Medication Safety

Can it be possible that medication errors are so prevalent in our healthcare system? Consider the opportunities for error. Assume a hospital that maintains an occupancy of 300 patients per day. Over the course of a one year, that equates to 109,500 patient days. Now assume a conservative estimate that each patient received 10 medications twice a day. In this hypothetical, medium-sized hospital, the opportunity for drug error would occur 2,190,000 times. Finally, assume that this hospital has a true 99.9% medication accuracy rate. Using that optimistic figure, the number of yearly medication errors would be 2,190.

The number of actual errors that occur in our healthcare system is, by most accounts, much higher. In a study of 36 medical facilities, the true error rate was determined to be 14.6%, which in our hypothetical hospital would trigger 319,740 medication errors.[1] How can that be? Why is the medication process so prone to error? One answer lies in the number of steps needed to administer even the simplest of newly ordered medications. The medication ordering process for a non-computerized, order entry system is summarized in the following:

> Orders are written by the prescriber ➡ orders are taken off the chart by a unit clerk and placed in a receptacle for delivery to pharmacy ➡ transportation or pharmacy picks up the order and brings to pharmacy ➡ orders are first reviewed by a pharmacy technician who triages the priority of the order ➡ order is placed into the pharmacy computer usually by a technician ➡ order is reviewed by a pharmacist ➡ order is approved and label is generated ➡ order is prepared and made ready for delivery back to the nursing unit ➡ order is transported by pharmacy or retrieved by nursing ➡ order is placed into patient unit dose bin or brought to the patient's room for administration ➡ order is checked against the original order ➡ medication is brought to the patient and patient identification is verified ➡ patient is administered the medication ➡ documentation of administration is made by nurse.

It is a virtual certainty that patients admitted to the hospital will receive multiple medications and each administration occurrence carries with it the risk of error or misadventure. The definitions used in the literature to discuss drug-related experiences are at times controversial. The following definitions are taken, in part, from the American Journal of Health-System Pharmacists:[2]

Medication misadventure – any event associated with the administration of medication that results in an unexpected or undesirable result

Medication error – any preventable event occurring from the inappropriate use of medication that has the potential to cause harm

Adverse drug event – an injury to the patient resulting from the use of medication

Adverse drug reaction – any unexpected, unintended, undesired, or excessive response to a medication.

Key Issues

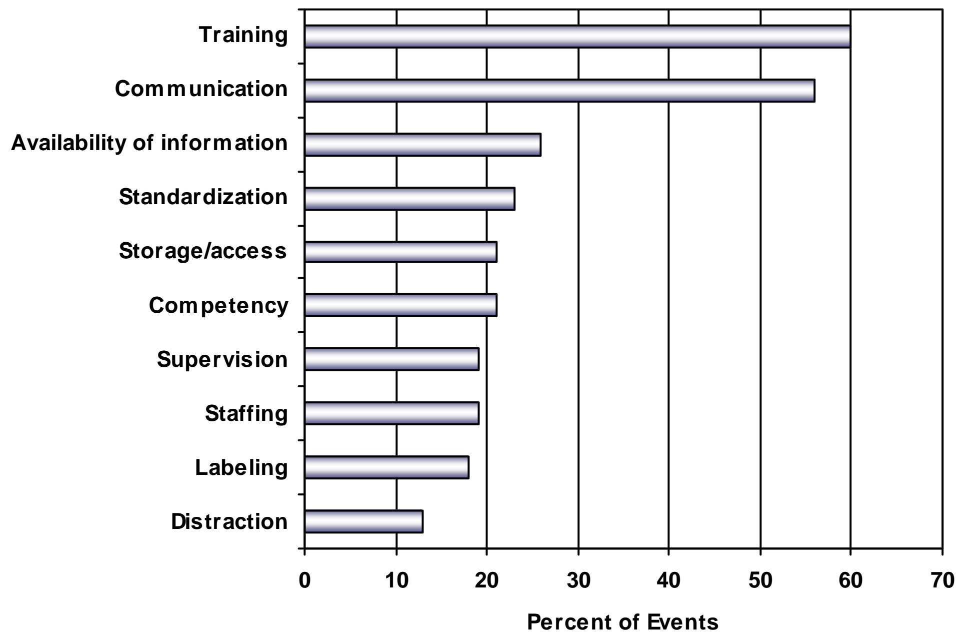
♦ Significance of medication error and adverse drug events

