The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human'

Amid signs of progress, there is still a long way to go.

by Robert M. Wachter

ABSTRACT: The Institute of Medicine's 1999 report on medical errors galvanized the public and health professionals. Before then, providers, health care organizations, and policymakers lacked the understanding and incentives to generate the changes in culture, systems, training, and technology to improve safety. Since 1999 there has been progress, but it has been insufficient. Stronger regulation has helped, as have some early improvements in information technology and in workforce organization and training. Error-reporting systems have had little impact, and scant progress has been made in improving accountability. Five years after the report's publication, we appear to be at "the end of the beginning."

Five years ago the Institute of Medicine (IOM) report on medical errors, *To Err Is Human*, galvanized the public and the health professions and led to congressional hearings, media exposés, and millions of anxious patients.[1] This paper examines the genesis and impact of that report and takes stock of where we are five years after its release. The set of incentives that promote patient safety—not simply the economic balance sheet, but also the political, ethical, and social forces experienced by doctors, nurses, health care executives, policymakers, and other key stakeholders—was woefully weak before 1999 and has grown much stronger since then. However, these forces have not yet become robust enough to generate the dollars, systems, training models, and culture to transform modern health care into the safe, reliable system that patients and providers deserve.

The IOM Report And Its Impact

As one measure of its impact, if one says "the IOM report," *To Err Is Human* immediately springs to mind, despite the fact that the IOM has published 234 reports since then. In fact, an argument can be made that the medical profession "discovered" the epidemic of medical mistakes five years ago through the IOM report, nearly as assuredly as we discovered the AIDS epidemic in 1981 and the SARS epidemic in 2003.[2]

Bob Wachter (bobw@medicine.ucsf.edu) is chief of the medical service, University of California, San Francisco, UCSF Medical Center, and is associate chair of the UCSF Department of Medicine.

DOI 10.1377/hlthaff.W4.534

Why did the report strike such a profound chord? In late 1999 the country was relatively prosperous and at peace, providing few competing objects for public angst. Skepticism about the U.S. health care system had grown after a decade of managed care.[3] Moreover, the intellectual foundations of patient safety had been laid by Lucian Leape, James Reason, and others in the prior decade.[4] These factors tilled the soil. But it was the IOM's use of the Harvard Medical Practice Study's decade-old results—in particular, the jarring analogy that deaths in the United States from medical errors would equal the downing of one jumbo jet per day—that generated the public and media attention that finally undermined the status quo.[5]

Predictably, much of the initial debate centered on this now-famous mantra of 44,000–98,000 deaths per year from medical mistakes.[6] Although my own conclusion is that the numbers are likely accurate, the bottom line is this: Even if it were not a jumbo jet of deaths per day but rather a Greyhound bus's worth, it is clear that a terrible danger had been, but could no longer be, ignored.[7]

How Did Health Care Become So Unsafe?

More than two centuries ago, in *The Wealth of Nations,* Adam Smith wrote, "The greatest improvement in the productive powers of labour...seem[s] to be the effects of the division of labour."[8] Although Smith recognized that the power of specialization to increase quality and efficiency might be limited by the extent of the market, he failed to fully appreciate the criticality of "production coordination"—ensuring the seamless flow of both goods and information—as production processes became more specialized. During the past half-century, we in health care made the same mistake.

When the tools of medicine were the doctor's intellect, the nurse's empathy, and a few simple surgical procedures and potions, there was little price to be paid for absent safety systems and lack of coordination. As medicine's tools became more powerful and technologically sophisticated, highly specialized teams were needed to deliver care. The modern intensive care unit (ICU), an invention of the 1960s and 1970s, vividly illustrates the problem. Patients there are supported by an extraordinary array of breathtaking technologies and pharmaceuticals (mechanical ventilation, dialysis, and vasoactive and thrombolytic drugs, to name a few), each accompanied by an armada of skilled professionals to manage their use. A critically ill patient might be seen by a half-dozen different physician-specialists and scores of nurses, respiratory therapists, pharmacists, social workers, clergy, and others, and receive hundreds of medications and tests. It should come as no surprise, then, that without a culture, procedures, and technology focused on flawless execution, errors would become commonplace. One study found that the average ICU patient experiences 1.7 errors per day, nearly one-third of which are potentially life-threatening. Most involve communication problems.[9]

As health care's progress rendered care more dangerous, four main forces lim-

ited our ability to answer the challenge: an outdated mental model for medical mistakes, collective inattention to patient safety, a reimbursement system that provided no incentives for safety, and a fragmented organizational structure.

