

Medication errors: a 21st-century perspective

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Over the past several years, increased attention has been given to the risks associated with medication use, especially within hospitals. The Institute of Medicine's 2000 report, *To Err is Human* (1), continues to stir an avalanche of interest from the government and the private and public sectors. This increasing scrutiny has emerged as regulators, payers, and patients have demanded not just incremental improvement in safety but giant steps toward medical perfection. This article addresses what has been accomplished, where we may be headed, and what is left undone.

LOW-HANGING FRUIT

Early efforts to improve medication safety within hospitals focused on rather obvious and easily corrected system problems that frequently caused significant patient harm. Concentrated electrolyte solutions have been removed from nursing medication preparation areas, where they might be inadvertently given to patients and cause disastrous consequences. Easily misidentified and similarly labeled products were often kept together on the shelf, a potentially confusing and dangerous circumstance! By removing these products from patient care areas and preparing them in the pharmacy with careful labeling, this type of error has become far less frequent in American hospitals. However, over time it has become more difficult to find gross examples of easily corrected safety issues, and subsequent efforts to improve medication safety have been far more difficult.

These worthwhile changes have rapidly progressed from being common-sense suggestions to strong mandates of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as summarized in its 2004 National Patient Safety Goals (2). As of January 2004, organizations failing to implement any of the listed goals will not receive full accreditation.

A CULTURE CHANGE

Early efforts in the area of patient safety sought to change medical culture so that errors and mishaps were more openly acknowledged and disseminated. A "culture of blame" had tended to suppress the reporting of errors and mistakes, making it more difficult to develop improvement strategies. Instead, emphasis has been shifted away from personal blame and suggestions of professional incompetence to a focus on "system" problems that permitted, set up, or facilitated a professional error. This has increased voluntary reporting of medication errors and the development of

multidisciplinary teams that review these reports, which at times conduct a "root cause analysis" to improve safety.

Unfortunately, two powerful detriments to a more open culture persist—medical malpractice litigation and state licensing board review. Although hospital committee activity that seeks to improve quality is legislatively "protected" from discovery by plaintiffs, there remains considerable hesitancy to allow information regarding errors to flow beyond a small group of leaders. Additionally, reports of medical errors may be filed in the employment records of the involved individuals, impacting future licensure of hospital privileges. An attitude of protecting the institution could potentially override the needs of patients and families. To counter this emphasis, hospitals are strongly encouraged to include nonmedical, nonhospital members from the community on their patient safety committees and hospital boards.

Hospitals within Baylor Health Care System (BHCS) use common definitions of medication errors, based on the severity of the effect on the patient's well-being. These definitions are adopted directly from those published by the National Coordinating Council for Medication Error Reporting and Prevention, an independent body comprising 25 national and international organizations (*Figure 1*). The council's general definition of a medication error is as follows:

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 health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (3).

A web-based reporting tool has been developed at BHCS that includes features not often found in other systems. When they file a report, users can select from a menu of likely "contributing causes." These causes include prescription problems, computer system problems, problems with the use of intravenous pumps, and lack of drug information. By sending reports that indicate a selected group of errors with similar underlying causes to a small team capable of impacting a part of the medication administration