Estimates of death related to medication error are concerning. The Institute of Medicine report, *To Err is Human,* suggested that medication errors result in up to 7,000 deaths yearly in the United States.[3] One of the largest studies that examined hospital-related medication errors included data obtained from 1116 hospitals (32% of US hospitals), reporting 430,586 medication errors.[4] Of these hospitals, 913 provided information on adverse outcomes. The mean number of total errors reported yearly per hospital was 385. As might be expected, there was variability between hospitals. Analysis of the reported errors, however, did yield some important information. On average, the hospitals reported negative patient outcomes (undefined in this study) as 19 ± 25 per year per hospital. Adjusted for the average number of occupied beds, the medication error rate was calculated to be 2.3 ± 4 per occupied bed. Similarly, adverse patient outcomes resulting from medication errors were estimated to be 0.12 ± 0.3 per occupied bed. Other conclusions gleaned from this report include the following:

- Approximately 5% of all patients admitted to the hospitals experienced a medication error during their hospital stay
- Based on the number of medication errors, one medication error occurred approximately every 23 hours
- Medication errors that resulted in adverse patient outcomes occurred in 0.25% of admitted patients
- A medication-related adverse outcome occurred every 19 days.

Adverse drug events (ADEs), which may or may not be due to error, also are frequently observed within our hospitals. One referenced study reported that the rate of ADEs was 6.5 per 100 hospital admissions.[5] When examining these ADEs, approximately 1% were fatal and 12% were felt to be life-threatening. Another study helped to provide perspective on the impact of adverse drug reactions throughout the nation.[6] More than 2.2 million hospitalized patients experienced a serious adverse drug reaction yearly and, of these, over 100,000 were fatal. Medication errors and adverse drug events impose a threat on the safety of our patients and impart a high financial burden on the healthcare system. In 1995, adverse drug events, which include medication errors and preventable and non-preventable adverse events, were estimated to cost $76 - $136 billion yearly.[7] This included the need for treatment, hospitalization, drug therapy interventions, lost time from work, and litigation.

It is difficult to determine the exact number or percentage of adverse drug events and errors that occur in hospitals. It is possible, however, to say that medication errors represent the third most frequent cause of sentinel events (11.4%) reported to The Joint Commission (TJC).[8] Though this TJC reporting program is voluntary, the relatively large number of events that occur due to medication errors demand attention. TJC has addressed this issue in recently released accreditation standards deal with later in this chapter. Examining the root causes of these sentinel events provides at least some direction for hospital administrators who wish to curtail these preventable events. As can be seen from the graphic below,[8] the two leading causes of medication errors resulting in sentinel events are deficiencies in personnel training and breakdowns in communication.



How do error and ADR rates compare at individual hospitals? That question is very difficult to answer other than to say that whatever the reporting system used, it probably is a mere snapshot of what is really happening in our hospitals. Low error rates are frequently more indicative of a poor reporting system than a system with good controls. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), recommended against comparative error rate data in a June 11, 2002 statement (http://www.nccmerp.org/).[9]

> *The National Coordinating Council for Medication Error Reporting and Prevention believes there is no acceptable incidence rate for medication errors. Use of medication error rates to compare health care organizations is of no value. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Health care organizations should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication use system to prevent future errors, and potential patient harm. The value of medication error reports and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the health care organization's analysis of the information, and its actions to improve the system to prevent harm to patients.*

