

Error in Medicine: What Have We Learned?

I don't want to make the wrong mistake.

Yogi Berra

Over the past decade, it has become increasingly apparent that error in medicine is neither rare nor intractable. Traditionally, medicine has downplayed error as a negligible factor in complications from medical intervention. But, as data on the magnitude of error accumulate—and as the public learns more about them—medical leaders are taking the issue seriously. In particular, the recent publication of the Institute of Medicine report has resulted in an enormous increase in attention from the public, the government, and medical leadership (1).

Human Error in Medicine

Several books have been defining markers in this journey and highlight the issues that have emerged. Of particular note is *Human Error in Medicine*, edited by Marilyn Sue Bogner (2), published in 1994 (unfortunately, currently out of print) and written for those interested in error in medicine. Many of the thought leaders in the medical error field contributed chapters, and the contributions regarding human factors are especially strong. The book is a concise and clear introduction to the new paradigm of systems thinking in medical error.

In the foreword to this book, Reason provides in condensed form his thoughts about the evolution of theory on the nature of human error and accidents (3). There has been a transformation in thinking and research about medical error and injury, much of which has used information from other industries. Conventionally, the single focus of both the medical profession and the medicolegal system has been on individual culpability for error. Other industries, however—especially high-risk industries such as aerospace and nuclear power—have produced enormous improvements by focusing on redesigning their systems to minimize human error. Reason, drawing from analysis of such disasters as the explosion of the space shuttle Challenger and the 1987 Kings Cross underground subway fire in London, observes that systems often contain “latent errors”—errors waiting to happen (4). Safeguards, or “defenses,” are often built in but are inadequate, so that a series of failures can easily align to produce disaster. As the extent of the problem of error

in medicine has become more apparent, people both inside and outside medicine have begun to examine medicine's systems and processes with this kind of “human factors” thinking in mind.

In an early chapter of *Human Error in Medicine*, Leape reviews the data from the Harvard Medical Practice Study (5). This work was a landmark, in large part because it was the methodologically strongest study of its time to examine the epidemiology of iatrogenic injury. The study assessed a random sample of patients discharged from New York hospitals in 1984. Serious iatrogenic injury occurred in 3.7 percent of hospitalizations (6). On the basis of these results, it was estimated that iatrogenic injury contributed to as many as 180 000 deaths annually in the United States (7). This is four times the number of deaths caused by traffic accidents. Other industries have done much better; although airplane crashes get headlines, in 1998 *no* domestic airplane fatalities occurred in the United States. Nonfatal medical injuries resulting in disability or prolonged hospital stay occur in another 1.3 million U.S. patients per year (7). Even though medical professionals conscientiously strive to avoid the “wrong mistake,” two thirds of medical injuries are estimated to be preventable under the prevailing standard of care (7).

In the human factors section of the book, Cook and Woods discuss the difficulties that arise between the “sharp end,” practitioners who actually care for patients, and those at the “dull end,” persons who control many of the resources (for example, administrators) (8). They argue that although superficial analyses are often focused at the sharp end, dull-end factors are more important than generally appreciated and contribute critically to most accidents.

Later chapters examine how such thinking has been applied in anesthesia (9, 10), which has been the leading specialty at addressing error systematically. Helmreich and Schaefer (9) discuss data on the factors that influence team performance in the operating room and find that interpersonal and communications issues play a key role, although most organizations devote little or no resources to support training in human factors and human interventions. The authors suggest that more attention to the dull end could provide even better results; however, because of a variety of improvements, such as oxygen monitoring, anesthesia has registered the largest safety gains of any specialty. Gaba—one of

the top researchers in this field—discusses the “chain of evolution of events” and how mistakes can often be recognized as such only in the context of a specific, dynamic, complicated situation (10).

The Quality Perspective

The link between the patient safety movement and the older, better-established quality improvement movement has often been uncertain: At times, the two groups have seemed to be entirely unaware of one another. Journalist Michael Millenson’s highly acclaimed book, *Demanding Medical Excellence* (11), published in 1997, shows how the two disciplines fit together. Quality, he argues, should be thought of as providing patients with the best possible medical care, and this requires continual progress not only at the highest levels of medical performance but also in shoring up the reliability and consistency of our most routine and basic tasks. While the book targeted the general public, most of those who have read it have some connection with medicine.

