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001b. fax	To: Jeffrey Lipton (3 pages)	06/12/1999	P6/b(6)
001c. letter	Barry Freedman to Caroline and Stanley Stein (1 page)	07/23/1999	P6/b(6)
001d. report	re: personal medical (16 pages)	02/22/2000	P6/b(6)
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ISSUE BRIEF

NATIONAL
HEALTH
POLICY
FORUM

Improving Quality and Preventing Error in Medical Practice

Wednesday, March 15, 2000

11:30 am to noon - Lunch

Noon to 2:00 pm - Discussion

Congressional Hall of Honor, Fifth Floor

Reserve Officers Association of the United States

One Constitution Avenue, NE

(Across from the Dirksen Senate Office Building)

A discussion featuring

Paul H. O'Neill

Chairman

Alcoa, and

Chairman

Working Together Consortium

Healthcare Initiative

Pittsburgh

John D. Clough, M.D., F.A.C.P.

Chairman

Division of Health Affairs

Cleveland Clinic Foundation

John M. Eisenberg

Administrator

Agency for Healthcare Research
and Quality

Kenneth W. Kizer, M.D., M.P.H.

President and Chief Executive Officer

National Forum for Health Care Quality

Measurement and Reporting

Nancy Ridley, M.S.

Assistant Commissioner

Bureau of Health Quality Management

Department of Public Health

Massachusetts

Registration: Please call **Dagny Wolf** at 202/872-1392 as soon as possible.

The
George
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University
WASHINGTON DC

Improving Quality and Preventing Error

Front pages of major newspapers and lead stories of network newscasts had a startling common message just after Thanksgiving: medical mistakes are killing people! The genesis of the outcry was the release of a report by the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System*.

The concerns expressed in the IOM report are not really news, since iatrogenic injury and therapeutic adverse outcomes are as old as medicine. Ernest Codman in 1910 proposed a system of tracking patient outcomes and studying those that were negative. Landmark studies by Lucian Leape, Troyen Brennan, and colleagues documenting "adverse events" in hospital settings were first published in 1991. The National Patient Safety Foundation at the American Medical Association (AMA) and the National Patient Safety Partnership brought together by the Department of Veterans Affairs (VA) were both founded in 1997. The National Health Policy Forum and the Joint Commission on the Accreditation of Healthcare Organizations both sponsored meetings on patient safety in 1999, while the Medicare Payment Advisory Commission also called for legislative and regulatory attention to reducing medical errors.¹

Without doubt, however, the IOM report gave visibility to a problem that had largely been ignored—despite the fact that medical error is responsible for more deaths per year than motor vehicle accidents or breast cancer. Several legislators, as well as President Clinton, have recently signaled their intent to take action on the issue.

The IOM's specific recommendations are not without controversy. Should reporting of at least some kinds of errors be mandatory, and where would the line be drawn? How large a role should government play, at what level, and who will bear the costs? What level of investment will be required for data collection, protection, dissemination, and—of critical importance—analysis? Who will develop standards and definitions? How can a workable framework for apportioning responsibilities and promoting cooperation among all parties be determined? How can all health care facilities put into operation procedures such as computerized prescription entry that can be shown to save lives? What has prevented them from doing so?

While such questions may seem abstract, this Forum session will make them more concrete by looking at current efforts already under way at various administra-

tive levels. To begin, Paul O'Neill, chairman and former chief executive officer of Alcoa, will describe how the vision of an injury-free workplace that he pursued and virtually achieved at Alcoa is being translated into a vision of a city free of medication errors and nosocomial (treatment-caused) infections. In fact, eradication of these errors is just one element of a health quality initiative O'Neill is spearheading in the greater Pittsburgh area. John Clough, M.D., will discuss the Cleveland Clinic's error reduction efforts, focusing on both internal and external challenges, obstacles, and stimuli.

Other speakers will address IOM recommendations more directly. Nancy Ridley, assistant commissioner for health quality management in the Massachusetts Department of Public Health, will relate her experience with the state's mandatory error reporting system. Kenneth W. Kizer, M.D., M.P.H., president of the National Forum for Health Care Quality Measurement and Reporting—also known as the National Quality Forum—and past under secretary of health in the Department of Veterans Affairs, will draw on his experience with the VA's error-reduction program and will comment on the National Quality Forum's role in setting national standards. John Eisenberg, administrator of the Agency for Healthcare Research and Quality (AHRQ), will speak about the creation of a Center for Patient Safety and the role of AHRQ in funding quality research.

ISSUE BRIEF/No. 753

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QUALITY IMPROVEMENT IN THE PRIVATE SECTOR

Just as the concerns about medical error have a history that antedates the IOM, so do efforts to address them. In addition to the public policy and cooperative group responses referenced above, individual institutions also have put programs into place. The Cleveland Clinic faces many of the same hurdles that other provider organizations have confronted; these include, as Clough has put it, "ten different databases, none of which communicate with each other." The clinic is working to systematize data collection. But at the same time that technical improvements are undertaken, the delicate process of cultural change proceeds. Clough sees three barriers to candor in any medical institution: fear of legal liability; managerial defensiveness (the initial impulse to shoot—or quietly bury—the messenger); and mistrust in the ranks of new programs billed (by management) as "constructive."

Desirable as intramural progress is, improved outcomes for a population require cooperation among institutions, for example, in agreeing upon and adhering to standards, benchmarking performance, and making quality-related information available to consumers. The record of such collaborations is ambiguous. The Cleveland Health Quality Choice (CHCQ) program collected hospital data for a decade, publishing comparative report cards. Some hospitals felt the expense of collecting CHCQ data could be better spent more directly, criticized the measures, and saw little evidence that employers and consumers were using the report cards in selecting providers. The Cleveland Clinic system (with its nine hospitals) eventually pulled out, triggering the program's demise.

