

Florida Medical Errors: Reporting and Prevention

2 contact hour - \$15

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Author: JoAnn O'Toole, RN, BSN

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This course meets the requirement—both for initial licensure and biennial renewal—for a two-hour course on prevention and reporting of medical errors for healthcare professionals in the state of Florida (Florida Statute 456.013).

Instructions

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Course Objectives

When you finish this course, you will be able to:

- Describe the impact of the Patient Safety Quality and Improvement Act on healthcare practices in the United States.
- Describe Florida laws and requirements related to medical errors.
- Outline the seven main classifications of medical errors.
- Describe factors and practices that increase the risk of committing a medical error.
- Discuss populations that are particularly vulnerable to the effects of medical errors.
- State several healthcare practices that will reduce medical errors and create a culture of safety.
- Describe the systems approach to medical errors.
- Discuss five commonly-used systems approaches that have been shown to be effective in the analysis and reduction of medical errors.

Introduction

“Patient safety could be considered the study of ‘medical error’ as a disease. The more complex care becomes, the stronger we make new medications and keep patients alive with intensive procedures, the higher the probability of side effects, complications, and errors. Errors range from problems like forgetting to prescribe a patient’s regular medication when they are admitted to the hospital, to dramatic mix-ups like sending the wrong patient for a major surgical procedure.”

Dr. Kaveh G. Shojania

Medical errors are a common occurrence in the healthcare industry. According to the landmark Institute of Health (IOM) report, *To Err is Human: Building a Safer Health System*, there are 44,000 to 98,000 deaths each year in the United States or at least 120 deaths per day because of human error related to the delivery of healthcare. It is estimated that there are 7,000 deaths each year from medication errors alone and that medication errors occur in one of every five doses given in hospitals. According to the IOM report, more people in this country die each year from preventable medical errors than from motor vehicle accidents, breast cancer, or AIDS.

After the IOM report, much attention was focused on the epidemic of medical errors. What could be done to reduce and ultimately rid the American healthcare system of these errors committed by incompetent and sleep-deprived healthcare providers? According to Wachter and Shojania (2004) in their book *Internal Bleeding* say, “the problem is relatively straightforward and could be solved if all errors were reported to newspapers and to regulators, bad-apple physicians and nurses were purged and sleep-deprived residents and interns were allowed to get a little shut-eye”. They contend that most errors are made by “good but fallible people” who are working within flawed systems and that the systems need to be fixed. “It’s as if we spent the last thirty years building a really souped-up sports car, but barely a dime or a moment making sure it has bumpers, seat belts, and airbags.”

Although prior to the 1999 publication of the IOM report virtually all healthcare organizations engaged in investigations of events that caused harm to patients, few took a systems-based approach to problem solving. The focus was on individuals and mistakes, rather than on the events that combined to cause an incident to occur. Based on a “name and blame” culture, the emphasis of such investigations was not on prevention, but on punishment (US Department of Veterans

Affairs, 2009).

The Patient Safety Act

Traditionally, patient safety improvement efforts have been hampered by fear of discovery, resulting in under-reporting of medical errors and an inability to collect sufficient data for analysis of adverse events. The Patient Safety and Quality Improvement Act of 2005 was enacted to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. The act signifies the federal government's commitment to fostering a culture of safety (AHRQ, 2008a).

The Patient Safety Act:

- Encourages the development of patient safety organizations (PSOs) that work with clinicians and healthcare organizations to identify, analyze and reduce the risks and hazards associated with patient care.
- Fosters a culture of safety by establishing strong federal confidentiality and privilege protections for information assembled and developed by provider organizations, physicians, and other clinicians for deliberation and analysis regarding quality and safety.
- Speeds the process for identifying the risks and hazards associated with patient care within a protected legal environment (AHRQ, 2008a).

By creating PSOs to collect and analyze confidential information reported by healthcare providers, organizations can identify patterns of failure and propose measures to eliminate patient safety risks. Many states, including Florida have creating PSOs with the goal of improving the safety of healthcare in their states.

Florida Laws and Requirements

Florida was one of the first states to recognize the link between medical malpractice, medical errors, and patient safety. In 2004, largely in response to the 1999 IOM report, the Florida legislature established the Florida Patient Safety Corporation (FPSC), whose purpose it is to monitor patient safety throughout the state.

In 2005, the Florida legislature provided funding to the FPSC to establish a voluntary Near Miss Reporting System (NMRS), based on a successful system used in the commercial aviation industry. The objective of the program was to establish a state-wide near miss reporting system that was timely, anonymous, standardized, and easy to use. An important part of the NMRS was to provide immunity from legal penalties and sanctions (Florida Patient Safety Corporation, 2008).

Unfortunately, in response to an ongoing budget crisis, funding for the FPSC was rescinded for fiscal year 2008-2009 and the near-miss reporting system was suspended indefinitely. The FPSC has been forced to curtail many of its activities and has asked that near-miss reports not be submitted until further notice.

Despite the loss of funding, the near-miss program has yielded some important information. Studying a near miss—in which no harm comes to the patient—allows researchers to examine factors that lead to medical errors and to explore a facility's culture of safety. Of particular importance is the observation that as many as 10 to 200 near misses occur for every actual medical error (FPSC, 2008).

Researchers have noted that certain types of near misses recur with distressing regularity, largely due to the absence of facility-wide efforts to address the underlying cause of the near miss. Many facilities apparently feel that if no harm occurred there is no reason to investigate.

In 2004, two state amendments were passed by Florida voters: the Patients' Right-to-Know about Adverse Medical Incidents Act, known as Amendment 7, and the Three Strikes and You Are Out Act, known as Amendment 8. These amendments were aggressively promoted by the Florida Trial Attorneys and their passage reversed many of the patient safety gains of the FPSC legislation.

Amendment 7 eliminated confidentiality provisions recommended by the near-miss reporting program. It allows full access to all patient records, including all meetings, morbidity and mortality conferences, root cause analyses, and any other professional exchanges of information related to a patient's injury or death. Upon first analysis, this seems like good thing but risk management professionals say Amendment 7 has done immense harm to quality assurance and peer-review protections developed over the last 20 years and caused an immediate decline in the reporting of adverse events throughout the state (Barach, 2005).

Amendment 8 also had an unintended chilling effect on the reporting of near misses and adverse events. It directs the Florida Board of Medicine to revoke medical licenses from providers who have had three "adjudicated malpractice incidents". A strike is considered "any malpractice judgment, findings from disciplinary cases, decisions of binding arbitration finding malpractice, and malpractice judgments from any other state" (Barach, 2005).

It is hoped that new federal Patient Safety Organization regulations issued by the Department of Health and Human Services in 2008 will help resolve the situation Florida finds itself in. The new regulations, which went into effect on January 19, 2009, "describe a clear, legally-protected framework for how hospitals, clinicians, and healthcare organizations can work together to improve patient safety and the quality of care nationwide," says AHRQ Director Carolyn M. Clancy.

The rule establishes a framework by which hospitals and healthcare providers may voluntarily report information to PSOs on a privileged and confidential basis. It provides final requirements and procedures for PSOs, new entities with which clinicians and healthcare providers can work to collect, aggregate and analyze data—within a legally secure environment of privilege and confidentiality protections—to identify and reduce patient care risks and hazards (AHRQ, 2008d).

In 2008 the Florida Patient Safety Corporation officially endorsed the "SorryWorks" Program as an effective method for addressing medical errors. The goal of the program is to establish a process that involves an initial disclosure, close contact with the patient and family, and a resolution that includes open communication. The main points are to disclose and compensate quickly when an error has occurred, vigorously defend medically appropriate care, and learn from mistakes. For more information visit: www.SorryWorks.net.

Florida Reporting Requirements

Thirty-nine states, including Florida, have mandatory or voluntary systems for reporting medical errors. Florida requires that all licensed healthcare facilities establish an internal risk management program that includes: 1) the investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients, and 2) the development of

appropriate measures to minimize the risk of adverse incidents to patients (Florida Legislature, 2008).

In addition, healthcare facilities in Florida must electronically report data on hospital-acquired infections to Agency for Healthcare Administration, as specified in regulations. Facilities in Florida must also submit annual reports to the Department of Health about adverse/sentinel events (State Health Facts, 2008).

Types of Medical Errors

There are many ways that medical care can go wrong. Errors can be related to the administration of medications, adverse drug reactions, laboratory testing, surgery, and improper use or failure of medical devices.

Adverse Drug Reactions

Adverse drug reactions (ADRs) are a leading cause of injury and death—it is estimated that they cause 7,000 deaths annually in the United States. According to the Institute of Medicine, more than 2 million serious ADRs occur each year, 350,000 in nursing homes alone. In recent years the number of medications prescribed to patients has increased dramatically and not surprisingly, adverse drug reactions have also increased. “Whereas a patient admitted to the hospital typically undergoes one—or even no—surgical procedure, virtually everyone gets bombarded with an array of medications the whole time they’re there” (Wachter and Shojanian, 2004).

