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ISSUE BRIEF

NATIONAL HEALTH POLICY FORUM

Reducing Medical Error: Can You Be As Safe in a Hospital As You Are in a Jet?

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A discussion featuring

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Reducing Medical Error

U.S. health care is touted as the best in the world, though few would argue that a lucid system is in place or deny that there are major disparities in access as well as outcomes. Despite these recognized shortcomings, however, the phenomenal growth of U.S. medical knowledge and technological capacity has led most to assume that quality of care is at an all-time high. This is probably true in the aggregate, but for a variety of reasons recent years have brought increasing scrutiny to the subject.

In the years when health care costs were rising in double-digit leaps, most complaints about quality were voiced by purchasers who worried that fee-for-service incentives led to the delivery of more care than was necessary, sometimes with negative results. When the incentives began to change under managed care, concerns were heard from consumers unhappy with the resulting constraints on service.

It is not surprising, then, that much recent legislative attention at both state and federal levels has focused on protecting beneficiaries who fear they will not receive the services that were bargained or contracted for, especially when many of them are paying a considerably larger portion of benefit costs than previously. While beneficiaries and their advocates are concerned about access to state-of-the-art technology and procedures (sometimes in advance of proven effectiveness), relatively little attention has been paid to whether service delivery is executed as it should be. Not many people, it appears, appreciate how frequently errors occur, how large the discrepancies may be among institutions and providers, and how stubborn the obstacles to improvement.

As Michael L. Millenson observed in his 1997 book, *Demanding Medical Excellence*, "the frightening reality is that medical mistakes of all types are not unusual."[1] Research over several decades bears witness to the truth of this statement. The 1991 Harvard Medical Practice Study, for example, found that 4 percent of hospitalized patients in New York State suffered injuries stemming from treatment. Further, fully two-thirds of these iatrogenic injuries were caused by errors, and nearly 14 percent of them were fatal.

Extrapolating from the New York data, Harvard School of Public Health researcher Lucian L. Leape, M.D., estimated that 180,000 people in the United States die each year of iatrogenic injury—the equivalent, he wrote, of three jumbo-jet crashes every two days.[2] Other research has shown that 6.5 percent of non-obstetrical adult patients admitted to two teaching hospitals experienced an adverse drug event (ADE)—such as the wrong dose, a prescription for a drug to which they were allergic, or drug interaction—of which 28 percent were preventable.[3] Potential ADEs for another 5.5 percent of patients were intercepted before the drug was administered.

Reducing error rates is not a matter of drafting a bill and demanding compliance, as few Americans would welcome the prospect of set-in-statute clinical practice standards. Moreover, a legislative mandate to stop making mistakes cannot address the systemic complexities that form the context for error. However, some research-supported progress is observable; a variety of initiatives are under way in both the private and public sectors to promote quality care and reduce medical error.

This Forum session will address the opportunities for a systems-based approach to error reduction, noting the prevalence of errors, what it takes to identify them, and how they might be prevented through restructuring the delivery environment and retraining. It will consider how the latter approach has been used in the aviation arena and allow the audience to draw some parallels for the respective roles of health plans, providers, consumers, and policymakers interested in improving patient safety.

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BACKGROUND

It was in 1969 that John E. Wennberg, M.D., and Dartmouth colleagues first drew attention to the wide variation in medical care delivery across the country.[4] Thirty years later, Wennberg is still reporting disparities, such as the geographic variation in the proportion of breast cancer patients who receive breast-conserving surgery (less than 1 percent in some areas to over 50 percent in others), even though evidence shows this surgery to be as effective as radical mastectomy in terms of life expectancy.[5] The duration and persistence of practice variations indicate that they are not a function of managed care. To those who would point fingers at today's health plans, Robert Brook of RAND offers the reminder, "Managed care is not the problem. Quality is."[6]

