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Special Communication

Five Years After *To Err Is Human*

What Have We Learned?

Lucian L. Leape, MD; Donald M. Berwick, MD

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Five years ago, the Institute of Medicine (IOM) called for a national effort to make health care safe. Although progress since then has been slow, the IOM report truly "changed the conversation" to a focus on changing systems, stimulated a broad array of stakeholders to engage in patient safety, and motivated hospitals to adopt new safe practices. The pace of change is likely to accelerate, particularly in implementation of electronic health records, diffusion of safe practices, team training, and full disclosure to patients following injury. If directed toward hospitals that actually achieve high levels of safety, pay for performance could provide additional incentives. But improvement of the magnitude envisioned by the IOM requires a national commitment to strict, ambitious, quantitative, and well-tracked national goals. The Agency for Healthcare Research and Quality should bring together all stakeholders, including payers, to agree on a set of explicit and ambitious goals for patient safety reached by 2010.

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pecially necessary, such as the Adverse Outcomes Index developed by the Quality Assurance Committee of the American College of Obstetricians and Gynecologists, which is used in labor and delivery and includes weighted values for all complications (B. Sachs, Beth Israel Deaconess Medical Center, written communication, October 2004). Measures are crucially necessary to be able to demonstrate that changes improve safety and decrease costs.

The current reimbursement structure works against improving safety and actually rewards less safe care in many instances. For example, insurance companies sometimes will not pay for new practices that reduce errors, such as anticoagulation clinics operated by nurses, new information technologies, or counseling of patients by retail pharmacists. However, payers often subsidize unsafe care quite well, although unknowingly. In most industries, defects cost money and generate warranty claims. In health care, perversely, under most forms of payment, health

proved by the NQF; spru on teamwork and safety closure to patients follo

The electronic health i finally, an idea whose ti Many of the technical p as the lack of standards: ments and ensuring inter have held back adoptio or well on their way to federal government has information technologies Brailer, within the Depart and Human Services to stimulate dissemination. and health care systems realize that the substanti: vestment that is require tems in place in every hc ery physician's office wil handsomely within a few creases in efficiency and charges for costly advers

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and policies, share a common safety. Without commitment from the organization requires all life practices, a clear statement of responsibility of executive officials and health care as a true priority is not omitted. Substantial safety.

to making assurances. Identifying progress, improvement depends on the resources. Some executive types of specific types of tests (blood test),⁴² and more improvement of measures are essential.

Care professionals receive a premium for a defective product; physicians and hospitals can bill for the additional services that are needed when patients are injured by their mistakes.⁴³

What Do We Need to Do?

Despite these formidable barriers, health care is well poised to increase the pace of improving patient safety in the near future. As a result of the advances by the many stakeholders over the past 5 years, a critical mass of informed and concerned physicians, nurses, pharmacists, administrators, risk managers, and other individuals is in place to help organizations make substantial changes. Not only do these highly motivated individuals have the skills and knowledge needed to make changes, they have the tools they need in the form of tested and effective safe practices awaiting implementation.

Dramatic advances are likely within the next 5 years in at least 4 important areas: implementation of electronic health records; wide diffusion of proven and safe practices, such as those ap-

Services, have indicated in furthering the adoption of proven safe practices. wrestled with implementation of a set of practices. JCAHO over the past decade developed considerable changes, and Quality Improvement help them has also grown now be able to implement faster, and will find incentives to do so.

Training physicians and other professionals to another idea whose time has come. The interest in simulation techniques. The Council on Graduate Medical Education has now articulated as 2 of the core competencies to be inculcated in residency training schemes and hospitals and team training to the

to the corporate priority of financial health. At a national level, such a commitment has yet to emerge; indeed, it is not in sight.

If the experience of the past 5 years demonstrates anything, it is that neither strong evidence of ongoing serious harm nor the activities, examples, and progress of a courageous minority are sufficient to generate the national commitment needed to rapidly advance patient safety. Such a commitment is not likely to be forthcoming without more sustained and powerful pressure on hospital boards and leaders—pressure that must come from outside the health industry.

Mobilizing Pressure for Change

Where will this pressure come from? In England, the governmental response has been to establish a National Patient Safety Agency under the National Health Service, charged with stimulating and coordinating safety efforts throughout the system.⁴⁶ In the current US political climate, it is hard to imagine a similar effort by the federal government within the foreseeable future.

Can public outrage provide the pressure needed for change? Although surveys continue to show the public is concerned about medical errors and

iors, but it seems insufficient to do the job of transforming cultures, where the deeper solutions lie.

Can reimbursement provide the pressure for change? The current method of financing health care not only fails to provide incentives for safe care, it rewards unsafe care. That can change, and in fact, is changing. The pay for performance movement is gathering steam. Experiments with bonuses for physicians and plans who achieve goals of providing needed care, such as annual eye examinations for patients with diabetes mellitus, are well under way. Under the recent Medicare Modernization Act, the Centers for Medicare & Medicaid Services is launching some important and promising demonstration experiments that may offer evidence on the effect of improved payment schemes on safety efforts.

Whether these schemes will result in measurable improvements in safety remains to be seen. An important concern is whether current performance measures have sufficiently high sensitivity and specificity to accurately identify safer care when used in report cards or reimbursement plans. A second question is whether we have a sufficient number of validated measures to have a significant impact on safety, or on reimbursement. Finally, it seems likely

It may be equally important to begin to create negative financial consequences, or at least disincentives rather than financial rewards, for hospitals and other health care organizations that continue to tax the public and their patients with the burden of unsafe practices and resulting complications. Payment should not reward poor safety. In this regard, the recent decision by payers in Minnesota to cease paying hospitals for serious preventable adverse events⁴⁹ makes good sense and should be emulated by payers nationwide.