■ **A flawed mental model and collective inattention.** Before 1999 the mental model for medical errors held by the public, professionals, and regulators was one of individual culpability, a mindset reinforced by medical and nursing curricula, a tort-dominated system for accountability, and, importantly, human intuition. Without a tradition of systems thinking or an understanding of high-reliability organizations and the cost of complexity, the infrequent reports of errors that reached the public were naturally attributed to "bad apples," not only by patients and the media but even by clinicians themselves.[10] Since most doctors and nurses were working hard caring for patients (especially in light of the ever-increasing complexity), many came to think of medical errors as the unavoidable collateral damage of a heroic, high-tech war they otherwise seemed to be winning. Moreover, without a culture that promoted open discussion of errors, every case was viewed in isolation, with little sense by providers or the public of the breadth of the problem and the recurring patterns.[11] Since neither appreciated the true root cause of most medical errors, no significant pressure was brought to bear on executives, educators, regulators, and policymakers to focus on or invest in patient safety.

■ **The reimbursement system and the organizational dichotomy of U.S. health care.** Hospitals and physicians are paid the same regardless of the safety of the care they deliver.[12] The system thus creates no incentive to invest in safety; indeed, in many situations precisely the opposite occurs, as error-prone care leads to higher revenues through more per diem payments or more lucrative diagnosis-related group (DRG) designations.

Additionally, the traditional structure of American health care separates the physicians from the rest of the hospital enterprise, creating divergent bottom lines and incentive structures.[13] In an earlier era of physician self-sufficiency, the capacity for harm from this dichotomy was relatively small. But when physician involvement and leadership in safety became crucial, the absence of a unified organizational structure became highly problematic.

■ **Progress versus safety.** Taken together, these four problems created a milieu in which patient safety was quite naturally ignored. Added to specific issues in health care is the traditional inclination of all industries to focus on production or progress instead of safety.[14] The hard work and vigilance needed to ensure flawless execution always seem less exciting than progress, whether the product is a surgical procedure, a space shuttle launch, or national security.

Many in health care have looked to the field of commercial aviation for guidance and inspiration. Although aviation's enviable safety record and tradition of emphasizing safety and teamwork makes this appropriate, there are important differences: Aviation is advantaged by the relatively small number of airlines, a single federal regulator, its inability to "hide" major errors, and the comparative simplic-

ity of its mission and information needs.[15] But there is another crucial distinction: Pilots die at the same time as their passengers after a fatal error. Lacking this "skin in the game," health care providers, already overly busy and stressed, needed other incentives to drive the work of patient safety. By catalyzing intense public pressure and professional acknowledgement of the problem, *To Err Is Human* created new incentives, felt by both providers and the systems in which they work. The rest of this paper describes some of the responses to these pressures and my impressions of their impact.

Are We Making Progress?

After hearing of yet another sentinel event in their institutions, every patient safety leader I know laments how little headway we've made in the past five years. Yet signs of progress are unmistakable. I recently asked an audience of 400 practicing hospitalists (a new breed of physician specializing in inpatient care) whether they believed that safety was better, the same, or worse than it was in 1999.[16] The results, although anecdotal, were instructive and somewhat reassuring: 45 percent said that it was better, 38 percent thought that it was the same, and 17 percent felt that it was worse. They were even more hopeful about the future: 67 percent thought that care would be safer still five years from now; 22 percent, the same; and only 11 percent, worse. Fifty-five percent felt that their hospital had a "culture of safety."

What had made a difference? Instead of any one specific thing, nearly half attributed the improvements to "overall increased sensitivity to the issue for a variety of reasons," and almost a third to "regulations (i.e., JCAHO)" (Joint Commission on Accreditation of Healthcare Organizations). Interestingly, only 7 percent felt that clinical information technology had made the most difference, despite the fact that they came from relatively "wired" hospitals—28 percent of their hospitals had well-functioning computerized physician order entry (CPOE), more than twice the national average.[17]

Like these physicians, I believe that improving safety requires a multidimensional approach and that we have made some progress since *To Err Is Human.* I have identified five major areas of activities and initiatives that have marked the past five years. Although some of the efforts may be seen as cross-cutting, they fall into the following broad categories: (1) regulation, (2) error reporting systems; (3) information technology; (4) the malpractice system and other vehicles for accountability; and (5) workforce and training issues.

The grades I have assigned are offered in a relatively unscientific effort to stimulate thought and conversation, and, in light of constraints in both the length and scope of this paper, the examples I offer are illustrative rather than comprehensive. Additionally, my focus, like that of *To Err Is Human,* is on the issue of medical errors, and therefore my grades do not reflect efforts focused more broadly on quality (such as pay-for-performance programs and public reporting of quality measures).