There are three main causes for adverse reactions:

- As many as two-thirds of all patient visits to a doctor result in a prescription and there are more drugs and combinations of drugs being used than ever before.
- There were 2.8 billion outpatient prescriptions filled in 2001, equaling about 10 prescriptions for every person in the United States.
- Drug interactions increase exponentially when a patient is taking four or more medications (CDER, 2002).

The drug approval process may also play a role in the increase of adverse drug reactions. A drug that is tested in only a few thousand people may have an excellent safety profile in those patients. But some of these drugs require many more exposures to detect an adverse reaction—particularly reactions that occur in low frequency.

According a 2002 study, “Preventable Adverse Drug Reactions: A Focus on Drug Interactions”, most drugs are approved for use by the Food and Drug Administration (FDA) with an average of only 1,500 patient exposures and tested for relatively short period of time. Soon after entering the market, the drug may be taken by a few million patients and the low frequency adverse reactions can become a problem. For drugs that cause rare toxicity, the toxicity will only be detected after use by many more thousands of patients (CDER, 2002).

Systems Intervention

Many adverse drug reactions can be prevented and detected through the use of systems intervention. Tools such as computerized physician orders and prescription entry and bar coding systems have taken the guess work out of reading written prescriptions for nurses and pharmacists. Medication errors can potentially be reduced through the use of computerized medical records as well as drug-interaction screening software that detects and alerts the physician and pharmacist to potentially serious drug interactions.

Clinicians cannot rely solely on technology to prevent errors in prescribing and administering of medications. Incorporation of up-to-date computerized databases is invaluable, as is frequent consultation with other members of the healthcare team. Use of an organized, stepwise approach also helps prevent drug interactions. Use the “**AVOID Mistakes**” mnemonic to get all necessary information for the medication history:

Table 1: AVOID Mnemonic

Keyword	What to ask
Allergies	Ask the patient if there is any drug that should not be prescribed for any reason.
Vitamins or herbs	Ask the patient whether the patient is taking or has a reaction to any herb, vitamin, or “alternative” or “natural” product.
O ld drugs and O ver The Counter (OTC) drugs...in addition to all current drugs	Ask about old drugs (prescription and over the counter) and OTC drugs as well as current drugs the patient is taking. Some of these drugs may have relatively long-lasting effects (either toxicity or potential for drug interactions).
Interactions	Evaluate the potential for adverse drug interactions. Consider a behavioral contract between the physician and the patient to facilitate in an effort to help the patient reach the therapeutic goal, either in the case of drug dependence or adherence to a therapeutic regimen, with a clear plan.
Dependence potential	Is the patient drug dependent or at risk of dependence on, for example, opioids, benzodiazepines, alcohol, or other substances of abuse. Consider a behavioral contract between the physician and the patient to facilitate in an effort to help the patient reach the therapeutic goal, both in the case of drug dependence or adherence to a therapeutic regimen.
Mendel (genetics)	Genetics – Is there a family history of benefits from or problems with any drugs?

Anyone taking two or more medications is at risk for drug interactions. Categories of drugs that are considered very high risk for interactions include anticonvulsants, antibiotics, and certain cardiac drugs such as digoxin, warfarin and amiodarone. When a patient is taking multiple drugs use a systematic approach—such as the Stepwise Approach—to check for possible interactions.

Drug-Drug Interactions: A Stepwise Approach (CDER, 2002)

1. Take medication history. AVOID mistakes.
2. Remember high-risk patients.
 - Any patients taking two or more medications
 - Patients taking anticonvulsants, antibiotics, digoxin, warfarin, amiodarone, etc.
3. Check a current pocket or computer database reference guide.
4. Consult pharmacists/drug information specialists.

Reporting an Adverse Event

Because post-marketing surveillance of new drugs is so important, MedWatch, the FDA Medical Products Reporting Program, was established in 1993. The program has four general goals:

- Increase awareness of drug, device and other medical product-induced disease and the importance of reporting.
- Clarify what should not be reported—limit reporting to serious adverse reactions.
- Make it easy to report an adverse drug reaction to the FDA.
- Provide feedback to health professionals about new safety problems with pharmaceuticals and medical devices.

A postage-paid form is available in the back of the Physicians Desk Reference, from the FDA via the toll-free number 1-800-FDA-1088, or from the FDA/MedWatch website (www.fda.gov/medwatch).

Medication Errors

“When all types of errors are taken into account, a hospital patient can expect on average to be subjected to more than one medication error each day.”

Institute of Medicine, 2006

According to a 2006 Institute of Medicine report, *Preventing Medication Errors*, there are 1.5 million preventable adverse medication events in the United States each year costing as much as \$3.5 billion annually. The report notes that of the five steps involved in medication administration—procuring the drug, prescribing it, dispensing it, administering it, and monitoring its impact—errors occur most often during the prescribing and administration phases (IOM, 2006).

There is at least one death each day and 1.3 million people injured each year due to errors related to medication administration. It is estimated that medication errors occur in one of every five doses given in hospitals. Adverse drug events cause an estimated 700,000 emergency department visits each year (CDC, 2008a).

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 2007) urges medication error researchers, software developers, and institutions to use this standard definition to identify errors:

“A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

Some of the most common causes of medication errors are:

- Incomplete patient information (not knowing about patient allergies, other medicines they are taking, previous diagnoses, and lab results).
- Unavailable drug information (such as lack of up-to-date warnings).
- Miscommunication of drug orders that can include poor handwriting, sound-alike drug names, misuse of zeroes and decimal points, inappropriate abbreviations, and confusion of metric and other dosing units.
- Lack of appropriate labeling as a drug is prepared and packaged into smaller units.
- Environmental factors such as light, heat, noise, and interruptions that can distract clinicians from their medical tasks (CDER, 2008).

Currently, medication errors are reported to the FDA as manufacturer reports (adverse events resulting in serious injury and for which a medication error may be a component), direct contact reports (MedWatch) or reports from the United States Pharmacopeia (USP) or the Institute for Safe Medicine Practices (ISMP) (CDER, 2008).

Confusing Medication Names and Abbreviations

Drugs that are dispensed as the wrong medication underscore the need for clear interpretation and better communication between the doctors who write prescriptions and the pharmacists who fill them. Although errors occur at all levels of the medication use system, the FDA reports that about 10% of all medication errors reported result from drug name confusion (FDA, 2005).

Medication errors can occur between brand names, generic names and brand to generic names like Toradol and tramadol. But sometimes, medication errors involve more than just name similarities. Abbreviations, acronyms, dose designations, and other symbols used in medication prescribing also have the potential for causing problems (FDA, 2005).

For example, the abbreviation “D/C” means both “discharge” and “discontinue”. The national Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) notes that patients’ medications have been stopped prematurely when D/C—intended to mean discharge—was misinterpreted as discontinue because it was followed by a list of drugs (FDA, 2005).

Illegible handwriting, unfamiliarity with drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list can compound the problem. And, although some drug names and symbols may not sound or look alike, they could cause confusion when handwritten or communicated verbally (FDA, 2005).

To minimize confusion between drug names that look or sound alike, the FDA reviews about 400 brand names a year before they are marketed and about one-third are rejected. For example, the FDA changed a drug name after it was approved in 2005 because the diabetes drug Amaryl was being confused with the Alzheimer’s medicine Reminyl and one person died (FDA, 2005).

In order to prevent further confusion, the FDA recommends that physicians write prescriptions more clearly, print in block letters rather than cursive, avoid the use of abbreviations and indicate the reason for the drug. Pharmacists can help by keeping look-alike sound-alike products separated on pharmacy shelves, by avoiding stocking multiple product sizes together and by verifying doctor information that is not clear before filling a prescription (FDA, 2005).

The FDA and ISMP have launched a national education campaign to eliminate the use of ambiguous medical abbreviations that are frequently misinterpreted and lead to mistakes that result in patient harm. The campaign seeks to promote safe practices among those who communicate medical information (CDER, 2008).

