Medication Errors

Lessons learned and actions needed

By William N. Kelly

KELSEY WAS BORN ON AUG. 1, 1984. A well-baby check-up in 1985 revealed that she had Wilms' tumor—a cancerous, potentially lethal disease. Kelsey would frequent doctors' offices and hospitals in the months that followed. During this time, her parents noticed that medications which should have been given with food were given without food and conversely. In addition, several allergic reactions were narrowly avoided.

Back in the hospital, Kelsey was started on a more potent cancer drug. The order read 10 mg. On the third day of her hospital stay, she received 100 mg of the drug rather than 10 mg. "The doctor—and this happens every day and is probably happening right now—had meant to write 10 mg and he thought he did, but when we looked at the documentation it sure looked like 100 mg to me," her father said. "The pharmacist missed it, the resident missed it, the fellow missed it, the on-call doctor missed it and the nurse missed it, even though the first two doses had been 10 mg."

Kelsey survived the overdose, but the story continues. One night, Kelsey's mom awoke to find a nurse ready to put something into her daughter's IV line. She questioned the nurse. After the nurse succumbed to the pleas of a frantic mother, it was discovered the drug was for another patient.

Then, the final error occurred. A nurse came into Kelsey's room at the end of a night shift to flush her IV line. The nurse, who had worked multiple nights in a row and was now on her second shift of the day, introduced air into the IV line. Kelsey had a cardiac arrest and died soon after.

Summarizing what happened, Kelsey's father said, "It was not as if the providers were not good people, that the doctors did not want to practice good medicine, that the nurses did not want to take care of the kids at that institution and do the very best they could do. These healthcare providers were all good people who needed better support and better systems" (Roberg).

Medication Errors
Prevalence

In some industries, an error rate of five percent would be acceptable. In healthcare, error rates are much higher and the potential results more unacceptable. Research suggests that 19 percent of doses of medication in U.S. hospitals are administered in error [Barker(b) 1897]. A study in long-term care centers and small hospitals observed an error rate of 12.2 percent [Barker(a) 987].

Other studies suggest that 1.7 to 3.9 percent of patients who visit an emergency room do so because of a drug misadventure and 66 percent of these are preventable (Schneitman-McIntire, et al 1416; Dennehy, et al 1422). Even worse, the largest study so far suggests that 3.7 percent of hospitalizations occur because of the adverse effects of medication—some that were preventable. The extent of adverse drug events (ADEs) in older persons (65 and older) was recently reported in the *Journal of the American Medical Assn.* (*JAMA*) (Gurwitz, et al 1107). The overall rate of preventable ADEs was 13.8 per 1,000 person-years. Of the preventable ADEs, 38 percent were categorized as serious, life-threatening or fatal.

The prevalence of medication errors in community pharmacies is an iceberg— only it is submerged 85 percent below the waterline, largely because data on medication errors are considered proprietary. This is of concern because nearly 75 percent of prescribed medication is dispensed by community pharmacies. This problem seems headed for the acute stage since prescription drugs are often reclassified by U.S. Food and Drug Administration (FDA) for over-the-counter (OTC) use. The prevalence rates quoted

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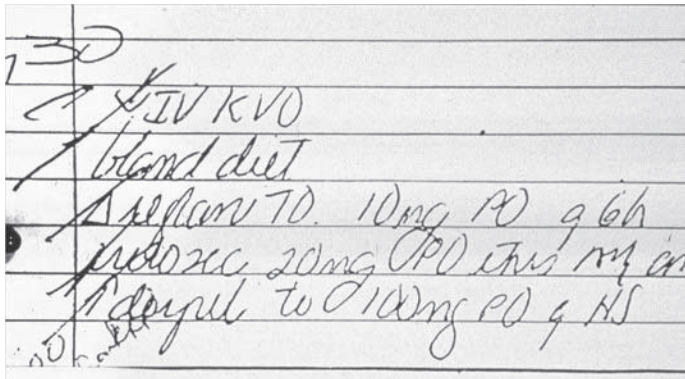
Photo 1 (above, left): On this patient chart, entries are not clearly written. Instead of Prilosec®, the drug Prozac® was mistakenly administered.

Photo 2: (above, right): A doctor wrote this order for a five-pound premature infant hospitalized for an infection. Because the "q" ("every") in the top line intruded on the lower line, the infant received three doses of 600 mg instead of 60 mg ampicillin.