But consensus is emerging that attention is urgently needed on a matter that cuts across treatment of all diseases and conditions, namely, reducing medical error. Eliminating needless peril and suffering obviously is a boon to patients, as well as to medical personnel whose training and practice adjure them to "do no harm." Cost is also a consideration, in that catching errors before injury occurs obviates the need to undertake corrective treatment procedures or to keep a patient in the hospital longer in order to recover from damage done during treatment. Adverse drug events in the hospital have been associated with an average 2.2-day additional length of stay and a cost increment of $3,244.[7]

To err is human, goes the old saw, and to be human is to make errors. Those who study the role of human factors in complex systems believe that the propensity to error can be mitigated by properly designed systems and safeguards. Conversely, errors may be rendered all but inevitable by badly designed systems. As Leape told the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in 1997,

> Human beings make mistakes because the systems, tasks, and processes they work in are poorly designed. Two medications with similar names or similar labels are an accident waiting to happen. Working double shifts or having twice as many patients to take care of is an accident waiting to happen.

A seemingly simple error may have a variety of root causes, or a variety of errors may be traced to the same source.

Health care delivery today entails complicated technology and numerous interactions among health care practitioners. There are many opportunities for things to go wrong and a good chance that the exact cause will not be pinpointed. In his classic 1994 article, "Error in Medicine," Leape suggested that, given the complex nature of medical practice and the multitude of interventions that each patient receives—the average in a 1989 study of an intensive care unit was 178 per day—a high error rate may not be surprising. This complexity also implies that the traditional pursuit of error-free individual performance, with blame and punishment for any lapse, may be an outmoded approach. While the individual in such an atmosphere may learn from mistakes and their aftermath, the lesson tends to be private; as Leape says in illustration, "Concentrating on one individual's defective knowledge improves the performance of one physician regarding one drug."[8] Incident analyses that stop with the finding "human error" are inadequate responses to a complex systemic problem.

Human Factors Research

Human factors research emerged as a discipline in response to the immense technological changes that occurred during and after World War II. Human factors specialists have studied the interface of human and machine in complex operating environments, such as airplane cockpits and nuclear power plant control rooms. They have observed that many errors are caused by flawed interface design and by complex interactions involving human operators. The precipitating event for disaster may be a relatively trivial malfunction or an external factor—even the weather. But more often than not, researchers say, a disaster occurs when a set of latent system features actively combine in an unexpected combination or sequence.

Researchers point out that enhanced safety really begins with efforts to understand not just the sources of failure, but also the sources of success. In fact, in spite of complexity and system design flaws, accidents are the exception rather than the rule; there are many more opportunities for failure than actual instances of it. That is, health care personnel do not make most of the mistakes they are "set up" to make.

Health care in the United States is a mix of models, styles, and stages. From financing arrangements to evolving scientific technology to relationships, change is a daily occurrence. Yet imposing or eliciting a particular change is still challenging. With the variety of care arrangements in operation, from solo fee-for-service to highly managed systems, is there a quality improvement strategy that can apply to all? Or is there a model available that can be adapted to health care? With respect to systemic quality improvement, what lessons do other disciplines offer?

Drawing Lessons from Aviation

One field in which human factors research has been particularly fertile is aviation. Comparisons of medicine and aviation raise interesting questions and suggest mechanisms and attitudes that medical facilities might consider. The comparison begins, perhaps, with the similarities between pilots and doctors: highly trained technically, accustomed to view themselves as bearers of ultimate authority (and responsibility), independent yet increasingly dependent on others of varying skill levels. Some researchers have focused on the similarities in pilots' and doctors' training and the demands they now face. Both are trained as individuals whose independent decisionmaking is critical, and yet—for optimal performance—they must operate as part of a team. As a pilot will not be airborne without a ground crew and an air traffic controller, a physician often relies significantly on nurses, technicians, and pharmacists to cooperate in his treatment plan. In the hospital or other institutional setting, even more personnel are likely to be added to constitute a caregiving team.