The FDA recommends that clinicians review the ISMP’s List of Error-Prone Abbreviations, Symbols and Dose Designation (see References for URL). The following tables list the dangerous notations:

Table 2a - Abbreviations

Table 2b - Dose designations

Table 2c - Drug name abbreviations

Table 2d - Symbols

Table 2a: Dangerous Abbreviations (NCCMERP, 2007)

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as “mg”	Use “mcg”
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use “right ear,” “left ear,” or “each ear”
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use “right eye,” “left eye,” or “each eye”
BT	Bedtime	Mistaken as “BID” (twice daily)	Use “bedtime”
cc	Cubic centimeters	Mistaken as “u” (units)	Use “mL”
D/C	Discharge or discontinue	Premature discontinuation of medications if D/ C (intended to mean “discharge”) has been misinterpreted as “discontinued” when followed by a list of discharge medications	Use “discharge” and “discontinue”
IJ	Injection	Mistaken as “IV” or “intrajugular”	Use “injection”
IN	Intranasal	Mistaken as “IM” or “IV”	Use “intranasal” or “NAS”
HS	Half-strength	Mistaken as bedtime	Use “half-strength” or “bedtime”
hs	At bedtime, hours of sleep	Mistaken as half-strength	
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use “units”
o.d. or OD	Once daily	Mistaken as “right eye” (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use “daily”
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use “orange juice”
Per os	By mouth, orally	The “os” can be mistaken as “left eye” (OS-oculus sinister)	Use “PO,” “by mouth,” or “orally”
q.d. or QD**	Every day	Mistaken as q.i.d., especially if the period after the “q” or the tail of the “q” is misunderstood as an “i”	Use “daily”
qhs	Nightly at bedtime	Mistaken as “qhr” or every hour	Use “nightly”
qn	Nightly or at bedtime	Mistaken as “qh” (every hour)	Use “nightly” or “at bedtime”
q.o.d. or QOD**	Every other day	Mistaken as “q.d.” (daily) or “q.i.d. (four times daily) if the “o” is poorly written	Use “every other day”
q1d	Daily	Mistaken as q.i.d. (four times daily)	Use “daily”

Abbreviations	Intended Meaning	Misinterpretation	Correction
q6PM, etc.	Every evening at 6 PM	Mistaken as every 6 hours	Use "6 PM nightly" or "6 PM daily"
SC, SQ, sub q	Subcutaneous	SC mistaken as SL (sublingual); SQ mistaken as "5 every;" the "q" in "sub q" has been mistaken as "every" (e.g., a heparin dose ordered "sub q 2 hours before surgery" misunderstood as every 2 hours before surgery)	Use "subcut" or "subcutaneously"
ss	Sliding scale (insulin) or ½ (apothecary)	Mistaken as "55"	Spell out "sliding scale;" use "one-half" or "½"
SSRI	Sliding scale regular insulin	Mistaken as selective-serotonin reuptake inhibitor	Spell out "sliding scale (insulin)"
SSI	Sliding scale insulin	Mistaken as Strong Solution of Iodine (Lugol's)	
i/d	One daily	Mistaken as "tid"	Use "1 daily"
TIW or tiw	3 times a week	Mistaken as "3 times a day" or "twice in a week"	Use "3 times weekly"
U or u**	Unit	Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., 4U seen as "40" or 4u seen as "44"); mistaken as "cc" so dose given in volume instead of units (e.g., 4u seen as 4cc)	Use "unit"

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Table 2b: Error Prone Dose Designations (NCCMERP, 2007)

Dose Designations and Other Information	Intended Meaning	Misinterpretation	Correction
Trailing zero after decimal point (e.g., 1.0 mg)**	1 mg	Mistaken as 10 mg if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers
No leading zero before a decimal dose (e.g., .5 mg)**	0.5 mg	Mistaken as 5 mg if the decimal point is not seen	Use zero before a decimal point when the dose is less than a whole unit
Drug name and dose run together (especially problematic for drug names that end in "l", such asw Inderal 40 mg; Tegretol300mg)	Inderal 40 mg Tegretol 300 mg	Mistaken as Inderal 140 mg Mistaken as Tegretol 1300 mg	Place adequate space between the drug name, dose, and unit of measure
Numerical dose and unit of measure run together (e.g. 10mg and 100mL)	10 m g 100 mL	The "m" is sometimes mistaken as a zero or two zeros, risking a 10- to 100-fold overdose	Place adequate space between the dose and unit of measure
Abbreviations such asw mg. or ml. with a period following the abbreviation	Mg mL	The period is unnecessary and could be mistaken as the number 1 if written poorly	Use mg, mL, etc. without a terminal period
Large doses without properly placed commas	100,000 units 1,000,000 units	100000 has been mistaken as 10,000 or 1,000,000; 1000000 has been mistaken as 100,000	Use commas for dosing units at or above 1, 000 or use words such as 100 "thousand" or 1 "million" to improve readability

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Table 2c: Error Prone Drug Name Abbreviations (NCCMERP, 2007)

Drug Name Abbreviation	Intended Meaning	Misinterpretation	Correction
ARA A	vidarabine	Mistaken as cytarabine (ARA C)	Use complete drug name
AZT	zidovudine (Retrovir)	Mistaken as azathioprine or aztreonam	Use complete drug name
CPZ	Compazine (prochlorperazine)	Mistaken as chlorpromazine	Use complete drug name
DPT	Demerol-Phenergan-Thorazine	Mistaken as diphtheria-pertussis-tetanus (vaccine)	Use complete drug name
DTO	Diluted tincture of opium, or deodorized tincture of opium (Paregoric)	Mistaken as tincture of opium	Use complete drug name
HCl	hydrochloric acid or hydrochloride		Use complete drug name unless expressed as a salt of a drug
HCT	hydrocortisone	Mistaken as hydrochlorothiazide	Use complete drug name
HCTZ	hydrochlorothiazide	Mistaken as hydrocortisone (seen as HCT250 mg)	Use complete drug name
MgSO ₄ **	magnesium sulfate	Mistaken as morphine sulfate	Use complete drug name
MS, MSO ₄ **	morphine sulfate	Mistaken as magnesium sulfate	Use complete drug name
MTX	methotrexate	Mistaken as mitoxantrone	Use complete drug name
PCA	procainamide	Mistaken as Patient Controlled Analgesia	Use complete drug name
PTU	propylthiouracil	Mistaken as mercaptopurine	Use complete drug name
T3	Tylenol with codeine No. 3	Mistaken as liothyronine	Use complete drug name
TAC	triamcinolone	Mistaken as tetracaine, Adrenalin, cocaine	Use complete drug name
TNK	TNKase	Mistaken as "TPA"	Use complete drug name
ZnSO ₄	zinc sulfate	Mistaken as morphine sulfate	Use complete drug name
Stemmed Drug Names	Intended Meaning	Misinterpretation	Correction
"Nitro" drip	nitroglycerin infusion	Mistaken as sodium nitroprusside infusion	Use complete drug name
"Norflox"	norfloxacin	Mistaken as Norflex	Use complete drug name
"IV Vanc"	intravenous vancomycin	Mistaken as Invanz	Use complete drug name

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Table 2d: Error Prone Symbols (NCCMERP, 2007)

Symbols	Intended Meaning	Misinterpretation	Correction
℥	Dram	Symbol for dram mistaken as “3”	Use the metric system
℥	Minim	Symbol for minim mistaken as “mL”	
X3d	For three days	Mistaken as “3 doses”	Use “for three days”
> and <	Greater than and less than	Mistaken as opposite of intended; mistakenly use incorrect symbol; “< 10” mistaken as “40”	Use “greater than” or “less than”
/ (slash mark)	Separates two doses or indicates “per”	Mistaken as the number 1 (e.g., “25 units/10 units” misread as “25 units and 110” units)	Use “per” instead of a slash mark to separate doses
@	At	Mistaken as “2”	Use “at”
&	And	Mistaken as “2”	Use “and”
+	Plus or And	Mistaken as “4”	Use “and”
o	Hour	Mistaken as “zero” (eg, q2 ^o seen as q 20)	Use “hr”, “h”, or “hour”

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Black Box and High-Alert Medications

In 1995, the Food and Drug Administration established the Black Box Warning System (BBW) to alert healthcare providers to drugs with increased risk for patients. These warnings are meant to be the strongest labeling requirement for drugs and drug products that can have serious adverse reactions or potential safety hazards, especially those that may result in death or injury. The black box warning appears on the label of a prescription to alert the patient and the provider about safety concerns, such as serious side effects or life-threatening risks. Some BBW drugs are Celebrex, warfarin, Avandia, Ritalin, estrogen-containing contraceptives and most antidepressants. Although a large percentage of patients are prescribed medications with black box warnings, many do not receive the advised laboratory monitoring (Hughes, 2008).

High-alert medications are medications that have a higher likelihood of causing injury if misused. Some of these medications also have a higher volume of use than other medications. Though medication mishaps with these high-alert drugs are no more frequent than other drugs, the consequences can be devastating (Department of Veteran Affairs, 2009). The top five high-alert medications are:

- Insulin
- Opiates and narcotics
- Injectable potassium chloride concentrate
- Intravenous anticoagulants
- Sodium chloride solutions above 0.9% (Hughes, 2008).

The National Center for Patient Safety (NCPS) promotes three principals to improve high-alert administration and distribution safety (Department of Veterans Affairs, 2009):

1. Reduce the number of drugs on a facility's formulary, and the number of concentrations and volumes; remove high-alert drugs from critical areas.
2. Have two individuals independently check the product to ensure it is correct, particularly when received in bulk and check equipment settings, as applicable, since some drugs are administered intravenously.
3. Minimize the size of vials or ampules in patient care areas to the dose commonly needed, reduce the total dose of drugs in a continuous IV drip bag, and reduce the concentration of the drug when possible.