- **Financial impact**

If the number of medication misadventures is as high as studies suggest, what is the impact on an already financially burdened healthcare system? Some minor adverse drug events and medication errors result in no apparent additional costs. For example, if a medication is ordered to be given three times daily and one dose is missed, it would be likely that many of us would consider that event to

have little, if any, cost impact. Of course, financial analysts would hasten to state that if any additional work is required, such as a telephone call to clarify the prescriber's intent, then the cost of that intervention must also be considered. Adverse events or medication errors requiring intervention, increased monitoring, or even prolonged hospitalization have more obvious cost implications. Pharmacists, nurses and other healthcare professionals prevent errors and adverse drug events everyday in all hospitals. This creates somewhat of a dilemma because, while we want professionals to intercede to prevent breaches in patient safety, it is more difficult to quantify the savings that occur as a result of these intercessions. Actual errors often are associated with tangible evidence of their cost as the result of increased monitoring, length of stay, etc.

One recent study found that approximately two patients in 100 experienced a preventable adverse drug event during their hospital admission. Calculated average increased hospital costs were $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital.[10] If these findings are applied to hospitals throughout the United States, the increased hospital costs alone of preventable adverse drug events affecting inpatients would approach $3 billion.

Can these costs be reduced? The most obvious way to reduce costs, to say nothing about patient safety, is to avoid adverse drug events. In one hospital's ICU, preventable errors were reduced by 66% when a pharmacist made rounds with the physicians and consulted on new orders throughout the day. The estimated annual savings were $270,000, an amount far exceeding the cost of the additional pharmacist.[11] Similarly, a pharmacist and nurse team reduced costs by just under $24,000 in a 91-day period when they actively participated in drug therapy intervention in a medical ICU.[12] The authors projected a yearly savings in excess of $500,000 if the project were expanded to other hospital intensive care areas. It has been predicted that for every $1 spent on clinical pharmacy services, $16.70 are saved.[13]

- **Causes of drug misadventures**

Medication errors occur at all steps in the medication process: ordering, dispensing, and administration. The causes for medication misadventures are many, which is not surprising given the billions of doses of medications administered yearly and the large number of individuals involved in the entire process. One reason why drug misadventures continue to occur is that hospitals may not fully utilize their data to prioritize and drive system improvements. One common problem that hospitals face is that these misadventures, and particularly errors, do not neatly fall into defined categories. As an example, assume a patient receives another patient's medication. It would be easy to assume that this error was the result of a poor patient identification technique. But that does not help understand why the error occurred. Was the patient identification wristband correct? Were there two patients with the same last name in the same room? Was the medication entered in the computer for the wrong patient? Determining the root cause of the error is the only way to eliminate the source of the error. Because incident reporting systems usually fail to identify root causes, the same errors may be repeated over and over again. It is important, therefore, to ensure that incident reporting systems and data are used to fuel analysis and corrective action in systems.

Healthcare professionals are at risk of error because they work in a hurried, pressure-ridden, and sometimes hostile environment.[14] Consider this scenario for the many reasons of patient misidentification.

> When a prescriber writes an order, he/she must first find the chart – not an easy task in many hospitals. All charts look alike, providing the first opportunity for error. Errors occur if the wrong chart is selected. The order may be written while on the run and in a milieu of noise and congestion. The unit clerk or nurse who first views the order is in the center of this chaos, yet they are expected to carefully review the order for correctness and direct the order to the next healthcare provider. If it is a drug order, the order is transported to

another hectic environment – the pharmacy. Here the staff is faced with hundreds of orders and have multiple distractions such as telephone calls for drug information, interruptions from nurses or aides who are looking for urgently needed medications, and interventions with other pharmacy staff members who are waiting for a double check on already processed orders. Finally, the drug makes its way back to the nursing unit where the nurse sorts through the pile of drugs received and makes a decision as to which medications require immediate attention. Often pulled in several directions at once, the nurse goes into the patient's room and administers the drug. During the process, she may well be deciding which of the three stat requests requires attention first.