I do this while fully recognizing that some of these "quality" strategies are likely to be applied over time to patient safety.

■ **Regulation: A–.** Although the surveyed hospitalists thought that JCAHO was the second most important force for change, in another recent survey, hospital leaders felt that it was the most important driver of progress in patient safety.[18] Two examples demonstrate why. Prior to JCAHO's safety goal requiring read-backs of patients' names and oral orders, virtually no American hospital had a strict policy mandating this commonsensical redundancy, despite the fact that many restaurants have long performed read-backs to avoid errors in processing take-out orders. Moreover, during the preregulatory days of "sign your site," some surgeons placed an "X" on the site to be operated on (as in "X marks the spot"), while others put an "X" on the wrong site (as in, "don't cut here"), a further argument for standardization through regulation. JCAHO's revamping of its methods to use more clinically realistic assessment tools (following patients through the course of their care, a process known as the "tracer methodology"), instead of its traditional focus on policies and procedures, has helped as well.[19]

Because physicians remain highly individualistic (which causes them to resist regulatory solutions and standardization), and hospitals continue to lack a robust set of incentives to drive patient safety, regulatory solutions have arguably been the most important early step, particularly when it comes to procedural safety (creating safe systems, standardization, and redundancies) in hospitals. Unfortunately, the history of regulation is beset with examples of overreaching and unintended consequences, both of which can ultimately hamper flexibility and innovation. Moreover, it is hard to regulate the creation of a safety culture and the implementation of information technology. Accordingly, while the amount of regulation is likely to grow, I think that much of the low-hanging fruit will be picked soon and that other drivers will become increasingly important.

■ **Error-reporting systems: C.** A recent article in the *New York Times* bemoaned the fact that many New York hospitals were not reporting all of their errors to the state, despite the fact that the law insists that they do so. Nowhere in this article was there any discussion about what was being done with all of the reports that were being submitted.[20] This is the Achilles' heel of error-reporting systems: the flawed notion that reporting has any intrinsic value in and of itself. The problem is not limited to government reporting systems but is also seen within hospitals, where a growing number of incident reports is often taken as evidence that safety is improving (that is, there is now a healthy "reporting culture"), although there is no persuasive evidence to support this association.[21]

Error-reporting systems can be powerful tools when the reports are used to improve systems or educate providers, and they are particularly valuable when those who submit reports subsequently learn that their submissions made a difference. There are certainly examples of successes; one is hospitals where incident reports do lead to meaningful actions instead of pie charts.[22] Another is the federally sup-

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ported Web-based journal that I am privileged to edit, *AHRQ WebM&M*, in which interesting reports of errors, submitted anonymously by readers, are accompanied by expert commentaries (the Web site now receives about 1,000 unique visitors each day).[23] But, unlike in aviation, in which reports of near misses help illustrate human factor problems that catalyze action, in health care, errors are so frequent, the number of man-machine interfaces are so voluminous, and we have so much catching up to do that the average patient safety officer would have a full plate for the next five years without a single new report. Reporting is an area in which new models, and far greater resources devoted to translating submissions into action, will be needed.

■ **Information technology: B–.** It seems self-evident that many, perhaps most, of the solutions to medical mistakes will ultimately come through better information technology (IT). We may finally be nearing the time when institutions and providers will not be seen as credible providers of safe, high-quality care if they lack a strong IT backbone. As this momentum grows, we are beginning to overcome a vexing chicken-and-egg problem: There were few excellent off-the-shelf IT systems available, in large part because the market for them was so weak, making software companies wary of investing in program development. Although proponents often treat IT as the Holy Grail for patient safety, it is worth remembering that most of the data regarding the value of IT have been generated from a handful of institutions with decades of commitment to IT and robust, homegrown systems.[24]

Yet, fueled in part by the bold prompting of the Leapfrog Group (the business coalition that promotes patient safety through public reporting and pay-for-performance initiatives), we are beginning to see a marked uptick in clinical information system implementations.[25] As more systems get up and running, many are seeing good results, particularly in decreasing medication errors. But we've also seen the dark side: from Cedars-Sinai (where the plug was pulled on a relatively user-unfriendly homegrown system after a physician rebellion), to Beth Israel–Deaconess (where one researcher's data caused a massive system to crash for several days, leading to the memorable *Boston Globe* headline, "Got Paper?").[26] More concerning are reports of multiple errors actually introduced by IT systems themselves.[27]