The NCPS also encourages standardized dosing procedures, careful screening of new products, and creating system redundancies—commonly known as double-checks (Department of Veterans Affairs, 2009).

Lab Errors

There are an estimated 7 to 10 billion laboratory tests performed each year in the United States, which influence approximately 70% of medical decisions. Any efforts to improve the quality of healthcare must consider laboratory medicine, its workforce, and its systems for ensuring quality and managing information (MMWR, 2005).

The laboratory testing process consists of the pre-analytic, analytic, and post-analytic phases. Errors can occur in all 3 phases but the highest rates of error occur in the pre-analytic phase of testing. The CDC recommends a more comprehensive quality management system (QMS), which has traditionally focused on the analytic phase with insufficient attention given to the pre- and post-analytic phases (Wolcott et al, 2008).

Poor communication among doctors, nurses, patients, and the laboratory and improper test selection and interpretation of results affect quality. Errors involving specimen collection include mislabeling, improper collection, and specimen contamination.

Recommendations for improvement of laboratory testing and error reduction include the implementation of systematic approaches such as the Toyota Production System and failure-mode analysis, which are being used in small and large labs and have contributed to financial savings, improved test quality, and reduced errors. There is also a need to standardize pre- and post-analytic performance measures, data collection, analysis and reporting methods.

Point-of-Care Testing

Computerized, hand-held medical devices allow many tests—once exclusively performed by trained healthcare personnel—to be done outside of the laboratory or clinic by people with limited experience and training. Known as point-of-care testing, the devices used are often not covered by the regulations that govern tests done in a laboratory setting.

Frequently, the personnel performing point-of-care tests are not required to undergo training and there is little quality control, proficiency testing, or routine quality assessment. Although by law these “waived” tests should have a small risk for erroneous results, this is not always the case. Errors can occur anywhere in the testing process, particularly when manufacturer's instructions are not followed and when personnel lack proper training. Errors in point-of-care testing such as

glucose and prothrombin time can have serious consequences because medication dosages are frequently determined by test results.

Surgical Errors

During the mid-1980's, Congress passed a law that mandated the Department of Veterans Affairs (VA) to report surgical outcomes annually and compare them to national averages. The VA created the National VA Surgical Risk Study in 44 Veteran's Administration medical centers. Using data collected from thousands of major operations, risk models were developed for the first time for 30-day mortality and morbidity following selected major surgeries (Khuri, et al, 2002).

This quality improvement program has been adopted by many private sector hospitals. In 1999, the American College of Surgeons collaborated with the VA to create the National Surgical Quality Improvement Program to identify opportunities and actions for improvement. During the first nine years of data collection by the VA hospitals, there was a 27% reduction in 30-day postoperative mortality and a 45% reduction in 30-day morbidity for noncardiac surgery performed at 128 VA hospitals (Khuri, et al, 2002).

Surgical Time Out

To address the problem of preventable surgical errors, the Joint Commission issued two National Patient Safety Goals in 2003 to target wrong-site surgery (Hughes, 2008):

1. Improve the accuracy of patient identification by using two patient identifiers and a time out before invasive procedures.
2. Eliminate wrong-site, wrong-patient, and wrong-procedure surgery using a preoperative verification process to confirm documents and to implement a process to mark the surgical site and involve the patient and family.

Both of these goals are ongoing priorities for the Joint Commission and are mandated for use in all hospitals. The surgical time out (STO) is done immediately prior to the start of the procedure to conduct a final verification of the correct patient, procedure, site, and implant. The surgical site must be marked and visible after prepping and draping of the patient. Using the STO as a "reflective pause or a preoperative briefing" involves the surgeons, anesthesiologists, nurse anesthetists, quality control specialists, and administrators. The STO has been shown in recent studies to be an effective quality control measure.

When an invasive or surgical procedure is planned for a clinical setting other than an operating room, a condensed version of the processes for operating room settings may be employed. There are five steps that need to be followed (The Joint Commission, 2003):

1. The consent form must be executed properly.
2. The operative site must be marked.
3. The patient must be identified using required techniques.
4. A "time-out" briefing is conducted prior to starting the procedure.
5. Two members of the team review pertinent imaging data prior to commencing the surgical procedure.

Patient Controlled Analgesia

Patient-controlled analgesia (PCA) has become a popular option for pain control since it was first introduced into hospitals in the 1970s for control of post-operative pain. A PCA pump is a

computerized machine attached to a patient's IV line that dispenses a predetermined amount of pain medication when the patient presses a button. In addition to its popularity and ease-of-use with patients and staff, PCA has been shown to have other medical benefits:

- Steady serum levels of medication;
- Easier coughing and deep breathing;
- Early ambulation;
- Improved pain relief; and
- Shortened hospital stays (D'Arcy, 2007).

Despite the benefits associated with the use of PCA, it is not without its problems. Errors related to its use are four times more likely to result in patient harm than errors associated with other medications. In a review of 9,500 PCA errors over a five year period in the United States, patient harm occurred in 6.5% of incidents, compared with 1.5% for general medication errors (Joint Commission Resources, 2008).

Persistent safety concerns have led the Joint Commission and the Institute for Safe Medication Practices (ISMP) to identify three areas where PCA errors are most likely to occur:

- Patient selection
- Pump and human errors
- PCA by proxy

Patient selection is a critical safety issue with patient-controlled analgesia. Some patients are not suitable for PCA because of their age, level of consciousness, psychological state, or intellectual capacity. When deciding on the use of PCA pump for pain management, the patient's medical condition and ability to use the PCA machine must also be considered.

Each facility should develop protocols and standardized order sets for PCA devices that address type of medication, dosing, concentration, and frequency. Because opiates are the primary medications used with PCA protocols respiration, heart rate, and blood pressure must be observed and monitored. The first 24 hours are important, since the effects of opiates on intellectual functioning can be unpredictable. Also monitor and observe the patient at night, since nocturnal hypoxia can be a serious side effect.

To avoid pump and human errors associated with patient-controlled analgesia, an easily programmable pump should be selected and the same model of pump should be used throughout the facility. Providers prescribing PCA should use standard order sets, pre-filled syringes with standard concentrations, and separate hydromorphone and morphine to different areas of the pharmacy. Providers must monitor for symptoms of opioid overdose and withdrawal and be provided with ongoing education and annual proficiency testing (D'Arcy, 2007).

Serious adverse events can result when medication is administered by caregivers, family members, or clinicians who are not authorized or trained in the use of PCAs or the drug being dispensed. These adverse events are known as PCA by proxy errors. These errors are the result of family members, friends, and even healthcare professionals hoping to assist the patient with pain control. This can result in oversedation, respiratory depression, and sometimes death.

To avoid PCA by proxy errors, educate patients, staff, and family members about the proper use of PCA. Advise visitors not to push the PCA button, even if the patient asks them to. Ensure that they fully understand the hazards of using analgesics. Consider posting warning signs that state, “Only the patient should press the button” (Marders, 2004).

Falls

Inpatient fall prevention has been an area of concern for almost 50 years. Traditional hospital-based incident reports consider all inpatient falls to be avoidable, and therefore falls are classified as adverse events. Indeed, falls are the most frequently reported adverse events in the adult inpatient setting. But underreporting of fall events is possible, so injury reporting is likely a more consistent quality measure over time and organizations should consider judging the effects of interventions based on injury rates, not only fall rates (Hughes, 2008).

Injuries are reported to occur in approximately 6% to 44% of acute inpatient falls. Serious injuries from falls, such as head injuries or fractures, occur less frequently, 2% to 8%, but result in approximately 90,000 serious injuries across the United States each year. Fall-related deaths in the inpatient environment are a relatively rare occurrence. Although less than 1% of inpatient falls result in death, this translates to approximately 11,000 fatal falls in the hospital environment per year nationwide. Since falls are considered preventable, fatal fall-related injuries should never occur while a patient is under hospital care (Hughes, 2008).

In the long-term care setting, 29% to 55% of residents are reported to fall during their stay. In this group, injury rates are reported to be as high as 20%, twice that of community-dwelling elderly. The increase in injury rates is likely because long-term care residents are more vulnerable than those who can function in the community. The current number of long-term care fatal falls has not been estimated; however, there are 16,000 nursing homes in the United States caring for 1.5 million residents in 2004. This population will likely grow in the coming years, thus fall and injury prevention remains of utmost concern (Hughes, 2008).

Healthcare-Associated Infections

Healthcare-associated infections (HAIs) are the most common complication associated with hospital care in the United States. Each year 2 million patients develop HAIs, resulting in 99,000 deaths and \$20 billion in healthcare-associated costs. Methicillin-resistant *Staphylococcus aureus* (MRSA) is the most common HAI and there has been a dramatic increase in the number of MRSA-associated hospital stays since 2000 (AHRQ, 2008b).

