

Medical Error Prevention

SYLVIA R. MILLER, BS, MS, ARNP-C



Health Studies Institute, Inc.

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Printed in the United States of America

Published by Health Studies Institute, Inc.

P.O. Box 6808, Deerfield Beach, Florida 33442-6808

www.healthstudies.com

Email: info@healthstudies.com

Sylvia R. Miller, ARNP-C, holds a BS in nursing from the University of Miami and a nursing MS from Barry University, where she was elected to the nursing honor society. From 1986 to 1996, she was assistant administrator of risk management at Jackson Memorial Hospital, Miami, Florida.

Ms. Miller has served as an advanced registered nurse practitioner at the Good News Care Center, the Perdue Medical Center (part of the Jackson Health System), and the Broward Sexual Assault Treatment Center. She nursed critical and immunocompromised patients at Jackson Memorial Hospital through 2002.

She is now a case manager at Jackson, involved with HIV/AIDS and asthma health education for Medicaid recipients. She also coordinates support groups for these patients.

Dear Health Care Professional:

As of 2002, twenty states have laws and/or rules on mandatory reporting of medical errors, and six more have regulations concerning related issues. Although this course cites examples drawn from Florida statutes, health care professionals everywhere will benefit from knowing what's at issue and how to deal with it.

This book is intended to provide accurate information to health care professionals. However, in a time of rapid change, it is difficult to ensure that all medical and/or health care information is entirely accurate and up-to-date. Therefore, the editor, author, contributor(s), and publisher accept no responsibility for any errors or omissions, and specifically disclaim any liability, loss, or risk incurred as a consequence, directly or indirectly, of the use and/or application of any of the contents of this book. Mention of products in this text is not intended as a recommendation of specific products or manufacturers, and does not reflect on the quality or efficacy of other products or manufacturers not mentioned herein. Readers are encouraged to confirm the information contained herein with other sources. The ultimate responsibility for patient care resides with the health care professional on the basis of his/her professional experience and knowledge of the patient.

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Directions

How to Get the Most Out of This Course

Many of our customers have found the following study method to be effective:

1. Read the Objectives.
2. For each chapter:
 - a. First skim, then read the text and study the tables.
 - b. When needed, use the text's Index to locate information.
 - c. Go at your own pace.
3. Answer the test questions. (*See below.*)

Objectives

At the end of this course, you will take a written test that will measure your ability to identify:

1. Patients at greatest risk of experiencing medical errors.
2. Types of medical errors and factors known to cause them.
3. Goals, requirements, and hindrances concerning reporting of sentinel events.
4. Procedures for mandatory and voluntary root cause analyses.
5. Recommendations for reducing and preventing specific types of medical errors.
6. Methods of communicating with and educating patients to increase their safety.

Chapter 1 Introduction

What Is a Medical Error?

In the medical literature, an error is generally defined as the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve a particular goal.¹ A medical error is defined as an adverse event or a near miss that is preventable with the current state of medical knowledge. An adverse event is an injury caused by medical management (rather than a patient's underlying disease/condition), which results in measurable disability. When an unexpected adverse event involves death or serious physical or psychological injury, or the risk thereof, it is called a sentinel event (such an event signals the need for immediate investigation and response). A near miss (close call) is an event or situation that could have resulted in an accident, illness, or injury, but did not, either by chance or through timely intervention.^{1,2}

Epidemiology

In the United States, medical errors occurring in hospitals and outpatient settings are a leading cause of injuries and deaths. Overall, the annual number of deaths from medical errors is estimated at 180,000, and many of these errors are preventable.³ Medication errors alone cause 7,000 deaths,⁴ and injure about 1.3 million people annually.⁵

Populations at Greatest Risk

Pediatric and geriatric patients probably account for the greatest number of victims of medical errors. Children cannot effectively communicate their health problems, and they require special drug calculations that often result in dosage errors. Elderly persons with memory deficits can also have difficulty communicating their health problems, and, when they require multiple medications, the opportunities for prescription and self-medication errors also multiply. Risks of becoming victims of medical errors are also increased for patients who: (1) are visually or hearing impaired; (2) are sedated because of psychiatric illness; (3) have renal or hepatic impairment; or (4) are anesthetized or comatose.

Hospital-Related Cases

According to the Institute of Medicine's report, "To Err is Human" (published by the National Academy of Sciences in 2000), at least 44,000 patients die in U.S. hospitals each year as a result of medical errors; some estimates are as high as 98,000.⁴ A wide range of errors can occur in hospitals. For example:

- *A 68-year-old nondiabetic woman becomes comatose for 7 weeks, then dies, after a nurse inadvertently flushes her occluded arterial line with insulin, instead of heparin.*⁶
- *A male patient's left (incorrect) knee undergoes arthroplasty after clinicians uncover, prep, and present it to a surgeon in the operating room; in the preoperating area, the right (correct) knee had been prepped.*⁷
- *Four patients in an Ohio nursing home and two patients in an Idaho hospital die after a large cryogenic vessel containing industrial-grade nitrogen is connected to the oxygen supply system.*⁸ (Note: Cryogenic vessels are used to contain material that is stored at very low temperatures.)
- *A 42-year-old woman has a hysterectomy, then suffers permanent injuries because she requires (1) a second surgical procedure to remove a laparotomy sponge left inside during the hysterectomy, and (2) a third procedure to resect 15 inches of her small bowel involved in a mid-pelvic inflammatory mass containing sponge remnants.*⁹
- *A 52-year-old man's lower right leg is amputated because of massive infection following knee surgery, during which a right thigh tourniquet was used despite his medically recorded lower-extremity circulation deficiency.*¹⁰

Outpatient Cases

Currently, at least 1 surgery out of 10 is performed in a doctor's office, and, by 2005, an estimated 10 million procedures will occur in this type of ambulatory setting. Although surgery is less costly in such settings, many lack standardization in anesthesia protocols and required staff credentials, and all lack the "safety net" of the wide range of expertise and recovery monitoring readily available in hospitals.¹¹ However, medical

errors of many types can potentially occur in any type of outpatient clinical, surgical, or office setting, and in a pharmacy, nursing home, or the private home of a patient. For example:

- *A 30-year-old man's lingual nerve is severed during extraction of one of his wisdom teeth by a general dentist.*¹²
- *A 44-year-old woman dies from massive blood loss after undergoing extensive cosmetic surgery in a California plastic surgeon's office.*¹¹
- *A 6-year-old New Jersey boy dies after receiving a tenfold overdose of cisplatin because the doctor's dosage order was transcribed improperly, with a decimal point omitted.*¹³
- *A 56-year-old man receives a 22% overdose of radiation and suffers burns because the radiation treatment planning system used by the facility had a software problem.*¹⁴
- *An 8-year-old girl's urine sample is mislabeled and reported by the laboratory to contain sperm; the error is discovered when the medical examiner's office determines that all cellular material in the urine has only male DNA and could not come from a female subject. A repeat urine test shows a urinary tract infection.*¹⁵

Professional Education

In 2001, the Florida Legislature passed a law [Florida Statute 456.013(7)] requiring every person licensed under a Department of Health board to complete a 2-hour prevention of medical errors course that includes root cause analysis, error reduction and prevention, and patient safety.¹⁶

The Veterans Administration has led the way in educating hospital staff; it requires staff members in all its facilities to take 15 to 20 hours of patient safety training each year.¹

A Systems Approach Is Needed

The traditional “naming, blaming, and shaming” approach to dealing with errors has hindered medical error reduction. It has led to a “conspiracy of silence,”

in which medical errors are often not discussed due to fear of reprisals and malpractice claims. Many medical errors and safety issues are not reported within health care facilities or to outside organizations that study such data to increase patient safety. Although some errors occur because of health care workers' negligence or lack of training, most are due to poor systems design and organizational factors (e.g., health care workers are sometimes expected to work long shifts to ensure patients are cared for, and/or function in environments that are not ergonomically designed for optimal work performance).¹

Preventing medical errors requires emphasis on safety and responsibility at all levels of health care organizations, whether inpatient or outpatient, or large or small; it requires a true team effort.³ Research shows that ensuring patient safety involves the establishment of operational systems that minimize the likelihood of any errors occurring at all and maximize the interception of them when they are about to occur. Therefore, a systems approach to discovering the causes of, and decreasing, errors is essential for the health of patients and the health care industry.