Aviation was not always safe; its early years were hazardous, and the perception has remained—in spite of fatality statistics—that flying is a more serious proposition than riding in a car. But the industry, recognizing safety as necessary for acceptance and growth, has steadily tried to improve. A collective goal of safe skies is aided by the natural alignment of incentives: pilot, crew, airline, and manufacturer all lose if a plane crashes.

Successful flights rest on attention to order and detail, an organized system that promotes teamwork, and a willingness to learn from mistakes. Error reduction in aviation is credited to several elements: establishment of an error reporting system, encouragement to pilots and other crew members to report errors and incidents, and a focus on teamwork training. A highlight is the Aviation Safety Reporting System (ASRS), a confidential system for reporting incidents (cases that violated good practice or established rules but did not result in an accident—"near misses"), analyzing their root causes, and communicating conclusions to those directly involved and to others who might face a similar situation. The ASRS receives about 30,000 reports per year.

The ASRS is funded largely by the Federal Aviation Administration (FAA), but operates independently. It was developed to replace a less successful predecessor within the FAA. Because the FAA is a regulatory and enforcement agency, reports to it were constrained by fear of punishment for errors. The ASRS, besides being independent, was designed from the beginning to be entirely confidential. Those reporting incidents are granted immunity from retaliation. (It should be noted that accidents involving passenger injury or damage to aircraft are reported to and investigated by the National Transportation Safety Board, a different process altogether.) Before ASRS reports are analyzed and entered into the database, identifying information is removed. The database is available to researchers. ASRS regularly communicates with the industry, reporting individual events and analyses of the larger problems they may point to.

Charles Billings, M.D., who developed the ASRS, offered specific guidance to the medical community during a conference on medical error sponsored by the Annenberg Center for Health Sciences, the Association for the Advancement of Science, the Joint Commission on Accreditation of Health Care Organizations (JCAHO), and the American Medical Association (AMA) in 1996. Billings stressed the importance of consensus among all stakeholders during system design and of keeping the system's operations objective and free of control by one or more stakeholders. The ASRS is voluntary, which Billings recommended, observing that "in one way or another, all incident reporting becomes voluntary," whether through inertia, gaming, or failure of the regulatory fine print to cover every eventuality. He also emphasized the importance of qualified analysis (for example, pilots who rotate through a period of service with the ASRS are expected to maintain their flying experience) and research capabilities.

Benefits of an external reporting system, as opposed to an in-house process, include a larger sample size and thus potentially the ability to spot patterns not discernible in a smaller sphere, resident expertise in data interpretation and human factors analysis, and wider feedback.

Another area in which comparisons between pilots and physicians may be instructive is training. A concrete illustration of adaptable teamwork training is provided by Dynamics Research Corporation, which developed an aircrew coordination training program for the U.S. Army. As will be described, this program moves the focus for aircraft operations away from the single-pilot model to a perspective in which the entire crew is responsible for effective operations. The training does not relieve the pilot-in-command of responsibility but does empower other crew members to get information, make recommendations, and actively intervene.

The payoffs from this training program for army aviation—an estimated 40 percent reduction in safety-related errors—prompted the army to investigate whether the behavioral approach used in aviation would

translate into other high-performance, high-stress team environments. Working with a group of 11 hospitals, both military and civilian, Dynamics Research has completed validation testing of its MedTeams module for emergency department personnel and plans to expand this to other medical team environments.

In considering a national error reporting system for health care, planners would have to address the question of volume. Leape has estimated that the reporting of only one-tenth of the medical "near misses" that occur annually would result in from 280,000 to over 1 million reports. Already operating is a segment-based reporting mechanism designed on ASRS principles, JCAHO's "sentinel events" program (discussed below), which received approximately 400 reports in 1998.