So why was the drug given to the wrong patient? Maybe it was written on the wrong chart or perhaps the right chart had the wrong addressograph on the order form. The pharmacy could have filled the medication for the wrong patient because a previous patient's computer file was opened and the order entered for the wrong patient. Perhaps the nurse misread the patient's name or was administering drugs to multiple patients at the same time. The possibilities are endless. Yet, this error may be classified solely as a patient identification error. One significant problem in evaluating medication errors is that many contributing factors may have caused the error to occur. Taken individually, each factor might appear to minor; however, collectively they may reveal flaws in the process.

It has been estimated that 75% of transcription errors are the result of distractions.[15] Handwriting is always a source of concern, especially with so many look/sound alike medications on the market. As a matter of fact, the Institute for Safe Medication Practices has called for the elimination of handwritten prescriptions by 2003.[16] There are a wide variety of types and causes of medication errors. The United States Pharmacopeia (USP) developed a voluntary reporting system named MedMARx, which uses standard definitions and collection methods in an attempt to gather meaning data. Recently, the USP released a report analyzing data from 41,296 reported medication errors from 184 medical facilities.[17] The tables below summarize these data separated by type and cause of errors. The full report is accessible at http://www.usp.org/frameset.htm?http://www.usp.org/cgi-bin/catalog/.

Table 1. Medication Errors by Type Reported to MedMARx[*] [17]

Rank	Error type	Reported occurrence rate (%) (does not total 100% due to multiple selection)
1	Drug omitted	29
2	Improper dose / quantity	23
3	Unauthorized drug	15
4	Prescribing error	10
5	Wrong time of administration	8
6	Extra dose	7
7	Wrong patient	5
8	Wrong drug preparation	5
9	Wrong route	2
10	Wrong administration technique	2
11	Wrong dosage form	2

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Table 2. Medication Errors by Reported Cause*[17]

Rank	Cause of error	Reported occurrence rate (%)
1	Performance deficit (e.g., distractions, workload increase)	42
2	Procedure / protocol not followed	20
3	Transcription inaccurate / omitted	14
4	Documentation	13
5	Computer entry	10
6	Communication	10
7	Knowledge deficit	9
8	Drug distribution system	4
9	Written order	4
10	Handwriting illegible / unclear	4

As emphasized earlier, adverse drug events may or may not be preventable. For example, assume a patient has a first-time allergic reaction to an antibiotic and develops a rash and respiratory symptoms. This adverse drug reaction would reasonably be classified as non-preventable. However, if the patient's records suggested a previous allergic reaction to similar antibiotics, then a more thorough analysis of the past allergic reaction could have resulted in avoidance of the problem. Of all adverse drug events, as many as one-half may be preventable.[18]

One analysis attempted to classify adverse drug reactions requiring hospital admissions, of which the average length of stay was just over 6 days.[19] The primary reasons for these adverse drug reactions are listed below.

Cause	ADRs contributed to event (%)
Toxic blood levels or laboratory abnormality	80
Inadequate monitoring as outpatient	67
Inappropriate dose	51
Patient noncompliance	33
Drug-drug interaction	26
Contraindication to therapy	3
Documented drug allergy	1

Regardless of the cause for drug misadventures, it is clear that the healthcare system has been slow to address and solve the root causes. It is not surprising that third-parties are acutely aware of the costs associated with drug misadventures, errors contributing to poor patient outcomes, and preventable adverse drug events.

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- **Regulatory and accrediting bodies and third-party influences**

Regulatory and accrediting bodies, in addition to third-party payers, are forces of change. Though their expectations may increase our obligations and, perhaps workload, they nevertheless encourage medical facilities to evaluate their expectations relative to patient safety.

The Joint Commission (TJC): Beginning January 1, 2003, the Board of Commissioners for TJC announced approval of six patient safety goals that where included in the accreditation standards.[20] Numerous recommendations provide guidance to accomplish the goals. Several of these goals and recommendations are pertinent to medication safety.

1) ***Improve the accuracy of patient identification.***
   a) *Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products.*

      Comment: Measures to accurately identify patients may be more difficult to implement than it might at first appear. For example, picture IDs may be helpful but are of little value in patients with head wounds and bandages. Patient safety websites that encourage member participation have actively engaged dialogue relative to this standard.