Photo 3 (bottom, right): Based on this order, a nurse gave 10 mg of colchicine (a powerful drug for gout) instead of 1 mg, resulting in the patient's death.
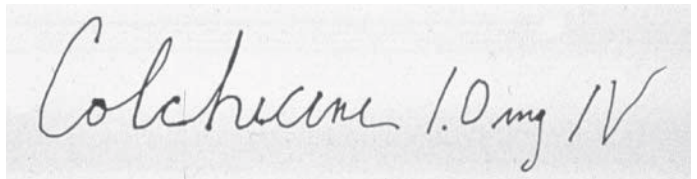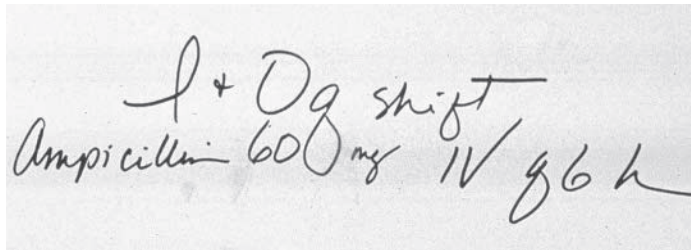
for medication errors do not include errors made with OTC drugs, herbal medicines and nutriceuticals. No system is in place to monitor interactions between prescription and OTC drugs. Therefore, the problem of medication errors is more severe than suspected.

Severity

Not all medication errors reach the patient. Nurses and pharmacists catch many errors through a system of checks and balances. U.S. Pharmacopeia (USP) manages an anonymous medication error reporting system (MedMAR$_x$) for more than 600 hospitals in the U.S. In 2001, only 39 percent of medication errors reported to USP reached the patient. Of these, three percent caused harm (Williams 1).

Who Commits Medication Errors?

Medication errors occur most often at the stages of prescribing and monitoring—61 percent in the recent study reported in *JAMA* (Gurwitz, et al 1112). Errors also occur in the administration stage (by nurses and patients) and less so in the dispensing stage. The recent *JAMA* study also showed that 21 percent of medication errors resulted from the patient not taking medication as prescribed.

Types of Medication Errors

Examples of medication errors include taking the wrong drug or the wrong dose, or receiving the right drug too often, not often enough or not at all. Receiving the wrong drug or the wrong dose usually causes the most harm.

Medication mishaps can also be classified as slips or errors (Leape 1853). Slips are defined as attention deficit errors—the person knew better, but because of inattention or distraction, s/he did something wrong. Almost everyone makes such errors (e.g., buying regular coffee when intending to buy decaffeinated coffee). The other kind of error is a mistake, which occurs because of lack of knowledge. An example is prescribing two drugs that interact; the prescriber should have known whether the drugs interact.

Cost of Medication Errors

The cost of ADEs is high. On average, preventable ADEs in hospitalized patients result in an extra 4.6 days in the hospital with an average extra cost of $5,857 [Bates, et al(a) 310]. This equates to nearly $2.8 million yearly for the average 700-bed teaching hospital. Johnson and Bootman have estimated that drug-related morbidity and mortality in ambulatory care settings costs $76.6 billion yearly (range of $30.1 to $136.8 billion) (1949). To put this in perspective, the annual cost of all diabetic care for one year in the U.S. is $45 billion.

A recent series of studies describes awards for

judgments and settlements in drug misadventure cases litigated and published from the mid-1970s to the mid-1990s. For drug-induced deaths, the mean award was $1,061,318 (range $35,000 to $9 million) [Kelly(a) 1321]. The mean award for drug-induced permanent disability was $4.3 million (range $20,000 to $127 million) [Kelly(b) 1327]. For drug-induced threats to life, the mean award was $1,152,182 (range $32,000 to $8 million) (Marcellino and Kelly 1400). Awards for these cases increased with each succeeding year [Kelly(c) 1406].

The Medication Use System

The medication use system (MUS) is complex. It encompasses 1) drug discovery and approval; 2) production and distribution; and 3) prescribing, dispensing, consuming, and documenting, monitoring and treating adverse effects. The complexity of this system was identified as early as 1987 in a manuscript entitled, "Prescribed Medications: System Control or Therapeutic Roulette?" (Rucker 167). Qualitative and quantitative evidence since then suggest that Rucker was correct. MUS was broken then and remains so today.