Setting Safety Goals

But for nationwide impact, we cannot rely on these piecemeal efforts to provide the pressure needed for change. If the payers and other parties are to have a significant impact on patient safety in the next 5 years, their efforts must be aligned behind common national safety goals. The most important single step that should be taken by the United States to align the forces of change would be to set and adhere to strict, ambitious, quantitative, and well-tracked national goals.

In November 2004, at the Commonwealth Fund-IOM meeting commemorating the fifth anniversary of the IOM report, participants called for a con-

the NQF; spread of training
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staffs.

Finally, the ethically embarrassing de-
bate over disclosure of injuries to pa-
tients is, we strongly hope, drawing to
a close. Although actual practice still lags
far behind the rhetoric,⁴⁵ few health care
organizations now question the impera-
tive to be honest and forthcoming with
patients following an injury. As evi-
dence accumulates that full disclosure
does not increase the risk of being sued,
it is becoming easier for physicians and
nurses to do what they know is the right
thing—tell the patient everything they
know when they know it.

These advances will be welcomed
and will have a measurable impact on
reducing medical errors and injuries
over the next 5 years. However, these
advances represent only a small frac-
tion of the work that needs to be done.
A truly national response to the IOM's
call to reduce preventable patient in-
juries by 90% requires that every health
care board, executive, physician, and
nurse make improving safety an abso-
lutely top strategic priority—fully equal

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ity Forum; 2002.

letter Health Care: A Consen-
on, DC: National Quality Fo-

rovement Project. A partner-
available at: <http://www.medqic>
ember 8, 2004.

fety Foundation. Available at:
Accessed December 3, 2002.

Medical Specialties. Status of
ble at: <http://www.abms.org>
y verified April 19, 2005.

, Lee J, et al. The impact of com-
ler entry on medication error
orm Assoc. 1999;6:313-321.

de AA. Improving safety with
N Engl J Med. 2003;348:2526-

), Clapp MD, et al. Pharma-
sician rounds and adverse drug
re unit. *JAMA.* 1999;282:267-

sters M, Mlynarek M, Nafziger
inding teams reduce prevent-
nts in hospital general medi-
Med. 2003;163:2014-2018.

armed patient: hospitals form
t deaths. *Wall Street Journal.*

Medication safety: one orga-
the challenge. *J Clin Out-*
3:27-34.

, Justeson J, Macken P, Lind-
rdization as a mechanism to
h care. *Jt Comm J Qual Saf.*

- intensive care units. *N Engl J Med.* 2004;351:1838-1848.
41. *Hospital Governing Boards and Quality of Care: A Call to Responsibility.* Washington, DC: National Quality Forum; 2004.
42. Agency for Healthcare Research and Quality. Quality indicators. Available at: <http://www.qualityindicators.ahrq.gov>. Accessed December 8, 2004.
43. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care.* 2003;12:194-200.
44. Leatherman S, Berwick D, Iles D, et al. The business case for quality: case studies and an analysis. *Health Aff (Millwood).* 2003;22:17-30.
45. Lamb R. Open disclosure: the only approach to medical error. *Qual Saf Health Care.* 2004;13:3-5.
46. National Patient Safety Agency. Available at: <http://www.npsa.nhs.uk/>. Accessed April 22, 2005.
47. Consumers Advancing Patient Safety (CAPS). Available at: <http://www.patientsafety.org>. Accessed December 8, 2004.
48. Persons United Limiting Substandards and Errors (PULSE). Available at: <http://www.pulseamerica.org/>. Accessed December 8, 2004.
49. Kazel R. Minnesota insurer won't pay hospitals for "never events." *American Medical News.* November 8, 2004. Available at: <http://www.ama-assn.org/amednews/2004/11/08/bisd1108.htm>. Accessibility verified April 20, 2005.
50. Institute for Healthcare Improvement. 100k lives campaign. Available at: <http://www.ihl.org/IHI/Programs/Campaign/>. Accessibility verified April 20, 2005.
51. Hillman K, Parr M, Flabouris A, et al. Redefining in-hospital resuscitation: the concept of the medical emergency team. *Resuscitation.* 2001;48:105-110.

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Basically, L. Leape appeals ~~to~~

to Pressure ^{that} Has to Come
from Others

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Five Years After *To Err Is Human* What Have We Learned?

Lucian L. Leape, MD

Donald M. Berwick, MD

FIVE YEARS AFTER THE INSTITUTE of Medicine (IOM) reported that as many as 98 000 people die annually as the result of medical errors and called for a national effort to make health care safe, it is time to assess our progress. Is health care safer now? And, if not, why not?

The IOM's report, *To Err Is Human: Building a Safer Health System*,¹ galvanized a dramatically expanded level of conversation and concern about patient injuries in health care both in the United States and abroad. Patient safety, a topic that had been little understood and even less discussed in care systems, became a frequent focus for journalists, health care leaders, and concerned citizens.