Pittsburgh hopes for greater success, both regionally and in building on the state's data analysis efforts. The Working Together Consortium's Healthcare Initiative (WTCHI) has brought employers, labor organizations, physicians, hospitals, health plans, and other stakeholders to the table to seek agreement on better ways to deliver and pay for health care. At this time, more than 75 leaders are working to make southwest Pennsylvania the nation's pacesetter in quality of clinical care and controlled costs through waste-free delivery. As a first step toward these goals, WTCHI members have committed to a campaign to eliminate medication errors and nosocomial infections in participating southwest Pennsylvania hospitals. The campaign embodies O'Neill's prescription for improvement: start by identifying a small number of goals that (a) are not debatable, and (b) require systemic change to accomplish.

The WTCHI charter illustrates the principle that error reduction, while a worthy goal in its own right, is only one step toward quality health outcomes for a population. O'Neill suggests that the organizing principle of a health system should be the individual patient and that the best system would be one in which the medical establishment withers away because the patient is healthy. Where medical intervention is required, it would be held to a recognized standard and, ultimately, judged by its impact on the patient.

Obviously, today's health care system is a long way from this nirvana. But O'Neill's ability to extrapolate from industry to health care is one of WTCHI's strengths. Health care is widely acknowledged to be well behind industries such as aviation and banking that invested early on in the information systems and training that have allowed them to perform more efficiently and effectively. Where leading manufacturers strive for "six sigma" quality (that is, fewer than 3.4 defects per million units), researchers such as Mount Sinai School of Medicine's Mark R. Chassin, M.D., have estimated that defect rates in some health care categories (such as diagnosing and treating depression or controlling hypertension) may reach 500,000 per million instances.²

BACKGROUND TO THE IOM REPORT

The final report (1998) of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry was titled *Quality First: Better Health Care for All Americans*. Among many recommendations, it included a chapter on reducing errors and increasing safety in health care.

Responses to the commission's report included various patient-protection bills modeled on the report's Consumer Bill of Rights and Responsibilities. Differing versions ultimately adopted by the House and the Senate are scheduled for conference. The bills share an emphasis on access and coverage issues, considering quality as a matter of whether beneficiaries in fact receive the services they believe they were promised.

The IOM in June 1998 established a Committee on the Quality of Health Care in America, under the chairmanship of William C. Richardson, Ph.D., and the staff direction of Janet Corrigan, who had filled the same role with the president's advisory commission. *To Err Is Human* is the first in a planned series of reports. Its focus is the actual delivery of medical care to patients who have access to and are using the health care system (though the authors acknowledge in passing

that, when someone needs medical attention, the worst quality is no care at all³).

The committee's research review revealed that medical error may account for as many as 98,000 in-hospital deaths per year, with a price tag of \$17 billion to \$29 billion attached to errors characterized as preventable.⁴ How has such a dismal situation come to be? The IOM committee explains:

A general lack of information on and awareness of errors in health care by purchasers and consumers makes it impossible for them to demand better care. The culture of medicine creates an expectation of perfection and attributes errors to carelessness or incompetence. Liability concerns discourage the surfacing of errors and communication about how to correct them. The lack of explicit and consistent standards for patient safety creates gaps in licensing and accreditation and lets health care organizations function without some of the basic safety systems in place. The lack of any agency or organization with primary responsibility for patient safety prevents the dissemination of any cohesive message about patient safety. . . . The external environment is not creating any requirement or demand for the delivery system to reduce medical errors and improve the safety of patients.⁵

It is this ignorance, fragmentation, and entrenchment that the committee hopes to combat with its recommendations.

Center for Patient Safety

The IOM committee believes that a focal point is needed for patient safety in health care, bringing together the various initiatives and mechanisms that now exist. Its report recommends creating a Center for Patient Safety within the Agency for Healthcare Research and Quality,⁶ and says the center should

- set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the president and congress on patient safety; and
- develop knowledge and understanding of errors in health care by developing a research agenda, funding centers of excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.⁷

The center's mission would be two-pronged: helping to prevent mistakes via research and education and analyzing and making available the lessons to be learned from errors already made.

The committee chose AHRQ as the site of the proposed center in part because the agency already is

involved in a range of quality-related activities, including patient safety. Indeed, the Healthcare Research and Quality Act of 1999, which reauthorized and renamed the agency, explicitly includes reducing errors in medicine among its required activities. AHRQ is also charged with linking research to practice improvement and identifying and disseminating information relating to the integration of quality information into purchaser and consumer decision-making. The IOM report observes that the agency's demonstrated ability to collaborate with other organizations, both public and private, is a strong argument in its favor.

Given the reauthorizing language, it does not appear that further legislative action would be required in order for AHRQ to establish a center for patient safety; however, funding is another matter. The IOM committee calls for initial annual funding of \$30 million to \$35 million, rising to \$100 million over time. (This compares with an annual \$200 million for the National Institute for Occupational Safety and Health, which conducts research and makes recommendations for the prevention of work-related illnesses and injuries.⁸)

The committee also weighed creating a stand-alone center or locating it within NIH before settling on AHRQ. The stand-alone idea, while facing a number of philosophical and budgetary hurdles, would have the advantage of independence from the regulatory function. AHRQ does not itself regulate but is part of the Department of Health and Human Services, which does. Some have suggested that provider organizations might be more comfortable with an independent center, given the role envisioned for it in analyzing error reports, discussed below. It might be remembered that the Aviation Safety Reporting System (ASRS), so often invoked as a model for health care, was created within NASA because an earlier attempt to establish such a system within the Federal Aviation Administration was stalled by distrust and fear of reprisal for reporting mistakes.

Reporting Systems

To Err Is Human points out that one way to learn from mistakes is to establish a reporting system. Two important functions can be served by a reporting system: it can hold providers accountable for performance, or it can point the way to improved safety. Theoretically, it can do both; in practice, it may be difficult to find a balance. The IOM committee addressed this tension by recommending a two-tiered system.

Mandatory Reporting. The committee recommended the following:

A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care settings.