In 1999, Kohn, et al from the Institute of Medicine (IOM) of the National Academy of Sciences authored a now-famous report, *To Err Is Human: Building a Safer Health System.* This report brought widespread attention to the frequency and cost associated with preventable adverse events in the healthcare system. IOM estimated that 44,000 to 98,000 hospital patients die each year in the U.S. because of medical errors. IOM concluded that "the status quo is no longer acceptable with respect to the medication use system" (Kohn 22). The report recommended a thoughtful, comprehensive approach to correcting problems. Some of these steps are bold and, thus, are being vigorously debated.

Major Reasons for Medication Errors

Is the problem of medication errors primarily associated with human error? Or, is the use of archaic practices and poor systems the true culprit?

Archaic Practices

Archaic practices such as these contribute to medication errors and need to be changed:

•**Handwritten prescriptions and drug orders.** Use of the prescription pad and the written medication order is outdated and dangerous for many reasons, not the least of which is poor handwriting. Photos 1-3 depict several examples of this problem.

•**Look-alike drug names.** Many drug names

look the same. For example, as Photo 4 shows, the drugs Xanax® and Tenex® look alike when poorly written, but their actions are different.

•**Sound-alike drugs and verbal orders.** Many drug names sound the same when a verbal order is given to a nurse or pharmacist. For example, Lodine® can sound like codeine, Seldane® sounds like Feldene®, Zocar® sounds like Cozaar®.

•**Use of abbreviations.** The medical profession has a long-standing practice of using abbreviations when writing orders and patient progress notes. This is for convenience—often at the expense of safety. As this example shows, when overused, abbreviations can be confusing: ". . . 73 YO WDWNAAF BIBA admitted to CPETU c/o PND & DOE. TBNA in EDTU last wk for CP relieved by NTG. Prev Adm for PTCA 1986, IATT 1997 & LARS 1999. ATSO Dr Jone." A text on medical abbreviations contains 15,000 abbreviations used in medical practice (Davis); this list grows each year. Many abbreviations are the same, yet have different meanings.

•**Similar packaging and labeling.** Much like packaging for consumer products (think caffeine-free Classic Coke vs. caffeine-free Diet Coke), drug packaging often looks similar (Photos 5-7).
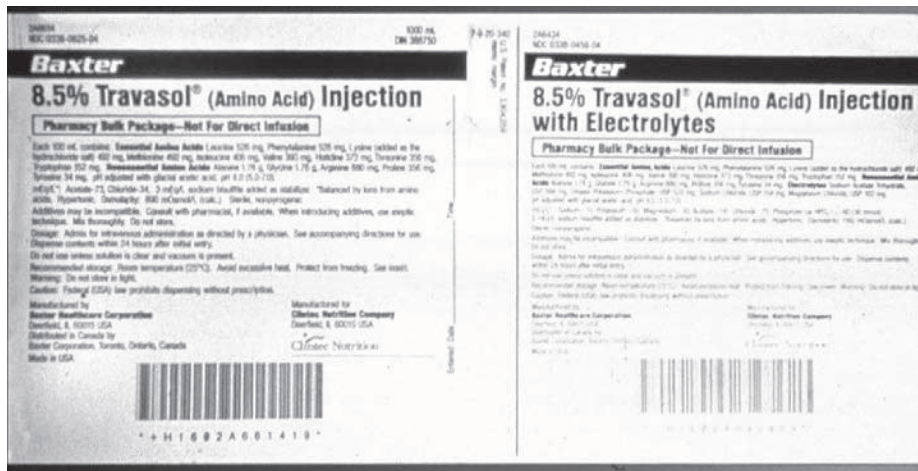
Poor Systems

Poor systems also contribute to medication errors.

•**Information overload.** Medical research information is increasing at an alarming rate, making it difficult for doctors and pharmacists to keep up. A wide gap exists between what should be done (evidenced-based medicine) and what is actually done. Some common practices of medicating patients are outmoded and harmful, yet are still used.

•**Lack of clinical decision support.** In addition to information overload, clinical decision support and alerts are lacking when ordering medication. In most hospitals, systems have not been designed to translate evidence-based medical knowledge into helpful road signs for prescribing.