Chapter Summary

1. An error is the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve a particular goal.
2. A medical error is an adverse event or a near miss that is preventable with the current state of medical knowledge.
3. In the United States, an estimated 180,000 people die as a result of medical errors each year.
4. Pediatric, geriatric, psychiatric, and sensory impaired patients are at increased risk of becoming victims of medical errors.
5. Medical errors can potentially occur in any type of health care setting, in pharmacies, or in patients' private homes.
6. Preventing medical errors requires a true team effort that focuses on operational systems, not on individuals.

Chapter 2 Types of Medical Errors

Medical errors include problems in practices, procedures, products, and systems.¹ They can include misdiagnosis, misuse of equipment, inaccurate laboratory reports, adverse drug events, surgical mistakes, and failure to provide treatment. In settings providing around-the-clock care, medical errors can also include incompatible blood transfusions, mistaken patient identities, suicides, infant abductions or discharges to the wrong families, injuries or deaths caused by falls or use of patient restraints, and institutionally acquired infections, burns, and pressure ulcers.

Sentinel Events

As stated in Chapter 1, these unexpected adverse events involve death, serious physical or psychological injury (i.e., loss of limb or function), or the risk thereof (e.g., any process variation for which a recurrence would carry a significant chance of serious adverse outcomes).² As an example, Table 1 summarizes reported outcomes of sentinel events, called Code 15 injuries, in Florida hospitals and ambulatory surgical centers during 2001.¹⁷

Outcomes	Hospital-reported injuries	Ambulatory surgical center-reported injuries	Total no. of injuries reported	Percentage of total no. of injuries reported
Death	321	21	342	33%
Brain damage	52	4	56	5%
Spinal damage	18	2	20	2%
Surgical procedure performed on the wrong patient	9	0	9	1%
Surgical procedure unrelated to the patient's diagnosis or medical needs	83	2	85	8%
Surgical procedure performed on the wrong site	39	13	52	5%
Wrong surgical procedure performed	10	6	16	2%
Surgical procedure to remove foreign objects remaining from a surgical procedure	116	3	119	11%
Surgical repair of injuries/damage resulting from a planned surgical procedure	286	66	352	33%
Totals	934	117	1,051	100%

Note: Totals do not include HMO reports and reports submitted for injuries that did not occur in the reporting facility.

Diagnostic Errors

These errors occur in both inpatient and outpatient health care settings. They range from incorrect

diagnosis to use of inappropriate diagnostic tests, failure to perform indicated tests or act on abnormal results, and delays in making diagnoses.^{4,18}

Incorrect diagnoses may lead to unnecessary invasive testing, or ineffective, wrong, or no treatment.¹⁹ The following example involves not only incorrect initial diagnosis, but lack of record checking and treatment as well:

*A 38-year-old man has an anal cyst (diagnosed as benign) surgically removed in a hospital. The excised tissue is then microscopically analyzed and found to be cancerous, but, because the man's records become confused with those of another patient, he is not told that he has cancer until nearly 6 months later. In the interim, he has to return to the hospital four times because of continued pain and discomfort, but, because his records do not indicate that he has cancer and no one rechecks the pathology results, he is diagnosed as having a sexually transmitted disease. Meanwhile, the cancer, which has been left untreated, continues to spread, and the man dies a year later.*²⁰

Treatment Errors

These errors include those made by health care workers during performance of surgery, a procedure, or a test, and when they allow avoidable delays in responding to abnormal tests or providing treatment.¹⁸ Chapter 1 gives several examples of documented treatment errors.

Surgical errors. Studies are revealing risk factors associated with surgical errors; for example:

1. A Florida study of outpatient liposuction procedure-related complications (43 cases) and deaths (8 cases) showed that these events occurred when patients underwent general anesthesia, instead of intramuscular or conscious sedation.²¹
2. A study of 126 surgical errors reported to the Joint Commission on Accreditation of Healthcare Organizations showed that 76% involved the wrong body part/site; 13%, the wrong patient; and 11%, the wrong surgical procedure. Analysis of these errors indicated the following risk factors: (a) the patients were emergency cases or had unusual physical characteristics (e.g., morbid obesity); or (b) the staff was unusually pressured to start or complete the surgery, had to use unusual equipment, had to perform multiple surgical procedures, or involved multiple surgeons.²²

Delays in treatment. Delays in treating patients in hospitals, especially in emergency departments, have resulted in patient deaths or permanent injuries. An American Hospital Association survey indicates that: (1) misdiagnosis is the most common reason for the delays; and (2) meningitis is the illness most often not diagnosed expeditiously.²³

Negligence. The Harvard Medical Practice Study indicated that, during 1984, 27.6% of adverse events in New York nonpsychiatric hospitals were due to negligence, and occurrence of these injuries and deaths was markedly higher among elderly patients.²⁴

Medication Errors

Medication errors are defined as preventable events involving inappropriate drug use or patient harm while health care workers, patients, or consumers are in control of a drug.²⁵ These errors occur in every type of health care setting, as well in patients' homes. Many are not reported; others are not detected because they cause minimal problems.²⁶

U.S. Pharmacopeia (USP) MedmarxSM (see Chapter 3) 2001 data from hospitals showed that:

1. Of 2,539 reported harmful medication errors, 353 required the patients to undergo initial or prolonged hospitalization; 70 required intervention to sustain life; and 14 resulted in death.²⁷ Insulin was the leading product involved in the harmful errors, and albuterol was the second leading product, particularly for omissions of its use. Drugs causing the 14 fatalities included: (a) cocaine, digoxin, heparin, meperidine, and potassium chloride [all of which are called high-alert medications, because the risk of patient injury is high if they are administered incorrectly]; and (b) ampicillin, doxorubicin, epinephrine, esmolol, iohexol, and polyethylene glycol 3350 with electrolytes.²⁸
2. In emergency departments, improper dosing or quantity was the leading medication error, and only 23% of such errors were intercepted before reaching the patient, as opposed to interception of nearly 39% of such errors in other hospital areas. Prominent among improper dosing errors were diltiazem, heparin, insulin, morphine, and pediatric diphtheria/tetanus toxoids.²⁹

Medication errors can occur at any step in the process of providing drugs to patients. For example, when clinicians choose drugs or communicate prescriptions to pharmacists, they may:

1. Select drugs that are inappropriate for patients' needs, interact adversely with other drugs patients

- are taking, or cause harm because of patients' allergies.
2. Select wrong drugs from computerized lists.
 3. Be confused by look-alike, sound-alike drug names (similar brand or generic names); these similarities cause about 15% of all medication error reports received by USP.³⁰ Health care workers can view USP's list of hundreds of similar drug names, published in *USP Quality Review*, No. 76, March 2001, at www.usp.org or obtain a copy by calling USP's Practitioner and Product Experience Department (800-487-7776).
 4. Write prescriptions illegibly or use often-misunderstood abbreviations shown in Table 2³¹ (e.g., a patient whose prescription for furosemide "40 mg Q.D." was misinterpreted by the pharmacist as "40 mg QID" died after following the latter directions).³² Handwritten decimal points lacking leading zeros or having trailing zeros also cause errors.³³

Medication errors can also occur when:

1. Pharmacists dispense prescriptions (e.g., if they are careless in documenting the order's nomenclature and dosage requirements, or in compounding, packaging, or labeling the drug).
2. Health care workers administer drugs (e.g., when they administer drugs at other than prescribed times or give patients the wrong drugs). In the late 1980s, 10 hospitalized patients died either because they were directly infused with concentrated potassium chloride (KCl), or they received the wrong drug (i.e., KCl was mistaken for sodium chloride, heparin, or furosemide because of packaging and labeling similarities).³⁴
3. Patients administer drugs to themselves (e.g., if clinicians fail to educate patients in self-administration of prescribed drugs, or when patients are too frail to take adequate control of their at-home use of medications).
4. Medication use is not monitored (e.g., if clinicians fail to determine patients' responses to prescribed drugs, or patients fail to report their adverse reactions to drugs).^{4,30,31,35}