The committee believes that mandatory systems should focus on identifying adverse events attributable to error that lead to serious patient harm or death. To be effective, such systems would need a common set of reporting standards, which would permit data to be tracked over time, compared across locale, and aggregated into national statistics. A commitment of resources adequate to enable systems to analyze what happened and follow up to ensure that appropriate steps are taken by the responsible health care organization is also critical to success.

The committee points to the National Quality Forum—another outgrowth of recommendations from the president's advisory commission—as the body best suited to develop and promulgate a core set of reporting standards to be used by states. As with AHRQ, its existing mission is compatible with this new role. The National Quality Forum already is charged with developing a measurement framework for health care quality and has appointed a framework board of health policy experts who have each committed 20 percent of their time to this effort. Federal legislation would be required to direct the group to promulgate national standards and encourage states to adopt them.

Error reporting is not a novel proposal. A survey conducted by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the spring of 1999 revealed that at least one-third of states had some form of adverse event reporting system in place. These systems vary in terms of being voluntary or mandatory, in volume of reporting, and in the types of facilities involved (several states focus mainly on nursing homes, for example.) Moreover, IOM follow-up has confirmed that few states aggregate data or analyze them to identify general trends. Reasons cited were a lack of resources to upgrade computer systems and inconsistency in reports submitted. A standardized format would address the latter concern. As to the former, the IOM calls on Congress to “provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it, and conduct follow-up as needed with health care organizations.”

Even if such assistance is forthcoming, there may be states that choose not to establish a mandatory error reporting system. In this eventuality, the IOM envisions the Department of Health and Human Services stepping into the breach. The department was also the fallback for states that chose not to implement the Health Insurance Portability and Accountability Act of 1996. When four states (including California) deferred to partial or full federal enforcement, the department had to assume the role of state regulator. It is unclear at this time what proportion of the country's error reporting responsibility might revert to department staff as well.

The call for mandatory reporting of serious error has drawn a mixed response from providers. All have championed the goal of error reduction, but the American Nurses Association's support for a mandatory system is offset by the AMA's misgivings. Former AMA president Nancy Dickey, M.D., raised the issue of malpractice, observing that what appears to be a straightforward step “actually engenders all sorts of problems with confidentiality and liability. . . . There are still insurance companies that would advise a physician not to say anything.”⁹ She added that the AMA is opposed to mandatory reporting.

The question of whether any reporting should be mandatory will be vigorously debated, but it is not necessarily the most significant issue involved in a national reporting system. It should be kept in mind, the IOM points out, that the purpose of such a system is not to collect and count reports. Analysis and communication are key. The limitations of state systems in these areas cause some to wonder why the IOM chose to recommend a network of state systems. Its report explains that flexibility is needed at this stage because no “best practice” has yet been identified. It is envisioned that the Center for Patient Safety would work with states to develop systems and that states would be able to choose to collect and analyze data themselves or to contract for these activities with an accrediting body or a quality improvement organization (QIO) (formerly known as a peer review organization (PRO), the entities that monitor utilization and quality of care under Medicare).

Some states have amassed considerable experience and expertise that a national system could draw on. An example is Massachusetts, where the Public Health Department's Division of Health Quality (DHQ) determines whether an error is a system problem or a practitioner problem. If the latter, it makes a report to the appropriate board of registration (nursing, medicine,

or pharmacy). If a systemic problem is indicated, DHQ performs extensive analysis. Teams write up their findings in a prescribed format and prepare a statement of deficiencies that cites specific state regulations and how they were violated. Other standards, such as Medicare conditions of participation, are incorporated by reference; for some diagnoses and procedures, DHQ has developed its own standards.

Voluntary Reporting. As the second tier of its reporting system, the IOM recommended that “the development of voluntary reporting efforts should be encouraged.” An amalgam of voluntary systems, the second part of the reporting scheme is designed to address near-misses and cases of “very minimal patient harm.”¹⁰ The committee did not propose a national system in this case, noting that a number of “good efforts” are already in operation, particularly in the area of medications.¹¹ Among these efforts are the following:

- The FDA’s Adverse Event Reporting System (AERS), a data base containing information about adverse drug reactions submitted directly to the agency or reported via the MedWatch system designed for use by health professionals.
- The Institute for Safe Medication Practice, which has campaigned for improvements in drug naming, packaging, labeling, and dispensing and which recently joined forces with the American Hospital Association in an initiative to reduce medication errors in hospitals.
- U.S. Pharmacopeia, which administers a voluntary medication error reporting system, including a component called MedMarx, which allows employees of subscribing hospitals to report error-related information anonymously via the Internet.

The committee also recognized that a national system like the aviation industry’s ASRS would potentially be inundated with reports and that a wide range of expertise would have to be maintained (for example, an analyst who understands drug interactions is not necessarily conversant with device manufacturing or home care staffing). They suggested that a number of “mini-systems” for different types of problems might be effective, provided that the systems had the capacity to communicate among themselves about overlapping problems.

The intent of voluntary error reporting is to study and enhance safety, not to hold reporting institutions accountable. This message seems to resonate with policymakers. In a Rose Garden speech responding to

the IOM report (and calling on federal agencies and contractors to institute safety programs) Clinton said:

Now let me be clear about one thing—ensuring patient safety is not about fixing blame. It’s about fixing problems in an increasingly complex system; about creating a culture of safety and an environment where medical errors are not tolerated. In short, it’s about working together to zero in on patient safety, and zero out preventable errors.”

Still, intent is one thing, and practical consequences another. Where data exists, there will be a corresponding interest in access to it—particularly on the part of plaintiffs and their attorneys in malpractice cases. The committee recognized that fear of legal discoverability or involvement in a legal process would contribute to underreporting of errors. Perhaps the central question for the success of a voluntary reporting system is confidentiality of the data reported. Thus, the IOM further recommended:

Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for the purpose of improving safety and quality.