Small but consequential changes have gradually spread through hospitals, due largely to concerted activities by hospital associations, professional societies, and accrediting bodies. All hospitals have implemented some new practices to improve safety. Fewer patients die from accidental injection of concentrated potassium chloride, now that it has been removed from nursing unit shelves²; fewer patients have complications from warfarin, now that many taking anticoagulants are being treated in dedicated clinics³; and serious infections have been reduced in hospitals that have tightened infection control procedures (J. Whittington, written communication, March 2005; K. McKinley, Geisinger Clinic, written communication, April 2005; and P. Pronovost, Johns Hopkins Hospital, written communication, January 2005).⁴

Five years ago, the Institute of Medicine (IOM) called for a national effort to make health care safe. Although progress since then has been slow, the IOM report truly "changed the conversation" to a focus on changing systems, stimulated a broad array of stakeholders to engage in patient safety, and motivated hospitals to adopt new safe practices. The pace of change is likely to accelerate, particularly in implementation of electronic health records, diffusion of safe practices, team training, and full disclosure to patients following injury. If directed toward hospitals that actually achieve high levels of safety, pay for performance could provide additional incentives. But improvement of the magnitude envisioned by the IOM requires a national commitment to strict, ambitious, quantitative, and well-tracked national goals. The Agency for Healthcare Research and Quality should bring together all stakeholders, including payers, to agree on a set of explicit and ambitious goals for patient safety to be reached by 2010.

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Although these efforts are affecting safety at the margin, their overall impact is hard to see in national statistics. No comprehensive nationwide monitoring system exists for patient safety, and a recent effort by the Agency for Healthcare Research and Quality (AHRQ) to get a national estimate by using existing measures showed little improvement.⁵ Although that estimate was largely based on insurance claims data, measures known to have low sensitivity for detecting quality improvement, little evidence exists from any source that systematic improvements in safety are widely available.

Perhaps inevitably, critics have pushed back against viewing safety as a problem of science—of system design. Public support for improving patient safety often turns instead on fixing blame. Despite the widely disseminated message from the IOM that systems failures cause most injuries, most individuals still believe that the

major cause of bad care is bad physicians, and that if miscreant clinicians were removed everything would be all right.⁶ Some have claimed that the emphasis on systems, and particularly, not blaming individuals for errors, will weaken accountability for physician performance.⁷ Related concerns have led to legislation imposing stricter reporting requirements on hospitals and physicians.⁸ The latest surge in the malpractice premium crisis has deflected interest of lawmakers from error prevention to an effort to put caps on malpractice settlements.

Although the proven measured fruits of the IOM report so far are few,

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its impact on attitudes and organizations has been profound. In addition, thanks to research sponsored by AHRQ, health care leaders have also learned a great deal about safety that they did not know in 1999. In sum, the groundwork for improving safety has been laid these past 5 years but progress is frustratingly slow. Building a culture of safety is proving to be an immense task and the barriers are formidable. Whether significant progress will be achieved in the next 5 years depends on how successfully those barriers are addressed.

Our goal is to summarize what has happened, analyze the reasons why improvement has not been greater, and make recommendations for what needs to be accomplished to realize the IOM's vision.

What Have We Accomplished?

The effects of the IOM report are evident in at least 3 important areas: viewing the task of error prevention, enlisting the support of stakeholders, and changing practices.

Viewing the Task of Error Prevention. First, the IOM report profoundly changed the way many health care professionals and managers think and talk about medical errors and injury. It truly changed the conversation. Although a substantial minority among both clinicians and the lay public continue to doubt that injury and mortality rates are as high as the IOM claimed,^{6,9,10} subsequent data from various sources suggest that the IOM may have substantially underestimated the magnitude of the problem.¹¹⁻¹⁶ Nosocomial infections alone, most of which are preventable, account for more than 90 000 deaths per year,¹⁷ and hospital-acquired bloodstream infections alone may rank as the eighth leading cause of death in the United States.¹⁸ Few individuals now doubt that preventable medical injuries are a serious problem. Far more physicians and nurses today ask not whether there is a problem but rather what they can do about it.

The concept that bad systems, not bad people, lead to the majority of er-

rors and injuries, which is a crucial scientific foundation for improvement of safety in all successful high-hazard industries, has become a mantra in health care. Skeptics abound but more and more health care leaders appear to accept the corollary that blaming individuals is usually neither fair nor effective as a mainstay approach in pursuit of safety. Interest in technologies to support safer care has increased, most especially with respect to computer-assisted physician order-entry systems; the decades-old stalled discussions about electronic health care records have acquired new life. Before the IOM report, deficient safety was simply not a problem widely known in the health care industry. Now, it is.

Some ambiguity exists about the relationship between safety as a desired characteristic of health care and the broader issues of health care quality in general. The IOM Roundtable on Quality of Care categorized threats to quality in 3 broad families: overuse (receiving treatment of no value), underuse (failing to receive needed treatment), and misuse (errors and defects in treatment).¹⁹ In its narrowest form, a focus on safety addresses only the third family, that is, a subset of the whole domain of quality of care.

However, mistakes by caregivers that lead to physical injuries are much less acceptable to patients than overuse or underuse, and cause far more emotional reaction. Indeed, the focus on active harm—misuse—may help explain the intense public interest in safety compared with quality improvement in general. Health care professionals, too, may feel far worse if they harm a patient directly than if they provide inappropriate care.

As attention to patient safety has deepened, the boundaries among overuse, underuse, and misuse have blurred. It seems logical that patients who fail to receive needed treatments or who are subjected to the risks of unneeded care are also placed at risk for injury every bit as objectionable as direct harm from a surgical mishap. Operationally, the terrain of quality is becoming more uni-

fied. Importantly, it is much clearer now that the most effective method to improve either safety or quality overall is to change the systems.