The problems of error in medicine are addressed in the chapter “First Do No Harm,” and then prevention strategies are covered in “Saving Lives, Bit by Byte.” Millenson begins by providing a history of the study of iatrogenic injury. He correctly points out that substantial data have been available for years. However, the publication of the results of the Harvard Medical Practice Study finally provided such detailed, incontrovertible evidence that the issue could no longer be ignored. In the prevention chapter, he argues that information technology could allow the provision of much safer care by linking disparate sources of medical knowledge and bringing them to clinicians at the time that clinicians need them. In particular, he puts special emphasis on routinely incorporating outcomes data. At times, Millenson can be too strident, and he does not get everything right—for example, he erroneously states that the Centers for Disease Control and Prevention has no definitions for iatrogenic infections—but this is perhaps the most readable, thorough discussion of the quality revolution in the popular press, and it should be required reading for physicians.

Physicians’ Reactions to Errors

Much of the new paradigm is far off from the way physicians usually manage error. Traditionally, physicians have had a fierce ethic of personal responsibility, seeing conscientiousness as the key attribute of a good physician and good medicine—not

of well-designed medical systems. This comes across clearly in Marianne Paget’s *The Unity of Mistakes: A Phenomenological Interpretation of Medical Work* (12), published in 1988, which probed the psyche of physicians on this topic. Paget analyzes in-depth interviews with 40 physicians and explores how physicians think about their mistakes, as well as the psychological turmoil that physicians go through as they confront them. The book demonstrates how difficult and common serious mistakes are for physicians, how hard each physician works to avoid mistakes, and yet (although Paget herself does not make this point) how limited individual effort is. Almost everyone in medicine works hard to avoid mistakes, and there does not seem to be much more room for individual effort to improve matters. An alternative path to progress is needed.

Medicine’s Changing Approach to Error

The first Annenberg meeting in 1996—which focused on error in medicine and brought together a wide variety of disciplines—was a watershed event. Many of the chapter authors in Bogner’s book, including Leape, Helmreich, and Cook and Woods, presented their view of the error “elephant.” For the first time, error experts from all over the world, from both inside and outside medicine, convened in one place to discuss this issue. Many of the leading experts who participated were from different disciplines and had not previously met.

In subsequent years, as those studying error examined risk and latent error in medical systems by using perspectives that were new to many, the shortcomings of the current approaches became obvious. Most of the technologies and ways we do things in medicine were never designed with human limitations in mind. Indeed, most medical processes were never consciously designed at all; rather, they were built with a series of makeshift patches. Few such processes in medicine would not benefit from a substantial overhaul.

Effective Prevention Strategies

Early on, drug errors were identified as the most common type of medical error, and numerous research groups have since succeeded in redesigning hospital pharmacy ordering and dispensing systems to markedly reduce in the incidence of drug errors. For example, implementation of unit dosing reduced the frequency of medication errors by 82% in one study (13). More recently, computerized physician order entry—in which physicians enter prescriptions online, where they can be checked for

problems—was shown in a randomized trial to decrease the frequency of serious medication errors by 55% (14). In addition, having a clinical pharmacist follow an intensive care unit team on hospital rounds was found to produce a 66% decrease in preventable adverse drug events (15). Researchers are now applying the tools of error analysis and human factors engineering more widely—to everything from surgical care to ambulatory medicine. In the area of fall prevention, for example, Tinetti and colleagues (16) found that a multifactorial intervention to reduce the risk for falling among community-living elderly persons resulted in a decrease in risk for falling of almost one third (incident rate ratio, 0.69), and the intervention appeared to be cost-effective (17).

The Industry Response

The health care industry has begun to mobilize to address these issues. The Joint Commission for Accreditation of Hospital Organizations (JCAHO) has altered investigations of major medical mishaps to focus not on blame and punishment of individuals but on root cause analysis. For example, after a Florida surgeon amputated a patient's wrong leg, the JCAHO identified that wrong-site surgeries occurred at a steady rate across the United States; they then developed process changes (marking the operative site while the patient is awake) to avoid the problem. The Institute for Healthcare Improvement has conducted several "breakthrough series" for large groups of health care organizations on medication errors and adverse drug events, which are intended to help hospitals learn effective strategies for preventing these events (18). These series have resulted in important reductions in specific types of medication errors at many of the participating hospitals.

In addition, major organizations are increasingly focusing on this area. The American Medical Association established the National Patient Safety Foundation in 1997. A group that includes national leaders in medicine as well as error experts has been convening at the John F. Kennedy School of Government at Harvard University for "Executive Sessions on Medical Error and Patient Safety." The Massachusetts Medical Society has developed an error reporting and feedback system, a superb but underfunded program that could serve as a model for enlightened regulation. Error reporting in this system is confidential and nonpersonal, and there is emphasis on getting hospitals to provide information about what changes they made in follow-up; in part because this medical society carries a "big stick," hospitals have been very responsive. And

recently, the National Patient Safety Partnership was established, which includes both government organizations, such as the Department of Veterans Affairs, Department of Defense, and Health Care Financing Administration, as well as many private and professional organizations. The first activity of this group was to emphasize the importance to health care organizations of the "Y2K" problem, and the second has been to put forward a list of medication "best practices."

