



Roundtable Discussion:

Reporting as a Means
To Improve Patient Safety

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Institute for Health Policy

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Kaiser Permanente Institute for Health Policy
One Kaiser Plaza
Oakland, California 94612
(510) 271-5962

EXECUTIVE SUMMARY

Background

The recent Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, has made an extraordinary contribution to American health by highlighting opportunities to improve patient safety. Among its recommendations, the report calls for both mandatory and voluntary external reporting systems of medical errors. This recommendation is made as part of a comprehensive strategy to improve patient safety by creating an environment that both requires and encourages health care organizations to identify errors, evaluate causes, and take appropriate action to improve performance in the future. The report concludes that such external reporting systems represent one important mechanism to expand knowledge of errors and the underlying factors that contribute to them. The IOM's recommendation for mandatory external reporting has generated much debate and some opposition. The need to create a safe environment for reporting adverse events in our litigious society is one of the concerns that have been raised about this recommendation. The controversy raises the question of how reporting can best be organized and used to improve patient safety.

Health Policy Roundtable

Twenty-three individuals from across the United States representing health care providers, aviation and medical safety systems, health care policy development, and organized labor met at Claremont Graduate University on March 16 and 17, 2000 to address the topic: *Reporting as a Means To Improve Patient Safety*. Organizations represented at the roundtable included: The Department of Veterans Affairs (VA), National Aeronautics Space Administration (NASA) Ames Research Center, The Permanente Federation, the Reforming States Group, American Federation of State, County and Municipal Employees (AFSCME), the California Medical Association, the American Hospital Association, AFL-CIO, The Joint Commission on the Accreditation of Healthcare Organizations, and the National Patient Safety Foundation. Several of the participants were part of the IOM deliberation on patient safety. The roundtable was cosponsored by the Kaiser Permanente Institute for Health Policy, the National Quality Forum, and the Peter F. Drucker Archive and Institute. David Lawrence, CEO, Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals, served as moderator for the discussion.

Goal

The purpose of the roundtable was to consider the IOM's recommendations for mandatory and voluntary reporting, and to explore ways to make a reporting system effective. Central to the roundtable's theme was the notion that an effective reporting system would both improve patient safety and enhance public trust in the medical care system.

Areas of Focus

The roundtable discussion focused on the following key questions:

- How have other industries met the goals of improving safety and accountability?

- What principles should guide the design of an effective system for improving patient safety and enhancing public trust in the care delivery system?
- How can reporting contribute to significant improvements in patient safety?
- What design elements are crucial for the operation of a successful patient safety reporting system?

Recommendations

The process of developing design principles led the group to propose a patient safety reporting system with voluntary and confidential reporting to a non-regulatory national entity as its centerpiece. This conclusion was based on significant experience demonstrating that reporting of adverse events is a key to improvement in patient safety and that if those who report are punished, then reporting will not take place. The proposed reporting system strategy builds upon the NASA Aviation Safety Reporting System (ASRS), the VA patient safety system and other existing systems. The strategy that emerged from the roundtable discussion emphasizes that patient safety improvements can best be achieved through a voluntary, confidential and protected, non-regulatory system. As an incentive for persons to make timely reports, the group proposed that reported events be eligible for reformed tort processes, in the event of a legal claim.

The proposed voluntary system is envisioned to encourage the reporting of adverse events and near misses from all stakeholders in the medical care delivery system. The recipient entity would analyze the information contained in the reports, create and maintain a data repository, and issue safety alerts. Reports would be confidential, non-discoverable, and inadmissible. Following analysis, reports would be de-identified and entered into a database available to the public. Candidates for the voluntary reporting entity include the NASA ASRS or a public-private partnership such as the National Quality Forum. In the latter case ASRS could provide initial technical assistance. In addition, the roundtable recommends creation of a National Center for Patient Safety to sponsor research, identify effective practices to promote safety, and monitor progress.

Two recommended policies appear most likely to achieve the aim of restoring public confidence in the medical care system: first, encouraging providers to report errors that injure patients directly to the patients or their relatives; and second, ensuring that the public has access to information about the progress made by health organizations toward creating safe environments for care. The latter would involve the use of licensing and accreditation standards and processes to evaluate, track the adoption of, and publicly report on the technologies and work processes employed by institutions to improve patient safety.

State mandatory reporting systems should remain in place, but focus on areas of established standards including regulatory violations, criminal conduct, intentional misconduct, and acts of impaired individuals.

<p>The patient safety reporting system discussed in this document builds on the roundtable discussion and is a synthesis of the concepts discussed. It does not necessarily represent the views of either the individual participants or the organizations that they represent.</p>
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INTRODUCTION

The Institute of Medicine (IOM) Report, *To Err is Human: Building a Safer Health System*, addresses the significant problem of medical errors and the opportunities to improve patient safety in the United States. In a manner few reports have done, it has mobilized the public, purchasers and the health care industry around the patient safety issue. The report calls for a variety of actions including the implementation of systems for the mandatory and voluntary reporting of medical errors. These recommendations are made as part of a comprehensive strategy to improve patient safety by creating an environment that encourages organizations to identify errors, evaluate their causes and take appropriate actions to improve performance in the future. The report concludes that mandatory, external reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them.

The difficulty of creating an environment that in our litigious society could encourage reporting is one of the concerns raised about the mandatory, external reporting recommendation. External reporting has become a subject of controversy and a number of organizations, in their testimony before the United States Congress, have stated opposition to it. Some of these positions are summarized in Appendix 1. In addition, various related questions have been raised about the IOM recommendations, including: What design principles should guide this effort? What should be reported, to whom, and in what detail? What reporting standards should be established? How can reporting and the analysis of the reported events best lead to improvement in patient care and safety?

To begin to examine and answer these questions, and to define design principles for reporting, a roundtable discussion on “Reporting as a Means to Improve Patient Safety” was held at the Claremont Graduate University on March 16 and 17, 2000. The participants are listed in Appendix 2. The meeting was cosponsored by the Kaiser Permanente Institute for Health Policy, the National Quality Forum, and the Peter F. Drucker Archive and Institute. The roundtable focused on the following questions:

- How can reporting contribute to significant improvements in patient safety?
- What can be learned from some of the most successful safety reporting systems?
- What design elements are crucial for the operation of a successful patient safety reporting system?
- What is the recommended structure for a reporting system for health care?

The information presented in this document is a product of the Kaiser Permanente Institute for Health Policy which builds on the roundtable discussion. It is not a consensus document and therefore does not necessarily represent the views of the participants or the endorsements of the organizations that they represent. The report is being disseminated with the intent of informing the debate about this important topic.

INSTITUTE OF MEDICINE RECOMMENDATIONS ON REPORTING AND THE ADMINISTRATION'S RESPONSE

Institute of Medicine Recommendations

In 1998, the National Academy of Science's Institute of Medicine (IOM) convened a Committee on Quality of Care in America to evaluate the quality of medical care in this country, raise awareness of the general public, and make recommendations to enable improvement. The committee focused first on medical errors because of the enormous burden to society of avoidable injury and the tremendous potential for improvement in the quality of care. In November 1999, the IOM issued a report on patient safety, *To Err Is Human: Building a Safer Health System*, which caught the attention of the public, policy makers and the media.

Key Findings

The IOM report has four key findings:

- **American health care is unacceptably unsafe today.** Errors in medical care account for as many as 44,000 to 98,000 deaths per year in the United States. This means that more people die from medical errors than from breast cancer, AIDS or motor vehicle accidents.¹ Adverse events occur among 3-4% of hospitalized patients; about one in ten results in death. Over half of these adverse events are preventable.²
- **Errors and threats to patient safety are generally not due to careless or incompetent individuals.** Latent errors or system failures pose the greatest threat to safety in our complex medical care system.³
- **Medical errors are preventable.** Other industries have demonstrated the ability to make substantial improvements in safety.
- **Safety improvement in health care will require significant cultural change.** Today errors are driven underground because people are afraid to talk about them.