Table 2. Dangerous Abbreviations

Abbreviation	Intended Meaning	Common Error
U	Units	Mistaken as a zero or a four (4), resulting in an overdose. Also mistaken for "cc" (cubic centimeters) when poorly written.
µg	Micrograms	Mistaken for "mg" (milligrams), resulting in an overdose.
Q.D.	Latin abbreviation for every day	The period after the "Q" has sometimes been mistaken for an "I," and the drug has been given "QID" (four times daily) rather than daily.
Q.O.D.	Latin abbreviation for every other day	Misinterpreted as "QD" (daily) or "QID" (four times daily). If the "O" is poorly written, it looks like a period or "I."
SC or SQ	Subcutaneous	Mistaken as "SL" (sublingual) when poorly written.
T I W	Three times a week	Misinterpreted as "three times a day" or "twice a week."
D/C	Discharge; also discontinue	Patient's medications have been prematurely discontinued when D/C (intended to mean "discharge") was misinterpreted as "discontinue," because it was followed by a list of drugs.
HS	Half strength	Misinterpreted as the Latin abbreviation "HS" (hour of sleep).
cc	Cubic centimeters	Mistaken as "U" (units) when poorly written.
AU, AS, AD	Latin abbreviation for both ears; left ear; right ear	Misinterpreted as the Latin abbreviation "OU" (both eyes); "OS" (left eye); "OD" (right eye).

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Drug Errors in Special Populations

Geriatric patients. As the most frequent users of medications, geriatric patients are at substantial risk for adverse drug events. They often have multiple chronic diseases that require the use of multiple drugs. The aging process can also disrupt or change elderly persons' absorption, metabolism, and excretion of drugs, and thus require alterations in prescribed dosing. In addition, results of U.S. surveys indicate that nearly 25% of noninstitutionalized elderly persons have been prescribed inappropriate medications.³⁶

Pediatric patients. USP's 2001 MedmarxSM data from hospitals showed that 29% of pediatric medication errors involved improper dosing or quantity, and 26%, improper procedure or protocol. Children usually must have much smaller drug doses than adults. Among other factors, clinicians must carefully consider each child's age, weight, and medication dosing frequencies. Incorrect conversions of weight from pounds to kilograms, or misplaced decimal points in the drug dosage orders can cause serious harm or fatalities.³⁷

A study of 60 children who died or suffered permanent neurologic injury after being sedated in dental and other clinical settings indicated that drug overdoses and interactions often cause these adverse sedation events. This risk is greatest when three or more sedating medications are used.³⁸

Transdermal Patches

Inappropriate use of transdermal patches has caused patient harm and deaths [e.g., the Food and Drug Administration (FDA) received a report of a man who died after his wife applied six fentanyl patches to his skin at one time]. Risks for errors with patch products abound because of their variations in dosages, shapes, sizes, and colors, and in where and how often they should be applied to the body. The overlay—the portion of the two-piece patch that secures the medicated portion to the skin and facilitates absorption of the drug—causes confusion; some health care workers and patients mistakenly throw the overlay away. Other problems include applying new patches on top of old ones, securing the overlay instead of the medicated portion to the skin, failing to remove the protective liner, applying patches to the wrong body site, or leaving patches where children and pets might chew on them.³⁹

Medical Gases

The FDA has received reports of several patient deaths and injuries caused by errors associated with provision of oxygen (a prescription drug) in hospitals

and residential health care facilities. The errors occurred because persons connecting large cryogenic vessels to oxygen supply systems thought they had selected vessels containing oxygen, when they had actually chosen those filled with industrial-grade nitrogen, argon, or carbon dioxide. They did not check the drug labels on the gas vessels, and, when fittings from the wrong vessels did not fit the oxygen supply system because of connection incompatibilities, they replaced the wrong vessels' fittings with compatible ones, and connected them to the oxygen supply systems.^{8,40}

Medical Device Errors

Medical devices regulated under the federal Food, Drug, and Cosmetic Act range from complex equipment to simple items (e.g., pacemakers, implants, ventilators, x-ray machines, thermometers, and cementing agents). Medical device errors can be related to design, manufacturing, or labeling defects, or user mistakes.¹⁴ One example involved the patient who had to undergo surgery to remove a transluminal catheter wire tip that had become detached during angioplasty.¹⁴ Other examples include the deaths of patients on long-term ventilation; many of these are caused by malfunction or misuse of an alarm, or an inadequate alarm.⁴¹

Chapter Summary

1. Sentinel events are unexpected adverse events involving death, serious physical or psychological injury (i.e., loss of limb or function), or the risk thereof (e.g., any process variation for which a recurrence would carry a significant chance of serious adverse outcomes).
2. Medical errors are often related to diagnosis, surgery, delays in treatment, provision and use of medications, and use of medical devices.
3. Medication errors can occur when clinicians prescribe drugs, pharmacists dispense drugs, health care workers (or patients) administer drugs, and when drug use is not monitored.
4. Clinicians should take into consideration the special physiologic needs of geriatric and pediatric patients when prescribing drugs for these age groups.

Chapter 3 Adverse Event Reporting

The goals of voluntary and mandatory reporting of adverse events (e.g., unexpected anaphylactic reactions to penicillin) are to analyze the information and identify ways to prevent future errors from occurring. Reporting and analysis of close calls, or “near misses” (e.g., intercepting contraindicated medication orders prior to their administration) and “no harm events” (e.g., a patient with a history of anaphylaxis in response to penicillin receives cephalosporin, but, by chance, does not experience an allergic reaction) can also prove beneficial in preventing medical errors.⁴²

Prior to the reporting, however, the immediate actions when an adverse event occurs can include: (1) taking appropriate care of the patient; (2) making the situation safe; (3) preventing immediate recurrence of the event; (4) notifying police or security, if applicable; and (5) preserving evidence and relevant data that will aid in fully understanding the situation.³

Reporting Requirements

Mandatory Reporting

State statutes. As of 2002, the following states had passed laws and/or rules on mandatory medical error reporting (mainly by hospitals): California, Colorado, Connecticut, Florida, Kansas, Massachusetts, Maine, Nebraska, New Jersey, New York, Nevada, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, and Washington.⁴³ The District of Columbia, Georgia, New Mexico, North Carolina, Oregon, and Wyoming have also passed regulations concerning related issues.⁴⁴ Because these laws and rules differ from state to state, health care workers should know what their specific state requires.

As an example, Table 3 describes reporting requirements for hospitals, ambulatory surgical centers, and mobile surgical facilities licensed in Florida under Chapter 395. According to Statute 395.0197(6)(a-b), these facilities must also submit to the Florida Department of Health, Agency for Health Care Administration (AHCA) an annual report summarizing all adverse event/incident reports they filed during the year; the AHCA reviews this information, including how it relates to conduct of

persons licensed under Chapters 458, 459, 461, and 466, who provide care at the facilities.⁴⁵

FDA: biologic products and drugs. Nationwide, the Food and Drug Administration (FDA) mandates that transfusion services; licensed biologic product manufacturers; and unlicensed, registered blood establishments report any event associated with biologic products (including blood, blood components, and source plasma) that represents a deviation in manufacturing.⁵⁰ Form 3500A should be sent promptly (not more than 45 days from the event date) to the FDA, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448; fax: (301) 827-3529. Form 3500A is available at www.fda.gov/medwatch/getforms.htm

Drug manufacturers, distributors, and packers are also required to report adverse drug events, using Form 3500A, and sending it to the FDA, Office of Post-Marketing Drug Risk Assessment, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857-9787. Further information is available at www.fda.gov/medwatch/report/mfg.htm

FDA: medical device errors. All U.S. “user facilities” (e.g., hospitals, long-term care facilities, ambulatory surgery facilities, outpatient diagnostic facilities, and home health care services) are legally required to report medical device-related deaths and serious injuries as follows:

1. Deaths related to the use of medical devices must be reported within 10 days of facilities’ awareness of events. Form 3500A (*see web address above*) should be sent to the device manufacturers, as well as to the FDA, Center for Devices and Radiological Health, MDR Reporting, P.O. Box 3002, Rockville, MD 20847-3002; fax: 301-827-0038.
2. Device-related injuries that are life threatening, cause permanent damage or impairment, or require surgery to prevent such damage or impairment must be reported to the manufacturers within 10 days of facilities’ awareness of the events.¹⁴