Enlisting the Support of Stakeholders. The second major effect of the IOM report was to enlist a broad array of stakeholders, some quite surprising, to advance patient safety. The first stakeholder was the federal government. Responding to the IOM recommendation, the US Congress in 2001 appropriated \$50 million annually for patient safety research. That support, although a tiny fraction of the \$28 billion budget for the National Institutes of Health, was enough to enlist hundreds of new investigators into patient safety research, essentially launching the academic base for that work. Research in error prevention and patient safety became a legitimate academic pursuit.

Unfortunately, in 2004 after only 3 years of support, federal funding for patient safety research through AHRQ became almost entirely earmarked toward studies of information technology. As crucial as such technologies are, this reallocation revealed a serious misunderstanding of the broad array of research that will be needed to address the safety problem, and is quickly starving the new recruits who would have pursued aspects of safety other than information technology.

Congress, however, did codify AHRQ as the lead federal agency for patient safety and AHRQ established a Center for Quality Improvement and Safety, which has become the leader in education, training, convening agenda-setting workshops, disseminating information, developing measures, and facilitating the setting of standards. Despite its limited budget, AHRQ has been an important voice for safety through its support for evaluating best practices, demonstrations to enhance reporting of adverse events, errors and near misses, its development of patient safety indicators now used by many hospitals, and its development of a roadmap of evidence-based best practices used by the National Quality Forum (NQF).

FIVE YEARS AFTER TO ERR IS HUMAN

The Veteran's Health Administration quickly emerged as a bright star in the constellation of safety practice, with system-wide implementation of safe practices, training programs, and the establishment of 4 patient-safety research centers.^{20,21}

A host of nongovernmental organizations have made safety a priority. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has led the way, tightening up accountability within health care organizations and requiring hospitals to implement new safe practices.²² The NQF, a public-private partnership to develop and approve measures of quality of care, developed a consensus process that generated standards for mandatory reporting²³ and created a list of high-impact evidence-based safe practices that the JCAHO and other organizations are now beginning to require hospitals to implement.²⁴ The Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention have joined with more than 20 surgical organizations in a new program to reduce surgical complications,²⁵ and many other specialty societies, particularly the American College of Physicians, have incorporated safety topics into their meetings, education, and research.

The National Patient Safety Foundation, originally housed by the American Medical Association, has become a major force in increasing awareness. Although the National Patient Safety Foundation remains short of stable funding, it has gained a national following and the annual conferences are a wellspring of education and research findings in patient safety.²⁶ The Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties are engaged in a massive effort to define competencies and measures in each specialty, both for residency training and continuing evaluation of practicing physicians.²⁷

The Institute for Healthcare Improvement has helped hospitals redesign their systems for safety through demonstra-

tion projects, system changes, and training in implementation of safe practices for thousands of physicians, nurses, and pharmacists. Several Quality Improvement Organizations have become skilled at helping hospitals reduce medication injury rates and other hazards.

Regional coalitions have sprung up across the country to facilitate stakeholders to work together to set goals, collect data, disseminate information, and provide education and training to improve safety. The original list of medication safety practices for hospitals was disseminated in 1999 by the Massachusetts Coalition for the Prevention of Medical Errors and later adopted by the American Hospital Association. Several large, integrated health care systems, notably Kaiser-Permanente, Ascension, and the Veteran's Health Administration, have been leaders in implementing new safe policies and practices. Hospital group-purchasing organizations, such as VHA and Premier, have made major commitments to disseminating safety information and practices.

Purchasers and payers have entered the arena, particularly the Leapfrog Group, formed by a number of major US corporations. The Leapfrog Group has strongly encouraged the adoption of a number of safer practices in hospitals, including computerized physician order entry systems, proper staffing of intensive care units, and the concentration of highly technical surgery services in high-volume centers. The most recent "Leap" focuses on implementation of the NQF's Safe Practices.

But the most important stakeholders who have been mobilized are the thousands of devoted physicians, nurses, therapists, and pharmacists at the ground level—in the hospitals and clinics—who have become much more alert to safety hazards. They are making myriad changes, streamlining medication processes, working together to eliminate infections, and trying to improve habits of teamwork. The level of commitment of these frontline professionals is inspiring. Most are making

changes, not primarily in response to mandates, but rather to improve the quality of care for their patients.

Changing Practices. The third effect of the IOM report was to accelerate the changes in practice needed to make health care safe. Initially, adoption of new safe practices was entirely voluntary. Some hospitals responded to recommendations for medication safety from regional coalitions or the American Hospital Association. Other organizations sent teams to Institute for Healthcare Improvement programs that trained them in rapid cycle improvement and the application of human factors principles in the redesign of their processes. Still others began to change practices in response to the Leapfrog Group mandate.

Following the 2002 publication by the NQF of a list of 30 evidence-based safe practices ready for implementation, the JCAHO in 2003 required hospitals to implement 11 of these practices, including improving patient identification, communication, and surgical-site verification.²⁷ Additional practices have been added for implementation in 2005.

It is too soon to evaluate the effect of the JCAHO requirements, and few large controlled studies of previously implemented changes have been performed. However, time-series data from hospitals and systems that have been working to improve safety are encouraging. The results achieved in implementing 12 practice changes are presented in the TABLE.^{4,28-35} If these results were replicated nationwide, the impact would be substantial.

