

quire the following: (1) clear articulation of the purposes for which the money is to be used, ie, seed grants, bridging funds, and equipment upgrades, (2) mandatory peer review conducted by funded investigators at the institution, (3) careful accounting of the uses and productivity of the investment, and (4) a new name for the program.

If the new NIH initiatives are to work, there must be a clear demonstration to clinical investigators that adequate funding of meritorious research will be available in the future. It is hoped that the K23, K24, and K30 grants will galvanize interest of young people to careers in clinical investigation. But if at the conclusion of this training meritorious proposals for well-trained individuals are not funded by the NIH at a recognizably significant level, the effort will fall short. This will require effective reorganization of study sections, efforts toward which are under way. The clinical research community also should support efforts by the NIH to obtain legislative ap-

proval for a graduated debt repayment for committed investigators to the field.

Clinical research always will depend on many health professionals, including physicians, PhD scientists, nurses, dentists, and social and behavioral scientists, who work together in the conduct of clinical research. The NIH Director's Panel has made a significant contribution and the NIH leadership has initiated important follow-up efforts, but the physician clinical investigator is still on the "endangered species"³ list. Perhaps these are the first important steps in changing that classification.

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Editorial

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Promoting Patient Safety by Preventing Medical Error

In 1995, a series of highly publicized medical incidents with serious adverse patient consequences awakened public and professional interest in safety in health care. In response to this increased awareness and recognizing that health care could learn much about safety from other industries, in October 1996, the American Association for the Advancement of Science, the American Medical Association (AMA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) joined with the Annenberg Center for Health Sciences to convene the first multidisciplinary conference on errors in health care.

Since then a number of initiatives in patient safety have been undertaken at both the state and national level, and many hospitals have intensified their efforts at preventing patient injuries, particularly those due to medication errors. Reports of serious overdoses of chemotherapy, for example, led to the development of protocols and preprinted orders to reduce calculation errors. Following reports of deaths from accidental injection of undiluted potassium chloride, many hospitals have removed concentrated solutions from nursing units. Recently, the President's Advisory Commission listed error prevention as a top priority for health care quality improvement.¹ Patient safety has come to the health care agenda.

It is none too soon. Modern health care presents the most complex safety challenge of any activity on earth. However, we have failed to design our systems for safety, relying instead on requiring individual error-free performance enforced by

punishment, a strategy abandoned long ago by safer industries such as aviation and nuclear power.²

The medical imperative is clear: to make health care safe we need to redesign our systems to make errors difficult to commit and create a culture in which the existence of risk is acknowledged and injury prevention is recognized as everyone's responsibility. A new understanding of accountability that moves beyond blaming individuals when they make mistakes must be established if progress is to be made.

A number of forces make implementing these concepts difficult, most notably an entrenched belief in the effectiveness of punishment for error prevention, a conviction richly reinforced by highly punitive legal and regulatory systems as well as the public media. Ironically, rather than improving safety, punishment makes reducing error much more difficult by providing strong incentives for people to hide their mistakes, thus preventing recognition, analysis, and correction of underlying causes.

The Human Contribution to Safety and Accidents

Just as recent celebrated accidents in medicine have directed attention to patient safety, previous highly visible accidents in other industries, such as power generation and transportation, drew attention to issues surrounding the label *human error* (eg, Three Mile Island in 1979, the capsizing of the *Herald of Free Enterprise* in 1982, various aircraft crashes). The intense interest in these events led to sustained, cross-disciplinary studies of the human contribution. To make sense of these catastrophes, as well as other less celebrated cases, various researchers have collected data about the multiple contributors to incidents, investigated the normal functioning of these settings, reexamined common assumptions, and developed new concepts and theoretical frameworks. The result has been a new look at the human contribution to safety and to risk.³

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Traditionally, error analysis has focused on identifying the cause. However, one basic finding from new look research is that accidents in complex systems occur primarily through the concatenation of multiple small factors or failures, each necessary but only jointly sufficient to produce the accident. Often these small failures or vulnerabilities are present in the organization long before a specific incident is triggered. All complex systems contain such latent factors or failures, but only rarely do they combine to create the trajectory for an accident.⁴