The committee judged the peer review privilege to be “the most promising existing source for legal data on errors.” Forty-nine states (excluding New Jersey, according to a JCAHO survey) have statutes protecting from discovery the records and deliberations of peer review committees. However, the significant variation among these statutes in scope and specifications suggests that a federal statute might be preferable. (This was also a recommendation made by the Medicare Payment Advisory Commission in its June report to Congress.) The IOM report points to statutes in Oklahoma and California that might serve as models and also notes that the federal Health Care Quality Improvement Act of 1986 (which established the National Practitioner Data Bank) establishes peer review immunity from damage suits when participants act in good faith in any peer review process that meets the act’s standards for structure and fair process.

QIOs may investigate instances of possibly substandard care delivered to fee-for-service beneficiaries. In such cases, their case review records are protected from subpoena. This protection, modeled on in-hospital peer review privilege, was written into the 1972 statute creating professional standards review organizations (PSROs), and carried over as PSROs evolved into PROs and QIOs. Its preservation has drawn some criticism: while providers have welcomed confidentiality, consumer groups have

long protested what many perceive as a “cover-up” attitude.

One limitation of peer review privilege is that it may be lost when information leaves the confines of an institution. The committee wrote:

Collaborative quality improvement efforts may be inhibited by the loss of statutory peer review protection that may occur when data are shared across institutions. Some form of protection appears necessary for each of the three components of an error reporting system: (1) the original reporters; (2) the various recipients of the information (including processors, investigators, de-identifiers, and analyzers; and (3) the reported information itself.¹²

POLICY ISSUES

The Bright Line

The IOM’s incorporation of a “narrowly defined” mandatory system and a much broader voluntary effort into its two-tiered system requires that a line be drawn between errors involving serious harm and those causing minimal damage. Where, in one case, a patient dies as a result of an error and, in another case, an error is caught before medication is administered to a patient, assigning the two cases to the mandatory and voluntary reporting systems respectively is easy. But there are bound to be borderline cases. Is an extra day in the hospital serious? What about a wound infection that led to pronounced scarring? What if the wrong medication were administered, with side effects such as sleepiness or gastric distress?

Another concern is that it may at times be difficult to isolate the effects of an error from other medical complications. This is a weakness in the frequently invoked National Transportation Safety Board (mandatory)/ASRS (voluntary) parallel, as the effects of a plane crash are fairly easily distinguished from any symptoms passengers may have brought on board. Is modern medicine so complex that it may not always be possible to recognize error?

Putting the Horse Before the Cart

Some analysts have already voiced concern that the debate over mandatory versus voluntary reporting will be a sticking point for implementing safety-improvement proposals. They believe it may be more useful first to come to agreement on—and establish in the public mind—what any kind of a reporting system is intended to accomplish and how its various parts fit together to

achieve an aim of improved safety and quality overall. What information is needed in order to define what good quality care is and whether care delivered in a particular case meets that standard? How can a process be designed to ensure collection of only data that will be used?

Error data collection and analysis now occurs primarily on an institutional basis (obviously with wide variation among institutions). Institutional data will need to be aggregated, used to develop comparison and benchmarking instruments, and interpreted so as to provide meaningful feedback. At the same time, the transfer of information from one level of a reporting system, such as a hospital, to another, such as a state, must not trigger legal liability if the overall system is to be effective.

Equally important is communication in the other direction. How will lessons learned by error analysis make their way through organizational layers to reach practitioners? How will entities at the same level (such as states) communicate amongst themselves, or must they rely on federal-level dissemination?

Another basic question is who will perform error analysis. In considering medical necessity determinations, review by a peer (be it another psychiatrist, a cardiologist, a family physician, or a nurse) has been a must-have for providers. Is it feasible that a team of analysts could replicate a group of hospital colleagues who are involved in a process that results in error?

The Role of the Individual

The IOM report focuses on the accountability of health care institutions, such as hospitals. Its proposed reporting systems posit error reports made by institutions once they have undertaken their own internal analysis. There is no mechanism for error reporting to an outside body by an individual, such as a nurse, within the institution, or by a patient who believes that he or she was harmed.

Like the IOM’s proposal, JCAHO’s sentinel event reporting policy focuses on institutions. Both expect an institutional response to an error (or a near-miss) to be part of the report. By contrast, the ASRS and the FDA’s AERS make provision for reports from individuals. This may be a matter of where analytical emphasis is placed. The ASRS and the AERS, in accepting reports of problems from an airline pilot or mechanic on the one hand or from a prescriber or consumer of prescription drugs on the other, seem to place greater responsibility on their own analysts to unravel the problem.

A central issue in pending patient protection legislation is the ability of a patient to appeal—and perhaps ultimately to file suit over—a decision that he deems a wrongful denial of care. Some of the same questions with respect to patient empowerment are raised by error reporting proposals. What options should a patient have? Focusing on institutions underlines the systemic complexities to which experts attribute most medical error and avoids searching for an individual scapegoat. But does deflecting attention from individuals to systems deemphasize the individual patient as well? As the health care system continues to move from institutional settings to more ambulatory and home-based care, the role of the patient in care delivery grows even more critical.

Finally, what are the rights of the patient or the patient's family members to be notified that an error has occurred? To what extent should they be privy to the results of an ensuing investigation by the health care organization?

Purchaser Commitment

A complaint sometimes voiced with respect to existing quality-reporting programs, such as HEDIS, is that, after information is laboriously (and expensively) collected, it carries little weight in employers' contracting decisions. Jon Gabel and colleagues, in a study conducted for the Commonwealth Fund, found that just 5 percent of employers offering an HMO rated HEDIS information as very important in selecting a plan.¹³ If safety-conscious organizations that are willing to learn from mistakes rather than conceal them are not rewarded by more patients and/or more advantageous contracts, error reporting loses the ability to drive change that the IOM envisions for it. Some large employers already are taking steps to factor patient-safety measures into their procurement processes. Medicare and Medicaid could have a powerful effect by following suit.