Another issue is closing the loop from analysis back to practice. The ASRS is successful in part because it is housed in an agency that has the authority to act on analysts' conclusions and that can require procedural changes. And pilots may have stronger incentives than physicians to keep their skills sharpened. For one thing, their own lives are on the line. Second, they are required to be recertified periodically, an active demonstration of ability rather than the more passive review of licenses and records that constitutes physician recredentialing by network managers or managed care organizations.

ERROR REDUCTION INITIATIVES

The level of attention paid to the problem of medical errors has accelerated markedly in recent years, with research and discussion leading to a number of improvement initiatives in both the public and private sectors.

Several large employers, including Motorola and General Electric (GE), have adopted a "Six Sigma" program to boost quality in all their operations. The name refers to the symbol used to indicate standard deviation from a normal distribution; six sigma, or six standard deviations, corresponds to a target error rate of 3.4 defects per million units or occurrences. Originally applied to manufacturing processes—only 3.4 defective widgets in every million coming off the line—the approach has been extended to services as well. In health care, the vision would be, for example, that no more than 3.4 of 1 million patients fail to be given a prescription for beta blockers following a heart attack. In that the National Committee for Quality Assurance reported a national average of 61.9 percent of such patients actually receiving a beta blocker prescription—that is, 381,000 per million are not—it is clear that health care has a long way to go.[9]

Still, recognition of the amplitude of errors is a necessary step toward improving them, and the Six Sigma companies are determined to persist. Charles R. Buck of GE has observed:

> A commitment to quality is every bit as much a cultural commitment as it is a set of quantitative tools and methods. The organizational culture facilitates many critical aspects of quality improvement. A quality culture makes it OK to seek out (yes, seek out!) mistakes or defects as opportunities for improvement.[10]

Other groups are committed to error reduction as well. The Institute for Healthcare Improvement (IHI) sponsors courses, conferences, and collaborative projects among health care organizations that will lead to measurable improvement in patient care. A year-long collaborative project on medication error reduction, chaired by Leape in 1996-97, focused the efforts of 40 organizations on documenting improvement in areas such as chemotherapy safety, standardization of medication processes, and safe handling of lethal drugs. IHI is also working with the Innovation Institute to look at models of adult learning and retraining that may help people to look at their work processes in a new way.

The American Society of Health-System Pharmacists (ASHP) convened an expert panel to study ways that practitioners and institutions could reduce the incidence of adverse drug events; seven "top-priority" recommendations were published with the group's endorsement in 1996.[11] AHSP also develops and makes available online therapeutic guidelines, including the recent "Safe Use of Automated Medication Storage and Distribution Devices."

In response to the 1996 Annenberg Conference on medical error referenced earlier, the AMA established the National Patient Safety Foundation (NPSF). The foundation is an independent, not-for-profit organization that serves as a forum for a variety of stakeholders (health care providers, consumer advocates, health product manufacturers, researchers, purchasers, and regulators) to explore the issues surrounding and impediments to patient safety. Its core mission is built on research, prevention and implementation, communication and trust-building, and education. The NPSF was an important participant in a second Annenberg Conference on medical error held in November 1998.

JCAHO has accredited hospitals since its founding by the American College of Surgeons, AMA, the American Hospital Association (AHA), the American College of Physicians, and the Canadian Medical Association in 1951; it has added other types of medical facilities and organizations (for example, home health

agencies, and managed care networks) in subsequent years. For some years, JCAHO has employed a sentinel event policy for error reporting, which requires JCAHO-accredited health care facilities to investigate "any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."[12] Any time such a sentinel event occurs, the facility is expected to complete a thorough root cause analysis, implement improvements to reduce risk, and monitor the effectiveness of these improvements. Additionally, there is a subset of sentinel events—those that actually result in harm—that accredited organizations are asked to report to the joint commission database.