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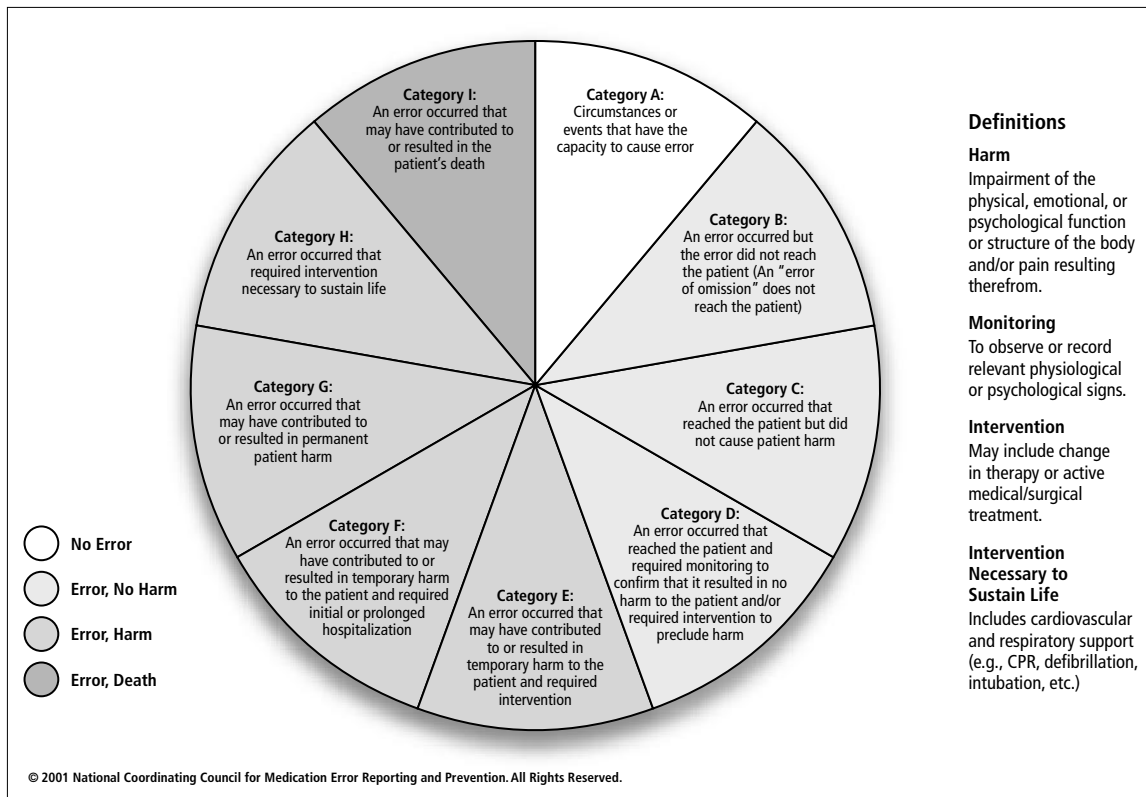


Figure 1. Index of the National Coordinating Council for Medication Error Reporting and Prevention for categorizing medication errors.

system, significant changes can be rapidly implemented, directly impacting patient safety. For example, a set of errors related to the computer system revealed medication ordering screens that were confusing, ambiguous, or inaccurate. These screens have been corrected, preventing similar errors. In this way, voluntary reporting of medication errors has allowed those directly involved in patient care to have substantial impact on safety.

"LET ME COUNT THE WAYS"

It is important that we measure the safety of our systems, as it is said, "You manage what you measure." There has been a trend in health care toward measuring "outcomes" and pushing for "evidence-based medicine." How else can it be said that a hospital is improving the safety of its care over time? Unfortunately, measuring medication safety continues to be a major obstacle. Definitions surrounding medication safety are fraught with difficulty. The terms *medication error*, *adverse drug event*, *side effect*, and *adverse drug reaction* are confusing and misunderstood (4). Is a medication dose that is delayed an hour while a patient is away from his room for a procedure an "error"?

Voluntary reports remain the mainstay of discovery, even though all acknowledge that these reports reveal only a very small fraction of occurrences. By what mechanisms can more events be discovered? In recent years, attempts at using computerized "trigger tools" have been employed with varying success (5). Computerized systems look for key triggers that might indicate that an adverse drug event has occurred. For example, administration of a benzodiazepine reversal agent might imply that a sedative has been used unsafely. This approach is being explored with some success. The types of discoverable events that might be associated with an adverse drug event include

certain laboratory results (low serum potassium, a positive stool test for *Clostridium difficile* toxin), ordering of certain medications (diphenhydramine, naloxone), or an unexpected change in a patient's condition (transfer to the intensive care unit, fall). Using computerized trigger tools is certainly much less labor intensive than manually reviewing charts or searching through discharge diagnostic codes, older methods still more commonly used.

USING EXPERT SYSTEMS

Increasing success is being achieved by using automated, rule-based detection systems to alert prescribers and pharmacists of potential hazards when the relevant data are received in clinical computer systems (6). In these scenarios, an order for a medication is automatically compared with specific existing laboratory data, vital signs, allergy information, and other data in the patient's chart. Sophisticated rules and algorithms have been developed that alert the verifying pharmacist when potentially hazardous conditions exist. For example, when low-molecular-weight heparin is prescribed, the computer system uses the patient's age, weight, gender, and most recent serum creatinine to estimate renal function. This information is compared with the new prescription to ensure that the heparin dose is within an appropriate range. Warning alerts are displayed and directed to the most appropriate professional.