•**Inadequate checks and balances.** The medication use process has some good checks and balances, but they are inadequate. Despite flawless prescribing and dispensing, a nurse can give the correct drug and correct dose to the wrong patient (which almost happened to Kelsey).

•**Lack of a centralized and standardized healthcare database.** Some organized healthcare systems still use manual systems. Even those settings that use electronic records encounter problems with computers not communicating with one another in a given institution. Furthermore, little information is shared between healthcare providers. For example, the community pharmacist is given a prescription, but has no information about the patient's other diseases and condition. Since many drugs are used for multiple problems, the pharmacist may not even know why the patient is taking a medication. Lack of a central-

ized healthcare database requirement contributes to poor continuity of care. In addition, healthcare providers must keep separate records on a patient, which can lead to errors (Schiff and Rucker 1024).

•**Punitive measures for those who commit any human errors.** Medication errors are grossly underreported by healthcare personnel. The three primary reasons for this are:

1) Personnel are too busy.

2) It is not easy to report medication errors. Many forms are involved.

3) Fear that the person who commits the error will likely be severely punished—perhaps even fired.

Due to underreporting, it is difficult to recognize trends, discover causal factors and identify preventive measures.

People

Healthcare personnel are taught "to first do no harm." No one wants to make an error, especially an error that harms someone. As Kelsey's father said, "These were all good people, trying to do the right thing. They were just in need of better support and better systems." Why do people make medication errors? Besides human imperfection, one can cite three common reasons:

•**Inadequate training.** Inadequate training of all involved—patients, doctors, pharmacists and nurses—leads to medication errors. Lack of knowledge is a nidus for errors.

•**Shortages of nurses and pharmacists.** Nurse and pharmacist shortages have been noted for some

Photo 4 (left): Look-alike drug names are a leading cause of medication errors. This prescription for Tenex® was read as Xanex®.

Photo 5 (below): A healthcare provider in a hurry might not notice that the amino acid solution on the right contains electrolytes.

Photo 6 (above): A deadly likeness: A container of standard saline solution that looks like sodium bicarbonate solution.

Photo 7: One of these two vials of Rocephin® is twice as strong as the other.
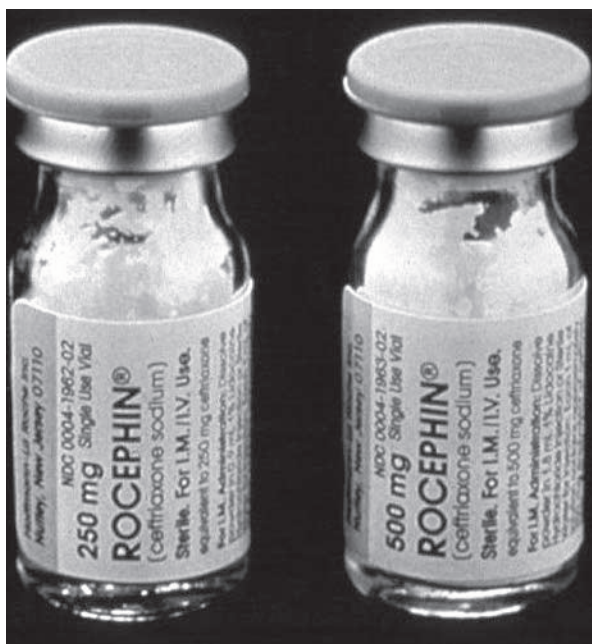
time. These shortages are undoubtedly resulting in more medication errors, although no data are yet available on this trend.

•**Overwork and fatigue.** This was likely a factor in Kelsey's case. In the final incident, the nurse had worked multiple nights in a row and was on her second shift of the day. Medical residents are known to work long hours. Only recently have regulations been promulgated to prevent them from working too many shifts consecutively.

Workable Solutions

The medication system, indeed the whole healthcare system, has been the victim of haphazard incrementalism (a.k.a. multiple Band-Aid fixes), especially as it relates to infrastructure. For the medication use system to work properly, changes in hospital policy, the implementation of evidenced-based safe medication practices and new public policy need to be considered.