The Culture of Medicine and the Culture of Blame

It has been widely observed that a major challenge to creating a culture of safety is the existing culture of medicine, wherein physicians are schooled to believe that they should be in control. While one might think that it would be a relief to admit one's human fallibility or at least interdependency, the issue of blame acts as a strong deterrent. Medicine may be a culture of perfection, but 21st century America seems to subscribe to a culture of blame, the notion that "someone should pay"

when harm is done. The IOM has tried to address this by recommending institutional accountability for serious harm and a parallel system of constructive, nonpunitive investigation and improvement. This is a delicate balance; whether fear of liability on one hand can co-exist with trust on the other remains to be seen.

Certainly the patient-safety advocates have been eloquent. Donald Berwick, president of the Institute for Healthcare Improvement and a member of the IOM committee, has said, "You don't get to safe systems that have human beings in them by yelling at them or asking them to try harder. You need to engineer the work environment so that normal human limits are respected."¹⁴

Some doctors, however, feel that looking to systems solutions is just another interference on the part of managed care. The chairman of medicine at a New York hospital recently profiled in the *New York Times* spoke to a group of interns about the importance of personal responsibility, warning them not to "ship the blame elsewhere—to a computer, to the next shift...to the system."¹⁵

THE FORUM SESSION

Key Questions

Among the questions to be addressed at this session are the following:

- What factors are critical in eliciting commitment to error reduction?
- Is the IOM's emphasis on error reporting as a central strategy the best way to proceed? What is the dynamic that will make a reporting system work as intended? How can information about medical errors and how to avoid (or correct) them be most effectively accumulated and disseminated?
- Should a Center for Patient Safety be created? Should it be part of a federal agency? Is AHRQ the right place for it? Should the center have any type of enforcement powers?
- Once error reports are made, who will analyze them? Just as active-duty pilots rotate through the ASRS, will practicing physicians and pharmacists rotate through state error-reporting systems? How will error systems counter probable physician complaints that they are not being evaluated by their peers?
- Is there a role for consumers in medical error reduction? What about provider professional societies?

- Why have not more institutions followed the lead of the Veterans Health Administration and implemented seemingly obvious safety procedures such as computerized prescription entry and bar-coding medications? What (or who) are the barriers to taking steps already known to reduce error?
- Is there a way to merge the two currents in patient protection? Can coverage appeals and other elements drawn from the Patient Bill of Rights and error analysis and practice improvement share common strategies?

Speakers

The five presenters featured in this Forum session are deeply involved in quality improvement and error reduction activities.

Paul H. O'Neill is chairman of Alcoa, having also served as the company's chief executive officer from 1987 through May 1999. Prior to joining Alcoa, he was president of International Paper Company. He was on the staff of the U.S. Office of Management and Budget from 1967 through 1977 and was named deputy director in 1974. He serves on a number of boards and as chairman of the RAND Corporation and the Working Together Consortium's Healthcare Initiative in Pittsburgh.

John D. Clough, M.D., F.A.C.P., is chairman of the Division of Health Affairs of the Cleveland Clinic Foundation. He joined the staff as a clinical rheumatologist in 1971, following three years at the National Institutes of Health. In 1979 he became chairman of the Department of Rheumatic and Immunologic Disease, a post he held until accepting his current position in 1991.

John M. Eisenberg, M.D., M.B.A., is administrator of the Agency for Healthcare Research and Quality, in the Department of Health and Human Services. Appointed to head the agency in 1997, he previously was chairman of the Department of Medicine and physician-in-chief at Georgetown University. He was a founding member of the Physician Payment Review Commission, which he chaired from 1993 to 1995.

Kenneth W. Kizer, M.D., M.P.H., is the president and chief executive officer of the National Forum for Health Care Quality Measurement and Reporting. Prior to taking this position last year, he served for five years as the under secretary for health in the U.S. Department of Veterans Affairs. His professional experience includes practice as an emergency medicine physician and a variety of positions in academia, philanthropy, and state government.

Nancy Ridley, M.S., is assistant commissioner for the Bureau of Health Quality Management in the Massachusetts Department of Public Health. She has spent 20 years managing a variety of state public health programs. For two years, she has been an active member of the steering committee of the Massachusetts Coalition for the Prevention of Medical Errors.

ENDNOTES

1. Medicare Payment Advisory Commission, "Report to the Congress: Selected Medicare Issues." Washington, D.C.: June 1999.
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Stanley Stein to Chris Jennings (2 pages)	02/22/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:

Medical Error

2012-0463-S

rc794

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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001b. fax	To: Jeffrey Lipton (3 pages)	06/12/1999	P6/b(6)

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Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:

Medical Error

2012-0463-S

rc794

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001c. letter	Barry Freedman to Caroline and Stanley Stein (1 page)	07/23/1999	P6/b(6)

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001d. report	re: personal medical (16 pages)	02/22/2000	P6/b(6)

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001e. letter	Stanley Stein to Linda Granowetter (2 pages)	02/22/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

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DAVID PRICE
4TH DISTRICT
NORTH CAROLINA

COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE BUDGET



CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515
February 2, 2000

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DURHAM, NC 27701
(919) 688-3004

Mr. Chris Jennings
Deputy Assistant to the President for Domestic Policy
The White House
1600 Pennsylvania Ave
Washington, DC 20215

Dear Mr. Jennings:

I want to bring to your attention the enclosed information from my constituent, Mr. Michael Clark. Mr. Clark serves as the Principal of IVC, Inc., a software development company located in Cary, North Carolina.

As you know, the Institute of Medicine's recent report on medical errors raised a number of concerns about patient safety in the United States. Mr. Clark's company, IVC, Inc. has been working to develop software products to address these errors. I thought this technology may be of interest to you as the Administration studies ways to implement the IOM's recommendations to ensure patient safety.

Please contact me if I can be any further assistance in this matter.

Sincerely,
A handwritten signature in black ink that reads "David Price".