In a slightly different scenario, when new laboratory results are obtained, the patient's medication profile is automatically examined for potential conflicts. This type of screening for potentially hazardous medication orders ideally occurs when an order is written, allowing the prescriber to get it right at the outset without depending on downstream professionals or systems to intercept the order. The best computerized physician

order entry systems have this feature and allow the review to be accomplished in a way that does not constantly interrupt work flow or saturate the doctor's attention with excessive alerts, warnings, and directives. Manufacturers of medication infusion pumps are beginning to offer devices that allow the programming of drug infusion protocols with predefined dose limits (7). If a dose is programmed outside of established limits or clinical parameters, the pumps halt or provide an alarm, informing the clinician that the dose is outside the recommended range.

ANALYZING EVENTS

There has been discussion within the patient safety community about whether emphasis is better placed on *medication variances* (wrong patient, drug, dose, time, or route) or on *harm to patients* (outcomes). James Reason's "swiss cheese model" (8) (Figure 2) illustrates how mishaps occur when several safety nets fail and each layer of safety procedure is not rigorously applied. The holes in the cheese slice represent a latent error or system failure waiting to happen. These could be human error, equipment failure, and so on. When the holes line up, meaning all the defenses fail and an organization's latent vulnerabilities are exposed, an incident occurs.

Because of the infrequent nature of catastrophic medication-related events, their analysis may not lead to changes that will improve safety on an everyday basis. On the other hand, each step in the medication administration system is easily measured, monitored, and analyzed.

APPROACHES TO IMPROVING SAFETY

Inaccurate transcription of medical orders occurs frequently, and this can flow downstream, injuring patients. An order for Celebrex, a cyclooxygenase-2 inhibitor used for arthritis, might be entered as Cerebryx, an antiepileptic drug, with vastly different consequences to the patient. At BHCS, programs to reduce transcription errors have included the following:

- Prescriber ordering and legibility audits—periodic reviews of prescriber compliance with medical staff regulations and JCAHO guidelines regarding the use of abbreviations, legibility, and prescriber identification
- Pharmacist order entry—entry and verification of medication orders by decentralized pharmacists at the point of care, alongside other members of the care team
- Computerized physician order entry
- Order document scanning—transmittal of an electronically scanned image to the central pharmacy, where it remains available for retrospective review

Another frequently occurring error occurs at the bedside, when what is administered is not what was ordered for that patient. All the policies, procedures, and built-in safety features can be powerless to prevent this type of error, which very obviously can have disastrous consequences. Computerized barcoding systems have emerged that can vastly reduce this type of error. Armbands on all patients have specific identifying barcode labels. Each medication order is also barcoded, as is each dose of every medication. At the time of administration, the computer reconciles all three, and if the patient, the medication, and the order are all correct, the nurse is given the "green light" to give the medication. Additionally, a record of the dose being given

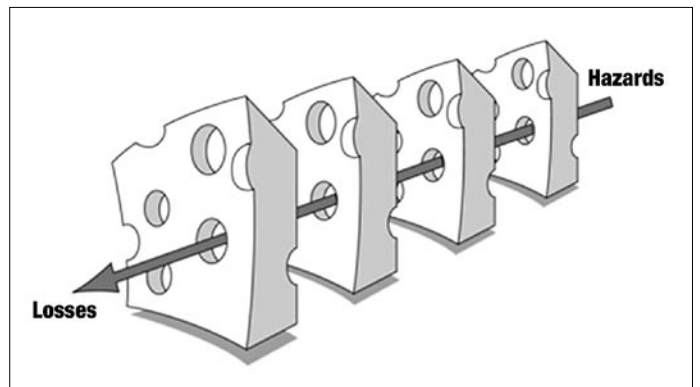


Figure 2. The "swiss cheese model" shows how hazards may reach a patient when safety nets fail. Reprinted with permission of Dr. James Reason.

is automatically recorded, along with the time, freeing the nurse from this tedious clerical activity. Reliable data are automatically generated that can be helpful for analysis and examination. In addition, sophisticated dispensing systems are employed that make it difficult for a nurse to select the wrong medication for a patient. Prescribing errors are also reduced by involving the entire care team in multidisciplinary rounds, decentralized pharmacy services, and other efforts to improve prescribing (care paths, protocols, guidelines, and formularies).