Changes in Hospital Policy

Hospitals can take several actions to reduce medication errors:

•**Make preventing medication errors a higher priority.** Hospital pharmacists and risk managers have worked to make sure medication errors are documented, reported and studied. However, they often receive limited support from hospital administration. Since the IMO report, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has strengthened its standards concerning medication errors. This has put pressure on nurses and pharmacists to do more reporting. However, many nurses and pharmacists say they have not been given adequate resources to comply with these new standards.

•**Limit use of verbal orders and abbreviations.** Verbal orders should be restricted to emergencies, and the policy should state that the person receiving the verbal order must "echo" what s/he heard. The verbal order should be followed by a written order. In addition, use of abbreviations should be limited to emergencies, and none that have more than one meaning should be used.

•**Create a safe reporting environment.** Medication

errors will remain under the radar until people feel secure reporting their errors and those of others.

Evidence-Based Safe Medication Practices

The Agency on Health Care Research and Quality (AHRQ) has identified seven evidence-based practices to reduce medication errors:

•**Use of computerized prescriber order entry (CPOE).** "CPOE refers to various computer-based systems of ordering medications which share the common features of automating the medication ordering process. Basic CPOE ensures standardized, legible, complete orders by only accepting typed orders in a standard and complete format" [Kaushal and Bates(a)].

Getting doctors to use computers to order medication in a hospital has been a challenge. It represents change and doctors are wary of any practice that takes more time. However, CPOE has been shown to reduce medication errors by an impressive 81 percent [Bates, et al(b) 319]. CPOE's potential for reducing errors is so convincing that the LeapFrog Group, a coalition of more than 100 major corporations which provide healthcare benefits, supports it as a key way for hospitals to reduce medical errors and prevent deaths caused by mistakes (LeapFrog).

•**Use of clinical decision support.** The real power of CPOE to reduce errors comes when clinical decision support software (CDSS) is added to the system. "Basic clinical decision support may include suggestions or default values for drug doses, routes and frequencies. More sophisticated systems can perform drug allergy checks, drug-laboratory value checks and drug-drug interaction checks, besides providing reminders about corollary orders or drug guidelines to the doctor when ordering drugs" [Kaushal and Bates(a)].

•**Eliminating the prescription blank.** E-prescribing uses handheld devices and desktop software to produce prescriptions electronically. Two-thirds of chainstore pharmacies recently signed up to receive prescriptions electronically (SureScripts). Will doctors use this new technology? A group of doctors in the Boston area is currently testing this approach. Early reports are that patients love it; they recognize that it reduces mistakes and decreases wait time at the pharmacy.

•**Use of protocols for high-risk drugs.** Not all drugs have the same degree of risk. Therefore, it makes sense to have policies, procedures and protocols for the most toxic drugs. For example, protocols for the use of anticoagulants (blood thinners) have been shown to reduce ADEs and the cost of care when these protocols are used (Gandi, et al).

•**Use of clinical pharmacists.** All pharmacists now graduate with doctoral degrees and some complete postgraduate residencies and fellowships. These pharmacists (some of whom are board-certified clinical pharmacists) are qualified to help doctors select, monitor and manage drug therapy. Use of clinical pharmacists has consistently improved the quality, safety and cost of therapy [Kaushal and Bates(b)].

•**Use of unit-dose drug distribution.** In unit-

dose dispensing, medication is dispensed in individual small packages that are labeled and ready to administer to the patient. Only a small quantity (not more than a 24-hour supply) of medication is available to the nurse in the patient's drawer. In addition, a double-check system is in place between pharmacy and nursing, as each gets a copy of the doctor's order. This distribution system (developed by pharmacists) has been available since 1960. It has been shown to significantly reduce medication errors versus other methods of medication dispensing (Murray and Shojania).

•**Use of barcoding and automated medication dispensing devices.** Barcoding of medication packaging and the use of automated dispensing systems—systems that package, count and dispense medication automatically—have also been shown to reduce medication errors (Murray).

However, if these devices are not set up properly, they can cause more errors. Most have improved drug dispensing, but not drug administering. Newer closed-loop systems are being tested. In a closed-loop system, the nurse passes a portable barcode reader (that communicates with the medication use system) over the patient's barcoded wristband, the nurse's barcoded name badge and the barcoded unit dose medication. If the patient, drug, dose and time are correct, a green light on the portable barcode reader signals that all is in order. The nurse then signals on the barcode reader that the medication has been administered and the system then automatically documents that the medication has been given.