Traditionally, error analysis has focused on individuals. The search for a cause typically stopped at the person or group closest to the accident, who it was determined, after the fact, could have acted differently in a way that would have led to a different outcome. However, the more researchers have looked at success and failure in complex work settings, the more they have realized the critical role of organizational factors that shape and influence the behavior of operational personnel. Reason summarized the results: "Rather than being the main instigators of an accident, operators tend to be the inheritors of system defects. . . . Their part is that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking."³

Traditionally, error analysis has focused on people as unreliable components. However, the new look has focused research on how people, individually, as groups, and as organizations, make safety. Research has examined the factors that affect how expertise is brought to bear in nonroutine situations,⁵ how people cope with multiple pressures and demands before an accident draws attention to the operation,⁶ and how some organizations achieve "high reliability."⁷

The new look at human error has shown that robust, high-reliability individuals, teams, systems, and organizations are able to recognize trouble before negative consequences occur.⁸ This means that processes that detect a situation heading toward trouble and redirecting it away from a poor outcome are critical to safety—the concepts of error tolerance, detection, and recovery. Evidence about difficulties, problems, and incidents reveals information about the underlying system—systemic vulnerabilities that can create or propagate trajectories toward failures.⁴ High-reliability organizations value such information flow and use this information to guide adaptive and constructive changes without waiting for accidents to occur.

We present descriptions of 4 examples of current efforts to promote patient safety.

National Patient Safety Foundation at the AMA

As a culture we continue to rely primarily on the threat of legal, financial, or disciplinary penalties to ensure patient safety, operating on the assumption that most patient injuries are the result of bad behavior, eg, incompetence, negligence, or corporate greed. This deterrent approach to safety, and the extensive legal and regulatory structures that support it, has had limited impact on reducing patient injuries. It is now clear that an additional approach is needed that continues to hold health care providers accountable, but moves beyond blame in investigating why health care accidents happen and how the risks of future accidents can be best identified.

Building on momentum from the 1996 Annenberg Conference, the National Patient Safety Foundation (NPSF) was launched as an independent not-for-profit organization in 1997 by the AMA and a broad partnership representing consumer

advocates, health care providers, health product manufacturers, employers, payers, researchers, and regulators.⁹

The NPSF is guided by a number of core premises and values. For example, the NPSF is premised on the belief that patient safety is central to quality health care, as reflected in the Hippocratic admonition "Above all, do no harm." Likewise, the NPSF understands that, because of its extraordinary complexity, the health care system is inherently risky and human error and organizational breakdown are to be expected, even among the most competent and conscientious health care delivery teams. Early identification of risk is the key to preventing patient injuries, and this depends on maintaining a culture of trust, honesty, integrity, and open communication among patients and providers in the health care system. It also depends on accumulating an integrated body of scientific knowledge focused on patient safety and the infrastructure to support its development. The NPSF is further premised on the belief that engaging the patient and the patient's family in continuous learning as partners in the delivery of care will improve patient safety.

The NPSF's mission is to promote the safety of the health care system by catalyzing action and supporting a fresh and honest discussion about the notions of risk, error, blame, and accountability. Four core strategies guide NPSF activity, including (1) promoting research to develop new knowledge about safety and human and organizational error, (2) implementing knowledge to develop applications for preventing avoidable patient harm, (3) fostering communication to enhance patient safety, and (4) developing educational approaches based in part on collaborative relationships with other complex enterprises (such as aviation and nuclear power) in which human safety issues also are investigated. By pursuing this mission, the NPSF is dedicated to serving as a community forum and leading the transition from a culture of blame to a culture of safety.

Massachusetts Board of Registration in Medicine Safety Program

What role should the government have in ensuring patient safety? How should physicians and hospitals be held accountable? The Massachusetts experiment is instructive. In 1987, the Board of Registration in Medicine implemented a program that requires hospitals, physicians, managed care organizations, and others to participate in risk management activities as a condition of licensure.¹⁰ Facilities must establish Patient Care Assessment systems and submit a quarterly report of all unexpected deaths and major complications of treatment. Reports must describe the event, the results of an internal investigation, and corrective actions. The board may request additional information, recommend changes, or even require a meeting with the chair of the board of trustees and chief executive officer.