Finally, a major practice change occurred in teaching hospitals in 2003 when all residency training programs implemented new residency training work hour limitations. These limitations were promulgated by the Accreditation Council on Graduate Medical Education and based on strong but not previously acknowledged scientific information on the relationships between fatigue and errors at work.³⁶⁻³⁹ While these work hour restrictions are an enormous step forward, they do not

address the most important cause of fatigue: sleep deprivation due to extended duty shifts. Recent studies have provided specific evidence of the pernicious effect of sleep deprivation on resident performance.⁴⁰

Barriers to Progress

The diversity and level of engagement in improving safety in health care is impressive. Ten years ago, no one was talking about patient safety. Five years ago, before the IOM report, a small number in a few pioneering places had developed a strong commitment, but its impact was limited and most of health care was unaffected. Now, the majority of health care institutions are involved to some extent and public awareness has soared. A growing patient safety movement is afoot.

But if so much activity is going on, why isn't health care demonstrably and measurably safer? Why has it proved so difficult to implement the practices and policies needed to deliver safe patient care? Why are so many physicians still not actively involved in patient safety efforts? What needs to be done to accelerate the pace of improvement in patient safety?

The answers to these questions are to be found in the culture of medicine, a culture that is deeply rooted, both by custom and by training, in high standards of autonomous individual performance and a commitment to progress through research. It is the same culture that in the latter half of the 20th century brought profound advances in biomedical science and delivered unprecedented cures to millions of US individuals. This culture is technically audacious and productive; many of today's most powerful drugs and treatments were not available as recently as 2 decades ago.

However, these advances created challenges to safety not faced by other hazardous industries that have succeeded far better than medical care in becoming safe, even ultra-safe. The first such challenge is complexity. Modern health care technology is almost certainly more complex than that of other

Table. Clinical Effectiveness of Safe Practices

Intervention	Results
Perioperative antibiotic protocol	Surgical site infections decreased by 93% ^{*†}
Physician computer order entry	51% Reduction of medication errors ^{28,29}
Pharmacist rounding with team	66% Reduction of preventable adverse drug events ²⁹
	76% Reduction of preventable adverse drug events ³¹
Protocol enforcement	95% Reduction in central venous line infections [†]
	92% Reduction in central venous line infections [‡]
Rapid response teams	Cardiac arrests decreased by 15% ³²
Reconciling medication practices	90% Reduction in medication errors ³³
Reconciling and standardizing medication practices	60% Reduction in adverse drug events over 12 mo (from 7.6 per 1000 doses to 3.1 per 1000 doses) ³³
	64% Reduction in adverse drug events in 20 mo (from 3.8 per 1000 doses to 1.39 per 1000 doses) [†]
Standardized insulin dosing	Hypoglycemic episodes decreased 63% (from 2.95% of patients to 1.1%) ³⁴
	90% Reduction in cardiac surgical wound infections (from 3.8% of patients to 0.4%) [§]
Standardized warfarin dosing	Out-of-range international normalized ratio decreased by 60% (from 25% of tests to 10%) ³³
Team training in labor and delivery	50% Reduction in adverse outcomes in preterm deliveries
Trigger tool and automation	Adverse drug events reduced by 75% between 2001 and 2003 ³⁵
Ventilator bundle protocol	Ventilator-associated pneumonias decreased by 62% [*]

*J. Whittington, written communication, March 2005.

†P. Pronovost, Johns Hopkins Hospital, written communication, January 2005.

‡R. Shannon, written communication, January 2005.

§K. McKinley, Geisinger Clinic, written communication, April 2005.

||B. Sachs, Beth Israel Deaconess Medical Center, written communication, October 2004.

industries. The dean of safety researchers, Professor James Reason, has observed that health care is also more complex than any other industry he knows in terms of relationships, with more than 50 different types of medical specialties and subspecialties interacting with each other and with an equally large array of allied health professions (oral communication, October 2003). The more complex any system is, the more chances it has to fail.

A second challenge is medicine's tenacious commitment to individual, professional autonomy. Creating cultures of safety requires major changes in behavior, changes that professionals easily perceive as threats to their authority and autonomy. Overlay this demand to change individual behavior with the challenges of learning a nonblaming systems-oriented approach to errors and establishing new lines of accountability, and it is not surprising that progress in achieving safety in health care is slow.

Fear poses a third major challenge. Many physicians greeted the horren-

dous mortality data published by the IOM with disbelief and concern that the information would undermine public trust. The normal human resistance to change was amplified by fear of loss of autonomy, antipathy toward attempts by others outside the profession to improve practice, and skepticism about the new concept that systems failures are the underlying cause of most human errors. An understandable fear of malpractice liability inhibits willingness to discuss, or even admit, errors.

The combination of complexity, professional fragmentation, and a tradition of individualism, enhanced by a well-entrenched hierarchical authority structure and diffuse accountability, forms a daunting barrier to creating the habits and beliefs of common purpose, teamwork, and individual accountability for successful interdependence that a safe culture requires.

In addition to these powerful cultural factors, lack of leadership at the hospital or health plan level impedes progress. Changing the culture, even

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changing a few practices and policies, requires that all personnel share a common vision and personally own safety. This cannot happen without commitment at the top level of the organization. Although the JCAHO requires all hospitals to implement safe practices, and the NQF has issued a clear statement about the responsibility of boards,⁴¹ few of the chief executive officers and boards of hospitals and health plans have made safety a true priority in their institutions or committed substantial resources toward safety.