Changes in Public Policy

Changes in public policy can often result in swift improvements. These suggested changes would help reduce medication errors; they are based on the author's experience working in the area of medication safety.

•**Pass federal regulation to control drug nomenclature.** Abolishing trade names for drugs would reduce confusion related to look-alike and sound-alike drug names. An alternative would be to allow the use of a brand name until the patent expires. After that, the generic name would be used along with the manufacturer name (e.g., quinapril; Pfizer). At minimum, drug names should be granted by FDA only after an independent body (such as USP) checks the name for safety. The likelihood of this occuring is probably low due to heavy industry resistance.

•**Do not punish those who report and commit medication errors.** Federal regulations should be passed to protect the reporting of medication errors. It should be protected from discovery and punitive actions by employers of healthcare professionals. The likelihood if this happening is high.

•**Establish a national center on patient safety.** The IOM report called for the establishment of a National Patient Safety Board (NPSB), but failed to delineate criteria for such a board, where it should be located and how it should be funded. In the author's opinion, these criteria should include that

the board be nonprofit, independent, scientific and unbiased. The likelihood of this happening is 50/50.

The best model available for such a center is the National Transportation Safety Board (NTSB). Since 1975, this agency has focused extensively on exploring why things go wrong and building safer systems. Some attribute its success to its independence. NPSB would research and collect information, maintain a national database of patient mishaps, perform root-cause analysis of each mishap, identify trends, and develop preventive measures, alerts and requirements as needed.

•**Separate risk assessment from risk management.** Recent events at NASA and on Wall Street illustrate what can happen when risk management and risk assessment are under the same umbrella. Safety often takes a back seat to increased efficiency (Watson 3A; McEachern 10). Based on this, vaccine safety should be separated from vaccine promotion (CDC), and drug safety separated from drug approval (FDA). The likelihood of this happening is remote, however.

•**Require reporting of any fatal medication incident.** This would include reporting fatal medication mishaps (for any reason, such as adverse drug reactions, drug interactions, allergic drug reactions and medication errors) to a national center for patient safety (Lawrence). This center would operate independently of its funding source (much like NTSB). The likelihood of this happening is 50/50.

•**Require barcodes on all unit-of-use drug dosages.** FDA should require barcoding on all single-use drug packages used in organized healthcare settings so the drug can be identified until the moment the dose is administered. In 2004, FDA issued a final rule that requires barcodes on the labels of thousands of human drugs and biological products (FDA).

•**Standardize imprint codes on all solid dosage forms.** All tablets and capsules should be identified with a unique standardized code so that the tablet or capsule can be readily identified by looking up the coding on the Internet or by calling a poison or drug information center. USP is assessing the feasibility of this process, but the pharmaceutical industry is hesitant and questions the need for such a system.

•**Provide low-cost loans for pharmacy and nursing students.** Americans are aging; as more fall into poor health, they will tax the healthcare system. Pharmacists and nurses are already in short supply. Low-cost students loans will stimulate admissions to nursing and pharmacy schools, and grants to these schools will help develop the infrastructure needed to train students. However, the likelihood of this occurring is low.

Progress Remains Slow

Most of the problems—and solutions—related to medication errors were known long before the 1999 IOM report. Medication error rates have been at the cited levels for many years. Progress has been hindered by four key factors: 1) hospital administration;

2) doctors; 3) pharmaceutical industry; and 4) haphazard incrementalism.

Hospital Administration

The increased safety delivered by the unit-dose system has been known since the early 1960s, yet some U.S. hospitals still do not use this system. Barcodes have been available for more than 20 years. The increased safety provided by barcoding and automated medication dispensing devices has been known for more than 10 years, yet most hospitals are not using this equipment. Studies repeatedly have shown a dramatic drop in preventable medication errors when CPOE with CDSS is implemented, yet only a few hospitals elect to use this safety strategy (Schiff 1456). Studies have also consistently shown that the use of clinical pharmacists in patient care areas helps to reduce the morbidity, mortality and cost of medication errors. Yet, most pharmacists are not employed in this capacity.

One reason for these disappointments is that few hospital administrators have patient care backgrounds; most have training in business. As a result, they do not relate to patient care as well as they do to financial information. Administrators often also argue that these techniques have not been shown to be cost-effective. Furthermore, patient safety is usually given lower priority than equipment, new construction, new labs and advanced equipment, which are seen to yield a return on investment.