Voluntary Reporting

JCAHO: sentinel event database. In 1995, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) created a sentinel event

database.⁴² JCAHO accepts voluntary reports of sentinel events from member institutions, patients and their families, and the media; it then collates and analyzes the data, and shares the results at www.jcaho.org⁴²

Table 3. Mandatory Reporting Requirements of Florida Statute 395.0197

Adverse events/incidents (including sentinel events) occurring in hospitals and ambulatory/mobile surgical facilities	Report to facility risk manager within 3 business days after occurrence	Notify AHCA* no later than 1 business day after risk manager receives report**	Full report to AHCA* within 15 calendar days after occurrence
1. Death of a patient.	395.0197(1)(d)	395.0197(7)(a)	395.0197(8)(a)
2. Brain or spinal damage to a patient.	395.0197(1)(d)	395.0197(7)(b)	395.0197(8)(b)
3. Performance of a surgical procedure on the wrong patient, a wrong-site surgical procedure, or a wrong surgical procedure.	395.0197(1)(d)	395.0197(7)(c–e)	395.0197(8)(c–e)
4. Surgical repair of patient damage resulting from a planned surgical procedure, where the damage was not a recognized specific risk as disclosed to the patient and documented through the informed consent process.	395.0197(1)(d)		395.0197(8)(g)
5. A procedure to remove unplanned foreign objects remaining from a surgical procedure.	395.0197(1)(d)		395.0197(8)(h)
6. A surgical procedure that is medically unnecessary or otherwise unrelated to a patient's diagnosis or medical condition.	395.0197(1)(d)		395.0197(8)(f)
7. Permanent disfigurement.	395.0197(1)(d)		
8. Fracture or dislocation of bones or joints.	395.0197(1)(d)		
9. A resulting limitation of neurologic, physical, or sensory function that continues after discharge from the facility.	395.0197(1)(d)		
10. Any condition requiring specialized medical or surgical intervention resulting from nonemergency medical intervention to which the patient has not given his or her informed consent.	395.0197(1)(d)		
11. Any condition requiring patient transfer to a unit providing a more acute level of care due to an adverse incident (not the patient's condition prior to the incident).	395.0197(1)(d)		

* AHCA = Agency for Health Care Administration, Florida Department of Health.

** The risk manager must determine within 1 business day whether the adverse event occurred within the licensed facility or arose from health care prior to admission to the facility. The notification to AHCA must be in writing and provided by facsimile device or overnight mail delivery. It must identify the affected patient, the type of adverse event/incident, the initiation of an investigation by the facility, and whether the event represents a potential risk to other patients.

Sentinel events that JCAHO reviews include:

1. Surgical procedures on the wrong patients, the wrong organs, or the wrong sides of the patients' bodies.
2. Medication- or treatment-associated patient deaths, paralyses, comas, or other major permanent losses of function (i.e., sensory, motor, physiologic, or intellectual impairments not present on admission, which require continued treatment or life-style change).
3. Suicides of patients housed in around-the-clock care settings.
4. Unauthorized departures of patients from around-the-clock care settings, which result in suicides, homicides, or major permanent losses of function.
5. Maternal deaths related to the birthing process.
6. Perinatal deaths unrelated to congenital conditions in infants with birth weights of more than 2,500 grams.
7. Facility-located homicides, assaults, or other crimes that result in patients' deaths or major permanent losses of function. Also, rapes that facilities determine have actually occurred (i.e., are not just alleged).
8. Hemolytic transfusion reactions involving administration of blood or blood products having major blood group incompatibilities.
9. Patient falls that cause death, or major permanent losses of function because of injuries sustained in the fall.
10. Infant abductions or discharges to the wrong family.^{2,3,46}

JCAHO's accreditation programs evaluate the quality of care provided by approximately 18,000 organizations (i.e., hospitals; ambulatory care centers and offices whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; assisted living residencies; hospices; home care agencies; clinical laboratories; and managed care entities).⁴⁷ Risk managers in these health care facilities and programs should periodically check the JCAHO web site for updates or changes in policies and reporting procedures (e.g., currently, sentinel events should be reported within 5 days of the event). To obtain a copy of the reporting form, risk managers should call the sentinel event hotline (630-792-3700), or JCAHO's Office of Quality Monitoring (630-792-5642), and then fax the completed form to 630-792-5636.²

FDA: adverse drug events. All health care facilities should submit reports of unintended noxious signs,

symptoms, or laboratory test abnormalities resulting from patients' taking of drugs to the FDA's.^{48,36}

1. Center for Drug Evaluation and Research—301-594-0095, or
2. MedWatch voluntary reporting program: 800-332-1088; fax: 800-332-0178; or FDA MedWatch, 5600 Fishers Lane, Rockville, MD 20857-9787.⁸ Confidential reporting can also be done via computer, using Form 3500 (available at www.fda.gov/medwatch/getforms.htm).⁴⁹

Reporting of adverse drug events can lead the FDA to require modifications in product packaging, changes in package inserts and promotional materials, and widespread dissemination of information through letters to health care workers and published alerts.¹

USP: medication errors. U.S. Pharmacopeia (USP) also offers confidential, internet-accessible (www.usp.org) reporting:

1. MedmarxSM, for hospital reporting and tracking of medication errors. During 2001, 368 hospitals subscribing to this program reported more than 105,000 medication errors; the data were analyzed and published for the benefit of all health care workers. Hospital subscription information is available from USP's Customer Service Department, 12601 Twinbrook Parkway, Rockville, MD 20852, or by calling 800-227-8772.
2. Medication Errors Reporting System, for any health care worker who encounters actual or potential medication errors. To report errors, workers can call 800-233-7767; email the USP's Practitioners' Reporting Network at prn@usp.org; or print the reporting form from www.usp.org and submit it online or fax it to 301-816-8532. USP forwards the data to the FDA and product manufacturers.

CDC: infections and vaccine adverse events. Acute care hospitals should make confidential reports of hospital-acquired infections to the National Nosocomial Infections Surveillance System, Centers for Disease Control and Prevention (CDC); see www.cdc.gov/ncidod/hip/NNIS/members/forms.htm

Adverse events associated with vaccinations should be reported to the CDC's Vaccine Adverse Events Reports System, P.O. Box 1100, Rockville, MD 20849-1100, which also forwards the reports to the FDA.⁵⁰ A reporting form can be obtained at www.vaers.org or by calling 800-822-7967.

Why Events Are Underreported

Results of medical services studies suggest that incident reports are submitted for only 1.5% of all adverse events.⁴² In fact, since January 1995, only 1,918 reviewable sentinel events have been reported to JCAHO's database.⁵¹

Health care workers are often silent regarding errors because they perceive a connection between reporting and medical liability. They are skeptical about the confidentiality of reporting systems, and whether persons who make reports will be shielded from legal exposure. In many states, critical incident reporting and analysis are considered legally protected, peer review activities; however, other states offer little or no protection.⁴²

Improving Reporting

Health care workers are more likely to report medical errors if they are:

1. Assured of confidentiality.
2. Protected from legal liability resulting from such reports.
3. Not unduly burdened by the effort involved in making reports.
4. Provided with timely feedback on the results of the reporting system's data analysis.¹

Procedures that may increase medical error reporting include:

1. Implementing additional anonymous or nonpunitive reporting systems.
2. Maintaining cultures conducive to reporting within health care facilities.
3. Actively soliciting physician reporting (e.g., direct physician interviews, supplemented by email reminders to increase detection of adverse events).⁴²

The success of reporting systems will depend in large part on whether health care facilities use the data to fuel institutional quality improvement, instead of using it to generate individual performance evaluations.⁴²

Informing Patients

As stated in the *VHA National Patient Safety Improvement Handbook*, "telling patients that their health has been harmed rather than helped by the care provided is never easy." Each health care facility must have in place a procedure for promptly informing patients and their families about adverse events, as well as measures being taken to minimize the impact of such events.³