MRSA Statistical Brief (AHRQ, 2008b)

- Hospital stays for MRSA infections more than tripled after 2000 and increased nearly tenfold after 1995.
- On average, hospital stays for MRSA infections cost \$14,000 compared with \$7,600 for all other stays.
- MRSA hospitalizations were highest among the elderly.
- Hospital stays for MRSA infections were highest in the South.
- The most common conditions associated with MRSA were skin infections (19% of all MRSA cases) followed by medical care complications (16%).

Four areas associated with healthcare-associated infections have been targeted for improvement by the Agency for Healthcare Quality and Research (2008b):

- Surgical site infections (SSIs).
- Central-line associated bloodstream infections (CLABSI).
- Ventilator-associated pneumonia (VAPs).
- Catheter-associated urinary tract infections (CAUTIs).

Hand hygiene is considered the best preventive measure for all HAIs and is universally recommended as key strategy to prevent HAIs of all types. Current recommendations encourage use of waterless, alcohol-based hand rubs (Ranji et al, 2007).

Surgical Site Infections

About 27 million surgical procedures are performed each year in the U.S. resulting in 290,000 surgical site infections (SSIs) and approximately 8,000 patient deaths. By definition, an SSI occurs at the site of surgery within 30 days of an operation or within one year of an operation if a foreign body is implanted as part of the surgery. About 70% of SSIs are superficial infections involving only the skin. The remaining infections are more serious and can involve tissues under the skin, organs, or implanted material. The majority of SSIs do not become life-threatening (CDC, 2008c).

Over 4 million orthopedic surgeries are performed in hospitals each year and depending on the type of operation, typically less than 1% of most orthopedic surgeries result in a SSI. Following orthopedic surgery, infection with *Staphylococcus aureus* causes about 50% of serious SSIs with about 50% caused by MRSA (CDC, 2008c).

Recommended interventions for prevention of surgical site infections include appropriate use of perioperative antibiotics, avoidance of shaving of the operative site, and perioperative glucose control (Ranji et al, 2007).

Bloodstream Infections

Bloodstream infections are a leading infectious complication among critically ill patients. They represent about 15% of all healthcare-acquired infections and affect approximately 1% of all hospitalized patients. The impact on patient outcome is tremendous—bloodstream infections increase mortality rates, prolong patient stay in an intensive care unit and in the hospital, and generate substantial extra costs (Hugonnet et al, 2004).

More than five million central venous catheters (CVC) are inserted into patients in the U.S. every year, which can cause several types of infections. The skin at the insertion site of the catheter may become infected—called an exit-site infection—or the internal surface of the device itself may become colonized with bacteria, which occurs in 25% of catheters left in place for five days (Ranji et al, 2007).

The clinical significance of colonization—along with migration of skin flora along the external surface of the catheter—predisposes to the most serious consequence of catheter-related infection—central-line associated bloodstream infection (CLABSI). This occurs when a patient develops bacteremic infection associated with the presence of a central venous catheter. It is estimated that one of the two types of infection above (exit-site infection or CLABSI) occurs in 3%

to 7% of catheters, resulting in approximately 80,000 episodes of CLABSI in the U.S. every year. Most of these infections occur in patients with temporary central venous catheters, often placed in ICU patients. Central-line associated bloodstream infections are estimated to result in an absolute increase in mortality of 10% to 30% for ICU patients and the total yearly costs to the U.S. health care system are between \$300 million and \$2 billion (Ranji et al, 2007)

Recommended interventions for prevention of central-line associated bloodstream infections include use of aseptic technique for the insertion of all central venous catheters and use of 2% chlorhexidine gluconate solution for skin disinfection at the CVC insertion site. Also, avoid insertion at the femoral site for nonemergency CVC insertion and remove CVCs that are no longer essential for care. Routine removal and replacement of a CVC over guidewire is explicitly discouraged (Ranji et al, 2007).

Ventilator-Associated Pneumonia

Pneumonia accounts for approximately 15% of all hospital-associated infections and about a quarter of all infections acquired in the intensive-care and coronary care units. It is the second most common hospital-associated infection after urinary tract infections. The primary risk factor for the development of hospital-associated bacterial pneumonia is mechanical ventilation and its associated endotracheal intubation (CDC, 2005b).

Ventilator-associated pneumonia (VAP) is estimated to occur in 9% to 27% of patients intubated for more than 48 hours. Patients with VAP have a higher risk of dying in the ICU than similar patients without VAP, though the magnitude of this risk is controversial. Patients with VAP remain hospitalized for 7 to 9 excess days, and costs are estimated to be between \$12,000 and \$40,000 per patient (Ranji et al, 2007).

The pathogenesis of VAP is dependent on the duration of mechanical ventilation, colonization with bacteria, aspiration of contaminated secretions, and impaired host defenses. Risk factors include:

- Factors that enhance colonization of the oropharynx and stomach by microorganisms such as administration of antimicrobial agents, admission to ICU, or presence of underlying lung disease.
- Conditions favoring aspiration into the respiratory tract such as insertion of a nasogastric tube, supine position, or coma.
- Conditions requiring prolonged use of mechanical ventilation with potential exposure to contaminated respiratory devices and contaminated hands, mainly of healthcare personnel.
- Factors such as extremes of age, malnutrition, and severe underlying conditions such as immunosuppression (CDC, 2005b).

Recommended interventions for prevention of ventilator-associated pneumonia include semi-recumbent positioning, minimizing the duration of mechanical ventilation by minimizing sedative administration (including daily “sedation holidays”), and use of weaning protocols (Ranji et al, 2007).

Catheter-Associated Urinary Tract Infections (CAUTIs)

Urinary tract infections associated with urethral catheters (CAUTI) are the most common healthcare associated infection in hospitals in the U.S. They account for approximately 40% of all HAIs and affect an estimated 600,000 patients per year. Over 30 million urinary catheters are inserted in hospitalized patients in the U.S. each year and in these patients, colonization of the catheter resulting in asymptomatic bacteriuria occurs in approximately 3% to 10% of patients per day. Once bacteriuria develops, approximately 25% develop symptomatic UTI, and approximately 3% develop bacteremia (Ranji et al, 2007).

Morbidity, mortality, and costs of CAUTI are much lower than those associated with central-line associated bloodstream infections, ventilator-associated pneumonia, and surgical site infections on a per-patient basis. But due to the frequency of urethral catheterization in hospitalized patients, asymptomatic bacteriuria and CAUTI are often treated with antibiotic therapy and may serve as a reservoir for resistant pathogens (Ranji et al, 2007).

Preventive strategies for CAUTI have been evaluated since the 1960s and focus on reducing unnecessary catheter use and reducing colonization of the insertion site and catheter apparatus. Use of a closed urinary drainage system was the first intervention proven to prevent CAUTI, and these systems are now in standard use. Avoiding obstruction of the drainage system and using aseptic insertion practices are also recommended (Ranji, 2007).

While urinary catheters are needed in certain common situations—principally, in postoperative states, with urinary incontinence, when there is a need for frequent urinary output monitoring, and with bladder obstruction—evidence shows that catheters are frequently kept in place when no indications are present, resulting in up to 50% of urinary catheter-days being unnecessary. This unnecessary catheter use predisposes to colonization and eventual symptomatic CAUTI (Ranji, 2007).

Factors That Increase the Risk of Errors

There are many systems factors that increase the likelihood of a medical error occurring. Some of the most important factors are risky behaviors by healthcare personnel, confusing medication names and abbreviations (discussed in a previous section), staffing issues, and sleep deprivation.

Risky Behaviors by Healthcare Personnel

At-risk behaviors are actions by healthcare providers that compromise patient safety. Healthcare personnel may engage in risky behaviors because the rewards are immediate and the risk of patient harm seems remote. They may engage in risky behaviors when they become comfortable and competent with a task and lose the perception of risk. These behaviors often result in convenience, comfort, and saved time (NCCMERP, 2007).

The perceived benefits of taking a risky shortcut leads to repeated at-risk behaviors, despite the healthcare provider's possible knowledge, on some level, that patient safety could be at risk. In addition, as one healthcare worker has apparent success with an at-risk behavior, they will likely influence fellow workers until that behavior becomes a standard practice (NCCMERP, 2007).

Risky behaviors often emerge because of system-based problems in healthcare organizations. Common at-risk behaviors include:

- Engaging in "Grab and Go" without fully reading the label of a medication before it is dispensed, administered or restocked.
- Intimidation or reluctance to ask for help or clarification.
- Failure to educate patients.
- Using medications without complete knowledge of the medication.
- Failure to double check high-alert medications before dispensing or administering.
- Not communicating important information such as patient allergies, diagnosis/co-morbid conditions, weight, etc (NCCMERP, 2007).