Another key barrier to making progress is a paucity of measures. Identifying problems, measuring progress, and demonstrating that improvement has been achieved all depend on the availability of robust measures. Some exist, such as measures of specific types of infections, certain laboratory tests (blood glucose), AHRQ's recent promulgation of a set of patient safety indicators,⁴² and the Institute for Healthcare Improvement's trigger tools for measurement of harm,⁴³ but many more measures are needed. More global measures are especially necessary, such as the Adverse Outcomes Index developed by the Quality Assurance Committee of the American College of Obstetricians and Gynecologists, which is used in labor and delivery and includes weighted values for all complications (B. Sachs, Beth Israel Deaconess Medical Center, written communication, October 2004). Measures are crucially necessary to be able to demonstrate that changes improve safety and decrease costs.

The current reimbursement structure works against improving safety and actually rewards less safe care in many instances. For example, insurance companies sometimes will not pay for new practices that reduce errors, such as anticoagulation clinics operated by nurses, new information technologies, or counseling of patients by retail pharmacists. However, payers often subsidize unsafe care quite well, although unknowingly. In most industries, defects cost money and generate warranty claims. In health care, perversely, under most forms of payment, health

care professionals receive a premium for a defective product; physicians and hospitals can bill for the additional services that are needed when patients are injured by their mistakes.⁴⁴

What Do We Need to Do?

Despite these formidable barriers, health care is well poised to increase the pace of improving patient safety in the near future. As a result of the advances by the many stakeholders over the past 5 years, a critical mass of informed and concerned physicians, nurses, pharmacists, administrators, risk managers, and other individuals is in place to help organizations make substantial changes. Not only do these highly motivated individuals have the skills and knowledge needed to make changes, they have the tools they need in the form of tested and effective safe practices awaiting implementation.

Dramatic advances are likely within the next 5 years in at least 4 important areas: implementation of electronic health records; wide diffusion of proven and safe practices, such as those approved by the NQF; spread of training on teamwork and safety; and full disclosure to patients following injury.

The electronic health record may be, finally, an idea whose time has come. Many of the technical problems, such as the lack of standards for data elements and ensuring interoperability that have held back adoption, are resolved or well on their way to solution. The federal government has appointed an information technologies czar, Dr David Brailer, within the Department of Health and Human Services to oversee and stimulate dissemination. Major payers and health care systems have begun to realize that the substantial up-front investment that is required to put systems in place in every hospital and every physician's office will be paid back handsomely within a few years by increases in efficiency and decreases in charges for costly adverse events.

The pace of adoption of safe practices will almost certainly accelerate. The JCAHO and several payers, including Centers for Medicare & Medicaid

Services, have indicated their interest in furthering the adoption of the NQF proven safe practices. As hospitals have wrestled with implementing the initial set of practices required by the JCAHO over the past 2 years, they have developed considerable expertise in making changes, and the capacity of the Quality Improvement Organizations to help them has also grown. Hospitals will now be able to implement new practices faster, and will find increasing incentives to do so.

Training physicians, nurses, and other professionals to work in teams is another idea whose time seems to have come. The interest in team training has grown rapidly over the past several years, abetted by the adoption of simulation techniques. The Accreditation Council on Graduate Medical Education has now articulated practice-based learning and systems-based practice as 2 of the core professional skills to be inculcated in all approved residency training schemes. Whole systems and hospitals are now providing team training to their entire medical staffs.

Finally, the ethically embarrassing debate over disclosure of injuries to patients is, we strongly hope, drawing to a close. Although actual practice still lags far behind the rhetoric,⁴⁵ few health care organizations now question the imperative to be honest and forthcoming with patients following an injury. As evidence accumulates that full disclosure does not increase the risk of being sued, it is becoming easier for physicians and nurses to do what they know is the right thing—tell the patient everything they know when they know it.

These advances will be welcomed and will have a measurable impact on reducing medical errors and injuries over the next 5 years. However, these advances represent only a small fraction of the work that needs to be done. A truly national response to the IOM's call to reduce preventable patient injuries by 90% requires that every health care board, executive, physician, and nurse make improving safety an absolutely top strategic priority—fully equal

to the corporate priority of financial health. At a national level, such a commitment has yet to emerge; indeed, it is not in sight.

If the experience of the past 5 years demonstrates anything, it is that neither strong evidence of ongoing serious harm nor the activities, examples, and progress of a courageous minority are sufficient to generate the national commitment needed to rapidly advance patient safety. Such a commitment is not likely to be forthcoming without more sustained and powerful pressure on hospital boards and leaders—pressure that must come from outside the health industry.

Mobilizing Pressure for Change

Where will this pressure come from? In England, the governmental response has been to establish a National Patient Safety Agency under the National Health Service, charged with stimulating and coordinating safety efforts throughout the system.⁴⁵ In the current US political climate, it is hard to imagine a similar effort by the federal government within the foreseeable future.

Can public outrage provide the pressure needed for change? Although surveys continue to show the public is concerned about medical errors and sensational cases provoke bursts of outrage, public concern is evanescent and thus an inadequate motivator for change. Even campaigns from patient advocacy groups^{47,48} have failed to stir many boards of trustees of hospitals to call for major organizational changes.