The report concludes that health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety.⁴

Recommendations

As a national target, the Committee recommended a 50% reduction in patient injuries from health care over the next five years. The report lays out a four-part comprehensive plan to reduce medical errors:

1. **A National Center for Patient Safety**—Establish a national focus through a Center for Patient Safety to provide leadership and to promote knowledge about error prevention. The

¹ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 22

² Ibid., pages 25-26

³ Ibid., page 56

⁴ Ibid., page 4

role of the Center would be to set national goals and track progress, issue an annual report to Congress and the President, develop and fund a research agenda, and disseminate information to the industry and public.

- 2. Mandatory and Voluntary Reporting Systems**—The committee believes that reporting of errors can serve two purposes: 1) to hold the health care system accountable; and 2) to identify system weaknesses and improve patient safety.⁵ The committee recommends both mandatory and voluntary reporting systems. It recommends establishing a nationwide, state-based, mandatory reporting system to collect standardized information about errors that result in serious injury or death and a voluntary reporting system for near misses or minor injuries⁶. The committee believes that the public has a right to know about errors that result in serious harm. The committee notes in the report that voluntary, confidential reporting should be encouraged by extending peer review protections to data and information in these systems. The committee calls for federal legislation to protect the confidentiality of certain information in order to encourage participation by health care organizations and providers in the voluntary reporting system.⁷
- 3. Set Standards for Safety**—The committee highlights the need to strengthen the standards for safety improvement that are set by accrediting and licensing organizations, group purchasers, and professional groups. The committee stresses those regulatory and accrediting bodies should make patient safety a key component of their evaluations. The report also recommends that licensing and certifying entities should implement periodic re-examinations of doctors, nurses, and other key providers to test their competency and knowledge of safety practices.⁸
- 4. Culture of Safety Inside Health Care Organizations**—The principal objective of all of the Committee's recommendations is to implement safety strategies inside health care organizations, including integrated health plans, hospitals, nursing homes, and outpatient facilities.⁹ The report identifies the need to develop a culture of safety focused on detecting, preventing and reducing errors.

Administration Response

On February 22, 2000, President Clinton unveiled initiatives to reduce preventable medical errors. The President's initiatives reflect his endorsement of the committee's recommendations, but in some ways go beyond them. The President's initiative includes administrative programs, executive actions, legislative direction, and collaboration with the states to enhance patient safety.¹⁰ The President's initiatives call for:

⁵ Ibid., page 74

⁶ Ibid.

⁷ Ibid., page 96

⁸ Ibid., pages 115-116

⁹ Ibid., page 5

¹⁰ White House Press Release, February 22, 2000

- The establishment of a new Center for Quality Improvement and Patient Safety, within the Agency for Health Care Research and Quality, at the Department of Health and Human Services, consistent with the IOM recommendations. The President announced that his FY 2001 budget includes \$20 million to conduct research on medical errors and create a new Center for Quality.¹¹
- The development of a new regulation that would require all hospitals participating in the Medicare program to implement patient safety initiatives and best practices. This initiative is similar to contractual requirements currently being proposed by the Leapfrog Group and planned by the Federal Employee Health Benefits Plans.
- The development of new standards by the FDA to deal with and help prevent medical errors caused by proprietary drug names and packaging that result in confusion with other drugs. The FDA will be required to develop the new standards within one year. The President is allocating \$33 million in the FY 2001 budget for medical error and adverse event reporting systems at the FDA.¹²
- Modernized patient safety programs at the Department of Veterans Affairs (VA) and Department of Defense (DoD) to reduce medication errors.
- Consistent with the IOM approach, the President's initiative recommends a combination of mandatory and voluntary reporting systems—with state-based mandatory reporting implemented in all 50 states within three years.

THE CURRENT CULTURE AND ENVIRONMENT ARE LIMITING FACTORS

Two of the major barriers to reporting of medical errors for the purpose of improving patient safety are (1) the lack of confidentiality protections for reporters; and, (2) the financial and emotional impact that can result from the tort litigation system if errors are discovered. Because of the threatening and contentious climate it creates, many argue that the litigation system actually impedes efforts to improve the quality of care rather than protecting patients. In such a culture and environment, it is difficult for providers to acknowledge mistakes. The system discourages providers from filing reports, seeking assistance, and collaborating with other providers and experts to improve quality and safety.¹³

Effectively improving patient safety requires understanding errors and their causes. Errors are more likely to occur in complex and technical systems and therefore, the medical care delivery system is inherently prone to accidents as it becomes increasingly complex.¹⁴ By estimate, 95%

¹¹ Ibid.

¹² Ibid.

¹³ The Health Care Liability Alliance, statement before the House Ways and Means Committee on Health Subcommittee, February 10, 2000

¹⁴ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 56

to 98% of medical errors are system errors¹⁵ that are not in the direct control of the medical care provider. System errors, may include poor process design, inadequate training, scheduling of long continuous shifts, language barriers, poor documentation, ambiguous definition of roles, and relying on memory for a complex set of instructions. Unfortunately, the foundation supporting many of the current efforts to reduce medical errors is not based on broad recognition of the systems nature of adverse events.¹⁶ This is complicated by societal norms that seek simple explanations even to complex problems and have a tendency to place blame on individuals when something goes wrong. The systems view of the nature of medical errors suggests that the greatest capability to effect change directed toward improved patient safety lies with the people who organize and manage care delivery systems—executives, clinical leaders, and boards of trustees -- rather than individual care providers.¹⁷

A safe environment and meaningful incentives are needed to transform the current culture of blame into a culture in which physicians and other health care workers can openly discuss medical errors and seek solutions. Many of the solutions will require system changes. The IOM Committee on Quality of Care in America acknowledges in its report that creating safety systems inside health care organizations is a more effective way to reduce errors than blaming people. In the report, the Committee emphasizes, “the focus must shift from blaming individuals for past errors to a focus on preventing future errors.”¹⁸

Health care organizations must focus on creating an internal culture that supports the discovery of system vulnerabilities, permits individuals to acknowledge errors, and encourages collaboration among medical care professionals to prevent future errors. Safety should be an explicit organizational goal demonstrated by strong directions from, and involvement of governance, management and clinical leadership.¹⁹ In addition, patients want assurances that adequate processes and systems are in place to ensure a safe care experience for themselves and their families.

Mandatory reporting regulations have thus far failed to produce useful information to reduce medical errors and improve patient safety due to a combination of factors. Perhaps the most significant factor is the punitive consequences of compliance – including fines, malpractice or other claims, and the attendant publicity that often surrounds those claims.²⁰ The fear of

¹⁵ From the statement of Donald Berwick, MD, before the Subcommittee on Health of the Committee on Veteran’s Affairs and the Subcommittee on Health and the Environment and the Subcommittee on Oversight and Investigations of the Committee on Commerce, U.S. House of Representatives, February 9, 2000.

¹⁶ Liang, B., Promoting Patient Safety Through Reducing Medical Errors, Southern Illinois University Law Journal

¹⁷ From the statement of Donald Berwick, MD, before the Subcommittee on Health of the Committee on Veteran’s Affairs and the Subcommittee on Health and the Environment and the Subcommittee on Oversight and Investigations of the Committee on Commerce, U.S. House of Representatives, February 9, 2000.

¹⁸ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 4.

¹⁹ Ibid., page 12.