Originally, the reporting of a sentinel event triggered an immediate review by JCAHO investigators and placing of the facility on probation, signaling a problem to all observers. In 1998, the joint commission revised its policy to give reporting organizations time to conduct their own reviews and implement corrective measures before JCAHO's taking any action. If the institution submits the results of this process to JCAHO within 30 days, it is not subject to "accreditation watch." On-site review by JCAHO personnel is ordered only if a potential ongoing threat to patient safety is determined still to be present.

In the absence of federal law protecting against public disclosure and potential punitive action, reporting of sentinel events is and will likely remain voluntary. However, even an institution that chooses not to report is required to conduct and share with the joint commission information concerning a root cause analysis and a plan for correction within 45 days. Organizations that do not comply or that refuse to share such information will be placed on accreditation watch and risk the loss of accreditation altogether.

The new level of autonomy is expected to encourage self-reporting, since it provides "the opportunity to substitute organizational learning for embarrassment."[13] Concerns about the confidentiality of sentinel-event information submitted to JCAHO remain, although (as communicated in an October 1998 "Dear Colleague" letter from president Dennis S. O'Leary, M.D.) the joint commission has appointed a legal issues task force and suggested prudent steps—such as naming JCAHO as a participant in the internal quality review process—for institutions to follow. It also intends to continue its pursuit of federal and state law protections for the confidentiality of information shared with accrediting bodies.

The Veterans Health Administration of the Department of Veterans Affairs (VA), as part of system-wide restructuring inaugurated in 1995, has implemented a patient safety improvement initiative. A key element (operating since June 1997) is a centralized patient safety registry and reporting system, which incorporates a patient safety handbook, a field-to-headquarters reporting system for sentinel events and near misses, a requirement to conduct root cause analyses, and an interdisciplinary review team that provides feedback to reporting facilities and information to the rest of the VA system.

In October 1997, the VA also established the National Patient Safety Partnership, whose founding members include the VA, the AMA, the AHA, the American Nurses Association, the Association of American Medical Colleges, JCAHO, the Institute for Healthcare Improvement, and the National Patient Safety Foundation, along with agencies such as the Food and Drug Administration, the Health Care Financing Administration, and the Agency for Health Care Policy and Research. This public-private partnership is dedicated to "improving patient safety by reducing adverse events and untoward outcomes of healthcare or healthcare related processes." The partnership is working with its member organizations to develop a compendium of best practices for reducing adverse drug events and plans to call on physicians, other health care practitioners, health care systems, and the pharmaceutical industry to adopt them.

The Food and Drug Administration (FDA) Modernization Act of 1997 authorized as a demonstration project the creation of Centers for Education and Research on Therapeutics (CERTS) under the aegis of AHCPR in collaboration with the FDA. As well as looking at new products and ways to improve their effective use, the centers' purpose, in the language of the conference report, is "to increase awareness of risks of both new uses and combinations of therapies," and, more generally, to educate the practitioner community. The CERTS charter includes error reduction research and education.

POLICY CONSIDERATIONS

It is only recently that the medical professions began to acknowledge how much they do not know and, indeed, the limits on how much a person can know or how perfect a performance can be reasonably expected. Mount Sinai School of Medicine professor Mark Chassin (also co-chair of the Institute of Medicine's National Roundtable on Health Care Quality), has observed that "we have created systems that depend upon idealized standards of performance that require individual physicians, nurses, and pharmacists to

perform tasks at levels of perfection that cannot be achieved by human beings." Some who agree with him are trying to institute change, but it is difficult to know how far beyond a cadre of dedicated proponents their message extends. As consumers and the popular press continue to focus on benefits, regarding denial of a service as poor-quality care, the need for redesigning systems and retraining medical professionals attracts little public attention.

And when a mistake is made, a patient harmed, a common response is a desire to sue. This is reflected in debates about liability, where the question is less whether wronged patients should be able to sue someone than who should be included in the range of liable parties and what recompense the patient is owed. Changing the culture of "someone must pay" could prove a Herculean task.