Notwithstanding these cautionary notes, the experience of the Department of Veterans Affairs (VA), Brigham and Women's Hospital, and other IT leaders demonstrates that clinical systems can be made to work and that providers can be taught to use (and like) systems if they are well built and implemented.[28] Some systems are even beginning to move from simple execution of computerized orders to IT's greater promise of providing decision support and stemming informa-

tion loss at hand-offs. Moreover, the appointment of David Brailer as national health information technology coordinator (the "IT czar"), the recent awarding of $139 million in IT grants by the U.S. Department of Health and Human Services (HHS), and the efforts to develop uniform data-sharing standards are clear evidence that the federal government is taking this issue seriously.[29] As the hospitalist survey indicates, though, patient safety and clinical IT are not synonymous; perhaps the greatest danger from IT is that institutions that have invested heavily in it may feel that they have spent all they can on safety.

■ **The malpractice system and other vehicles for accountability: D+.** Troyen Brennan and his colleagues' elegant research has documented that the malpractice system is terribly broken: It does a poor job of compensating patients, punishing the negligent, and protecting the innocent.[30] It also demoralizes physicians and is beginning to lead to major access problems in some locations and among some specialists. Nevertheless, I believe that the system's impact (both positive and negative) on patient safety tends to be overemphasized. Moreover, the debate over tort reform has centered on possible caps on pain-and-suffering awards, which, whatever their merits, would not fundamentally alter the dynamics of the malpractice system in terms of its influence on patient safety. Switching instead to a no-fault system for compensating victims of medical errors would alter these dynamics, but it has not generated much political support.[31] More promising is the notion of "enterprise liability," in which malpractice lawsuits would be directed at organizations (such as hospitals) rather than providers, providing a powerful impetus for systems change.[32]

In contrast to malpractice, I believe that the lack of accountability for poor performance does harm patient safety. I say this despite being fully supportive of the "no blame," "it's the system" approach to safety. Even with this as the (appropriate) general rule, there are some bad doctors and nurses, and our system of accountability (at the level of individual institutions, professional associations, and state licensing boards) does not know how to deal with them. Moreover, with the implementation of new safety systems (such as "sign your site" or read-backs of oral orders), a new problem has emerged: what to do with providers who willfully violate reasonable safety rules. Nothing undercuts an institution's effort to fully comply with safety regulations more than having an individual provider (particularly a prominent physician) regularly ignore the regulations. As James Reason, one of the giants of systems theory, notes, "Seeing them get away with it on a daily basis does little for morale or for the credibility of the disciplinary system. Watching them getting their 'come-uppance' is not only satisfying, it also serves to reinforce where the boundaries of acceptable behavior lie."[33]

To my mind, this category presents some of the most complex issues in patient safety: how to promote a no-blame culture for providers who make innocent slips or mistakes while holding persistent rule violators or incompetent providers accountable; how to compensate patients for harm without necessarily invoking the heavy hand of tort law; how to hold institutions accountable for allowing unsafe

conditions to persist without hammering them in the newspapers or the courts when they acknowledge their flaws. I believe that we have made virtually no progress in tackling these exceptionally thorny questions in the past five years.

■ **Workforce and training issues: B.** This relatively high grade represents the growing appreciation of the importance of workforce issues and a few examples of action. In the inpatient arena, I believe that the most positive development is the emergence of hospitalists—physicians who care for, and coordinate the care of, hospitalized patients. This field, in its infancy in 1999, has grown to more than 10,000 physicians and a professional society of 5,000.[34] Although hospitalists create yet another safety challenge (by generating a purposeful discontinuity at hospital admission and discharge), the advantages of having an on-site physician who is expert in hospital care and coordination far outweigh the disadvantages. Moreover, hospitalists have emerged as important advocates for safety and systems thinking, partly because of their mindset and partly because many receive hospital support, which creates the aligned incentives that most of their colleagues lack.[35]

Hospitalists are "site-defined generalist specialists"—physicians whose specialty is defined by the site of their practice setting, rather than by organ-specific or procedural expertise. In this way, they resemble intensivists and emergency medicine physicians, other specialties that have embraced patient safety. In fact, another important development has been research validating the safety and quality advantages of intensivists.[36] Unfortunately, the national shortage of these critical care physicians has limited their reach, although in many institutions, hospitalists or new models of ICU telemedicine have partly filled the void.[37]

On the ambulatory side, the situation is less hopeful. Although ideally primary care physicians would assume leadership roles in ambulatory safety, few have the time to do so. Moreover, the perceived unattractiveness of primary care careers has led to a marked drop-off in applicants for these positions and is likely to result in a major shortage in coming years.[38] Finally, few small practices have had the resources to invest in office-based IT, although larger ambulatory systems are proving that progress is possible.[39]

In terms of nursing, the dominant theme has been the national nurse shortage, particularly in acute care environments, and the increasingly persuasive research demonstrating that patient outcomes are compromised when there are too few nurses, their hours are too long, or they are undertrained.[40] Driven in part by these data, California has mandated minimum nurse-to-patient ratios, and other states may follow suit.[41] Assuming that Peter isn't robbed to pay Paul to meet these ratios, safety is likely to be improved.