Doctors

A few months after the IOM report was published, a blistering letter to the editor was published in JAMA (McDonald, et al 93). In essence, the critique suggested that the extent of morbidity and mortality from medical errors as cited by IOM could not possibly be correct. A recent report stated that only five percent of doctors view medical errors as one of the nation's leading healthcare issues (Traynor 116). In their eyes, the cost of medical malpractice insurance and lawsuits are much more important.

Pharmaceutical Industry

Dr. Arnold Relman, professor emeritus at the Harvard Medical School and former editor-in-chief of the *New England Journal of Medicine*, has said, "The American Health Care System cannot live without the pharmaceutical industry, but it may not be able to live with it either, unless the industry is greatly reformed" (Relman and Angell 27). Despite making drugs that can improve the quality of health, the pharmaceutical care industry can be uncooperative and self-serving (Cohen). For example, the industry

has been reluctant to discuss efforts to: 1) eliminate look-alike and sound-alike drug names; 2) eliminate or impose a time limit on the use of trade names; 3) change packaging and labeling to be safer; 4) standardize imprint codes (unique identification mark) on oral tablets and capsules; and 5) possibly make recommended doses higher than they need to be. The industry will argue that such changes require huge investments in research (both clinical and marketing) as well as high retooling costs to change packaging, labeling and imprint codes on drugs. The industry will also cite lack of data that such changes will improve patient safety.

To compound this issue, the FDA is no match for the deep pockets of the pharmaceutical industry (Pomper). The only advantage the agency has is its power to regulate. FDA personnel are well-qualified and committed individuals, but the agency is simply understaffed.

Haphazard Incrementalism

As noted, haphazard incrementalism refers to applying a Band-Aid where major surgery is indicated. This approach is the cause of many problems in the U.S. healthcare system, especially the infrastructure. A prime example is the medication use system that needs to be reviewed, questioned and overhauled, but instead is fixed with Band-Aids.

What Is Needed?

Several actions would speed improvement in medication safety. For example, greater awareness is needed of the fact that medication errors are a genuine problem. The system also needs to be redesigned. Every hospital should employ a medication safety officer (a clinician) and a health safety engineer. Failure mode and human factor analyses should become routine in healthcare. A continuous quality improvement movement is also needed. The medication use system should be continually monitored and improvements routinely made without major cost-effectiveness analyses and having to negotiate through layers of administrative approval.

Most important, leadership is essential. Who will lead the way to improve medication safety? Since neither the government nor private enterprise are likely to champion this cause, the greatest hope may lie in a coalition of healthcare practitioners, patient safety engineers and concerned consumers.

The last action needed to start a blaze of passion for improving medication safety is what Gladwell terms "a tipping point"—that magic moment when an idea, trend or social behavior crosses a threshold, tips and spreads like wildfire (Gladwell). Medication errors are unacceptable and something needs to be done about them now.

Gladwell offers three rules for tipping points: 1) the law of a few; 2) the stickiness factor; and 3) the power of context. The law of a few says that only a few people are needed to achieve a tipping point, but these people must have special skills. The maven knows something good when s/he sees it. The connector networks the idea with many people. The

Practical Implications

The healthcare system needs major improvement with respect to safety. To achieve these changes, the expertise of safety engineers is needed, especially in the following areas:

• redesign of the medication use system;

• look-alike medication packaging and labeling;

• order processing and validation;

• transfer of effective "fail safe" approaches from other industries.

salesperson sells the good idea. The idea must also be sticky—it must be packaged in a way to make it irresistible. Finally, an idea is exquisitely sensitive to the power of context. It must come at the right time and in the right place for people to take notice, have an interest and act, or the idea will not tip.

Conclusion

IOM rang the bell on the problem of errors in medicine. The idea that medication errors occur much too frequently and need to be prevented has been picked up by many mavens, and many connectors have been networking about the idea. Have the answers to the problem made so little progress because there are not enough salespeople? Or is the idea not sticky enough? It should be—medication errors can be fatal. Maybe the people who can make a difference in improving medication safety are not viewing the problem in the proper context. Perhaps they need to hear about Kelsey. Maybe then they would realize that this involves life and death and the idea would tip. ∎

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