²⁰ See, Institute for Safe Medication Practices (January 24, 2000) Discussion Paper on Adverse Event and Error Reporting in Healthcare; Statement of Randall R. Bovbjerg before the Committee on Commerce, Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations and Committee on Veterans’ Affairs: “[E]ven a long-standing mandate, as in New York or California, elicits only a few thousand reports of unnatural deaths or serious injuries a year (see Appendix D of To Err Is Human, pp. 210-217). The rate of error and serious injury found by hospital chart review in those states is far higher.” (February 9, 2000), p. 6.

malpractice litigation is a major barrier to openly discussing or reporting errors.²¹ The AMA testified before Congress that "...the very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient safety efforts. *** If the fear of litigation continues to pervade efforts to improve patient safety and quality, our transformation into a culture of safety on behalf of our patients may never be fully realized."²² Indeed, while individual practitioners are anxious to deliver safe care, and errors are rarely made based upon the incompetence or carelessness of one person, individual practitioners nonetheless genuinely fear tort claims and liability. Practitioners even fail to report errors to internal risk managers and defense attorneys, presumably, due to the severely punitive nature of the consequences of error.²³ Physicians within an enterprise liability model may have similar feelings of vulnerability.

Approaches that focus on punishing individuals instead of changing systems provide strong incentives for people to report only those errors that they cannot hide.²⁴ The issue of whether data submitted to a reporting system should be protected from disclosure, particularly in litigation, arose early in the IOM Committee discussions. Members of the committee had different views. Some believed all reported information should be protected because permitting external access to the information could lead to litigation, and the fear of litigation would interfere with disclosure of errors and the consequential efforts to improve safety. Other committee members supported public disclosure of reported information due to their belief that the public has a right to be informed of deficiencies in health care systems. Liability is part of the system of accountability and serves a legitimate role in holding people responsible for their actions. The IOM report reflects the committee's recognition of the alternative views.²⁵

Nevertheless, the prevailing culture in health care is at odds with the reporting and public disclosure of medical errors. Whether due to fear of peer criticism, malpractice liability, job loss, or undermining a colleague or an institutional employer, health care providers cannot be expected to report medical errors candidly absent a significant change in this "name and blame"

²¹ Larson, L., "Ending the Culture of Blame, A Look at Why Medical Errors Happen – and What Needs to Change," Trustee (February 2000), report of the Harvard Executive Session on Medical Error Reduction.

²² Statement of Nancy W. Dickey, M.D. before the U.S. Senate Committee on Health, Education, Labor and Pensions, January 25, 2000, p. 2.

²³ Statement of Randall R. Bovbjerg before the Committee on Commerce, Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations and Committee on Veterans' Affairs, February 9, 2000: "People are very reluctant to report on themselves or colleagues unless they have a reasonable expectation of confidentiality. Whatever one's views about the appropriateness of open confession of error, it is a practical reality that few medical practitioners want to do it within what they perceive as a litigious or vengeful environment. All our interviewees at reporting systems stressed the importance of confidentiality in getting practitioners to report; fears of legal and other repercussions are very strong. All said they thought reporting of errors falls vastly short of the true extent of error. It is difficult to get people to discuss potential failures at all, much less report them to regulators empowered to discipline them, especially if litigators may also get hold of them. Hesitation is built into behavior even without disclosure. Note, for example, that the first information a liability insurer or hospital risk manager often gets that something may have gone badly wrong in patient care is an inquiry or notice of suit from a patient's attorney. Reporting by the practitioners involved has traditionally been very low – even though they are contractually obligated to report claims, even though they're reporting only to the people whose job it is to defend them, and even though the reports are internal and confidential." p.5.

²⁴ Statement of Lucien Leape, M.D. before the U.S. Senate Committee on Health, Education, Labor and Pensions, January 25, 2000.

²⁵ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 95

mentality.²⁶ And from the perspective of the front-line physician, the culture of blame is expanding. “Managed care” litigation – often arising out of the questions about the medical judgment of a health care provider (whether in the medical or benefits context) – is increasing rapidly.²⁷ The increasing numbers of such lawsuits, together with the associated media coverage, have a chilling effect on physicians hesitant to jeopardize the institutions with which they are associated for fear of bankrupting them or exposing themselves indirectly to adverse publicity and “guilt by association.” To design an effective system of reporting for the purpose of improving patient safety, the “culture issue” and the framework associated with it requires explicit consideration and modification, if that system ultimately is to be effective.

SAFETY REPORTING IN THE AIRLINE INDUSTRY

The IOM report highlighted the airline industry safety reporting system as a model from which the health care industry could learn. The National Aeronautics and Space Administration (NASA) Aviation Safety Reporting System (ASRS) was discussed in the IOM report because it represents a sophisticated, long-standing, and highly successful external reporting system.²⁸ A second, recently developed safety program within the aviation industry, the Aviation Safety Action Program (ASAP) is designed to provide feedback on potential safety hazards for organizational action. Both ASRS and ASAP are reporting systems that may contain design elements appropriate for safety improvement programs in health care organizations.

Aviation Safety Reporting System (ASRS)

The ASRS is a safety program serving the airline industry that solicits information about actual or potential hazards to safe aviation operations from pilots, air traffic controllers, flight attendants, maintenance personnel, and others. ASRS was created within NASA after an earlier attempt by the Federal Aviation Administration (FAA) to establish such a reporting system was stalled by distrust and fear of reprisal for reporting mistakes among members of the aviation community.²⁹ The program was established in 1976 under an agreement between the Federal Aviation Administration (FAA) and NASA. The FAA provides most of the program’s funding. The NASA Ames Research Center administers the program, assures confidentiality, receives all reports submitted to the program, and sets policies in conjunction with the FAA and a fifteen-member industry advisory committee.³⁰

²⁶ Physicians are aware of and react to varying levels of medical malpractice litigation. Physicians’ perceived risk of being sued is higher than their actual risk of being sued.

²⁷ Lexington Insurance (Boston), the largest malpractice reinsurer of managed care organizations in the United States, has reported a 252 percent increase in claims against such organizations between 1990 and 1997. Brennan, T.A. and Studdert, D.M., “The Problems with Punitive Damages in Lawsuits Against Managed Care Organizations,” 342 N.E.J.M. 4, January 27, 2000, p.280-283.

²⁸ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 82.

²⁹ National Health Policy Forum, Improving Quality and Preventing Error in Medical Practice, Issue Brief No. 753, from a discussion on March 15, 2000

³⁰ Statement of Linda Connell before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, February 10, 2000

The ASRS program features a voluntary, confidential, and non-punitive reporting structure. Any person may submit a report to ASRS. The data collected by ASRS is used exclusively to reduce the likelihood of aviation accidents through the identification and communication of system deficiencies, support of aviation system policy and planning, and safety research. Persons who submit reports to the ASRS program are offered two types of protection: confidentiality and limited immunity. The key factor of the program's success is the continuing trust that it has established by holding the reports it receives in strict confidence.

Through the guaranteed limited immunity provisions in the ASRS program, the FAA will not use the information reported to ASRS in an enforcement action, and will waive fines and penalties for unintentional violations of federal aviation regulations if reported to ASRS within 10 days of the event. Accidents and criminal acts are not protected within ASRS and reports of such incidents are not accepted by the system.