Minimizing At-Risk Behaviors

When patient harm occurs, an organization often focuses on the "sharp end" of the medication-use process—the front-line healthcare workers involved in the event or engaged in the at-risk behavior. However, punishment based only on the outcome when other instances of at-risk behavior by an individual or group go unnoticed is often ineffective and can send the wrong signal to staff (NCCMERP, 2007).

Risky behaviors can emerge because of systems-based problems within a healthcare organization such as an organizational culture with a high tolerance of such behaviors. Organizational behaviors should be reviewed regularly. Unnecessary complexity in processes provides many opportunities for healthcare providers to take risks when providing care to a patient. The National Coordinating Council on Medication Error Reporting and Prevention (2007) makes the following recommendations to reduce medication errors associated with at-risk behaviors:

- Eliminate organizational tolerance of risk.
- Determine systems-based reasons for risk-taking behavior.
- Increase awareness of at-risk behaviors.
- Eliminate system-wide incentives for at-risk behaviors.
- Motivate through feedback and rewards.

Staffing and Patient Safety

Staffing is inseparably linked to patient safety. For several decades, healthcare researchers have reported an association between nurse staffing and the outcomes of hospital care. Nurses are experiencing higher workloads than ever before for several reasons: increased demand for nurses, inadequate supply of nurses, reduced staffing and increased overtime, and reduction in patient length of stay (Hughes, 2008).

Results from 94 observational studies from 1990 to 2006 in the United States and Canada showed that for every additional registered nurse (RN) full-time equivalent per patient day there was a relative risk reduction in hospital related mortality of 9% in ICUs and 16% in surgical patients. Greater RN hours spent on direct patient care was associated with decreased risk of hospital-related death and shorter patient stays (CDC, 2004).

Conversely, for every additional patient per RN per shift there was a 7% increase in relative risk of hospital acquired pneumonia, a 53% increase in pulmonary failure, a 45% increase in

unplanned extubations and a 17% increase in medical complications. More overtime hours were associated with an increase in hospital-related mortality, hospital acquired infections, shock, and bloodstream infections (CDC, 2004).

Several factors are related to nurse staffing and patient safety:

- The demand for nurses has increased.
- The supply of nurses has decreased and is expected to get worse.
- Hospitals have reduced their nursing staffs.
- Healthcare organizations have reduced patient length of stay.
- Nurses today take care of sicker patients (Hughes, 2008).

The consequence of high nursing workload includes adverse effects on patient safety and decreased job satisfaction for nurses, which contributes to high turnover and an increased nursing shortage (Hughes, 2008).

Sleep Deprivation

Studies have shown that failure to obtain adequate sleep is an important contributor to medical errors. In addition to jeopardizing patient safety, clinicians who fail to obtain adequate sleep are also risking their own health and safety. According to the National Center for Sleep Disorders Research, sleep loss is the leading cause of drowsy driving and sleep-related vehicle crashes. Drowsy drivers have slower reaction times, reduced vigilance and information processing deficits which make it difficult to detect hazards and respond quickly and appropriately. Decreased sleep has also been linked to the increasing epidemic of obesity (Hughes, 2008).

Individuals working night and rotating shifts rarely obtain optimal amounts of sleep. Night shift workers have been shown to obtain 1 to 4 hours less sleep than normal. Sleep loss is cumulative and by the end of the workweek, the sleep loss may be significant enough to impair decision-making, initiative, integration of information, planning, and vigilance. These effects may not be recognized by the sleep-deprived individual until they are severe (Hughes, 2008).

Studies have also shown that moderate levels of prolonged wakefulness can produce performance impairments equal to or greater than blood alcohol levels that are deemed unsafe for driving or operating heavy machinery. Despite reported nurse satisfaction with 12 hour shifts, recent studies have shown that these longer shifts and frequent overtime are associated with difficulty staying awake on duty, reduced sleep times, and nearly triple the risk of making an error (Hughes, 2008).

Populations of Special Vulnerability

Anyone who takes medication has some risk of a harmful effect. But, there are some groups that have an increased risk of adverse medication events. Children, the elderly, and those with limited English skills and poor health literacy are at a high risk for adverse events.

Pediatric Patients

Children less than 5 years old are twice as likely as older children to go to an emergency department for an adverse drug reaction. Most of these ED visits are due to young children eating or drinking medications on their own without adult supervision (CDC, 2008d).

Pediatric patients face four distinct issues that set them apart from the rest of the hospital population. These four issues, when taken together, make the hospital a high-risk environment for hospitalized children

- **Development:** As children mature both mentally and physically, their needs for healthcare goods and services change.
- **Dependency:** Hospitalized children are dependent on caregivers and parents to convey key information and their care must be approved by parents or their surrogates during all encounters.
- **Different epidemiology:** Most hospitalized children require acute episodic care, not care for chronic conditions as with adults.
- **Demographics:** Children are more likely to live in poverty and experience racial and ethnic disparities in healthcare and they are more dependent on public insurance (Hughes, 2008).

Older Adults

Adults older than 65 years are twice as likely as others to visit an emergency department for an adverse drug event, and 7 times more likely than younger adults to be hospitalized for this reason. Most of these hospitalizations are due to a few drugs that require careful monitoring to prevent problems such as Coumadin, insulin, Dilantin, and digoxin (CDC, 2008).

Hospitalized Elders

The elderly, or those older than 65 years, are projected to increase to 20% of the population by 2030. In 2002, the elderly made up more than 40% of hospitalizations in the United States and these numbers are expected to rise as the population ages. The average length of a hospital stay for older patients has declined since 1990. Shorter stays increase the challenge to properly assess and address the care needs of older adults during hospitalization and upon discharge. The focus of assessment and care is generally on resolving the immediate problem and less attention is given to the underlying risk of functional decline and the vulnerability to hospital-associated complications (Hughes, 2008).

The older patient has increased risk for functional decline during hospitalization due to decreased mobility and other risks of hospitalization. For the frail elderly in particular, hazards of hospitalization include falls, delirium, hospital-acquired infections, adverse drug reactions, and pressure ulcers (Hughes, 2008).

Elders in the Community

For many older adults in the community, the ability to remain independent in their homes depends on the ability to manage a complicated medication regimen. Nonadherence to medication regimens is a major cause of nursing home placement in older adults. In the United States, an estimated 3 million older adults are admitted to nursing homes due to drug-related problems at an annual cost of more than \$14 billion (Hughes, 2008).

Older adults are the largest users of prescription medications, yet with advancing age they are more vulnerable to adverse reactions to the medications they are taking. About 30% of hospital admissions of older adults are drug-related. Older adults discharged from the hospital who are taking more than five drugs are more likely to visit the ED and be rehospitalized during the following six months (Hughes, 2008).

After the age of 75, older adults have decreased comprehension of medication instructions. Living arrangements influence the older person's ability to handle their medications properly. In addition, older adults have difficulty adhering to complex medication regimens and the more complex the regimen, the less likely they will adhere to it (Hughes, 2008).

Medication reconciliation is the first step in helping older adults with medication management. Multiple studies have shown discrepancies of 30% to 66% in medications that were ordered and those actually being taken. Pharmacy reviews can also be an effective tool to reduce adverse drug events in older patients. There are a variety of drug interaction programs that can quickly identify adverse drug interactions (Hughes, 2008).

Another cause of non-adherence in the elderly is difficulty with medication procurement. In a study of elderly patients at 15 days after hospitalization, 27% had not filled their new prescriptions. Patients who participate in programs that provide pharmacy delivery and refill reminders have higher compliance than those who do not (Hughes, 2008).

Poor vision and decreased manual dexterity are also problems for the elderly. It is common for medication bottle caps to be left off or not properly closed so the patient can access the medicine. One study showed that almost one-half of the elderly patients stated that they were not able to read the labels on the bottles due to poor eyesight, inability to read English, or small writing on the bottles (Hughes, 2008).

Poor cognition is associated with inability to follow medication regimens. Forgetting is a major reason medication doses are missed. The most common type of non-compliance is dose omission, but over-consumption is also a common mistake in older people (Hughes, 2008).

Older adults have narrow therapeutic windows and require close monitoring, especially when on multiple medications. A review of ED visits of patients 65 years and older found that more than 10% of the visits were related to an adverse drug event and more than 30% had at least one potential adverse drug interaction in their medication regimen (Hughes, 2008).

Patients with Limited Health Literacy or Limited English

Health literacy is the degree to which individuals have the capacity to obtain, process and understand basic health information and services. It includes the ability to understand instructions on prescription bottles, appointment slips, doctors' directions and consent forms, and the ability to negotiate complex healthcare systems. It requires good reading, listening, analytical, and decision-making skills. Only 12% of adults in the U.S. are considered to be proficient with these skills; more than ninety million people have difficulty understanding and using health information (AHRQ, 2008e).

Poor health literacy increases the risk of medical errors and decreases the probability of good outcomes from healthcare. It is a stronger predictor of a person's health than age, income, employment status, education level, and race, and is linked to poor health. As a result of poor health literacy, patients often take medicines on erratic schedules, miss follow-up appointments, and do not understand instructions like "take on an empty stomach" (AHRQ, 2008e).