2) ***Improve the effectiveness of communication among caregivers.***
   a) *Implement a process for taking verbal or telephone orders that require a verification "read-back" of the complete order by the person receiving the order.*
   b) *Standardize the abbreviations, acronyms and symbols used throughout the organization, including a list of abbreviations, acronyms and symbols not to use.*

      Comment: This standard implies a need for monitoring and enforcement. Some hospitals have attempted to place "hard stops" (i.e., the order cannot be filled until rewritten or clarified) on such policies. That is difficult when considering that the patient may not receive his/her medication on a timely basis. Implementation of such a policy requires thoughtful process improvement to support the desired behavior by clinicians.

3) ***Improve the safety of using high-alert medications.***
   a) *Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.*
   b) *Standardize and limit the number of drug concentrations available in the organization.*

      Comment: So called "high-alert" medications are subject to dosing errors. Although concentrated electrolytes such as potassium chloride and sodium chloride are mentioned by name, other concentrated drugs used by the pharmacy should be considered. Examples might include multiple-dose vials of antibiotics and drugs provided in concentrated solutions meant for dilution prior to administration.

4) ***Improve the safety of using infusion pumps.***
   a) *Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization.*

Additional information may be accessed at The Joint Commission website at http://www.jointcommission.org/

Blue Cross/Blue Shield of Michigan (BCBSM): In an effort to influence the quality of hospital-based patient care, BCBSM has developed a financial incentive program that rewards hospitals for meeting annual performance goals. One section of the incentive plan is focused on medication safety. An advisory committee, known as the Medication Safety Task Force, provides input to the content of the performance criteria. This task force is the composed of members of BCBSM, the Michigan Pharmacists Association, and the Michigan Health and Hospital Association. Medication safety is the task force's primary target and each year they develop performance criteria, which are tied to the incentive reward. The 2002 initiatives include:[21]

- A hospital, board-approved multidisciplinary medication safety plan along with its functional components
- Compliance with any 5 of 12 criteria that promote medication safety (see Tools and Templates)
- Implementation of one of four medication practice improvement programs (see Tools and Templates)

Food and Drug Administration: The FDA's principle charge is to ensure the safety and efficacy of medications before allowing them to be approved for use in the United States. Safety, in this respect, reflects the side effect profile of medications and the "risk versus benefit" analysis that is an integral part of the approval process for all new drugs. Until recently, the FDA has played a relatively minor role in addressing medication errors that occur due to naming nomenclature or labeling. Safety as it relates to the prevention of medication errors has not met the scientific rigor of clinical trials. Post-market analysis and case reports of errors largely drive any effort by the FDA to request and/or require manufacturers to revise packaging or drug names. Hundreds of drugs have so-called "look-alike, sound-alike" names.[22] Recently, the FDA sent letters to more than one hundred drug manufacturers requiring label changes. FDA suggestions included highlighting portions of confusing drug names (e.g., oxycodone) and the use of "tall man" lettering, which emphasizes specific parts of a drug name. For example, confusion between chlorpromazine and chlorpropamide (which has resulted in a patient death) might be avoided if these names were printed on the label as chlorproMAZINE and chlorproPAMIDE.

Legislative Action**:** State and Federal governments are moving closer to mandating programs that will enhance medication safety. California Senate Bill 1875 was developed to *eliminate or substantially reduce medication-related errors*. The California Institute for Health Systems Performance developed a model plan to help hospitals respond to this recent California legislative action.[23] The United States Congress has several bills pending that specify address medication safety (see http://rs9.loc.gov/cgi-bin/query).

♦ Medication safety advocates

There are many excellent organizations that have dedicated themselves to patient safety and, in varying degrees, specifically to medication safety. The reader is advised to consult the list of websites provided later in this chapter. Several organizations stand out as impressive forces for change specifically for medication safety.