A medical-error case frequently cited is the 1994 death of *Boston Globe* columnist Betsy Lehman from a chemotherapy overdose administered in the Dana-Farber Cancer Institute. In January 1999, a Massachusetts licensing body, the Board of Registration in Nursing, decided to pursue disciplinary action against the nurses involved in the case. Although the nurses were exonerated by Dana-Farber and JCAHO, the board determined that they should have questioned the orders they were given by physicians. Dana-Farber president David G. Nathan, M.D., defended the nurses' standards of practice, blaming an ambiguous treatment protocol and noting that the institute had adopted a wide range of corrective actions since the incident.[14] (Leape, in an editorial published in the January 12 edition of the *Boston Globe*, called the board's decision "misguided, inappropriate, and harmful," and praised Dana-Farber for holding the institution, not the nurses, accountable for Lehman's death.)

This example illustrates the "sides" to the medical error issue. Clearly, no one is suggesting that reducing errors is anything but desirable. However, significant resistance to openness about errors has grown up in a climate where shame and retribution have been visited on those judged to have erred. The traditional view has been that punishment is an effective deterrent to others who might be careless, but many medical personnel have come to believe that relying on punishment stifles willingness to address errors and ability to correct them and in effect serves as an incentive to conceal them.

If elements of the medical professions still are operating under the "someone must pay" approach, it is not surprising if many consumers feel the same. Perhaps consumers need to be better informed on what causes errors and how their own alertness might contribute to safety. But it is difficult to know what specific information to provide them. Hospitals are unlikely to announce the number of near misses for the quarter, nor to publish infection rates for a consumer to use as a basis of comparison. Many feel that a necessary first step is building consumer awareness that a problem exists. Proponents of the new system-based thinking also are pondering how consumers might learn to draw a distinction between negligent acts that result in harm and errors that cause harm but are not a matter of individual fault.

As purchasers as well as regulators of health care, federal agencies and lawmakers may choose to play a role in error reduction. A number of options have been proposed in discussions among analysts. For example, it has been suggested that the FDA look at standards for drug naming, labeling, and packaging. AHCPR, which already funds research evaluating various treatments and technologies, might undertake an error-reduction initiative. Under S. 300, introduced January 22, AHCPR's CERTS program would be made permanent. Some hope the National Patient Safety Partnership's best practices, when published, may be reflected in government contracts.

THE FORUM SESSION

In this Forum session, **Lucian L. Leape, M.D.,** adjunct professor at the Harvard School of Public Health and a leading researcher on the subject of medical error reduction, will review his findings on the causes and correctives of medical error and share his thoughts on action needed at a policy level to advance the improvement process. **Robert Simon, Ed.D., C.P.E.,** chief scientist, Crew Performance Group, Dynamics Research Corporation, will describe how his team has taken the error-reduction strategies they developed for aviation and applied them to medical care. **Kenneth Kizer, M.D.,** undersecretary for health in the Department of Veterans Affairs will talk about his agency's patient safety initiatives. **Sen. Bill Frist** (R-Tenn.) will offer his unique perspective—as lawmaker, physician, and pilot—on safety strategies and policy directions.

Issue Questions

The discussion will incorporate the following questions:

- What steps might hospitals or other facilities take in attempting to reduce error systematically?

- How can data best be marshaled to enable error-reduction programs?
- What technology would assist in reducing medical errors?
- Is there a bright line between preventable (error-caused) and nonpreventable accidents? Is some residual level of error inevitable? What is an "acceptable" margin of error?
- Do providers need explicit protections, such as guaranteed anonymity, to encourage them to report errors quickly and candidly?
- Should hospitals and other facilities be responsible for compensating patients for damage due to error?
- Is there a role for consumers in medical error reduction? How can consumers best be educated on this issue before they become patients?
- In what ways might government need to play a different or stronger role?
- What are the appropriate public- and private-sector roles in error reduction?

ENDNOTES

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