DAVID PRICE
Member of Congress

DP:jk

Enclosures

February 2, 2000

The Honorable David Price
United States House of Representatives
Washington, DC

Dear Congressman Price:

Thank you once again for contacting us regarding our healthcare information system products. We are committed to making a difference in the way that healthcare is administered in this country. Toward this goal, we have under development several software systems that can be used by hospitals and other healthcare institutions to improve efficiency, cut costs, and improve the quality of patient care.

When we became aware of the recent IOM report disclosing the high rate of accidental deaths in our nation's hospitals from treatment errors, we realized that our product, Med-E-Path, can have a direct and immediate effect on this problem. By applying computer technology to well-established treatment plans we can insure on-time completion of tests and treatments, and notification of lapses or oversight in treatment protocols.

I have attached a one-page overview of our product, known internally as "Med-E-Path". It is a high-level document, with no technical details. If more detailed information would be appropriate, we will certainly be happy to supply it upon request.

Additionally, Congressman Price, we invite you to visit us at our offices in Cary to see first-hand what we are doing to change healthcare.

Sincerely,

Michael Clark
IVC, Inc.
110 MacKenan Drive
Suite 200
Cary, North Carolina 27511
(919) 468-9901 ext. 101
mdc@ivc.com

Med-E-Path - Product Description

Hospitals currently utilize paper-based treatment plans (clinical paths) to reduce the cost and improve the quality of care. Treatment plans identify all the activities required for treating patients with a specific condition or illness, based on medically accepted standards of care. These plans insure that care is consistent, high quality, and cost-effective for all patients placed on a treatment plan. However, they are traditionally paper-based and labor intensive, which makes the process prone to miscommunication and handwriting errors.

Our web-based treatment plans address this deficiency by (1) communicating orders and results electronically in real time, (2) providing immediate notification when orders have not been performed as scheduled based on accepted standards of care, (3) maintaining an audit trail of performed activities, allowing for future cost-benefit analysis, and (4) providing physicians and others with remote access to the latest information on the care and treatment of patients. This allows the treatment process to achieve peak performance by automating the data collection, communication, and order entry process, thus reducing errors and cost in healthcare delivery.

Clinician and Nursing

Med-E-Path will track all active clinical path patients, where all patients are in the system, communicate test/study results, identify which patients are behind schedule, and why, as well as supply notification of any conflicts that arise due to slippages for clinicians and nurses. This allows them to manage their patients and their time in the most effective manner.

Ancillary/Support Services

Web-based treatment plans will allow ancillary/support services to forecast demand for their areas and manage the staff and resources appropriately. This is not only for clinical areas (ex. lab and radiology), but for non-clinical areas also (ex. admissions and patient transport).

Administrators

Administrators will be allowed to examine patient flow through the complete hospital system. They can review timed performance against agreed upon standard performance levels and key activities can be correlated to positive outcomes. Negative outcomes can be correlated to specific events and corrected.

JCAHO

The Joint Commission on Accreditation of Healthcare Organizations strongly encourages hospitals to consider clinical paths as a tool to reduce cost and improve the quality of patient care.

Contact Information

IVC, Inc.
110 MacKenan Drive, Suite 200
Cary, NC 27511

919-468-9901 x110

info@ivc.com

Web-Based Clinical Paths: Med-E-Path

Company Description

IVC, Inc. is an integration, custom software, and e-commerce infrastructure company that provides information technology and business consulting leadership for healthcare and other industries. Our depth and breadth of talent can quickly assess any problem and develop multiple strategies to resolve IT and business issues. We apply the best of both business and technology to help our customers identify business processes that could be improved and create total system solutions that will scale as business grows. IVC was incorporated in 1997. The company currently has 20 employees and generates annual revenues of \$2 million.

MANAGEMENT TEAM

The management team at IVC, Inc. has the right combination of entrepreneurial, technical, and healthcare expertise. The experience in software development and systems integration provides the leadership and methodologies for developing the Med-E-Path product. The healthcare background at the executive and operational level gives the necessary insight into solving our customers' problems with providing healthcare services. Start-up firms are not new to the IVC team. We have experience with several small, self-funded start-ups. Med-E-Path is much larger than the previous start-ups, but IVC's experience with start-ups is valuable.

Steve Thiedke

Steve co-founded IVC, Inc. in 1987 and over the past 10 years he has participated in the creation of several successful businesses in the Triangle area. He has 20 years experience in software industry. His focus has been in telecommunications, expert systems, and software development. Steve was formerly a senior engineer with Nortel and GTE, and a technical director at Imonics Corporation.

Andrei Mitran

Co-founder of IVC, Inc., Andrei has 20 years of experience as a programmer, system architect, and a technical manager. His most recent tasks include leading a call center and Internet banking application in Portugal and a customer service center with a large telecommunications provider in the United States. Andrei is responsible for setting strategic technical direction of IVC, Inc. He holds a BS in Computer Science from Brock University in St. Catharines, Ontario, Canada.

Jerome Stracke

Jerome previously served as Chief Operating Officer of National Healthcare Logistics, a management services company for large integrated healthcare networks. Also, he acted as the Consulting Director for BSG Corporation and a consulting/advisor for Baxter/Allegiance Healthcare Corporation. Jerry began his healthcare career in 1979 at Saint Joseph's Hospital in Omaha, Nebraska. Moving to Evanston Northwestern Healthcare in 1981, he became Vice President of Corporate Purchasing & Materials Service. Being responsible for a \$100 million budget, he was instrumental in introducing and implementing a 36-month business plan, which let

to a 20% total cost reduction in pharmacy and medical/surgical areas. He accomplished this through the introduction of "stockless" and continuous quality improvement programs.

William Fulkerson

William has focused on process improvement through operational reporting, work measurement, and process analysis throughout his career. Prior to joining IVC, Inc. he worked as a Senior Management Engineer for DukeUniversity Health System and was responsible for identifying process improvement opportunities in the inpatient and outpatient setting through performance monitoring and operational observation. He received a B.S. in Mathematics from Saint Bonaventure University and a Masters in Operations Research from North Carolina State University.