Institute for Safe Medication Practices (ISMP)**:** Many would agree that the ISMP has served a leadership role in promoting medication safety. Founded by pharmacist Michael Cohen in 1994, ISMP is known worldwide for its ceaseless prodding of drug manufacturers, the FDA, and hospitals to develop practices that promote medication safety. A non-profit organization, ISMP is *dedicated to the safe use of medications through improvements in drug distribution, naming, packaging, labeling, and delivery system design.* The organization publishes a bi-weekly newsletter entitled the *ISMP Medication Safety Alert* and has recently begun a monthly publication geared toward medication

misadventures in the outpatient setting. Additional information regarding ISMP may be obtained at their website (http://www.ismp.org/).

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP):
NCC MERP is an organization consisting of representatives that span from medical science to public advocacy groups. Among its 20 representatives are the FDA, the American Medical Association, the American Society of Health-System Pharmacists, JCAHO, and the National Patient Safety Organization. Its primary objective is to promote nationwide awareness for medication error reporting and prevention. NCC MERP works closely with other patient safety organizations, state healthcare affiliates, national professional and managed care organizations, and third-party payers. The NCC MERP website is located at http://www.nccmerp.org/.

Challenges

- **Finding the best reporting methods**

One large challenge facing hospitals is the way in which medication errors are reported. Medication errors are almost always directly linked to an individual or individuals. Although many hospitals promote the concept of a non-punitive environment, it is nevertheless difficult to disclose errors that may reflect negatively on one's self. Additionally, medication errors that are considered minor may not seem worth reporting. Reporting a medication error via incident reports is often time consuming. Faced with stressful patient care responsibilities, it is easy to understand why many consider the completion of incident reports as inconsequential. Of course, the problem with under reporting is that it is impossible to obtain a true picture of a hospital's source of errors. As stated in the subtitle of one publication, *you can't fix what you don't know about.*[24]

Although the vast majority of hospitals rely on incident reporting tools to evaluate medication errors, most would agree that many errors are unreported even in the most conscientious environment. The literature is inconclusive as to the best method of collecting, analyzing, and reporting medication errors. Flynn et al. compared three such methods – observation, chart review, and incident reporting – in an effort to determine reported rates of 457 medication errors in 36 healthcare facilities.[1] Direct observation detected an error rate of 14.6%. Patients' charts were later examined to determine if the error was documented. Using chart review, the error rate dropped to 0.9%. Finally, incident reports were analyzed. The rate of errors fell to a mere 0.04%. None of the 35 errors determined by a physician panel as "potentially clinically significant" were reported via incident reports. The same study compared error detection capabilities and cost per dose when using registered nurses, licensed practical nurses, and pharmacy technicians as data collectors. A summary of these findings is presented in the table that follows.

Table 3. Comparison of RNs, LPNs, and pharmacy technician relative to medication error detection accuracy and cost

Detection method Observer	Percent of errors detected	Average employee cost per dose ($)
Observation		
RN	70	6.65
LPN	92	4.56
Pharmacy tech	80	2.87
Chart reviews		
RN	6	0.50
LPN	2	0.87
Pharmacy tech	7	0.56
Incident reports	n/a	
RN		4.29
LPN		6.19
Pharmacy tech		2.61

n/a = errors were reviewed but not detected by observer.

The authors concluded that *pharmacy technicians were more efficient and accurate data collectors*.

What can be done to encourage reporting of medication errors? First, the reporting tool needs to be readily accessible and easy to use. Second, the environment must honestly reflect the purpose of the reporting tool. If employees believe that reporting errors may subject them to criticism or disciplinary action, it is unrealistic to assume that self-reporting will flourish. Finally, healthcare professionals must see a purpose for reporting and understand the analysis and improvement process that follows an incident report. If concerns about patient safety are perceived to not effectuate change, trust and confidence in the reporting system is lost. The patient safety culture must be inbred into everyone who cares for patients.