The immunity provision within the system was a prime motivation for employees to submit reports in the initial launch of ASRS. Another critical factor that has enabled ASRS to evolve into a highly trusted reporting system is the perception by the aviation community of NASA as an independent "white hat" research organization, not a regulator. The first reports submitted to the system after its inception contained limited and guarded responses. ASRS gained the trust of the aviation community over a relatively short amount of time and the report volume ramped up quickly. After its first five years in operations ASRS was receiving approximately 10,000 reports each year. The program currently receives approximately 36,000 reports each year. All names and other potentially identifying information are removed from reports before they are entered in the ASRS database. More than 470,000 reports have been submitted since the program began and not a single reporter's identity has been revealed.³¹

The importance of confidentiality to the success of ASRS should not be underestimated. Analyses of the ASRS data indicate that over 70% of the reports received contain statements revealing human error.³² It is not unusual for reporters to ASRS to discuss their own operational mistakes and why they occurred. Because of the high level of trust that ASRS has engendered over the years, reporters are comfortable revealing information that they would not otherwise be inclined to share with others. Confidential incident reporting provides insight into events from the human perspective that rarely can be obtained through other methods.³³

Retired aviation professionals (e.g., pilots, air traffic controllers, flight attendants, and mechanics) serve as the ASRS report analysts and review each report for relevant safety information. Only a subset of all reports received are fully analyzed and included in the database. Through a triage process, reports containing the most valuable safety messages are identified and added to the database. The reports in the database feature a narrative description of the incident and include key words and codes that facilitate retrieval and analysis. Although ASRS is a confidential system, reports are not anonymous. In order to increase the validity and value of the data reported, ASRS analysts may contact the incident reporters to obtain additional information and discuss the safety event with the reporter. Prior to entry in the database, the

³¹ Ibid.

³² Ibid.

³³ Ibid.

narrative text is de-identified in order to protect the reporter and other personnel associated with the incident, while preserving the safety message.³⁴

Members of the aviation community have visible evidence that they are helping to improve aviation safety through their contributions to the reporting system. The ASRS program provides feedback in the form of reports that summarize research and analysis, alert messages, and a monthly safety bulletin. ASRS alert messages serve to notify the aviation community of problems that may require immediate action. The ASRS database is accessible to the public at the ASRS Internet site, on a CD-ROM product, or through an established ASRS search request process.

Aviation Safety Action Program (ASAP)

On January 14, 2000, President Clinton announced a new public-private partnership designed to encourage better reporting of safety concerns by aviation employees to their employer. The Aviation Safety Action Program (ASAP) brings together FAA, airlines, and employee unions in a collaborative effort to mitigate errors.

The ASAP program provides a vehicle for employees to identify and report safety issues to airline management and the FAA for resolution without fear of legal enforcement action, under certain circumstances.³⁵ The FAA retains its ability to prosecute cases involving substance or alcohol abuse, or intentional falsification by aviation employees, and to refer cases of potential criminal activity for prosecution by the Department of Justice.³⁶ ASAP started with demonstration projects sponsored by several commercial airlines including American Airlines, Alaska Airlines, and USAir.³⁷ These demonstration projects gave the airlines data that they could use to identify safety risks and take corrective actions before incidents occur. Within ASAP, a committee comprising representatives from airline management, the employee union and an FAA inspector come together weekly to review and analyze reports and agree on corrective actions. Failure of the airline to follow through with the corrective actions identified by the committee can result in the termination of the program.³⁸

³⁴ Ibid.

³⁵ Federal Aviation Administration Advisory Circular No. 120-66, January 8, 1997

³⁶ The White House Press Release, President Clinton Announces New Public-Private Partnership to Increase Aviation Safety, January 14, 2000

³⁷ Federal Aviation Administration Advisory Circular No. 120-66, January 8, 1997

³⁸ Ibid.

LESSONS FROM THE VETERANS' HEALTH CARE SYSTEM EFFORTS TO IMPROVE PATIENT SAFETY

The Veterans Health Administration is the nation's largest fully-integrated care delivery system with medical treatment facilities in every state, including 172 hospitals, 600 outpatient clinics, 132 nursing homes, 206 counseling centers, and 73 home health agencies.³⁹ In 1998, the Department of Veterans Affairs (VA) created the National Center for Patient Safety (NCPS) as part of a risk management initiative that calls for continuous evaluation of patient care, acknowledgement and learning from errors, open reporting of adverse events, and redesign of care delivery systems.⁴⁰ The mission of the NCPS is to lead activities and programs concerned with identifying errors, potential errors, and improving patient safety at Veterans Health Administration facilities.

As its first priority, the NCPS set out to create systems and processes to facilitate the identification and analysis of weaknesses in the VA care delivery system that have an adverse impact on patient safety. The NCPS wanted to create a reporting system that would allow identification of preventable adverse events as well as "close calls"—incidents that might have caused an accident or injury, but did not.⁴¹ The search for a viable reporting model within a large health care delivery system to serve as a template was unsuccessful. Consequently, NCPS sought assistance from experts with backgrounds in aviation and space travel safety, and human factors engineering. Experts from the Aviation Safety Reporting System (ASRS) advised the VA that an ideal reporting system must: (a) be non-punitive, voluntary, confidential and de-identified; (b) make extensive use of narratives; (c) have interdisciplinary review teams; and most importantly, (d) focus on identifying vulnerabilities rather than attempting to define rates of error.⁴² The VA has used these principles for the design of its current mandatory reporting system and for a new voluntary system that is currently under development.

Under the guidelines of the VA's mandatory reporting system, staff are required to report adverse events and close calls within 24 hours of detection. Reported events are evaluated using a Safety Assessment Code Matrix that identifies key factors by severity categories.⁴³ These assessment codes are used for comparative analysis and to decide who needs to be informed about the incident. An aggregate root cause analysis is conducted in some cases to identify trends or patterns not revealed by individual case analyses.⁴⁴ Reporters receive feedback about the actions taken as a result of their report, regardless of the severity of the event.

³⁹ Luciano, Lani, Reducing Medical Errors and improving Patient Safety, The National Coalition on Health Care/The Institute for Healthcare Improvement, February 2000

⁴⁰ Department of Veterans Affairs News Release, "National Health Care Leaders Announce New Partnership", October 6, 1997

⁴¹ Statement of James Bagian, MD, PE, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, February 10, 2000

⁴² Ibid.

⁴³ VHA National Patient Safety Improvement Handbook Draft, January 19, 2000

⁴⁴ Ibid.

The VA's error reporting strategy is enabled by liability protections afforded to the VA and its government employees.⁴⁵ This exemption in federal law protects physicians and other employees from being individually sued by patients or their families in the event of a medical error that results in injury.⁴⁶ This unique exemption has enabled the VA to capture a large amount of data. Although this protection plays a major role in the success of the reporting system, NCSP leaders acknowledge that the fear of job loss or punishment is still an obstacle to reporting errors.⁴⁷

The VA is obligated to inform patients and their families about injuries resulting from adverse events and the options for resolution available to them. They have accumulated evidence that patients desire acknowledgement of errors from their caregivers and this communication reduces the likelihood that patients will take legal action.⁴⁸

The NCPS has recognized the value of voluntary reporting in its effort to create a culture of safety within their care delivery system. Efforts are underway to implement a separate de-identified voluntary reporting system modeled after NASA's Aviation Safety Reporting System.⁴⁹ The external voluntary reporting system will permit both employees and patients to report adverse events or close calls in a non-punitive environment. The voluntary system is expected to draw out information that individuals are currently hesitant to submit to the mandatory reporting system for fear of reprisal.

In an effort to further promote a culture of safety, the VA has instituted an awards program that provides financial incentives for employees to develop patient safety improvement processes. Rewards of up to \$5,000 for individuals and \$25,000 for institutions are given for the identification of processes or practices that minimize or eliminate risks to patient safety.

The NCPS's focus on reporting medical errors and identifying corrective action programs has put the VA in the forefront of the nation's patient safety improvement efforts. Given the VA's national presence and standing as a prominent government agency, it is uniquely positioned to serve as a national laboratory to find solutions to patient safety problems and lead the health care industry's efforts to improve patient safety.⁵⁰

REPORTING SYSTEM DESIGN PRINCIPLES

After reviewing the airline industry and VA experiences with safety improvement through reporting of errors, roundtable participants discussed the design elements that should be reflected in an ideal reporting system. The participants focused on two primary functions of medical event reporting: 1) to learn from errors to avoid future adverse events; and 2) to increase the public's

⁴⁵ Title 38, United States Code, Section 7316.