What about regulation? One of the star players in the safety movement over the past 5 years has been the JCAHO, which has steadily increased the demands on hospitals to take patient safety seriously and indicated its commitment to continue to press for adoption of more proven safe practices. But regulation works as a sustainable force for change only when those organizations being regulated see those changes to be in their longer-run self-interest. The threat of decertification can produce evanescent, compliant behav-

iors, but it seems insufficient to do the job of transforming cultures, where the deeper solutions lie.

Can reimbursement provide the pressure for change? The current method of financing health care not only fails to provide incentives for safe care, it rewards unsafe care. That can change, and in fact, is changing. The pay for performance movement is gathering steam. Experiments with bonuses for physicians and plans who achieve goals of providing needed care, such as annual eye examinations for patients with diabetes mellitus, are well under way. Under the recent Medicare Modernization Act, the Centers for Medicare & Medicaid Services is launching some important and promising demonstration experiments that may offer evidence on the effect of improved payment schemes on safety efforts.

Whether these schemes will result in measurable improvements in safety remains to be seen. An important concern is whether current performance measures have sufficiently high sensitivity and specificity to accurately identify safer care when used in report cards or reimbursement plans. A second question is whether we have a sufficient number of validated measures to have a significant impact on safety, or on reimbursement. Finally, it seems likely that pay for performance, like all other methods of reimbursement, will have its own unanticipated perverse incentives that could undermine its effectiveness.

A better approach would be to favor in-payment hospitals and physicians who actually achieve high levels of safety. What about incentive bonuses for driving levels of ventilator-associated pneumonia, surgical site infections, or central line infections to zero, or close to zero? These levels have already been achieved in a small number of hospitals committed to safe care (P. Pronovost, Johns Hopkins Hospital, written communication, January 2005).⁴ Payment incentives could accelerate widespread adoption of these practices with savings in life and money that would be enormous.

It may be equally important to begin to create negative financial consequences, or at least disincentives rather than financial rewards, for hospitals and other health care organizations that continue to tax the public and their patients with the burden of unsafe practices and resulting complications. Payment should not reward poor safety. In this regard, the recent decision by payers in Minnesota to cease paying hospitals for serious preventable adverse events⁴⁹ makes good sense and should be emulated by payers nationwide.

Setting Safety Goals

But for nationwide impact, we cannot rely on these piecemeal efforts to provide the pressure needed for change. If the payers and other parties are to have a significant impact on patient safety in the next 5 years, their efforts must be aligned behind common national safety goals. The most important single step that should be taken by the United States to align the forces of change would be to set and adhere to strict, ambitious, quantitative, and well-tracked national goals.

In November 2004, at the Commonwealth Fund–IOM meeting commemorating the fifth anniversary of the IOM report, participants called for a concerted effort to set clearly defined achievable goals for improving patient safety over the next 5 years—goals with measurable end points.

We call upon the AHRQ to bring together the JCAHO, NQF, American Hospital Association, American Medical Association, Leapfrog Group, and all of the major payers, including the Centers for Medicare & Medicaid Services, to agree on a set of explicit and ambitious goals for patient safety to be reached by 2010. The list provided by the Commonwealth Fund–IOM would be a good place to start. It is short, concrete, and achievable. This list called for a 90% reduction in nosocomial infections, a 50% reduction in medication errors, a 90% reduction in errors associated with high-harm medications, and 100% elimination of

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the NQF "never" list.³⁴ In its 100 000 Lives campaign,³⁰ the Institute for Healthcare Improvement has adopted these as well as so-called rapid response teams to prevent failures to rescue.³¹ Not only would these results measurably improve safety overall, but also achieving them would require institutions to make a high-level commitment and to develop effective teams, 2 critical elements of the culture change that is needed.

Technically, results like these are not out of reach. With sufficient will and leadership, they lie entirely within our grasp. The primary obstacles to achieving these results for the patients who depend on physicians and health care organizations are no longer technical; the obstacles lie in beliefs, intentions, cultures, and choices. All of those can change. The most important lesson of the past 5 years since the IOM spoke out on one of the major public health issues of

our time is that we will not become safe until we choose to become safe.