ORGANIZATION

Highly skilled employees are on the IVC, Inc. team. They possess significant experience in information technology. Approximately two-thirds of the employees are programmers with a wide-range of experiences. They are trained in the latest tools and methodologies relating to software development.

IVC, Inc. has a relatively flat reporting structure. This allows us to react to change quickly and thus nurture an entrepreneurial attitude amongst the employees. It also enables us to attract highly skilled and creative people to the organization.

Online NewsHour

ONLINE FOCUS

MEDICAL MISTAKES

February 22, 2000



Gwen Ifill leads a discussion on the president's proposed guidelines to reduce the number of medical mistakes, after a background report.

The Health Unit is a partnership with the Henry J. Kaiser Family Foundation.

[Click here to listen to this segment in RealAudio](#)

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GWEN IFILL: And joining me are Dr. John Eisenberg, director of the Agency for Health Care Research and Quality. The agency is part of the Clinton administration's Health and Human Services Department. And Carmela Coyle, senior vice president for Policy at the American Hospital Association, which represents 5,000 hospitals and health systems across the country.



It's critical when we have systems in place for learning from those errors that are made that clinicians and hospitals feel comfortable in reporting those errors and that the systems be confidential.

DR. JOHN EISENBERG,
Healthcare Research
& Quality Agency

Carmela Coyle, the President says this is a good idea, that early reviews from Congress are encouraging for the President's proposal. What does the hospital association think?

Outside Links

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Association](#)

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Research and
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CARMELA COYLE, American Hospital Association: The president's proposal does contain some good ideas but also contain as number of unanswered questions that really need to be addressed to make certain that this is a prescription for

patient safety.

GWEN IFILL: What are those questions?

CARMELA COYLE: Two of the critical questions have to do with the protection of and confidentiality of the information that's included in these reports. What's critical to the success of any error reporting system is the protection and the confidentiality of that information so that we can create an environment in which doctors and nurses and others feel comfortable talking about their mistakes -- so that we can learn from them and prevent those mistakes from happening again.

GWEN IFILL: Dr. Eisenberg, what about the confidentiality concerns?

DR. JOHN EISENBERG, Healthcare Research & Quality Agency: Well, Ms. Coyle is exactly right. It's critical when we have systems in place for learning from those errors that are made that clinicians and hospitals feel comfortable in reporting those errors and that the systems be confidential. In fact, we've gone so far as to suggest that the protections that exist in our peer review organizations, which are called peer review protections, be extended beyond those.



GWEN IFILL: What are peer reviews?

DR. JOHN EISENBERG: If a report has been assembled based on a hospital's experience in areas are other areas of quality and reported to another organization, that information is confidential and isn't to be disclosed unless it's disclosed in a very controlled way. We've proposed a limited number of serious events, as the president mentioned, death and serious adverse events, which would be the only ones that would be disclosed. The other events would be kept confidential so the hospitals could learn from them. But we think it's critical that the public have access to the information that they need in order to be sure the health care system is safe for them.

Assessing responsibility for mistakes



GWEN IFILL: Well, the question I guess for me is how do you do that? It's nice you both agree a confidentiality is important for medical professions but what about -- I'm speaking for the patient here -- why shouldn't these people be

held responsible, personally responsible for the mistakes they make?

DR. JOHN EISENBERG: What's key about this initiative that we've proposed is that the solution to the errors problem is not to blame individuals, but to look for system solutions. The answers are going to be in systems because physicians don't practice by themselves anymore. Nurses don't practice by themselves. They practice in teams and the solutions are going to have to be solutions from those teams from systems.

Our concern is some enterprising malpractice attorneys may be able to dig back through that information, identify caregivers and then we won't achieve the real objective, and that is understanding what happened and preventing it from happening again.

EMMA COYLE
American Hospital Association



CARMELA COYLE: And the issue of discovery protections in a liability context and confidentiality are critical, because if those protections aren't there, we'll end up driving these errors underground. And what we want to do is bring them to the surface so we can learn from them. I think some the concerns we have with the current proposal is the language around these protections remains very vague. We're encouraged but we need to be certain that those discovery protections will, in fact, be in place while patients' names and the names of doctors and nurses involved will be kept confident confidential, the name of the hospital in which an error occurred will not be kept confidential. Our concern is some enterprising malpractice attorneys may be able to dig back through that information, identify caregivers and then we won't achieve the real objective, and that is understanding what happened and preventing it from happening again.

GWEN IFILL: Is that a weakness - that this is a full employment act for liability lawyers?

DR. JOHN EISENBERG: Absolutely not. In fact, I think what we'll see with this program is with the proper protections of the data, but disclosure of those very serious event, that the public will be protected, that the medical community will be able to learn from those errors and, in fact, the best protection against medical liability is to reduce the errors that cause the liability in the first place. We think this proposal will do just that.



GWEN IFILL: Let's go back to what the president proposed today. He is urging states to impose mandatory reporting requirements within five years, saying that would cut the error rate by 50 percent, urging how -- what does that do and what happens if the states don't actually want to do it?

DR. JOHN EISENBERG: We've proposed that we have a three-year period during which we work with the states and the hospital community, to develop the best programs that we can develop. But we evaluate them to see if the best practices are best, to learn how we can put these programs together in the most successful way. Then in three years we evaluate how the states are doing, the success of the reporting system and giving information to the public that's valuable and learning from it and then we give a report

back to the president from this inner-agency coordinating task force to give advice about what should happen next.

GWEN IFILL: Sounds like a lot of red tape that in the end doesn't take you necessarily where you want to go.

DR. JOHN EISENBERG:

It's a cautious approach because we understand that the public wants to know this information but we want to be sure that the information the public gets is accurate information. We think this is the right start -- a limited number of publicly disclosed events to start off and then to work with the states and others to find the best way of giving other information to the public.