Chapter Summary

1. The goals of voluntary and mandatory reporting of adverse events are to analyze the data and identify ways to prevent future errors from occurring.
2. As of 2002, 20 states had passed laws on mandatory medical error reporting (mainly by hospitals), and 5 states plus the District of Columbia had passed laws on voluntary reporting of medical errors. These statutes differ from state to state.
3. The Food and Drug Administration (FDA) mandates that: (a) transfusion services, biologic product manufacturers, and registered blood establishments report adverse events associated with biologic products; (b) drug manufacturers, distributors, and packers report adverse drug events; and (c) "user facilities" report medical device-related deaths and serious injuries.
4. Programs for voluntary reporting of medical errors include: (a) sentinel events, to the Joint Commission on the Accreditation of Healthcare Organizations; (b) adverse drug events, to the FDA's Center for Drug Evaluation and Research and MedWatch program, and U.S. Pharmacopeia's MedmarxSM and Medication Errors Reporting System; (c) hospital-acquired infections, to the Centers for Disease Control and Prevention's (CDC's) National Nosocomial Infections Surveillance System; and (d) vaccine adverse events, to the CDC's Vaccine Adverse Events Reports System.
5. Health care workers are more likely to report medical errors if they are: (a) assured of confidentiality; (b) protected from legal liability; (c) not overburdened by the report-making procedures; and (d) provided with timely feedback on data analysis.

Chapter 4 Root Cause Analysis

The goals of a root cause analysis (RCA) are to determine: (1) what happened; (2) why it happened; and (3) what can be done to prevent it from happening again.⁵² Any health care facility can develop and use a structured RCA to carefully analyze adverse events (particularly sentinel events), correct faulty systems and procedures, and thereby prevent errors and near misses. An RCA's cardinal tenet is to avoid the pervasive and counterproductive culture of individual blame for medical errors.⁵³ An RCA is not used for intentional acts of wrongdoing; these are immediately addressed with administrative actions.

Mandatory RCAs

Any health care facility can voluntarily perform an RCA following an adverse event or near miss. However, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requires its member institutions to perform RCAs for the types of reported sentinel events that it reviews (*see Chapter 3 for examples of JCAHO-reviewable sentinel events*). Currently, 80% of sentinel events made known to JCAHO are self-reported by institutions; 20% are discovered through other sources such as the media.⁴⁷ An RCA (including an action plan) must be submitted to JCAHO within 45 days following the discovery of a sentinel event, and failure to perform and submit a satisfactory RCA places health care facilities and organizations at risk for loss of their accreditation.⁴⁷

RCAs are time-consuming and labor intensive. Once a sentinel event has been identified for analysis, a multidisciplinary team is assembled to direct the investigation. The team members should be trained in the techniques and goals of RCAs.⁵³

The RCA Process

To be thorough and credible, an RCA must:

1. Involve the persons most familiar with the adverse event, experts from frontline services and other disciplines, and leadership of the facility.
2. Be as impartial as possible. Human factors should be determined, but the primary focus should be on related systems and processes rather than individuals' performance.

3. Continually dig deeper by asking why at each level of cause and effect.
4. Identify risks and their potential contributions.
5. Identify improvements and changes that need to be made in systems or processes.⁵²

To determine what happened, an RCA team must do structured interviews, review documents, and/or make field observations—progressing from special causes in clinical processes to common causes in organizational processes. Using the data collected, the team determines the sequence of events preceding and following the sentinel event, and the common underlying factors of the sequence.⁵³ Each human error or procedural violation has a preceding cause, and root cause statements must clearly show the “cause-and-effect” relationship. Negative descriptors (e.g., inadequate or careless) should not be used in these statements, and it should be remembered that failure to act is a root cause only when there is a preexisting duty to act.^{3,52}

Lastly, the RCA team summarizes the underlying causes and their relative contributions, and identifies administrative and systems problems that need redesign.⁵³ The facility or organization then implements a corrective action plan, evaluates it, and updates its patient safety information system.³

An RCA template. Any health care facility can use or modify for its purposes JCAHO's step-by-step template for performing an RCA (available at www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/forms+and+tools/rca-word-framework.doc). Examples of the kinds of questions on JCAHO's RCA template are:

1. What happened?
The RCA team must obtain a complete description of the sentinel event.
2. When and where did it happen?
The RCA team must determine the date, day, and time of the sentinel event, and the location in which it occurred.
3. During what activity or process did the sentinel event occur, and which steps in that activity or

process were involved in the event?
For example, if the RCA team suspects that an adverse event is related to epinephrine unavailability or use of outdated epinephrine, it can refer to the facility's inventory-tracking checklist to determine whether a step was missed or if the existing process is flawed. Table 4 is a suggested inventory-tracking checklist that outpatient clinics might use to ensure that

- emergency epinephrine 1:1000 is always available.
4. Which human, equipment, controllable environmental, or uncontrollable external factors were involved in or relevant to the sentinel event or its outcome?
For example, the RCA team should determine if the health care staffing level was adequate, and if equipment performance affected the outcome.
 5. How well do the facility's health care workers communicate, and is risk identification a high-priority goal of the facility's culture?
The RCA team should determine if lack of either health care worker communication or risk identification was involved in the outcome.

Weekly check made (date)	Number used this week	Quantity left in stock	Shelf life	Expiration date	Order was placed on (date)	Order was received on (date)
02-03-03						
02-10-03						
02-17-03						
02-24-03						

What an RCA Can Reveal

Chassin and Becher⁵⁴ recently reported the results of an RCA analysis showing that 17 distinct errors interacted to cause one “wrong-patient” adverse event:

A 67-year-old woman, admitted to a hospital for cerebral angiography, was mistaken for another patient with a similar name who needed an invasive cardiac electrophysiology study. After 1 hour into the electrophysiology study, health care workers realized they had the wrong patient, and aborted the procedure.

In summary, the series of errors began with a nurse's use of only the patient's last name (no other identifying information) when she telephoned another department to have a patient transported to the electrophysiology laboratory. Despite the facts that the nurse receiving the telephone call had no written order for the procedure and the patient stated that she was unaware of plans for it, the nurse transported the patient to the laboratory. This patient had not signed a consent form for the procedure, and four nurses, an electrophysiology attending, and an electrophysiology fellow failed to verify her identity. By the time a radiology attending went to the patient's room,

discovered it was empty, and asked why she was undergoing an unscheduled procedure, the electrophysiology fellow had already inserted femoral sheaths and begun stimulating her heart via an intracardiac electrophysiology catheter. Fortunately, the procedure was aborted at this point, and the patient was returned to her room in stable condition.

As a result of its RCA, the hospital formulated a corrective action plan that included the following:

1. Hospital-wide, it required that:
 - Patients not leave their floors for tests and procedures unless there are written orders in their charts authorizing them.
 - Nurses match patients' full names, medical record numbers, and dates of birth before releasing patients in response to telephone calls from procedural areas.
2. In its cardiology laboratory, it required that:
 - Patients' names be matched with their dates of birth or medical record numbers on the internal email schedule.

- Patients' identities be thoroughly verified (e.g., verifying patients' names and wristbands, written orders, reasons for procedures, and matching wristbands to schedules and medical records).⁵⁴

Creating a Culture of Safety

RCAs play a vital role in reducing adverse events, but health care workers involved in such events worry about potential job loss and humiliation, and organizations are wary of legal implications of disclosure of the events and RCA results.^{47,53} Therefore, JCAHO has collaborated with widely recognized patient safety experts to implement additional standards that will encourage organization leaders to "create a culture of patient safety," emphasizing the needs for teamwork and effective communications among responsible caregivers. Findings from the Sentinel Event Database indicate that communication breakdown is the most common underlying causative factor involved in all types of sentinel events.