The board also issues safety advisories, calling attention to hazards such as chemotherapy dose calculations and concentrated intravenous potassium chloride solutions. It has convened panels of experts to develop safety guidelines for intravenous conscious sedation, for potassium chloride administration, and for prevention of suicides by inpatients with psychiatric illnesses.

Several features of this program are noteworthy:

- It holds health care organizations accountable for having safety programs and responding to accidents.

- It calls for active participation in safety programs by physicians.
- It places primary responsibility for safety on the only unit that can correct faulty systems, the hospital or managed care organization.
- Reporting is nonpunitive. Hospitals need not identify physicians; information is confidential, even from the board's own enforcement staff.
- It "carries a big stick." The board can prohibit physicians from practicing at noncomplying facilities, in effect closing them down.
- It is responsive. The board becomes engaged if facilities do not react aggressively.
- It is proactive. The board identifies pervasive threats to safety and issues policies to thwart them.
- It is amazingly nonbureaucratic, functioning with only 3 staff members and 3 volunteer board members.

Eight hundred Massachusetts health care facilities have established Patient Care Assessment systems. The board receives about 500 incident reports and meets with 3 to 4 trustee board chairs annually. Hospitals have grudgingly accepted this oversight and now have few complaints. Board guidelines have been widely adopted. This nonpunitive system for stimulating safety and ensuring accountability seems to work although objective data are yet to come.

New Initiative at the JCAHO

Although we know it is impossible to practice error-free medicine, the serious clinical errors that we have made still haunt us, and it is hard to share them with colleagues. Yet, if we are not able to learn from each other's mistakes, how can we grow as physicians?

Currently, the disincentives to disclosing errors seem much stronger than the incentives.¹¹ It is therefore encouraging and courageous that the JCAHO has revised its policy on reporting medical errors. Under the new format, when a serious mistake is reported by an accredited institution, the organization will be given time to investigate the event and institute corrective measures. Formerly, the JCAHO would immediately conduct a review and place the organization on accreditation watch, thereby alerting the public to a possible downgrade of accreditation status.

The intent of the commission is laudable, because it provides the opportunity to substitute organizational learning for embarrassment. Whether or not public advocates or the press will accept these motives or find them merely self-serving will depend on several factors. First, the organizations will have to conduct their internal review and remediation with vigor, honesty, and candor. Any hint of cover-ups could be devastating. Second, appropriate disclosure and, when appropriate, restitution must be made to injured parties. Third, the medical profession must prove that it will be supportive of these new procedures.

In the end, the old forces that compel us to hide our errors may doom the commission's experiment. That would be unfortunate because its defeat would strike a blow at the potential for our already strong system of medical care to become even better.

Patient Safety Improvement Initiative of the Veterans Health Administration

As the largest integrated health care system in the United States, the federal government's principal direct health care

Goals of the National Patient Safety Partnership of the Veterans Health Administration

1. Review existing patient safety research and identify needs for additional investigation.
2. Identify and learn from the experience of relevant safety interventions from non-health care industries (eg, aviation, transportation, and nuclear power).
3. Review existing patient safety databases and identify needs for a national monitoring system and barriers to creating such a system.
4. Promote individual health care organization commitment to patient safety improvement.
5. Promote systemwide protocols for improving patient safety.
6. Promote systemwide structure and mechanisms for timely exchange and feedback of patient safety-related information.
7. Identify performance measures and benchmarks for patient safety.
8. Involve health care consumers, including patients, as active participants in improving patient safety and explore with them the role of consumers in promoting patient safety.
9. Develop consensus on a national agenda to enhance patient safety.
10. Advance a national position (policy) regarding patient safety and take action to facilitate its local implementation.
11. Promote awareness and sensitivity to these issues in the education and training of health care professionals.