A 2003 survey by AHRQ classified U.S. adults as either proficient, intermediate, basic, or below basic with health literacy skills. More than half have intermediate skills such as being able to read

instructions on a prescription label. About a quarter have basic skills such as being able to read a pamphlet and understand why a test might be appropriate. Fourteen percent had below basic skills—of these, 7 million were non-literate in English (AHRQ, 2008e).

Populations most vulnerable to poor health literacy include:

- The elderly (age 65 and up): two-thirds have marginal or inadequate literacy skills and 81% of the patients at a public hospital could not read or understand basic materials such as prescription labels.
- Minority and immigrant populations with limited English proficiency (LEP).
- Low income: Approximately half of Medicare/Medicaid recipients read below the fifth grade level.

Reducing Errors and Increasing Patient Safety

Hospitals, healthcare personnel, patients, and the public must work together to create a culture of safety, decrease the effects of medical errors, and improve the safety of healthcare. Each of us has a role to play.

Creating a Culture of Safety

A culture of safety should permeate all aspects of the work environment and encourage every individual in an organization to project a level of awareness and accountability for safety. Successful safety strategies involve strong leadership at the organizational level, well-trained clinicians who thoroughly understand the safety goals of the organization, and informed patients and family members. Involving personnel from various areas and disciplines while planning and implementing activities improves the culture of safety and is essential to its success. Those personnel who participate on committees or teams serve as conduits of information to others (CDC, 2004b).

Organizations can use three important strategies to communicate their involvement in and commitment to safety: 1) include safety-related statements in the organization's mission, vision, values, goals, and objectives, 2) give high priority and visibility to safety committees, teams, and work groups, and 3) require action plans for safety in ongoing planning processes (CDC, 2004b).

Many studies have shown the effectiveness of creating a blame-free work environment. If management discusses problems in an open and blame-free manner healthcare workers are more likely to report hazards. Providing feedback when a problem is first observed and recommending improvements is a key component of good management. Individual accountability must be promoted; this communicates a strong message about the organization's commitment to a safe healthcare environment all levels of the organization (CDC, 2004b).

The Agency for Healthcare Research and Quality's "10 Practical Tips for Hospitals" provides basic tips for organizations seeking to improve their culture of safety (AHRQ, 2007b):

1. Assess and improve your patient safety culture.
2. Build teamwork.
3. Limit shifts for hospital staff, if possible.
4. Insert chest tubes safely.
5. Prevent central line-related bloodstream infections.
6. Make good use of senior ICU nurses.
7. Use reliable decision-support tools at the point of care.
8. Set up a safety reporting system.
9. Limit urinary catheter use to 3 days.
10. Minimize unnecessary interruptions.

Employees perceive the presence of a culture of safety built on multiple factors:

- Actions taken by management to improve safety.
- Worker participation in safety planning.
- Availability of written safety guidelines and policies.
- Availability of appropriate safety devices and protective equipment.
- Influence of group norms regarding acceptable safety practices.
- Socialization processes around safety that personnel experience when they first join an organization (CDC, 2004b).

Healthcare practitioners who prescribe and dispense medications are at the front lines of medication safety and play a key role in supporting a successful culture of safety. When dispensing medications they should use a systematic approach such as the Five Rights of Medication Administration—a tool that encourages providers to pause and verify that the medications they are about to give are safe and accurate.

The Five Rights of Medication Administration are:

1. Right Patient—Verify the correct patient by always asking the patient his or her name and looking at the name band.
2. Right Time—Make sure the patient receives the medication at the time it should be given.
3. Right Dose—Verify the correct dose. Check the original order with the medication being given. If unsure of an order, ask the person who wrote it to clarify.
4. Right Route—Double check to make sure the medicine will be given via the proper route.
5. Right Drug—Ensure that the correct drug was prescribed and that the correct drug will be administered.

Note: Also ask about any allergies a patient may have (sometimes referred to as the Sixth Right).

More than 40% of medication errors are believed to result from inadequate medication reconciliation in handoffs during admission, transfer, and discharge of patients. About 20% of these errors are believed to result in harm. Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient's record or medication orders (Hughes, 2008).

According to the Joint Commission, medication reconciliation should be done “to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions”. It should be done at every transition of care when new orders are written or existing orders rewritten. Because interactions can occur between prescribed medications, over-the-counter medicines, or dietary supplements, they should all be part of a patient’s medical history and medication reconciliation (Hughes, 2008).

Patients can improve the safety of their care by taking an active role in their own medical treatment. A study by the Agency for Healthcare Research and Quality and the Kaiser Family Foundation revealed that more than half of all Americans believe that preventable medical errors do not occur often. Errors should be of great concern to patients—research has shown that consumers who get more involved with their healthcare greatly improve the safety of their care. Patients should ask questions, understand their condition and evaluate their options. (AHRQ, 2004).

The Agency for Healthcare Research and Quality (2004) recommends that patients use these Five Steps to Safer Healthcare:

1. Ask questions if you have doubts or concerns.
2. Keep and bring a list of all the medicines you take.
3. Get the results of any test or procedure.
4. Talk to your doctor about which hospital is best for your health needs.
5. Make sure you understand what will happen if you need surgery.

Systems Approaches to Medical Errors

“Human fallibility is like gravity, weather, and terrain—just another foreseeable hazard.”

Wachter and Shojania, *Internal Bleeding*

An important contributor to medical errors is lack of communication between co-workers, departments, shifts—even different organizations and levels of care. Many different doctors, nurses, and other healthcare professionals see a particular patient for different aspects of the patient’s care. This makes creating a culture of safety a huge organizational challenge, one that needs to be evaluated constantly and systematically. According to the Institute of Medicine, most medical errors are the result of systems failures that require analysis on a systems level to understand their cause and to promote corrective action.

Root Cause Analysis

Root cause analysis (RCA) is a systems approach that asks three basic questions that provide the framework for information collection.

1. What is the problem?
2. Why did it happen?
3. What can be done to prevent it from occurring again?

According to the book *Internal Bleeding*, “RCA attempts to write a second story about the actions that led to error—to look past the obvious, sharp-end scapegoats and find the other culprits,

however deeply they may be embedded in the system” (Wachter and Shojania, 2004).

RCA provides a structured framework for sentinel event analysis. The Joint Commission describes a sentinel event is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.”

In 1997, the Joint Commission (then called the Joint Commission on the Accreditation of Healthcare Organizations) mandated the use of root cause analysis in the investigation of sentinel events or medical errors in accredited hospitals. There are two main categories of error:

1. Active error, which usually occurs when humans interact with a complex system, and
2. Latent error, which represents failures of system design (Hughes, 2008).

Root cause analysis is used to identify trends and assess risk when human error is suspected with the understanding that systemic factors—rather than individual factors—are likely the root cause of the problem. The goal is to avoid a culture of blame. Systematic application of RCA can uncover root causes that link varied accidents such as a variety of serious adverse events occurring at shift change. Careful analysis may suggest system changes designed to prevent future incidents (Hughes, 2008).

Once a sentinel event has been identified for analysis a multidisciplinary team is assembled to direct the investigation. The team members must be trained in the techniques of RCA because the tendency to revert to personal bias is strong. Multiple investigators allow for comparison and corroboration of major findings and increase the validity of final results (Hughes, 2008).

Accident analysis is generally broken down into the following steps:

1. Data collection, which establishes what happened through interviews, document review, or field observation. These data are then used to make a timeline of events before and after the accident.
2. Data analysis, which is a process that examines the sequence of events and determines common underlying factors. During this phase of RCA, investigators establish how the event happened by identifying failures in the sequence and determining why the event occurred.

At the conclusion of the RCA, the team summarizes the underlying causes and their relative contributions, and begins to identify administrative and systems problems that might be candidates for redesign (Hughes, 2008).

The TeamSTEPPS Approach

Another systems approach to the problem of medical errors is the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) approach. A key point is that even though the delivery of care requires team work, members of these teams are rarely trained together and they often come from separate disciplines and diverse educational programs (AHRQ, 2008c).

Given the interdisciplinary nature of the work and the necessity for cooperation among those who perform it, teamwork is critical to ensure patient safety. Teams make fewer mistakes than individuals, especially when each team member knows his or her responsibilities. Simply conducting training or installing a team structure does not ensure the team will operate effectively

(AHRQ, 2008c).

There are three phases to the TeamSTEPPS approach. Phase I involves assessment and setting the stage. Phase II includes planning, training, and implementation. Phase III sustains and spread improvements in teamwork performance, clinical processes, and outcomes (AHRQ, 2008c).

Plan-Do-Study-Act

Another systems approach to eliminating medical errors is called Plan-Do-Study-Act approach (PDSA). This strategy has been widely used by the Institute for Healthcare Improvement and many healthcare organizations. One of the unique features of this strategy is the acknowledgement that change is cyclical in nature and benefits from small and frequent PDSAs rather than big and slow ones, before changes are made systemwide.