The standards also create new prospective analysis requirements, using Failure Mode and Effects Analyses. These are expected to create learning and preventive opportunities without the actual experiences of adverse events.⁴⁷

Chapter Summary

1. The goals of a root cause analysis (RCA) are to determine: (a) what happened; (b) why it happened; and (c) what can be done to prevent it from happening again, while avoiding the counterproductive culture of individual blame for medical errors.
2. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requires its member institutions to perform an RCA for reported sentinel events that it considers reviewable.
3. A credible RCA should be focused on systems and processes related to the adverse event, not on individuals' performance.
4. The RCA team must continually dig deeper by asking why at each level of cause and effect.
5. When RCA findings determine a need for system redesign, the facility develops a corrective action plan, which it implements and evaluates.
6. A step-by-step template for performing an RCA is available at www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/for+ms+and+tools/rca-word-framework.doc
7. The RCA team investigating a sentinel event must determine: (a) what happened; (b) when and where it happened; (c) during what activity or process it occurred, and which steps in the activity or process might have been involved; and (d) if human, equipment, or environmental factors were involved.
8. JCAHO encourages health care organization leaders to "create a culture of patient safety."

Chapter 5 Error Reduction & Prevention

Use of appropriate safety practices can reduce the risk of adverse events related to patient exposure to medical care across a wide range of diagnoses, diseases, and conditions.⁵⁵

Reducing System Errors

In its report, “To Err is Human,”⁴ the Institute of Medicine recommends principles to be followed in the design of safety systems in health care facilities; these include:

1. Making patient safety a priority objective and the responsibility of all staff members.
2. Providing the necessary financial and human resources for medical error analysis and systems redesign.
3. Designing jobs for safety (e.g., by dealing with the effects of work hours, workloads, staff distractions, and staffing ratios), and redesigning the workplace to reduce the error possibilities (e.g., by providing lower beds for persons at risk for falls).
4. Avoiding reliance on health care workers' memories (e.g., by establishing protocols, standardizing work processes, and using checklists, dosing cards, and drug-interaction software).
5. Using work constraints (e.g., pharmacy computers that will not fill a child's prescription unless the patient's weight is entered) and special barriers (e.g., locks that prevent infusion of fluid until syringes and indwelling lines match).
6. Avoiding reliance on human vigilance (e.g., by using automation, checklists, and rotating workers who perform repetitive tasks).
7. Simplifying key processes (e.g., by decreasing multiple order and data entry).
8. Training in teams those staff members expected to work in teams.
9. Creating a learning environment within health care facilities and organizations by:
 - Promoting staff communication.
 - Encouraging reporting of medical errors and hazardous conditions, and ensuring no reprisals for such reporting.
 - Making sure that all health care workers have easy access to:

—MedWatch safety alerts for drugs, biologic products, devices, and dietary supplements (available at www.fda.gov/medwatch/safety.htm), and

—Sentinel Event Alerts (available at www.jcaho.org), which describe specific sentinel events, lessons learned from root cause analyses of the events, and steps that health care facilities and organizations can take to avoid the occurrence of such events in their own settings.⁴⁷

Learning About the Patient

All types of health care facilities are obligated to take thorough patient histories before initiating treatment, except in life-threatening emergencies. Whether history taking involves a clinical interviewer who records patients' responses or having patients write answers on a questionnaire, the questions should include at least those concerning:

1. All medications and supplements patients are currently taking, and allergies or previous adverse reactions to any drugs.
2. Past and present history of cardiovascular, pulmonary, carcinogenic, hematologic, endocrine, gastrointestinal, genitourinary, neurologic, and skin/musculoskeletal diseases.
3. Lifestyle and habits, such as use of alcohol, tobacco, or illegal drugs, and unintentional weight gain or loss.
4. Pregnancy status and family violence.
5. Whether the patients wish to talk to the physician, dentist, or other clinician privately.

Patients' answers to history-taking questions often serve as “red flags,” signaling that special precautions must be taken when providing treatment.

High-Priority Safety Practices

After reviewing 79 medical practices likely to improve patient safety, University of California (San Francisco) researchers considered the following to need the most widespread implementation:

1. Appropriate use of prophylaxis against venous thromboembolism (VTE)—occlusion within the venous system—in at-risk patients (e.g., those over

age 40 who are undergoing major surgery and have an underlying hypercoagulable state, prior VTE, or cancer, as well as those undergoing hip or knee arthroplasty or hip fracture surgery).⁵⁶

2. Use of perioperative beta-blockers for patients at high risk for cardiac events during noncardiac surgery. Myocardial events occur in 2% to 5% of patients undergoing noncardiac surgery and as many as 30% of patients undergoing vascular surgery; mortality is nearly 60% per perioperative cardiac event.⁵⁷
3. Appropriate use of antibiotic prophylaxis in surgical patients. An antimicrobial agent is administered just before an operation begins (timed so that a bactericidal concentration is present in serum and tissues by the time the skin is incised) to reduce intraoperative microbial contamination to a level that will not overwhelm host defenses and result in infection. Therapeutic levels in serum and tissues should be maintained until a few hours after the incision is closed in the operating room.⁵⁸
4. Removal of pooled, contaminated oropharyngeal secretions above the endotracheal tube cuff via suctioning of the subglottic region to prevent ventilator-associated pneumonia.⁵⁹
5. Use of pressure-relieving bedding materials to prevent pressure ulcers.⁶⁰
6. Patient self-management of warfarin, to achieve appropriate outpatient anticoagulation and prevent complications.
7. Appropriate provision of nutrition, with an emphasis on early enteral nutrition in critically ill and surgical patients.
8. Preventing infections and complications during insertion of central venous catheters (CVCs) via: (a) use of real-time ultrasound guidance, which provides visualization of the desired vein and surrounding anatomic structures;⁶¹ (b) wearing of maximum sterile barriers (i.e., sterile gloves, long-sleeved gowns, a mask, and a full-size drape); and (c) use of antibiotic-impregnated CVCs in critically ill or immunocompromised patients requiring short-term catheterization (i.e., 2 to 10 days).⁶²
9. Asking patients to recall and restate what they have been told during the informed consent process (see *Informed Consent in Chapter 6*).

Preventing Diagnostic Errors

Radiographs. Misinterpretation of radiographic studies often causes medical errors in both inpatient and outpatient facilities. Fewer than 20% of hospitals have full-time, on-site, board-certified radiologists. The

American College of Radiology recommends that—when interpretation can be delayed without harm to patients—all imaging procedures culminate in written, expert opinions from radiologists or other licensed physicians specifically trained in diagnostic radiology.⁶³

Laboratory tests. An Agency for Healthcare Research and Quality study found that use of a computerized reminder system to alert physicians to the proper timing of repeat tests can reduce the number of patients subjected to redundant laboratory tests.^{19,64}

Preventing Treatment Errors

Surgery. The New York State Department of Health's guidelines for preventing wrong-site surgery, wrong procedures, and wrong-patient surgery recommend the following:

1. Enhanced communication among surgical team members, and between surgeons and patients.
2. Three independent verifications of the surgical site, location, and correct patient identification. As one of these verifications, the surgeon of record should mark or unequivocally identify the body site and/or side prior to surgery. The facility should determine the marking technique.
3. The attending of record should sign the consent form prior to the induction of anesthesia, confirming the document's accuracy, including the description of the procedure.
4. Whenever possible, the surgeon of record or his/her designee should see and talk to the patient in the perioperative area on the day of surgery.
5. When laterality (the procedure is specific to one side of the body) is at issue, the words *right* or *left* should be entirely spelled out on the operative schedule and the operative consent form.
6. For operating room settings (for other settings, use appropriate personnel), the circulating nurse will ensure that the:
 - Correct patient is present.
 - Surgeon of record signed the consent form on the day of surgery.
 - Appropriate body site or side has been identified or marked for surgery.
 - Surgeon has determined and selected for display appropriate and relevant radiologic films for the procedure.
 - Surgeon(s), anesthesia personnel, and circulating nurses have agreed on the planned procedure, and that this verification has been documented in the patient's medical record.⁶⁵

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also recommends:

1. Involving the patient in marking the surgical site.
2. Using a verification checklist that includes, for example, the patient's x-rays or imaging studies and medical records.
3. Having each surgical team member orally verify the patient, surgical site, and procedure in the operating room.²²

Blood transfusions. JCAHO recommends that health care workers use at least two patient identifiers (neither to be the patient's room number) whenever administering blood products or medications.⁶⁶

Diathermy treatments. The Food and Drug Administration (FDA) reports that patients with implanted metallic lead risk serious injury or death if exposed to diathermy treatments (i.e., therapeutic generation of heat within tissue via high-frequency current). For example, a patient died after receiving diathermy following oral surgery, because the interaction of the diathermy with the implanted device caused severe brain damage in the area of implanted lead electrodes. Both shortwave and microwave diathermy, in both heating and nonheating modes, can cause this interaction, and should not be used on patients who have any implanted metallic lead, or implanted device that may contain lead (e.g., cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, and spinal cord stimulators). Clinicians should also not administer shortwave or microwave diathermy therapy to patients who have had implants in the past, unless absolutely certain that both the implants and all lead have been entirely removed (lead often remains after implant removal). The FDA does not expect ultrasound diathermy to produce the adverse interaction.⁶⁷ (Electrocautery devices were not included in the report.)