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REFERENCES

- Kohn KT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.
- Joint Commission on Accreditation of Healthcare Organization. Sentinel event trends: potassium chloride events by year. Available at: <http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/set+potassium.htm>. Accessed April 2, 2005.
- Kelly JJ, Sweigard KW, Shields K, Schnelder D, John M, Eisenberg Patient Safety Awards: safety, effectiveness, and efficiency: a Web-based virtual anticoagulation clinic. *Jt Comm J Qual Saf*. 2003;29:646-651.
- Whittington J, Cohen H. OSF Healthcare's journey in patient safety. *Qual Manag Health Care*. 2004;13:53-59.
- 2004 National Healthcare Quality Report. Rockville, Md: Agency for Healthcare Research and Quality; 2004.
- Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med*. 2002;347:1933-1940.
- Wolfe S. Bad doctors get a free ride. *New York Times*. March 3, 2003;sect A:25.
- Levinson D. New Pennsylvania law requires error reporting for learning purposes. *Rep Med Guidel Outcomes Res*. 2004;15:1-2, 5-6.
- McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA*. 2000;284:93-94.
- Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000;284:95-97.
- Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.
- Gunwitz J, Field T, Judge J, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med*. 2005;118:251-259.
- Phillips DP, Christenfeld N, Glynn LM. Increase in US medication-error deaths between 1993 and 1993. *Lancet*. 1998;351:643-644.
- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998;279:1200-1205.
- Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. *Arch Surg*. 2002;137:611-618.
- Zhan C, Miller M. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA*. 2003;290:1868-1874.
- Centers for Disease Control and Prevention. Monitoring hospital-acquired infections to promote patient safety—United States, 1990-1999. *MMWR Morb Mortal Wkly Rep*. 2000;49:149-153.
- Wenzel R, Edmond M. The impact of hospital-acquired bloodstream infections. *Emerg Infect Dis*. 2001;7:174-177.
- Chassin MR, Galvin RW. The urgent need to improve health care quality: Institute of Medicine National Roundtable on Health Care Quality. *JAMA*. 1998;280:1000-1005.
- Heget JR, Bagian JP, Lee CZ, Gosbee JW, John M. Eisenberg Patient Safety Awards: system innovation: Veterans Health Administration National Center for Patient Safety. *Jt Comm J Qual Improv*. 2002;28:660-665.
- Kizer KW. Re-engineering the veterans health-care system. In: Ramsaroop P, et al, eds. *Advancing Federal Sector Health Care: A Model for Technology Transfer*. New York, NY: Springer-Verlag; 2001.
- Joint Commission on Accreditation of Healthcare Organizations. Joint Commission announces national patient safety goals. Available at: <http://www.jcaho.org/news+room/latest+from+jcaho/npsg.htm>. Accessed December 3, 2002.
- Serious Reportable Events in Patient Safety: A National Quality Forum Consensus Report. Washington, DC: National Quality Forum; 2002.
- Safe Practices for Better Health Care: A Consensus Report. Washington, DC: National Quality Forum; 2003.
- Surgical Care Improvement Project. A partnership for better care. Available at: <http://www.medqic.org/scip>. Accessed December 8, 2004.
- National Patient Safety Foundation. Available at: <http://www.npsf.org/>. Accessed December 3, 2002.
- American Board of Medical Specialties. Status of MOC programs. Available at: <http://www.abms.org/MOC.asp>. Accessibility verified April 19, 2005.
- Bates DW, Teich JM, Lee J, et al. The impact of computerized physician order entry on medication error prevention. *J Am Med Inform Assoc*. 1999;6:313-321.
- Bates DW, Gawande AA. Improving safety with information technology. *N Engl J Med*. 2003;348:2526-2534.
- Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA*. 1999;282:267-270.
- Kucukarslan SN, Peters M, Mlynarek M, Nafziger DA. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. *Arch Intern Med*. 2003;163:2014-2018.
- Landro L. The informed patient; hospitals form "SWAT" teams to avert deaths. *Wall Street Journal*. 2004.
- Rozich J, Resar R. Medication safety: one organization's approach to the challenge. *J Clin Outcomes Manage*. 2001;8:27-34.
- Rozich J, Howard R, Justeson J, Macken P, Lindsay M, Resar R. Standardization as a mechanism to improve safety in health care. *Jt Comm J Qual Saf*. 2004;30:5-14.
- Institute for Healthcare Improvement. Reducing adverse drug events: Missouri Baptist Medical Center. Available at: <http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/ImprovementStories/ReducingAdverseDrugEventsMissouriBaptistMedicalCenter.htm>. Accessibility verified April 20, 2005.
- Samkoff JS, Jacques CH. A review of studies concerning effects of sleep deprivation and fatigue on residents' performance. *Acad Med*. 1991;66:687-693.
- Pilcher JJ, Huffcutt AI. Effects of sleep deprivation on performance: a meta-analysis. *Sleep*. 1996;19:318-326.
- Gaba DM, Howard SK. Fatigue among clinicians and the safety of patients. *N Engl J Med*. 2002;347:1249-1255.
- Harrison Y, Horne JA. The impact of sleep deprivation on decision making: a review. *J Exp Psychol Appl*. 2000;6:236-249.
- Landrigan C, Rothchild J, Cronin J, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med*. 2004;351:1838-1848.
- Hospital Governing Boards and Quality of Care. A Call to Responsibility. Washington, DC: National Quality Forum; 2004.
- Agency for Healthcare Research and Quality. Quality indicators. Available at: <http://www.qualityindicators.ahrq.gov>. Accessed December 8, 2004.
- Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care*. 2003;12:194-200.
- Leatherman S, Berwick D, Iles D, et al. The business case for quality: case studies and an analysis. *Health Aff (Millwood)*. 2003;22:17-30.
- Lamb R. Open disclosure: the only approach to medical error. *Qual Saf Health Care*. 2004;13:3-5.
- National Patient Safety Agency. Available at: <http://www.npsa.nhs.uk/>. Accessed April 22, 2005.
- Consumers Advancing Patient Safety (CAPS). Available at: <http://www.patientsafety.org>. Accessed December 8, 2004.
- Persons United Limiting Substandards and Errors (PULSE). Available at: <http://www.pulseamerica.org/>. Accessed December 8, 2004.
- Kazel R. Minnesota insurer won't pay hospitals for "never events." *American Medical News*. November 8, 2004. Available at: <http://www.ama-assn.org/amednews/2004/11/08/bisd1108.htm>. Accessibility verified April 20, 2005.
- Institute for Healthcare Improvement. 100k lives campaign. Available at: <http://www.ihl.org/IHI/Programs/Campaign/>. Accessibility verified April 20, 2005.
- Hillman K, Parr M, Flabouris A, et al. Redefining in-hospital resuscitation: the concept of the medical emergency team. *Resuscitation*. 2001;48:105-110.