⁴⁶ Luciano, Lani, Reducing Medical Errors and improving Patient Safety, The National Coalition on Health Care/The Institute for Healthcare Improvement, February 2000

⁴⁷ Ibid.

⁴⁸ VHA National Patient Safety Improvement Handbook Draft, January 19, 2000

⁴⁹ Statement of James Bagian, MD, PE, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, February 10, 2000

⁵⁰ Under Secretary for Health's Information Letter, Department of Veterans Affairs, July 9, 1998

trust in the medical care system. The following section describes the design principles for these goals.

DESIGN PRINCIPLES TO IMPROVE PATIENT SAFETY⁵¹

1. View patient safety as a top priority

Health care organizations should implement meaningful patient safety programs with defined executive responsibility. The leaders of health care organizations should make a visible commitment to patient safety by ensuring that systems and procedures are in place that enable those involved in the delivery of care to work in coordination toward the common goal of improving quality. A culture of continuous quality improvement should be created in health care organizations to foster the identification of system vulnerabilities and learning from errors. This will help create an environment supportive of reporting.

2. Use reports for prevention, not punishment (i.e., non-punitive)*

Real improvements in quality and patient safety can result from the reporting of system failures, acknowledgment of mistakes, open discussion about errors and collaboration among professionals to improve quality. The ultimate purpose of the medical event reporting system should be to: 1) identify errors and systems vulnerabilities and 2) learn from those errors to prevent future events. The information gathered through the reporting system should not be used for punitive purposes. The threat of punishment discourages reporting, discussion, analysis and improvement. Rather than focusing on the rate or frequency of errors, the reporting system should concentrate on gaining knowledge about the root causes of mistakes in order to avoid their repetition.

3. Make the purpose of the reporting system clear to all stakeholders*

Patient safety reporting systems within health care organizations should be highly visible and clearly understood by providers, other health care workers, patients and their families. Communications to all stakeholders should emphasize that quality and safety improvement is the first priority of the reporting system.

4. Exercise broad and active leadership *

A health care organization's commitment to patient safety should be demonstrated through active leadership at the executive level, establishment of explicit organizational goals, and close management oversight of safety systems and programs. Executive leaders should make quality

⁵¹ * Use of an asterisk denotes that a similar design principle is included in the QuIC Task Force report to the President, *Characteristics of an Ideal Reporting System for Learning*, February 2000.

and patient safety the top priority of their organizations. Safety programs should include defined accountabilities for executives and their staffs.

5. Encourage reporting of all adverse events and close calls

The scope of events targeted by the reporting system should not be limited. The system should encourage reporting of preventable adverse events that result in death or serious harm, as well as close calls and errors that do not result in serious injury. However, events involving criminal acts, intentional unsafe acts, acts of impaired individuals, or abusive conduct should be reported to appropriate regulatory or legal entities, not to the patient safety reporting system.

6. Accept reports from all stakeholders*

All stakeholders, including patients and their families, should be encouraged to report errors, near misses and adverse events.

7. Maintain confidentiality of all reports *

Reports submitted to the patient safety reporting system should be non-discoverable, inadmissible in court or other proceedings, and de-identified of individual and institution information after analysis, but before input into the database. Data collected and analyzed by health care organizations to improve safety and quality should also be protected. Confidentiality protections minimize the fear of punishment for unintentional errors and encourage reporting. The disclosure of health system, facility or individual names would be counterproductive. Experience in the aviation industry demonstrates that confidentiality encourages reporting. A confidential reporting system is likely to result in a greater volume of reports that will enhance the opportunities for learning. However, under no circumstances should confidentiality protections serve as a shelter for illegal acts or negligent behavior.

8. Assure that the system captures appropriate detail and is easy to use*

The patient safety reporting system should not impose an unnecessary burden on health care systems or individuals. The system should employ a uniform and user-friendly reporting format that includes clear and simple instructions.

9. Experts analyze reports and identify effective corrective actions *

Reports should be submitted to an entity with the skills necessary to analyze adverse events and near misses. The data should be used by the entity to identify patterns of errors. Health care organizations should be encouraged to adopt evidence-based best practices in order to prevent future errors.

10. Identify system vulnerabilities

Most errors are a result of system deficiencies rather than incompetent or negligent providers. Adequate attention and resources must be devoted to support the analysis of reports of adverse events to identify the system attributes that contribute to errors. System vulnerabilities are often best addressed at the health care facility level where the root cause analysis process can focus on why an event occurred and uncover major improvement opportunities.

11. Provide timely feedback to reporters and stakeholders *

The reporting system should provide useful feedback to health care professionals and facilities. Entities that perform research and analysis, and serve as a clearinghouse for information should make recommendations to individuals and organizations on the frontlines of care delivery regarding demonstrated best practices in patient safety. Purchasers and regulators should use their influence to promote the implementation of effective error-reduction initiatives. The public should be informed about those hospitals and health systems that have adopted these safety practices.

12. Test the system before large scale roll-out*

Demonstration projects should be implemented to provide feedback on the effectiveness of the patient safety reporting system prior to broad implementation.

13. Provide incentives to report errors and adapt successful safety practices

To encourage reporting of errors in a blame-free environment, the patient safety reporting system should encourage the extension of certain protections to individual and institution reporters. The confidentiality of reported data must be protected so that physicians and other health care professionals are encouraged to report all adverse incidents without fear that their cooperation will increase their exposure to lawsuits for professional liability or other sanctions. Any potential increased exposure to fines, suit, or reprisals, will discourage physicians from voluntarily reporting close calls and adverse events.⁵² Certain protections may require legislation. For example, legislation will be required to extend peer review protections to data collected and analyzed by health care organizations for safety and quality improvement purposes. Public reporting of the implementation of safety structures and processes will provide an incentive for organizations to adoption of such practices.

⁵² Statement of the American College of Physicians—American Society of Internal Medicine to the Subcommittee on Health and Environment Subcommittee on Oversight and Investigation, Committee on Commerce and the Subgroup on Health Committee on Veteran’s Affairs, U.S. House of Representatives, February 9, 2000.

DESIGN PRINCIPLES TO IMPROVE PUBLIC TRUST

1. Make patient safety the first priority.

Health care providers should incorporate the principle “do no harm” into their daily practices and make patient safety their top priority. Health care staff should visibly demonstrate their commitment to patient safety and be empowered to take action to avoid medical errors. Understandable information on patient safety and patient reporting forms should be provided to patients so they can report adverse events that may occur to them at any point along the care continuum.

2. Demonstrate interest and actions in improving patient safety.

Providers of health care should publicly announce and visibly demonstrate their ongoing commitment to improving patient safety. Throughout the entire continuum of a patient’s care experience, the patient should be provided understandable information on patient safety. Professionals in the health care system should be open to receiving information on medical errors from all who are involved in the healthcare process, including patients and their families. Patients should be assured that those delivering their health care will report medical errors that cause them harm. Reports should be made to the patient harmed, the institution in which the care was provided, and to the entity responsible for collecting information on medical errors. Procedures should be established to ensure that providers take actions to resolve problems raised in medical error reports. In addition, the public should be informed of the health care system’s efforts to identify and take action against providers who (1) are not appropriately accredited, licensed or credentialed, (2) are abusive to patients, (3) provide care while impaired, (4) act intentionally to cause patient harm or (5) engage in a criminal act by providing or failing to provide care.