Preventing Medication Errors

Table 5 provides tips on preventing medication errors. Additional tips, most of which apply to patients of all ages, appear in *The Journal of Pediatric Pharmacology and Therapeutics*, 2001;6:426-442.²⁶

U.S. Pharmacopeia (USP) recommends that all health care facilities implement nonpunitive medication error reporting programs, such as USP's nationwide MedmarxSM, so health care workers can learn from others. Health care facilities should also:

1. Educate their staff on appropriate practices for safely providing medications for patients.^{27,29}
2. Implement strict protocols for administering and dispensing high-alert medications (see *Medication Errors in Chapter 2*), and purchase unit-dose medications and pre-mixed intravenous solutions.²⁷
3. Store drugs with confusing names out of order alphabetically, or put them in alternate locations.³⁰
4. Maintain a list of the medications kept within the facility, identifying look-alike and sound-alike drugs as "high risks for drug mix-ups."³⁰
5. Design workflow in a manner that improves staff communication and minimizes distractions and interruptions.²⁹
6. Automate the medication process through the use of patient photo identification on wristbands, and computerized systems such as those discussed below.²⁷

Computerized systems. Health care systems must garner both financial and organizational support before introducing these systems, if they are to be successfully implemented and used.⁶⁸ The Department of Defense and Department of Veterans Affairs (VA), serving over 11 million patients nationwide, are implementing computerized physician order entry (CPOE) systems.¹ The State of California recently enacted legislation stipulating that acute care hospitals implement information technology such as CPOE to reduce medication-related errors. CPOE refers to a variety of computer-based systems for ordering medications; basic CPOE ensures standardized, legible, complete orders by only accepting typed orders in a standard and complete format. Most CPOE systems include or interface with clinical decision support systems (CDSSs). Basic clinical decision support includes suggestions or default values for drug doses, routes, and frequencies; more sophisticated CDSSs can perform drug allergy checks, drug-laboratory value checks, and drug-interaction checks.⁶⁸

For dental professionals, the July 2002 *Dental Clinics of North America* includes Umar's discussion of computer-aided CDSSs that can reduce the likelihood of human error during dental treatment.⁶⁹

Table 5. Tips on Preventing Prescription Medication Errors

Actions	Preventative measures
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Writing prescriptions	<ul style="list-style-type: none"> • Make sure that each medication order has both the generic and brand names (not abbreviated) for the drug ordered.³⁰ For children, always include the date of birth and current weight.²⁶ • Avoid using dangerous abbreviations, including units of measure and abbreviated directions for administering the medication (see Chapter 2, Table 2, for a list).³³ • Round out dose amounts to avoid the use of decimals.¹³ Do not place a decimal and a trailing zero after whole numbers (e.g., write 2 mg, <u>not</u> 2.0 mg). However, when a decimal expression is less than a whole unit, use a leading zero (e.g., write 0.2, <u>not</u> .2).^{26,33} • Include the purpose of the drug, so the pharmacist can screen the order for proper drug, dosage, and duration, and can intervene when multiple prescribers unknowingly order duplicate therapy.³⁰ • Describe how dosage calculations were performed (e.g., pediatric doses are often based on milligrams of medicine/kilogram of body weight, which requires converting each child's weight from pounds to kilograms) so pharmacists or persons administering drugs can recheck them.¹³ Calculate the dosage using validated computer-based algorithms, or always have manual calculations double-checked.³⁷
Communicating prescriptions	<ul style="list-style-type: none"> • When giving verbal prescription orders, ask pharmacists to clearly repeat them in their entirety (i.e., the drug's name, its correct spelling, the dosage, and any other instructions for the patient), or carefully reiterate the entire order to the pharmacist.³⁰ • Minimize verbal medication orders; require that most orders be written or entered electronically.²⁹
Dispensing prescriptions	<ul style="list-style-type: none"> • In hospitals, increase the number of pharmacists in all patient-care areas.^{27,29} • Implement strict protocols for dispensing high-alert medications, and purchase unit-dose medications and pre-mixed intravenous solutions²⁷ [e.g., because patients have died after being directly infused with concentrated potassium chloride (KCl) available in nursing units, JCAHO recommends that this product and other concentrated electrolytes be available only in hospital pharmacies, unless appropriate, specific safeguards are in place].^{34,66}

The VA has also implemented computerized medical records in all of its 172 hospitals, making it possible to provide complete information about patients at the point of care. It has also begun to use bar code technology for blood transfusions and medication administration (e.g., a hand-held, wireless bar-coding system has reduced medication errors by 70% at relatively low cost at VA health care facilities.)¹

Also available are computerized adverse drug event (ADE) alert monitors that use rule sets to search for drug names, and laboratory levels or drug-laboratory interactions that frequently reflect an ADE. The information captured with these monitors is used to alert a responsible clinician, who can then change therapy based on the issue in question. It is also useful for pharmacists.⁷⁰

Anesthesia. Twenty-two percent of anesthesia adverse events are related to failure to check anesthesia equipment adequately.⁷¹ The FDA's 14-item anesthesia apparatus checkout list is available at: www.fda.gov/cdrh/humfac/anesckot.pdf⁷² The FDA list is a template that health care facilities can modify to accommodate differences in equipment and variations in their practices.

Medical oxygen. To prevent patient deaths caused by medical gas mix-ups, the FDA recommends that:

1. Health care facilities receiving cryogenic vessel deliveries store medical-grade gases separately from industrial-grade gases.
2. All personnel handling medical gas vessels should be trained to:
 - Recognize the various gas vessel labels and to examine them carefully.
 - Make sure each vessel they connect to the oxygen system bears a 360° wrap-around label designating *medical oxygen*, if that is the kind of label their suppliers use.
 - Properly connect medical gas vessels to the oxygen supply system, and never change the fittings on these vessels.
3. Verification be made (by a knowledgeable person) that the correct vessel is connected to the oxygen system, prior to introduction of the gas into the system.^{8,40}

Avoiding Medical Device Errors

Ventilator use. To prevent deaths and injuries associated with ventilator use, JCAHO recommends:

1. Ensuring effective staffing for ventilator patients at all times (to allow direct observation of such patients, instead of overdependence on alarms).

2. Implementing regular preventive maintenance and testing of alarm systems.
3. Ensuring that alarms are sufficiently audible with respect to distances and competing noise within health care units.⁴¹

Drug-administering devices. The Institute for Safe Medication Practices recommends that clinicians and pharmacists teach parents how to properly use devices they must use to administer medicine to their children. In one reported case, a parent was not told that the cap on the nozzle of a syringe had to be removed before use of the syringe. The man was able to draw antibiotic into the syringe with the loosely fitting cap still on; however, when he put the nozzle into his baby's mouth to administer the antibiotic, the cap popped off, and the baby was asphyxiated.¹³

CT radiation. The FDA reports that pediatric and even small adult patients may sometimes receive more radiation than needed to obtain diagnostic computed tomography (CT) images. To prevent this exposure, the FDA recommends that health care workers:

1. Eliminate inappropriate referrals for CT scanning [e.g., magnetic resonance imaging (MRI) systems deliver no x-ray radiation].
2. Reduce the number of multiple scans with contrast material.
3. Optimize CT settings (i.e., adjust CT scanner parameters appropriately for each individual's weight and size, and the anatomic region being scanned; *for details, see the cited reference*).⁷³

Chapter Summary

1. System errors can be reduced by making patient safety a priority of all staff members; designing jobs for safety; redesigning the workplace when necessary; and promoting staff communication, error reporting, and familiarity with safety alerts on drugs and sentinel events.