♦ **Technology**

Drug knowledge has expanded well beyond human ability to recall even the most important contraindications, adverse effects, drug interactions, etc. Furthermore, each time a drug policy or procedure is approved, we expect the physician, pharmacist, or nurse to comply. Oftentimes, failure to comply is merely our inability to remember. Thus, it is vital to our goal of patient safety to assist the healthcare professional by providing and utilizing technology whenever possible.

***Computerized prescriber order entry (CPOE)*:** Many patient safety advocate groups promote the implementation of computerized prescriber (or physician) order entry systems.[25, 26] Advantages of CPOE include:

- elimination of handwriting discrepancies
- immediate error checking for dosage, frequency, route of administration, etc.
- drug interaction and allergy checking
- drug information databases if tied to formularies, policies, and external data sources
- tools to document administration of medications by nursing
- immediate transmission of orders to multiple disciplines
- data to analyze drug utilization and workflow

Unfortunately, there are substantial barriers to the implementation of CPOE. In 1998, less than 2% of hospitals in the United States had either full or partial use of CPOE.[27] Cost and vendor selection are two major obstacles. Though some suggest that implementation of CPOE costs only several million dollars, the UMMHC experience is that a system capable of providing order entry, MARs, medication

documentation, and support for dose checking, drug interactions, etc. is far more expensive. Additionally, the cost of maintaining such a system is by no means insignificant. This is not to say that CPOE is not a worthwhile endeavor – there is little question that it can help to reduce errors. However, this technology comes at a cost that may frustrate even the most robust advocates for CPOE. For CPOE to be successful, the system must be user friendly. A summary report by the Leapfrog Group[27] focuses on this and a number of other concerns that should be addressed when considering CPOE (http://www.leapfroggroup.org/CPOE%20Reports.htm).

Bar coding**:** Bar code technology is widely used to manage inventory, price commodities, and follow transactions. Used appropriately, bar coding could assist healthcare professionals with patient identification, allergy checking, documentation of correct medication administration, and billing. However, computer vendors have been slow to embrace bar-coding for a variety of reasons. Some place the blame on drug manufacturers, who have been slow to place bar codes on their products. Others would challenge drug dispensing and administration systems, which vary in every hospital. The Food and Drug Administration recently held meetings to discuss plans that would require manufacturers to bar code all unit-dose packaging. The reader is encouraged to search the FDA website (http://www.fda.gov/) for comments and discussions on this topic.

- **Informing patients about their medications**

Although much effort has been made toward educating patients regarding health-related issues, it has been estimated that one-half of all prescriptions are taken incorrectly, and as many as one out of every ten hospital admissions may be caused by medications.[28] Failure to take medications as prescribed also leads to increased healthcare expenditures. In a 1990 study of elderly patients admitted to hospitals, it was determined that 11.4% were noncompliant with their physician's orders.[29] At that time, the estimated cost per occurrence was determined to be $2,100. Obviously, that dollar figure would be higher if adjusted for today's economy.

Interestingly, failure to inform and educate patients about their medications is also subject to litigation. The duty of pharmacists to warn patients of potential drug hazards has been tested in the courts in at least two states.[30] In Baker v. Arbor Drugs (Royal Oak, Michigan), the Michigan Court of Appeals ruled that when Arbor Drugs advertised its screening for drug interactions by way of its computer, the company assumed a duty to warn the patient. Failure to do so in this case resulted in a settlement of $100,000. Similarly, in an Arizona legal suit (Lasley v. Shrakes Country Club Pharmacy, Inc.), the court ruled that pharmacists have a duty to warn the patient *irrespective of any duty the prescribing doctor owes the patient.* Quoting a spokesperson for the National Association of Boards of Pharmacy, *(the association) has argued that, from a public health perspective, there should be a duty to warn because of the educational level of the pharmacist and the fact that the pharmacist is the last line of defense before the consumer or patient ingests the drug.* Nationally, the Omnibus Budget Reconciliation Act of 1990 required that pharmacists council patients in outpatient settings. According to Jesse Vivian, a pharmacist and attorney in the Detroit area, pharmacists will eventually find that they have a universal requirement to become “information managers” for their patients.[30]