3. Treat patients as partners in the effort to reduce medical errors.

Patients should be empowered to assist in improving patient safety by understanding the causes of errors, working with providers to minimize them, and participating in the reporting of medical errors when they occur. Health care is provided along a continuum and in non-integrated health care systems, the steps in the process are often unorganized, unconnected and unrelated. Along the care process, the patient may be the only common and organizing link in the care experience. The patient, or when appropriate the patient’s representative, should be encouraged by health care staff to take an active role in identifying adverse events and should be provided with a means to report medical errors that occur at any step along the care continuum.

4. Implement credible control systems and credible reporting processes.

The quality measures, accreditation, licensure and credentialing standards applicable to health care providers should be credible and meaningful indicators of the providers’ capability to provide safe care. In the case of individual providers, these standards should also assess their education, skill and training to provide safe care. Various governmental and private entities

operate to regulate, license, credential, accredit or audit providers of health care. These entities should assure the public that their systems will identify and take appropriate action against providers who (1) are not appropriately accredited, licensed or credentialed, (2) are abusive to patients, (3) provide care while impaired, (4) act intentionally to cause patient harm or (5) engage in a criminal act by providing or failing to provide care.

In addition, a credible reporting system should be developed to collect and compile reported medical errors and close calls. An independent, non-regulatory body without any conflicts of interest or biases should operate the system. The system should be designed to obtain accurate and complete information on adverse events and reporters to the system should not fear retribution. The entity collecting the medical error reports should offer information, not solutions to the problems. By collecting and analyzing information on medical errors, the entity will develop new information that can be used for research on patient safety.

5. Use the information reported to improve public safety.

Health care providers must be committed to the ultimate goal of reducing medical errors. Reporting errors is one step in the process to achieve that goal. Another key step is to analyze the errors and examine their root causes. The patient safety improvement system should incorporate procedures to enable health care providers to learn from errors and take action to reduce future similar errors and improve public safety.

6. Give the public information on institutional progress in adopting patient safety best practices.

The public should be provided with information on the patient safety structures and processes implemented by health care institutions. This information will assist patients in comparing institutions and create an incentive for providers to implement systems improvement. This information should be presented in various formats designed to be understandable and useful for audiences with varying needs and interests and cultural and educational backgrounds.

RECOMMENDATIONS

The principles described above were used to design a reporting system that would improve patient safety and help build public trust in our health care system. The reporting system's design was influenced by evidence from health care and other industries that if individuals who report to the system are punished, reporting will not take place and safety improvements will be impeded. For this reason, the IOM committee recommendation that reporting be made to state regulatory agencies, even with stringent confidentiality provisions, will not be nearly as effective as voluntary reporting, in a non-regulatory environment, in achieving high levels of reporting and improved patient safety. The experience of the airline industry, which has been a leader in reporting and safety improvement, is a testimonial to this fact. Given our current culture of blame in medicine, which is reinforced by our tort system, special efforts are required to promote

an environment in which errors can be viewed as opportunities for improvement and system redesign.

The proposed patient safety reporting system has five key elements:

1. Patients should be informed when they have been injured while receiving care.
2. Public reports should be made summarizing institutional implementation of effective safety practices.
3. A non-regulatory, national entity should be the primary external vehicle to collect information on adverse events and near misses, on a confidential and voluntary basis, to create an effective basis for systems improvement and to promote learning regarding patient safety. This reporting system should provide incentives for reporting.
4. Existing state mandatory reporting systems should focus on significant licensing violations.
5. A National Center for Patient Safety should be established to conduct and coordinate patient safety research.

A discussion of each of these elements is provided below.

Patients should be informed when they have been injured while receiving care.

Few ethicists would argue with the notion that health care providers have a professional and ethical obligation to inform patients and their families about errors in the care process that cause injuries. The American College of Physicians–American Society of Internal Medicine, acknowledges that “physicians have such an obligation to disclose to patients information about procedural or judgement errors made in the course of care if such information is material to the patient’s well-being.”⁵³ However, there are many instances when this does not occur. This lack of disclosure leads to a loss of patient and public trust in the health care system and an environment in which the issues surrounding an event or error cannot be openly discussed to promote system change and patient safety improvement. Informing the patient of an error is an important first step in enabling that error to be openly discussed with the goal of improving systems so that the error may be prevented in the future. Disclosure of such information is an important objective in the minds of many injured patients.

The countervailing forces that prevent such disclosure are significant and run deep within the health care culture. These forces include professional pride, a desire to avoid personal or institutional embarrassment, fear of job loss, and fear of litigation along with the wrenching experience of the existing tort system. The culture of blame that hangs over the medical care system is also a significant impediment. Open, honest communication with patients, in the context of safety improvement, is an important intervening step in this unhealthy cycle.

⁵³ American College of Physicians—American Society of Internal Medicine Ethics Manual, 1998, pages 8-9.

Public reports should be made summarizing institutional implementation of effective safety practices.

Implementing a system of learning and patient safety improvement require priority and action within health care organizations. The IOM report recognizes this and recommends that: “Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with a defined executive responsibility. Patient safety programs should: (1) provide strong, clear, and visible attention to safety; (2) implement non-punitive systems for reporting and analyzing errors within their organizations; (3) incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and (4) establish interdisciplinary team training programs such as simulation, that incorporate proven methods of team management.”⁵⁴ The report also recommends that “health care organizations implement proven medication safety practices.”⁵⁵

Medication safety practices were highlighted in the IOM report as an area for significant improvement because medication errors occur frequently and are often preventable. Best practices exist in other areas and additional best practices will be identified as patient safety improvement receives greater attention and as the recommended reporting systems are implemented. Efforts should be taken to identify and study practices to determine their effectiveness. Practices that are proven effective should be promoted and the most effective required to be part of a health care organization’s patient safety program by regulatory and accreditation agencies.

Regulatory and accreditation entities should incorporate the adoption of structures, processes, and best practices with demonstrated effectiveness in safety improvement in their standards and reviews. As a way to build public trust, encourage compliance and provide the public with useful information about patient practices in health care organizations, accreditation and/or regulatory agencies should publish information regarding institutional progress in adopting effective patient safety practices. This information would help to differentiate health care organizations and provide incentives for further improvement.

A non-regulatory, national entity should be the primary external vehicle to collect information on adverse events and near misses, on a confidential and voluntary basis, to create an effective basis for systems improvement and to promote learning regarding patient safety.

To complement active reporting within institutions, and to promote learning and improvements in patient safety, reporting to a non-regulatory national entity should be encouraged. Although the IOM report calls for both voluntary and mandatory reporting of errors, in the final analysis all reporting is voluntary even though state or federal laws may impose penalties for non-reporting. The airline industry experience demonstrates that voluntary reporting report works effectively as a basis for learning and safety improvement if the reporting is to a non-regulatory entity with

⁵⁴ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, page 135.

⁵⁵ Ibid., page 136.

confidentiality protections and incentives. Such a system should be the primary vehicle for external reporting of medical errors and those in the health care industry should carefully study the elements of the Aviation Safety Reporting System (ASRS) and build upon those with proven effectiveness. As noted earlier, the ASRS has the following characteristics:

- Non-punitive
- Voluntary
- National
- Reports are made to a non-regulatory entity
- Data is collected from multiple sources
- Reporters are guaranteed confidentiality
- Reporters have incentives to report due to the provision of limited immunity to regulatory action
- Identifies improvement opportunities and issues alerts
- The de-identified database is available for review and analysis

Creating a safe environment for reporting is an essential element for reporting to occur. Reports should be confidential, non-discoverable and inadmissible. These are such basic requirements that the IOM devoted an entire chapter in its report to these issues.⁵⁶ It recommended that: “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 purposes of improving safety and quality.” Unless those who report are guaranteed that the act of reporting itself does not lead to any punitive action, reporting will simply not occur. It is thus important, to create a firewall between the national reporting entity, which should for obvious reasons be non-regulatory, and any state or federal regulatory structure. To help ensure ongoing confidentiality, reports, once analyzed, should be de-identified prior to their entry into a database and the original reports destroyed.