SUMMARY

Improving patient safety in hospitals has been at the forefront of national interest, in some ways even surpassing discussions of medical financing. Dramatic cases are highly publicized by the media, adding public pressure for safety but also damaging the reputations of our most highly regarded health care institutions. This interest and emphasis has led hospitals to reexamine their approaches to safety and allocate increased resources toward this laudable goal. Technology not only has added immensely to the complexity of care but has been a powerful tool for ensuring safety in the medication administration system, with approaches ranging from computerized physician order entry and barcode labeling and administration systems to automated medication and dose checking. BHCS has made a substantial commitment to integrating this technology throughout its facilities. Technology should present enormous opportunities to improve prescribing, make care more efficient, and enhance patient safety. Nonetheless, no computerized system can be more than a helpful advisor to the dedicated and knowledgeable professionals working together, in an open and constructive environment, to provide the best possible care for their patients.

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Invited commentary

Medications, mistakes, and American priorities: It's time to make health care safe

In this issue of *BUMC Proceedings*, Rosen provides a good introduction to the evolving challenges of safely providing medications to patients (1). This review builds nicely on the thorough and wide-ranging review of the history of quality at Baylor provided by Ballard et al (2). In framing the broader issue of patient safety—into which the important points in Rosen's review fit—it is important to emphasize several important concepts: 1) our nation's health system commonly provides what would have been considered miracles less than a century ago, and 2) justifiable pride has tended to distract from seeing significant problems that still deserve attention.

The 2000 report from the Institute of Medicine (IOM) shocked both the lay and professional communities by the magnitude of hospital-associated deaths due to errors (44,000–98,000 per year) (3). Unfortunately, the ensuing debate about the accuracy of these figures tended to distract investment in efforts to address this crisis. A recent report by HealthGrades indicates

that the IOM figures may well underestimate the problem by a factor of two (4). To move past the debate about accuracy and create a case for both commitment and action to reduce errors, the IOM and HealthGrades data might better be considered in practical terms:

- The annual death toll in US hospitals from medical errors is equivalent to 1) the total death toll of all four September 11, 2001, disasters happening every 1 to 2 weeks for a year; 2) loss of all aboard a jumbo jet every day for a year; or 3) 2 to 4 times the annual number of US traffic fatalities.
- Hospital patients face a risk of dying from a medical error that is nearly the same as the risk of dying from skydiving and about 3000 times higher than the risk of dying from a crash of a commercial flight.
- Error-related death in hospitals (excluding ambulatory errors) is between the third and the sixth leading cause of death in the USA, depending upon which estimate is used.

Table 1. Comparison of major threats in the USA

Issue	Terrorism	Hospital errors
Source of threat	External fanatics willing to die for their "cause"	A "swiss cheese" system of care that does not sufficiently respond to the natural frailties of professionals (memory lapses, inaccurate assumptions, communication gaps, etc.); viewed as difficult to change
Loss of American lives	<5000 during the last 4 years	250,000–750,000 during the last 4 years
Awareness of the problem	Everyone in the USA is aware and concerned; government is committed; relevant professionals are actively engaged	Concern is growing by the public and employers (Leapfrog); very limited government action; professionals typically discount the problem or are too busy to engage in improvement
Financial investment in improving safety	Approaching \$1000 per US resident during the last 2 years in federal initiatives to combat terrorism	<\$1 for every US resident spent by the US Agency for Healthcare Quality and Research to improve patient safety
Efforts under way	Major military actions in Iraq and Afghanistan; new mandatory airport screening; restructuring of the intelligence agencies of the US government; worldwide monitoring of electronic communication	Institute of Medicine reports; new national organizations and meetings; required reporting of quality of care to receive a 0.4% increase in the government payment rate; encouragement of public reporting of hospital actions taken to improve patient safety

Comparing the national response to the September 11 disasters and to the crisis of medical errors is worthwhile and, hopefully, thought provoking (Table 1). This comparison is meant to imply not that the US war on terrorism might be excessive but that the investment in improving our safety when we are hospitalized is far too small.