CARMELA COYLE: And one of the good ideas included in the president's proposal is one that would have the government's agency for health care research and quality actually take a look at the existing systems out there today, evaluate them and understand why they're under-used. We've got a number of reporting systems today, both voluntary and mandatory, and what we know is they're not used well. One of the reasons is because of this lack of discovery and confidentiality protections.

Big problem, or perception problem?

GWEN IFILL: Do hospitals actually think this is a big problem or is this a perception problem?



CARMELA COYLE: This is a very serious problem and hospitals are taking that problem very seriously. We began work at the end of last year where hospitals across the United States have dedicated an initiative toward working specifically to prevent and reduce medication errors, which are one of the single largest causes and sources of medical errors in the United States. So we're serious about; it's an issue that must be addressed.

It's critical that we begin to create reporting systems and encourage the voluntary reporting of ... close calls because while it may have been a close call this time, we want to capture that, learn from it and prevent it from becoming a serious event in the future.

CARMELA COYLE,
American Hospital
Association

GWEN IFILL: Dr. Eisenberg, there are about half a dozen states, which already imposed their own reporting requirements. Do you have any track record for them? Do you have any idea whether what you're suggesting they do has worked in the states which have already put it in place?

DR. JOHN EISENBERG:
We have a little information from almost 20 states that have mandatory programs in place now, and the early results from the research in that area shows that these programs can be successful in reducing errors and improving patient safety.



GWEN IFILL: They can be but are they?

DR. JOHN EISENBERG: Some of them are but in most cases we just don't have the research that tells us how successful they are and how they can be most successful. That's one of our plans is to work with the states, find out what works best and then disseminate that throughout the country.

GWEN IFILL: One of the things that this report says that doctors will now be asked to report is not only medical errors but also near-misses. What's a near-miss and how do you report one?

CARMELA COYLE: I think it's important to understand the distinctions in medical errors. There are those errors that result in serious harm or death of a patient. There are other adverse events, and then there are the so-called close calls where a mistake may have been made, but it did not result in any noticeable impact on the patient. It's critical that we begin to create reporting systems and encourage the voluntary reporting of those close calls because while it may have been a close call this time, we want to capture that, learn from it and prevent it from becoming a serious event in the future.

GWEN IFILL: And what is the incentive for the physician to report a close call when everything turned out fine?

DR. JOHN EISENBERG: Professionalism and the desire to do better and earn for future patients. What we think we can put together is a system of reporting that helps professionals and their patients do a better job of improving patient safety.



GWEN IFILL: Presume for a moment that the president's plan is not the beyond end all of this. What would you suggest as an alternative to address what you say is a very big problem?

CARMELA COYLE: Unfortunately Washington has oversimplified this issue into one of voluntary versus mandatory reporting, and the issue is much more complex than that. We think at the core of a successful system is this notion of protecting the information so caregivers feel comfortable talking about mistakes so we can learn from them. We also think that Washington has been focused on external reporting systems to outside organizations. There's a lot that can be done within healthcare organizations today, making certain that not only do we have systems in place to capture mistakes when they occur, but that we can share best practices of what are the components of those systems that really are most effective, share that across the United States and improve the learning from those mistakes into the future?

GWEN IFILL: Okay. The gauntlet is thrown to you then, doctor. What exactly -- why can't the government step out of it and trust hospitals to fix this problem on their own?

DR. JOHN EISENBERG:

We trust the hospitals that they'll do what they can. We think we can work together with the hospitals. And, in fact, the initiative that the president proposed today is a multifaceted one with every part of the government that's involved in healthcare quality, the Food and Drug Administration, the Defense Department, the Veterans Affairs, all working together with the hospital industry to see what we can do together to improve patient safety.



Real improvements?

GWEN IFILL: If we don't know whether this has worked in the past and there is some disagreement about how this will work in the present, how do we know that we are actually doing anything to improve patient safety?

DR. JOHN EISENBERG: One thing we do know is that there are certain patient safety practices which have been demonstrated to work. They've been demonstrated to decrease errors and improve patient quality. And we've asked in the Health Care Financing Administration, which is part of the Department of Health and Human Services and runs the Medicare program, they're going to ask every hospital to have a patient safety program in place, that will be part of what they ask every hospital to do to participate in the Medicare program. And we expect the hospital industry will want to collaborate for us so that we can stimulate every hospital to put those patient safety

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Healthcare Research
& Quality Agency

programs in place, but not just that, to let the patients know which patient safety programs those hospitals do have in place.



CARMELA COYLE: And one of the things that we've already done is to send a series of successful practices, lists of things that are known to actually reduce and prevent errors to all 5,000 hospitals and health systems in the United States and to encourage them to use those practices. I think at its core what's really going to drive a patient's safety is when a doctor or a nurse comes to work everyday, they're coming there to help patients. They're coming there to care and to cure. When they make mistakes, it's a devastating experience for them, and it's part of this concept of professionalism. They have don't want those mistakes to happen.

GWEN IFILL: There is bipartisan legislation working its way through Congress that would address some of these issues. Is it something you would support?

CARMELA COYLE: The proposal that will ultimately come out of this I think we have yet to see. The president has a proposal on the table. There are a number of congressional proposals that are on the table and others that will be developed.

GWEN IFILL: Will any of them suit you?



CARMELA COYLE: I think most certainly. I think if the critical issue is addressed and that is ensuring the protection of this information and the confidentiality of the information so doctors and nurses feel comfortable talking about mistakes.

GWEN IFILL: Is there anything on the hill you can see yourself working with?

DR. JOHN EISENBERG: I testified this morning before a joint meeting of the Senate Health Appropriations Committee and the Health, Education, Labor and Pensions Committee, and I was very impressed by the bipartisan commitment on both of those committees to do a good job of responding to the Institute of Medicine report. And I think the same kind of commitment is in the House of Representatives. We're going to look very carefully at the legislation that's proposed.

GWEN IFILL: John Eisenberg and Carmela Coyle,
thank you both very much.



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