Reporting should be easy, yet structured to capture adequate detail. Reporting should be encouraged from all stakeholders, including providers, other health care workers, patients and their families. One approach, to be further explored, is whether the same reporting instrument can serve both organizational and institutional improvement needs, in addition to the needs of a national reporting entity. Reporters will need assurances that actions will not be taken against them due to reporting unless they have been involved in a criminal act or otherwise violated the law. Criminal acts, intentionally unsafe acts, acts of impaired individuals, and abusive conduct should continue to be reported to legal and regulatory entities and should not be reported to or included in the voluntary reporting system.

A national voluntary reporting system is recommended even though there are smaller reporting systems already functioning in some areas, such as medication errors and anesthesia errors. A national focal point for reporting errors is needed to make reporting easy and to efficiently and effectively assemble the data necessary to identify systems improvements. Further design efforts are needed to explore how to build upon or link to existing systems. One approach would be for the national entity to contract with existing systems or specialty organizations for analysis. This approach would help to assure that adequate expertise is available for learning and system

⁵⁶ To Err Is Human: Building a Safer Health System (Advance Copy), Institute of Medicine, 1999, pages 94-113.

improvements. The alternative of developing state-oriented systems, as has been suggested by some, is unlikely to be as successful because of the difficulty in assembling the expert resources for this task and the potential to sub-optimize learning about issues since such issues are not unique to states. Because of small numbers of occurrences, some trends may not be evident in sub-national reporting and analyses. In building a national reporting system, consideration should be given to organizations that can link to both the public and private sectors that will need to use the learnings of the system. NASA's Aviation Safety Reporting System might play a role in the startup and/or operation of the system. The National Quality Forum, which has already been charged to work on reporting standards and related issues, would be another possible entity to conduct or sponsor this activity. To enhance success, consideration should be given to phased-in implementation on a geographic or other sub-national basis so that early issues and problems can be identified and resolved prior to national implementation.

Creating a confidential, non-regulatory reporting system and protections against reprisals for reporters to the system are necessary but not sufficient steps to assure that reporting occur. The existing culture of blame and the legal environment in which health care operates provide powerful incentives to discourage reporting. Fear of malpractice litigation is a major barrier to openly discussing or reporting errors and it is important to address this disincentive. Under the ASRS, in addition to guaranteed confidentiality, limited immunity for an unintentional violation of FAA regulations is provided to those who report. Accidents and criminal activities are not protected and should not be reported to the ASRS. Similar incentives and protections need to be developed within any reporting system used in the health care industry. One such incentive would be to make individuals and organizations reporting adverse events and errors eligible for reformed tort processes in the event of a claim. This could take a number of forms and two have been suggested. One would be to apply California Medical Injury Compensation Reform Act (MICRA) standards in situations where reporting has taken place and a claim is filed. MICRA provisions include caps on non-economic damages; elimination of joint and several liability to hold defendants liable in proportion to their degree of fault; offsets of awards from collateral sources; reasonable limits on statutes of limitations; and limits on attorney contingency fees.⁵⁷ Another approach would be to make such claims subject to a no-fault compensation approach. The IOM report notes the potential for such a system to promote reporting by eliminating the adversarial inquiry into fault and blame that characterizes the current liability system.⁵⁸

Some have noted that when “punishment” for the reporting of errors is removed, reporting increases—often by 10 or even 20-fold.⁵⁹ There is also additional evidence that suggests that the cultural changes necessary to implement a potentially effective reporting system are possible with a no-fault medical injury compensation process. No-fault systems operate with significant physician participation. For example, in Sweden more than 90 percent of claims submitted are initiated by physicians on behalf of injured patients,⁶⁰ and 60 to 80 percent of physicians actively

⁵⁷ Werner, M., American College of Physicians, *Beyond MICRA: New Ideas for Liability Reform*, 1995

⁵⁸ *To Err Is Human: Building a Safer Health System* (Advance Copy), Institute of Medicine, 1999, page 95.

⁵⁹ Leape, L. National Coalition on Health Care and the Institute for Health Care Improvement, *Report of Proceedings*, February 22, 2000, “Can We Make Health Care Safe?” p. 2.

⁶⁰ Testimony of Troyen A Brennan, M.D. before the Subcommittee on Health and the Environment, November 10, 1993.

participate in the claims made.⁶¹ American physicians are prepared to report medical injuries in a systematic effort to identify risk factors for medical injuries, and then to prevent them.⁶² The VA may also be an example of where the culture of safety is permitted to flourish in the absence of personal or institutional litigation since individual physicians and the VA itself are immune from suit.⁶³ In addition to improved reporting, a no-fault system has the potential to increase the fairness of the current legal system and improve patients' trust in the health care industry.

Existing state mandatory reporting systems should focus on significant licensing violations.

Little is known about the effectiveness of existing state mandatory reporting systems in improving patient safety. The IOM report embraces mandatory reporting at the state level primarily to create public accountability, although concerns have been raised that mandatory reporting will directly conflict with patient safety improvement by discouraging reporting.⁶⁴ Understanding the benefits of existing state systems and the characteristics that promote patient safety improvement should be a significant research priority. While that research is undertaken, caution is recommended in the development of new state systems to avoid the potential of hindering patient safety improvement activities. Existing state systems should focus on significant licensing violations and capture information about criminal acts, intentionally unsafe acts, acts of impaired individuals and abusive conduct, all of which require regulatory intervention. It is not likely that efforts to improve the safety of health care will move ahead at the required pace if all attention focuses on mandatory reporting. Because of the legal climate and fears associated with public disclosure, virtually any efforts to expand mandatory reporting can be expected to "chill" voluntary efforts that are a primary impetus for change and improvement.

A National Center for Patient Safety should be established to conduct and coordinate research in this area.

The final element of the patient safety reporting system recommended is the creation of a National Center for Patient Safety. As suggested in the IOM report, the Center should be housed within the Agency for Healthcare Research and Quality. The Center should focus on developing knowledge and understanding of errors in health care, evaluating methods for identifying and preventing errors, monitoring progress in achieving goals, funding dissemination, and communication to improve patient safety. The Center is seen as a critical partner of the recommended entity that should be created to receive reports on a national basis. The Center would use the reporting entity's database to conduct or support patient safety research. The Center should review the existing reporting that already occurs within institutions, and to state agencies and other voluntary systems to identify effective practices which could complement the national, voluntary reporting system.

⁶¹ Brennan, et al., 60 *Law & Contemp. Prob.* 1, "Can the United States Afford a "No-Fault" System of Compensation for Medical Injury?" (Winter/Spring 1997). It should be noted that the Swedish administrative process is part of an exceedingly generous and comprehensive social insurance system.

⁶² Testimony of Troyen A. Brennan before the Senate Finance Committee re Medical Malpractice and Health Care Reform, May 1994.

⁶³ The United States of America is the sole defendant.

⁶⁴ *To Err Is Human: Building a Safer Health System* (Advance Copy), Institute of Medicine, 1999, page 78

CONCLUSION

The consensus at the Claremont roundtable was that the two primary functions of medical error reporting are to: (1) learn from errors to avoid future adverse events; and (2) restore public confidence in the medical care system related to safety. The experiences shared by roundtable participants underscored the difficulties in simultaneously trying to achieve both public accountability objectives and significant improvements in safety. Safety improvement efforts rely on voluntarism, collaboration and trust and it will take demonstrated progress on patient safety improvement by health care organizations to bolster public confidence in the care delivery system. While roundtable participants concluded that mandatory reporting of serious adverse events at the state level should continue, and be focused and strengthened where possible, there was general acknowledgment that significant progress toward safety improvement and learning from errors will occur most successfully within a voluntary event reporting system. These perspectives are consistent with the conclusions of the IOM report.