Discussion

Where We Are Now

The sleeping giant has awoken. Both the public and purchasers are increasingly aware of the safety problems in medicine, and they are applying pressure. As a profession, we are at a crossroads. We have solid epidemiologic data to demonstrate that iatrogenic injury is a major problem. Leaders are now recognizing that the traditional response—that physicians do the best they can—is no longer enough. And medicine has an increasingly robust array of tools to improve the safety of care. Human factors and root cause analysis, in particular, offer ways to dissect individual accidents and understand why they occur (19). Methods that have been effective at reducing error rates in other industries and appear applicable to medicine include simplifying, standardizing, reducing unnecessary reliance on memory, implementing forcing functions (reengineering a process to prevent a specific error, such as requiring a foot on the brake pedal to put a car in reverse), improving information access, reducing reliance on vigilance, and reducing the number of handoffs in the system (18). Already, evidence suggests that these and other strategies can dramatically reduce certain types of error.

However, we are still only at the beginning. Although concrete measures for error reduction have been demonstrated, they have yet to be widely adopted. Moreover, the information that does exist relates to only a few specific areas, such as adverse drug events; even in this domain, the information largely is only from inpatient care. By and large, errors in medicine have gone unrecognized, unreported, and unanalyzed.

Where We Go From Here

The first difficult step is making the transformation to seeing medical systems and processes as the critical source of most error, not individuals. That requires moving away from a culture of fear about admitting error and blame (20), and both the leadership and individuals within the systems must make

this journey. When other industries have successfully made the leap, they have not abandoned the traditional ethic of personal responsibility but rather transformed it so that individuals take responsibility for reporting error and fostering improvements. This takes strong leadership and conviction. Yet, unless errors and accidents are tracked on a routine basis and then used to improve care, we will be condemned to repeat the mistakes of the past.

Another pivotal problem is that complications are persistently underestimated. No matter how protected individuals are, self-report is consistently unreliable. Chart review is effective but too expensive for routine use. There is some promise, however, that computerized event monitoring, in which a program sits over a database and looks for signals that an adverse event may have occurred, will offer an effective way of obtaining this information at a reasonable cost (21–24). Such surveillance for nosocomial infections has been effective at reducing their incidence. Although to date such monitors have primarily been used to detect adverse drug events, they will undoubtedly be used more broadly in the future—tracking, for example, pneumothorax rates after thoracentesis, as well as patterns of surgical and bleeding complications.

Finally, progress will require overcoming significant organizational and financial obstacles. The task of reviewing existing medical practices using a systems approach is daunting enough—few medical processes would not benefit substantially from a “ground-up” overhaul. Success will require considerable effort to change organization, staffing, training, and technology and, although safer systems tend to save resources over time, at least a minimum initial investment will be required (25). Unfortunately, during this turbulent time in medicine, severe financial pressures are forcing leaders to focus on short-term economic survival alone. As a result, safety is being left behind.

The traditional solution to this issue—which has had serious problems—is regulation, by accrediting bodies such as the JCAHO. Although the JCAHO has substantially overhauled its approach to this issue and is now moving in a more optimal direction, it has lagged behind quality efforts in other areas, such as ISO 9000, a set of international quality standards. Other regulatory bodies, such as the state boards for professionals, still often take an absurdly punitive tack, a notable example being the State Board of Nursing in Massachusetts, which punished all 18 nurses who cared for a patient who suffered a chemotherapy overdose.

An alternative to regulation for stimulating health care organizations to improve the safety of the care they provide is for payers to provide financial incentives. The Medicare Payment Advisory

Commission, for example, has suggested that the Health Care Financing Administration consider providing higher payment for institutions that implement systems that have been demonstrated to improve safety, such as physician order entry (26). In addition, a group of the largest employers, dubbed the “Leapfrog Group,” has banded together to drive quality forward (27); this group is considering contracting preferentially or giving better rates to organizations that adopt recommendations documented to improve outcomes, with one of the first being computerized physician order entry in hospitals.

Conclusion

It is evident that the status quo is no longer acceptable. Furthermore, we know much more about what to do about reducing the consequences of error than we did, although it is still not nearly enough. The next, painstaking task will be routinely measuring what we do, making the results publicly available, and then going through the systems of medicine, one at a time, and bringing them forward to the 21st century.

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Spring Fever

Timid in April, yellow-green buds
 Now wantonly coat the world
 With fairy powder, including my nose and eyes
 Which, ignoring the pharmacy on my windowsill,
 Insist it's May.

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