provider, and the nation's largest provider of health care professional training, the veterans health care system is in a particularly advantageous position to advance knowledge about medical errors and processes for improving patient safety. The top-to-bottom restructuring of the veterans health care system, initiated in 1995, has aimed at ensuring the consistency and predictability of high-quality health care being delivered at the 173 Veterans Affairs hospitals and nearly 900 other sites of Veterans Affairs care delivery.¹²⁻¹⁶ As part of this reengineering effort, the Veterans Health Administration (VHA) has implemented a multidimensional process that is outcome focused with a system-wide quality management framework. A key element of the VHA quality management strategy has been a Patient Safety Improvement Initiative.¹⁷

The VHA's former Patient Incident Reporting System has been changed to establish a new centralized Patient Safety Registry and Reporting System. The Patient Safety Registry and Reporting System includes a patient safety handbook, a field-to-headquarters reporting mechanism for both sentinel events and unplanned clinical occurrences (near misses), a requirement to conduct root cause analyses for such incidents, and an interdisciplinary expert review team at VHA headquarters that provides feedback to medical treatment facilities and disseminates information to the rest of the Veterans Affairs system.¹⁷ Since the new patient safety reporting system began in June 1997, each of VHA's 22 integrated service networks has increased reporting of patient safety incidents and medical errors.

On October 6, 1997, the VHA also established the National Patient Safety Partnership, with the founding members including the VHA, AMA, American Hospital Association, American Nurses Association, American Association of Medical Colleges, JCAHO, Institute for Healthcare Improvement, and NPSF. This public-private partnership recognizes the magnitude and complexity of the medical error problem and the fact that medical errors occur in all types of health care delivery systems, by all types of health care professionals, and with all forms of health care financing. The specific goals of the National Patient Safety Partnership are listed in the Table.

The VHA also has initiated a specific Patient Safety Improvement Awards Program to increase the emphasis on this important aspect of clinical practice. Under this program, front-line caregivers and other health care practitioners, as well as facilities, who identify adverse events or potential patient safety

situations and improved processes or practices that minimize or eliminate the risk of an untoward outcome may receive a financial reward along with other recognition. Larger rewards are targeted for improvements that reduce or eliminate life-threatening risks and have system-wide application.¹⁸

Also, the VHA has convened an Expert Advisory Panel on Patient Safety System Design that has been charged with reviewing VHA's current patient safety reporting system, the Aviation Safety Reporting System, National Aeronautics and Space Administration Safety Reporting System, and other potential models that could be used by the VHA. A new patient safety reporting system is being designed that builds on the experience of the Aviation Safety Reporting System and adapts this model to the health care setting. Implementation of pilot projects is expected in 1998. Unlike the Aviation Safety Reporting System, which only records near misses, the VHA envisions a system that will record both near misses and incidents causing patient harm. The VHA believes that the complexity and understanding of the cause-and-effect relationships of medical errors is such that all patient safety incidents need to be recorded and analyzed while maintaining absolute confidentiality of this information.

Changing a Culture

To solve a problem, that problem must first be recognized. Unfortunately, error in medicine is real and common. The good news is that we have recognized the problem of error in medicine. The next step has been to go public with the problem, to study it, and to create methods to solve it. Many groups are now addressing this. It will then be necessary to implement methods that are found likely to reduce the probability of error. Buoyed by successful efforts in anesthesiology,¹⁹ in particular, we are now beginning to implement methods in a broad range of initiatives.

The main change that will be needed is a change in our culture. Increasingly, patients and physicians in the United States live and interact in a culture characterized by anger, blame, guilt, fear, frustration, and distrust regarding health care errors. The public has responded by escalating the punishment for error. Clinicians and some health care organizations generally have responded by suppression, stonewalling, and cover-up. That approach has been less than successful. Medical harm, by and large, is not the result of ignorance, malice, laziness, or greed on the part of the people or organizations involved. The risk of error is ever present. Systems can be created that will

reduce the probability that these mistakes will occur and be implemented, thus preventing harm to patients.¹⁹ Error prevention and error detection and correction before harm are the goals. System changes can do that. We now hope to create a predominant culture of error recognition, accountability, honesty, and rapid and fair settlement for injuries, addressing the risk of harm as a systems problem and preventing the problems from occurring again in that or similar settings.

Join us in converting a culture of blame that hides information about risk and error into a culture of safety that flushes information out and enables us to prevent or quickly recover from mistakes before they become patient injuries.

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