- **The patient’s role in medication safety**

Although there are many articles written in the lay press that encourage patients to take an active role in their health care, studies such as one conducted at the Albany Medical Center in New York,[31] repeatedly demonstrate that patients do not understand or possess essential knowledge about the medications they consume. In this study, *only 15% of the elderly emergency department patients (over age 65) could correctly list all their medications, dosages, frequencies, and indications*. On average, patients failed to list at least one prescription medication taken regularly. In another study, discrepancies between the medication prescribed and the medication actually taken by the patient occurred in as many as 76% of patients.[32]

Consumers may not have enough knowledge to properly use over-the-counter (OTC) medications. In a survey conducted for the National Council on Patient Information and Education,[33] 60% of the patients polled reported taking one or more OTC drug within the past 6 months. A third of these patients admitted to taking medication beyond the recommended dose believing that more is better when it comes to medications. Approximately 36% of patients combined several OTC medications at the same time, yet only 20% of patients knew the active ingredient of the products they consumed.

Do healthcare consumers fear medication mistakes? The Commonwealth Fund 2001 Heath Care Quality Survey highlighted problems that patients experienced relative to medication errors.[34] Of the patients surveyed, approximately 16% received the wrong medication or wrong dose from a community pharmacy. One of three patients reported a medication error as a hospital inpatient, 22% of which were classified by the patient as serious. Errors aside, 20% of patients found prescriptions labels difficult to understand and 26% found the medication instructions too difficult to comprehend.

Clearly, patient education and participation in their own healthcare decisions should be encouraged. Recently, the JCAHO initiated just such a campaign, which they call “Speak Up”.[35] Speak Up is an acronym that stands for:

> *"**S**" is for speaking up with questions or concerns about their health care.*
> *"**P**" is for paying attention to the health care they're receiving, for example, whether they're getting the right treatments and medications.*
> *"**E**" is for educating themselves about their diagnosis, as well as tests and treatments they will be undergoing.*
> *"**A**" is for asking a family member or friend to act as their advocate in negotiating the health care system.*
> *"**K**" is for knowing what medications they are taking and why they are taking them.*
> *"**U**" is for using an accredited health care organization or hospital.*
> *"**P**" is for participating in all decisions that affect their treatment.*

When hospitalized, patients should be encouraged to freely ask questions of their healthcare providers. They should ask why tests are being performed, and they need to understand the results of these tests in terms that make sense to them. Whenever a medication is administered, patients should question the purpose of the medication (especially if new) and challenge the use of the medication if it does not make sense to them. For example, if the patient is given a medication to reduce blood pressure and he/she does not have hypertension, the patient should inquire why that medication was prescribed. If the medication looks different from the medication they received from the previous dose, they should inquire why its appearance has changed. The same advice is true if the number of tablets or capsules is different than previously taken. The Agency for Healthcare Research and Quality has developed a list of patient safety tips, which includes the following relative to medications:[36]

1. The single most important way you can help to prevent errors is to be an active member of your health care team.
2. Make sure that all of your doctors know about everything you are taking. This includes prescription and over-the-counter medicines, and dietary supplements such as vitamins and herbs.
3. Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.
4. When your doctor writes you a prescription, make sure you can read it.

5. Ask for information about your medicines in terms you can understand—both when your medicines are prescribed and when you receive them.
6. When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?
7. If you have any questions about the directions on your medicine labels, ask.
8. Ask your pharmacist for the best device to measure your liquid medicine. Also, ask questions if you're not sure how to use it.
9. Ask for written information about the side effects your medicine could cause.
10. Speak up if you have questions or concerns.

By being alert to these triggers, patients can serve as their own patient safety advocate and become an active member of the healthcare team.

In conclusion, medications represent a major source of errors and adverse effects in hospitalized patients. As with other types of errors, system approaches are needed to assist healthcare providers. A multidisciplinary effort, which includes patient education, is needed to analyze and reduce the likelihood of medication errors and adverse drug effects.

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