Physician training has also been influenced by the safety movement. In 2003 the Accreditation Council for Graduate Medical Education (ACGME) began enforcing limits on residents' duty hours (maximum of eighty hours per week or thirty hours per shift).[42] Many observers, including me, believe that these regulations probably harm safety in the short term by increasing the number of hand-offs but

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ultimately improve safety by decreasing fatigue among trainees. A recent study found that intensive care residents working shorter shifts committed fewer errors.[43] As we limit residents' hours, it will be important to consider and try to mitigate the inevitable trade-offs, such as the information "voltage drops" caused by additional transitions in care and the possible creation of a shift-work mentality in residents.[44]

I believe that the ACGME's duty-hours regulations are only the start of a new emphasis on trainees as key components of safety programs, in terms of not only working conditions but also their culture and socialization. We can expect this emphasis to be manifested by new methods to ensure that trainees' competencies (both traditional clinical competencies and those related to patient safety) are better defined, inculcated, and measured. This increased emphasis on competency assessment is likely to extend beyond the formal training period; more and more specialty medical boards are requiring periodic recertification by their diplomates, although the requirements for physicians remain far less stringent than those imposed on pilots.[45]

Another aspect of medical education that has been traditionally neglected is teamwork and simulation training; these strategies received much more attention after the IOM report's release. The best-known model is one drawn from aviation ("crew resource management"), in which participants are trained to tamp down hierarchies, use checklists and other redundancies, and communicate clearly, particularly in crises. Emerging data support the premise that such training can be adapted to clinical situations and lead to improvements in performance and safety.[46] Simulator training may achieve many of the same benefits and may also improve technical performance by both trainees and experienced providers needing to learn new techniques.[47]

Unfortunately, there is a huge gap between the promise of teamwork and simulator training and their application. Despite the fact that patient outcomes are increasingly determined by how well teams function under pressure (for example, promptly facilitating emergency coronary angioplasty and stenting in patients with acute myocardial infarction), no teamwork training is yet required of providers, and few medical and nursing schools include it in their curricula. Even when institutions have invested in such training, it is usually offered in small organizational units (the neonatal ICU, for example), not institutionwide. Simulator training, because it is more resource-intensive, is even less well developed: Even institutions known as "simulator centers" generally use simulators to train medical students or discrete specialists (such as anesthesiologists). As more data demonstrate the best models for teamwork training and simulation and prove that such

training does change clinical practices and culture, more pressure will be brought to bear on schools and health care institutions to make it a standard part of training and assessment. That will be a welcome development.

Conclusion

The past five years have demonstrated that patient safety resonates deeply with the public; that attacking medical mistakes effectively takes new mental models, research, technologies, and training; and that investments in safety can save lives.[48] At this point, I would give our efforts an overall grade of C+, with striking areas of progress tempered by clear opportunities for improvement.

Although institutions (including the federal government, foundations, health plans, hospitals, and clinics) are investing more in patient safety than they did prior to 1999, we still have a ways to go. For example, the federal investment in safety, mostly through the Agency for Healthcare Research and Quality (AHRQ), remains about 1/500th of its investment in medical progress, as reflected in the budget of the National Institutes of Health.[49] Although important research has come from AHRQ's early investment, its volume and impact have been limited by this underfunding.

Similarly, few hospitals have made major investments in safety (such as for paid safety officers or in teamwork or simulator training), particularly outside of IT. It is difficult to "blame" hospitals for this: Most lack large sources of capital that would allow them to make such expenditures without harming other important clinical initiatives or their ongoing revenue streams. Yet this underinvestment demonstrates that the business case for safety, although more compelling than it was before 1999, remains inadequate to the size of the task. In fact, the most important question going forward is this: What is the right mix of financial, educational, research, regulatory, organizational, and cultural activities and forces to catalyze the far greater investment (in money, time, and attention) that will be needed to make health care significantly safer?

Five years after *To Err Is Human*, we have reached the end of the beginning. Our patients clearly do not think that our work is done. Do we?

This work was supported by a grant from the Commonwealth Fund.

NOTES

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