2. Taking a thorough medical history prior to administering medications or other kinds of treatment to patients is an important step in preventing medical errors.
3. High-priority safety measures include appropriate: (a) prophylaxis against venous thromboembolism; (b) antibiotic prophylaxis in surgical patients; (c) use of perioperative beta-blockers; and (d) patient self-management of warfarin use.
4. Ways to prevent diagnostic errors include: (a) having radiologists provide written opinions on x-ray results, instead of persons not trained in diagnostic radiology; and (b) alerting physicians to the proper timing of repeat laboratory tests via computerized reminder systems.
5. Preventing wrong-site or wrong-patient surgery and wrong procedures involves: (a) enhanced surgical team-patient communication; and (b) oral, written, and marked verifications of the correct surgical site and patient.
6. Neither shortwave nor microwave diathermy should be used on patients who have any implanted metallic lead, or implanted device that may contain lead.
7. Preventing medication errors involves: (a) educating health care workers on standardized methods of storing, prescribing, dispensing, and administering drugs; (b) improving staff communication; (c) minimizing distractions and interruptions; and (d) automating the medication process. It also involves implementation of the safety tips described in Table 5.
8. Health care workers should follow the Food and Drug Administration's (FDA's) 14-item list for checking out anesthesia equipment, as well as the FDA's recommendations on the handling of medical oxygen vessels.
9. Clinicians and pharmacists should teach parents how to properly use the devices used at home to administer medicine to children.
10. To avoid exposing pediatric patients to more radiation than needed during computed tomography (CT), health care workers should optimize CT settings as recommended by the FDA.

Chapter 6 Patient Safety

Pediatric Patients

U.S. Pharmacopeia recommends that parents take the following steps to help prevent medication errors involving their children:

1. Provide all hospital and outpatient health care workers responsible for the child's care with a list of all drugs and dietary supplements the child is taking, and alert them to any allergies the child has. Children who have life-threatening allergies should wear a MedicAlert bracelet at all times.
2. Confirm with health care workers that the child's medication dosage is correct (i.e., the child's weight in pounds must be divided by 2.2 to convert his/her weight into kilograms).
3. Notify health care workers if the child, whether hospitalized or outpatient, has any negative side effects from administered drugs.
4. Provide the child's school with a list of the child's allergies or other medical conditions, in case an emergency arises during school hours.³⁷

Educating Patients

When educating patients, health care workers should consider any cognitive, developmental, or degenerative changes that might hamper patients' learning. If patients have such problems, health care workers should include family members in the educational process, so they can provide:

1. Clear nontechnical information about the patients' illnesses, prescriptions, and treatments.
2. Telephone numbers where they can be reached if further questions arise.

If patients have language barriers (e.g., English as a second language), health care workers should:

1. Obtain an interpreter or ask patients to bring an English-speaking family member.
2. Provide written materials in the primary language of patients, if possible.
3. Make sure written material is in easy-to-understand, nontechnical language.
4. Ask patients or their family members to repeat what has been taught.
5. Clarify any areas of misunderstanding.

Informed Consent

The process of obtaining informed consent (legally required in all states) is a means of ensuring that patients understand the risks and benefits of a treatment or medical intervention. However, consent is often not truly "informed," because only about 50% of the U.S. population understands commonly used medical terms, and procedures used to obtain informed consent often do not adequately promote patients' comprehension of the information provided. Methods that Pizzi et al.⁷⁴ suggest to improve and ensure patients' understanding include:

1. Reducing the complexity, and improving the readability, of consent forms, and providing consent forms in the primary language of patients.
2. Providing written materials, drawings, and diagrams to accompany oral conversations.
3. Using multimedia (e.g., videotapes).
4. Asking patients to recall and restate the key elements of discussions about planned procedures, including their risks and benefits.⁷⁴

Patient Participation

Informed, involved patients are more likely to accept their physicians' choices of treatment and to help make the treatment work. Table 6 describes ways in which patients can be active members of their health care teams, and take part in decisions about their health care.^{75,76} Patients can learn about their medical conditions and treatments by asking their clinicians and by using other reliable sources (e.g., www.guideline.gov provides current National Guideline Clearinghouse information).

Chapter Summary

1. Parents should make sure that all health care workers treating their children know what drugs and dietary supplements their children are taking, as well as allergies their children may have.
2. Medical errors can be reduced only through a team approach that includes health care workers, patients, and health care organizations.
3. Communication and education are key factors in a safe health care process.

Table 6. Safety Tips for Patients

Regarding:	Patients should:
Medicines	<ol style="list-style-type: none"> 1. Make sure that all their physicians, dentists, and other clinicians have an up-to-date list of all prescription and over-the-counter drugs, and dietary supplements (e.g., vitamins and herbs) they are taking. At least once a year, patients should “brown bag” their medicines and supplements and take them to their clinicians’ offices, discuss the use of them, and make sure they are listed in their medical records. 2. Make sure their health care providers and pharmacists know about any allergies and adverse reactions they have had to medicines, herbs, or foods. 3. Make sure they can read any prescriptions that clinicians write, before leaving clinics. If patients cannot read handwritten prescriptions, it is likely that pharmacists will have the same problem. 4. Ask both prescribing clinicians and dispensing pharmacists: <ul style="list-style-type: none"> • What is the medicine for? • How is it to be taken, and for how long? • What side effects are likely, and what should be done if they occur? • Is the drug safe to take with other medicines and dietary supplements currently taken? • What foods, drinks, or activities should be avoided while taking this medicine? 5. Ask the pharmacist, when picking up the drug: <i>Is this the medicine that my doctor prescribed?</i> About 88% of medicine errors involve the wrong drug or dose, according to a Massachusetts College of Pharmacy and Allied Health Sciences study.⁷⁵ Alerting pharmacists to the medical conditions being treated also helps ensure that prescriptions are interpreted and filled correctly. 6. Ask their pharmacist about any unclear directions on the medicine label; for example, does “four doses daily” mean taking a dose every 6 hours around the clock, or just during regular waking hours? Before leaving pharmacies, patients should make sure they have printed directions for taking their prescriptions. 7. Ask their pharmacist about the best device to use for measuring liquid medicine, if unsure. Many persons use household teaspoons, which may hold from 3 to 7 milliliters; marked devices are more accurate. 8. Make sure they have printed information about the prescribed drug’s side effects and its potential adverse interactions with other drugs. If patients can recognize when they are suffering adverse side effects, they can report them right away and get help before these reactions get worse. 9. Be sure they know how to correctly use devices (e.g., inhalers) required to administer certain medicines. If possible, patients should practice using the device in front of the prescribing clinician.
Hospital stays	<ol style="list-style-type: none"> 1. Choose, if possible, hospitals at which many patients have undergone the needed procedure or surgery. 2. Consider asking all health care workers to wash their hands before providing direct-contact treatment. 3. Make sure that they and their physicians and surgeons agree and are clear on exactly what surgery will be done. Wrong-site surgery is 100% preventable (e.g., the American Academy of Orthopaedic Surgeons urges its members to sign their initials directly on the site to be operated on, before the surgery). 4. Ask physicians to explain the home treatment plan before being discharged from a hospital.
Medical treatment in general	<ol style="list-style-type: none"> 1. Speak up if they have questions/concerns. Patients have a right to question anyone involved in their care. 2. Make sure that someone, such as their primary physician, is in charge of their care. This is especially important if patients have many health problems or are in a hospital. 3. Make sure that all health care workers involved in their care have the necessary health information, and not assume that everyone knows everything (e.g., that they have heart disease or smoke). 4. Clearly identify themselves to health care workers. Patients should keep wearing identification bands (if issued), and, if they have common names, ask to have their birth dates checked in the records to reduce chances of mistaken identity. Hard-of-hearing patients should inform health care workers of this problem, and double-check that it is their name being called in offices and clinics. 5. Ask a family member/friend to be an advocate who can speak up, in case they need help. 6. Know that “more” is not always better. Patients should determine why tests or treatments are being done and how they will help them, as they might be better off without some procedures. 7. Make sure they know the results of tests, and ask what the results mean and if additional follow-up care is needed. Patients should not assume that “no news is good news.”

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