The PDSA cycle tests a change by “developing a plan to test the change (Plan), then carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act)”.

Toyota Production System

The Toyota Production system, traditionally used in the manufacture of cars—has resulted in what is called the Lean methodology. It is driven by the identification of customer needs and seeks to improve processes by removing activities that are not of value (waste). This method uses root cause analysis to investigate errors—seeking to improve quality and prevent similar errors from recurring (Hughes, 2008).

Two reviews of projects using Toyota Production System methods reported that several healthcare organizations have improved patient safety and quality by systematically defining the problem using root-cause analysis, then setting goals, removing ambiguity and workarounds, and clarifying responsibilities. When it came to processes, team members in these projects developed action plans that improved, simplified, and redesigned work processes (Hughes, 2008).

The Toyota Production System is used to make it “crystal clear”:

- Which patient gets which procedure (output),
- Who does which aspect of the job (responsibility),
- Exactly which signals are used to indicate that the work should begin (connection), and
- Precisely how each step is carried out.

Hospitals in Pennsylvania, Utah, and Montana have successfully applied the Toyota Production System to eliminate unnecessary daily activities associated with “overcomplicated processes, workarounds, and rework”. They have involved front-line staff throughout the process, and rigorously tracked problems as they are experimented with throughout the problem-solving process (Hughes, 2008).

Conclusion

“It may seem a strange principal to enunciate as the very first requirement in a hospital that it should do the sick no harm.”

Florence Nightingale in Notes on Hospitals, 1859

As healthcare has become more complex, it has increased the probability that medical errors will occur. According to the landmark 1999 Institute of Medicine report, *To Err is Human*, medical errors are a common occurrence. There are 44,000 to 98,000 deaths each year in the United States or at least 120 deaths each day due to human error in the delivery of healthcare.

Prior to the IOM report it was recognized that medical errors occurred, but the focus was on ridding the healthcare system of the incompetent doctors and nurses who were committing these errors. It was thought that error could be prevented by simply investigating the events and individuals that cause harm to patients. Few of these investigations however, focused on the cluster of events that came together in an unfortunate sequence to allow an error to occur.

Since 1999 the focus of medical error prevention has been on systems and how they create an environment that allows these errors to occur. Quality, we have come to learn, can be defined, measured, and improved.

Resources

1. Institute for Safe Medicine Practices (ISMP) is a non-profit organization devoted entirely to medication errors and safe medication use. The Institute “collects and analyzes reports of medication hazardous conditions, near-misses, errors, and other adverse events”. ISMP also “disseminates timely medication safety information, risk reduction tools, and error-prevention strategies” (ISMP, 2009).
2. The California Hospital Patient Safety Organization (CHPSO) was created by the California Hospital Association and was the second PSO in the nation.
3. The Alliance for Patient Medication Safety strives to foster “a culture of quality within the profession of pharmacy that promotes a continuous systems analysis to develop best practices that will reduce medication errors, improve medication use and enhance patient care”. (<http://www.medicalnewstoday.com/articles/118625.php>).
4. The Florida Patient Safety Corporation was established in 2004 by the Florida legislature “to collect, analyze, and evaluate patient safety”. (www.visionbroward.org/docs/J._Cruickshank_FPSC_slide_presentation.ppt).
5. Additional Florida PSOs listed by AHRQ are:
 - Apollo Publishing, Inc.
 - Center for Patient Safety and Security, LLC.
 - Florida Patient Safety Corporation.
 - Mednax PSO, LLC.
 - Quality Circle for Healthcare, Inc.
 - Ryder Trauma Center.

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Post Test

1. Which has the highest yearly death rate in the US?
 - a. AIDS.
 - b. Motor vehicle accidents.
 - c. Breast cancer.
 - d. Preventable medical errors.

2. Prior to the 1999 report on medical errors by the Institute of Medicine (IOM) the emphasis of error investigation was on punishment, not prevention.
 - a. True
 - b. False

3. The goal of the 2005 Patient Safety and Quality Improvement Act is to:
 - a. Discourage the establishment of laws regarding confidentiality.
 - b. Encourage the development of patient safety organizations (PSOs).
 - c. Provide good quality, safe equipment to patients in need.
 - d. Create a Near Miss Reporting system.

4. The Florida Patient Safety Corporation (FPSC) was established to:
 - a. Monitor patient safety throughout the state of Florida.
 - b. Provide medical insurance for uninsured Florida residents.
 - c. Monitor health-related accidents in the aviation industry.
 - d. Punish healthcare providers with too many “near miss” medical errors.

5. The SorryWorks Program is:
 - a. Required for licensed healthcare facilities in Florida.
 - b. A new version of the Near Miss Reporting System.
 - c. A program that endorses open communication with patient and family when addressing medical errors.
 - d. A program that prevents medical errors from being reported to patient and family.

6. How many serious drug injuries occur annually in nursing homes?
 - a. 100,000
 - b. 350,000
 - c. 1 million
 - d. 25,000

7. The goal of the FDA MedWatch program is to:
 - a. Increase awareness of drug, device, and other medical product-induced disease.
 - b. Represent medical professionals in malpractice lawsuits.
 - c. Decrease the number of reports on adverse drug reaction sent to the FDA.
 - d. Provide feedback to insurance companies about recurring safety problems.

8. In hospitals it is estimated that medication errors occur in one of every ___doses.
 - a. 5
 - b. 75
 - c. 200
 - d. 500

9. Having physicians write medication orders in block letters using commonly recognized abbreviations will improve the medication error rate.
 - a. True
 - b. False

10. Most lab errors occur in the:
 - a. Pre-analytic phase.
 - b. Analytic phase.
 - c. Post-analytic phase.
 - d. Outpatient setting.

11. A surgical time out (STO) is:
 - a. A break by the surgical staff before patient arrives to review the procedure.
 - b. A discussion with the patient about what procedure is to be done.
 - c. Done immediately prior to the start of the procedure to conduct a final verification.
 - d. Done after the procedure to verify paperwork is complete.

12. To decrease medication errors associated with PCA, all of the following are recommended **except**:
 - a. Use the same model of PCA pump throughout a facility.
 - b. Advise visitors to push the PCA button when the patient asks them to.
 - c. Use standard order sets and pre-filled syringes with standard concentrations.
 - d. Give staff ongoing education and annual proficiency testing about PCA use.

13. Inpatient falls are:
 - a. Probably over-reported.
 - b. Avoidable and therefore classified as adverse events.
 - c. Traditionally considered to be unavoidable.
 - d. Not common in adult inpatient settings.

14. The best prevention measure for healthcare-associated infections (HAI) is:
 - a. Wearing gloves during most patient contacts.
 - b. Culturing all pre-school children for MSRA infections.
 - c. Use of oil-based hand cleaning products to develop an infection barrier on your hands.
 - d. Hand hygiene and the use of waterless, alcohol-based hands rubs.

15. Which of the following is a recommended intervention for prevention of surgical site infections?
- Do not use perioperative antibiotics.
 - Close shaving of the operative site.
 - Avoid perioperative glucose control.
 - Avoid shaving of the operative site.
16. What is a recommended intervention for prevention of ventilator-associated pneumonia?
- Supine position with heavy sedation.
 - Semi-recumbent positioning.
 - Maximizing sedative administration but minimizing the duration of mechanical ventilation.
 - Consistent sedation and avoiding the use of weaning protocols.
17. Studies about night shift workers have shown that:
- They usually get the same amount sleep as day workers.
 - They recognize sleep loss deficits before they become severe.
 - Sleep loss may impair decision-making, initiative, integration of information, planning, and vigilance.
 - Sleep loss is not cumulative and can easily be made up with extra sleep.
18. Twelve-hour shifts and frequent overtime shifts are associated with:
- Improved efficiency while on duty.
 - No reduction in sleep times.
 - Weight loss.
 - Nearly triple the risk of making an error.
19. Root cause analysis is used to:
- Ascertain, analyze, and assign blame for a sentinel event.
 - Identify problems when individual factors are the likely cause of a human error.
 - Identify trends and assess risk when systemic factors are the likely cause of a human error.
 - Ascertain the likelihood and outcomes of a mass-casualty event.

(continued on next page)

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Please answer each of the following questions. Questions with asterisks (*) are required.

* 1. This course met the goals and learning objectives.

Yes No

* 2. The author was well prepared to write about the content in a way that facilitated my learning.

Yes No

* 3. This course was free from commercial bias.

Yes No

* 4. The learning activity met my continuing education needs.

Yes No

* 5. The learning activity took me 60 minutes per contact hour. (If you answer "No", please enter the total time it took to finish the course, test, and evaluation.)

Yes

No**

** If your answer was "No", how long did it take to finish the course, test, and evaluation?

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