**Official “Do Not Use” List by JCAHO**

<table>
<thead>
<tr>
<th>Do Not Use</th>
<th>Potential Problem</th>
<th>Use Instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>U (unit)</td>
<td>Mistaken for “0” (zero), the number “4” (four) or “cc”</td>
<td>Write “unit”</td>
</tr>
<tr>
<td>IU (International Unit)</td>
<td>Mistaken for IV (intravenous) or the number 10 (ten)</td>
<td>Write “International Unit”</td>
</tr>
<tr>
<td>Q.D., QD, q.d., qd (daily)</td>
<td>Mistaken for each other</td>
<td>Write “daily”</td>
</tr>
<tr>
<td>Q.O.D., QOD, q.d.o, qod (every other day)</td>
<td>Period after the Q mistaken for “I” and the “O” mistaken for “I”</td>
<td>Write “every other day”</td>
</tr>
<tr>
<td>Trailing zero (X.0 mg)*</td>
<td>Decimal point is missed</td>
<td>Write X mg</td>
</tr>
<tr>
<td>Lack of leading zero (.X mg)</td>
<td></td>
<td>Write 0.X mg</td>
</tr>
<tr>
<td>MS</td>
<td>Can mean morphine sulfate or magnesium sulfate</td>
<td>Write “morphine sulfate”</td>
</tr>
<tr>
<td>MSO4 and MgSO4</td>
<td></td>
<td>Write “magnesium sulfate”</td>
</tr>
</tbody>
</table>

* Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.

**Exception:** A “trailing zero” may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.
TABLE 2
Drug safety communications

<table>
<thead>
<tr>
<th>Date</th>
<th>Product(s)</th>
<th>Safety Issue and Web Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 14, 2013</td>
<td>Incretin mimetic drugs for type 2 diabetes Byetta, Bydureon (exenatide); Victoza (liraglutide); Januvia, Janumet, Juvisync (sitagliptin); Onglyza (saxagliptin); Nesina, Kāzano (alogliptin); Tradjenta, Jentadueto (linagliptin)</td>
<td>Investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes</td>
</tr>
<tr>
<td>March 12, 2013</td>
<td>Zithromax, Zmax (azithromycin)</td>
<td>Risk of potentially fatal heart rhythms</td>
</tr>
<tr>
<td>February 26, 2013</td>
<td>Sensipar (cinacalcet)</td>
<td>Pediatric clinical trials suspended after report of death</td>
</tr>
<tr>
<td>February 20, 2013</td>
<td>Codeine</td>
<td>Safety review update of codeine use in children; new boxed warning and contraindication on use following tonsilllectomy and adenoidectomy</td>
</tr>
<tr>
<td>January 10, 2013</td>
<td>Insomnia drugs containing zolpidem (Ambien, Edluar, zolpimist)</td>
<td>Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses</td>
</tr>
</tbody>
</table>

References

1. Which of the following is not a component of a safe medication system?
   a. Administration of the drug.
   b. Preparation and dispensation of the drug.
   c. Selecting the generic equivalent that provides the best profit margin.
   d. Selection and procurement of the drug by a pharmacy.

2. According to the ISMP MERP program, all health care professionals should report actual or potential medication errors that occur due to all of the following factors, except:
   a. Staff misconduct.
   b. Wrong drug, wrong strength, wrong dose.
   c. Errors in transcription.
   d. Calculation errors.

3. Assume the scenario where a prescriber has written an order for three daily doses of lorazepam, 0.5 mg, to be administered at bedtime, with discontinuation after the third dose. When visiting the floor on the fourth night, the pharmacist notes that the nurse has taken a dose of lorazepam from the floor stock, and is preparing to administer it to the patient. The pharmacist immediately recognizes the potential error and stops the nurse from administering the dose. This situation could be described as:
   a. Lucky.
   b. A near-miss.
   c. A pharmacist overstepping his or her responsibility.
   d. A safe and efficient way to run a nursing unit.

4. When determining whether an adverse event is to be considered “serious,” FDA requires it to include at least one of the following attributes?
   a. Fatal.
   b. Life-threatening.
   c. Requires a hospitalization.
   d. All of the above.

5. Which of the following was not an FDA recommendation to improve medication safety?
   a. List all products by generic name.
   b. Spell out brand names in lower case to distinguish them from generic names.
   c. Spell out the word “units.”
   d. Do not abbreviate names.