Making mistakes is part of being human. All of us must engage in efforts to improve our ability to consistently deliver the care that patients need and deserve, even when it involves effort to change our systems and habits. The golden rule applies here: the care we and our families receive will be no better than the care that we typically deliver to others.

Baylor Health Care System facilities have recently required physicians to participate in both surgical site marking and a “time out” before all procedures to ensure the identity of the patient, the intended procedure, and the presence of necessary personnel, equipment, charts, and relevant radiographs. A few physicians were irate over the inconvenience and argued that they hadn’t made a mistake of the kind that was being prevented. Would we feel as comfortable flying if the preflight checklist done by pilot and copilot were done only when they felt like it or when they had had a prior problem? We take a few seconds every day to put on seatbelts, even though the risk of having a fatal accident is only about one in a million per day, so what’s different about taking 30 seconds to ensure everything is right before a procedure?

It is important for all those involved in caring for patients to raise their expectations and build a culture that embraces the characteristics of the high-reliability organizations shown in Table 2. Consider the culture issues surrounding hand-washing. Nosocomial infections are common, and while only some are preventable, it is estimated that 20,000 to 50,000 people die annually as a result. How routinely do health providers wash their hands before seeing a patient? Some of the time, most of the time, nearly all of the time? When surgeons and operating room nurses prepare for surgery, they *always* scrub. The culture of the operating room is such that a professional who was in too much of a hurry to scrub would not be permitted access to the patient. Are professionals who fail to wash their hands before a patient visit doing so as a result of a conscious decision? Typically not, but to make it easier to remember, alcohol foam dispensers are in every patient room. How do you think you might react if a patient or nurse reminded you to wash your hands? Would you find this a constructive reminder or would you be irritated? If you’d be irritated, why? These are important and sometimes difficult issues. Progress will be required to fully deliver on Baylor’s commitment to be “the most trusted source of comprehensive health services” and indeed for us all to realize in a fuller way our own professional potential.

How can those in health care participate? When standardized order sets are being developed or revised, join the groups working on them to make sure they meet the needs of you and your patients. Care paths, protocols, guidelines, and order sets are not “cookie-cutter” medicine; they provide reminders so that human

Table 2. Characteristics of high-reliability health care organizations

<ul style="list-style-type: none"> • Vigilantly identify errors/problems • Display high levels of teamwork • Nonpunitively report errors • Learn from mistakes • Allocate resources to safety to ensure progress 	<ul style="list-style-type: none"> • Develop good communication • Use system thinking to minimize risk • Have strong leadership support • Develop structures that support safety • Engage everyone (including patients) in safety
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oversights are less likely to result in poor patient care. When reminded to wash your hands or perform a procedure-related “time out,” consider it a helpful reminder for the benefit of the patients, not an assault on your autonomy. Medicine is practiced in teams, and we need to value every team member’s contributions and to build effective relationships. When mistakes happen, consider them opportunities to learn, and let patient safety or quality personnel know about them. Doing so will not expose you to greater threat of licensure revocation or malpractice litigation. For physicians, when nurses ask for clarifications about orders or read them back to ensure they are right, be patient. They are following policy and acting professionally in the interests of *your* patients. When clinical transformation begins where you work during the next several years, help in the planning and use of the tools that will help you have access to more useful information to make the best decisions about your patients.

Real progress has been made in patient safety at Baylor, and more is planned. Risk-adjusted mortality in Baylor Health Care System hospitals has dropped by 10% in 3 years. Baylor has achieved very high objective performance in the care of patients with acute myocardial infarction, congestive heart failure, and pneumonia. These data are publicly available on the Centers for Medicare and Medicaid Services website (5).

Only by investing our energy and other resources will the care of patients realize the 6 major quality goals defined by the IOM: care that is safe, timely, effective, efficient, equitable, and patient-centered (STEEEP). This issue is owned by us all. It is not a physician, nurse, administrator, or patient “problem” to handle. Only by raising our shared expectations and by working together will the care we deliver to patients be as good as we would like it to be for ourselves and our families.

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Patient Safety Officer

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