There is little practical experience with safety improvement through event reporting in the health care industry to draw upon for the design of a reporting system. The proposed strategy that emerged from the roundtable discussion builds on the experience of the NASA Aviation Safety Reporting System that demonstrates that reporting of errors and near misses can be used as a means to improve safety. The proposed strategy is founded on the premise that reporting of medical errors will most effectively support actual improvements in patient safety within a system that is confidential, non-regulatory, and voluntary. It supports the development of a blame-free culture necessary to identify the changes required to design safer systems of care, and it encourages the adoption of known effective safety improvement structures and processes across health care institutions. The key question to be answered is whether the aviation model can be validated in health care.

Additional work is required to develop the details of the proposed reporting system. The Kaiser Permanente Institute for Health Policy, in conjunction with the NASA Aviation Safety Reporting System and The National Quality Forum will continue exploration of relationships between event reporting and safety improvement. The next steps in this endeavor will include the identification of design features of a voluntary medical error reporting system related to such items as system scope, key processes, and desired characteristics. We will also seek to identify the enablers and barriers to the success of a voluntary reporting system as well as its relationship to existing reporting systems. Questions to be addressed in this next phase of work include:

- What is the scope of reportable events?
- What reporting aggregation is most appropriate?
- How should the voluntary reporting system interface with other existing reporting systems?
- What type of expertise is needed to review and analyze the reports and how should this expertise be acquired?
- How should reporters and information be protected?
- How is data shared outside of the reporting entity?

Selected Views on Reporting Medical Errors

	Mandatory Reporting	Voluntary Reporting	Protection for Report	What Should be Reported?	To Whom Should Report be Submitted?	Other
American Association of Health Plans	Support (but only with strong confidentiality protections)	Support (but only with strong confidentiality protections and malpractice reform)	Support	Aggregate data stripped of individual and institutional identifiers	Report to a national entity, then to research organization for analysis	Call for significant malpractice reforms tied to error reporting
American College of Physicians—American Society of Internal Medicine	Support (narrowly defined reporting requirements)	Support (but individual confidentiality must be protected)	Support	A public/private sector body, such as The Quality Forum, should define what to report		Physicians have professional obligation to report serious errors
American Federation of Labor—Congress of Industrial Organizations	Support	Support (but confidentiality must be protected)	Support (identities should not be released without due process, formal findings, and protections for workers)	Institution-specific aggregate information	Report to a federal entity	Comprehensive protections against retaliation for workers who report medical errors and safety concerns
American Health Quality Association	Support	Support	Support (ensure confidential treatment by requiring reports be sent to protected PROs)	Aggregate data stripped of individual and institutional identifiers at state level	Report to PROs, aggregate state-level data released to public	Providers not making progress on error reduction should be reported to state or federal agency, or to JCAHO

Selected Views on Reporting Medical Errors

	Mandatory Reporting	Voluntary Reporting	Protection for Report	What Should be Reported?	To Whom Should Report be Submitted?	Other
American Hospital Association		Support (if non-punitive)	Support		Use mechanisms currently in place (e.g., VA, JCAHO, Institute for Safe Medical Practices)	Call for further study of existing reporting systems
American Medical Association	Oppose (no evidence of effectiveness—inefficient allocation of resources)	Support (if non-punitive and protected)	Support (expand peer review protections)			National dissemination of identified solutions would be more valuable than mandatory reporting
American Nurses Association	Support	Support		Track adverse events and document organizational risk factors		Protect a nurse's right to speak out about errors and safety concerns
American Osteopathic Association and American Osteopathic Healthcare Association	Oppose (no evidence of effectiveness)	Support use of state medical error reporting programs already in place	Support (expand peer review protections)	Only information stripped of identifiers		Reports must be available to facilities, accreditation organizations, and other health care organizations, as well as federal agencies

Selected Views on Reporting Medical Errors

	Mandatory Reporting	Voluntary Reporting	Protection for Report	What Should be Reported?	To Whom Should Report be Submitted?	Other
Anesthesia Patient Safety Foundation	Oppose (pre-mature course of action)	Support	Support (expand peer review protections)		Report to National Center for Patient Safety	Call for further study of existing mandatory systems
Foundation for Accountability	Support		Oppose	Facility safety records reported for consumer decision making	Consumers	Patients have right to know the risks they face when receiving medical care
The Health Care Liability Alliance	No new reporting requirements without confidentiality protection	No new reporting requirements without confidentiality protection	Support (protect all safety and quality reports)		No new federal Center—focus on getting information to people on front lines of health care quality	Call for tort system reform
The Joint Commission of Accreditation of Healthcare Organizations		Support (but must have protection against disclosure)	Support (protect confidentiality of mandatory or voluntary reporting for serious events)	JCAHO reportable sentinel events	Shared data among responsible oversight bodies with public accountability for patient safety	Encourage root cause analysis following sentinel event to form appropriate action plan
National Patient Safety Foundation	Support (with very specific provisions)		Support	“near hits” as well as fatalities and injury	Report to a national clearinghouse	NPSF database should serve as a model for the clearinghouse

Selected Views on Reporting Medical Errors

	Mandatory Reporting	Voluntary Reporting	Protection for Report	What Should be Reported?	To Whom Should Report be Submitted?	Other
National Quality Forum	Support (but must have protection against disclosure)	Support (but must have protection against disclosure)	Support		Report to National Center for Patient Safety	
Quality Interagency Coordination Task Force (QulC)	Support (will consider findings of research to determine effectiveness of mandatory reporting)	Support	Support (but not to shield illegal or negligent behavior)	Mandatory systems should be limited to serious, preventable and identifiable adverse events; aggregate data stripped of individual and institutional identifiers made public	Report to state agencies	
U.S. Pharmacopeia	Oppose	Support	Support (expand peer review protections)	Facility “report card” or other indicators that best practices are adopted—action in response to error	Use survey processes of state boards of pharmacy, HCFA, or JCAHO	Suggest facility report card of implemented best practices—this would be the most effective tool for consumers

Appendix 2

ROUNDTABLE PARTICIPANTS*

JAMES BAGIAN, Department of Veterans Affairs

LINDA CONNELL, NASA Ames Research Center

MOLLY JOEL COYE, The Lewin Group, San Francisco

ROBERT M. CRANE, Kaiser Permanente

FRANCIS J. CROSSON, The Permanente Federation

PAULINE FOX, The Permanente Federation

KENNETH JENNINGS, VentureWorks

PATRICK JOHNSON, Utah Health Policy Commission; Reforming States Group

ANN KEMPSKI, American Federation State, County and Municipal Employees (AFSCME)

KENNETH W. KIZER, The National Quality Forum

DAVID LAWRENCE, Kaiser Permanente

JACK LEWIN, California Medical Association

KAREN MILGATE, American Hospital Association

MARCI NIELSEN, AFL-CIO

DENNIS O'LEARY, The Joint Commission on the Accreditation of Healthcare Organizations

DONALD PALMISANO, The National Patient Safety Foundation

SUSAN PENNEY, California Medical Association

MELISSA STEGUN, The National Quality Forum

NAN STONE, Peter F. Drucker Archive and Institute

STEADMAN UPHAM, Claremont Graduate University

STANLEY WATSON, Kaiser Permanente

JED WEISSBERG, The Permanente Federation

STEVEN R. ZATKIN, Kaiser Permanente

** Note: The patient safety reporting system presented in this document builds on the Roundtable discussions and is a synthesis of concepts discussed, but does not necessarily represent the views or the endorsement of individual participants or the organizations that they represent.*