



KAISER PERMANENTE

Design Considerations
for a
Patient Safety Improvement
Reporting System

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NOTICE

THIS DOCUMENT IS A SYNTHESIS OF THE CONCEPTS DISCUSSED AT TWO ROUNDTABLE MEETINGS HELD DURING 2000 IN WHICH MANY STAKEHOLDERS EXPRESSED THEIR OWN VIEWS AND THOSE OF THEIR ORGANIZATIONS. THIS PAPER IS NOT MEANT TO IMPLY THAT THERE WAS CONSENSUS ON ANY GIVEN ISSUE. IN FACT, THERE WAS A WIDE RANGE OF OPINIONS. THE FOLLOWING REPORT REPRESENTS THE VIEWS OF THE AUTHORS AND DOES NOT NECESSARILY PRESENT THE VIEWS OF INDIVIDUAL PARTICIPANTS NOR THE ORGANIZATIONS THAT THEY REPRESENT.

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I. Introduction

The Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, issued in November 1999, has made an extraordinary contribution to American health care by highlighting opportunities to improve patient safety. Among its recommendations, the report calls for both mandatory and voluntary external reporting systems for medical errors. The report concludes that such external reporting systems represent important mechanisms to expand knowledge of errors and the underlying factors that contribute to them, as well as holding providers accountable for their performance. This paper focuses on voluntary systems because non-punitive reporting models hold the greatest potential for the discovery of system vulnerabilities and improving safety.

Despite the staggering number of errors and close calls that occur in the United States health care system, our experience with adverse event reporting is relatively recent and limited. Joint Commission on Accreditation of Healthcare Organizations (JCAHO), for instance, initiated a voluntary sentinel event reporting program for hospitals in 1996; however, they are still addressing compliance and resistance issues stemming from concerns regarding the confidentiality and protection of data.¹ Manufacturers and providers report unexpected, adverse events involving medical products to the U.S. Food and Drug Administration. In addition, there are well-established voluntary reporting programs, such as the US Pharmacopeia Medication Errors Reporting program and the ECRI International Medical Device Problem Reporting System, that receive reports of emerging problems from the frontline of care delivery. Nevertheless, much variability exists among these reporting systems in their purpose, scope of reportable events, and impact on patient safety. Although interest in patient safety is growing, over two-thirds of states have not established medical error reporting systems.

Other industries, notably aviation and nuclear power, offer health care important lessons about improving safety. The experience of the aviation industry demonstrates that voluntary reporting works effectively as a basis for learning and safety improvement, if the reporting is to a non-regulatory entity with confidentiality protections and incentives. The case for voluntary and confidential medical error reporting systems, as opposed to mandatory and punitive reporting systems, is influenced by experience from health care and other industries that if individuals who report to a system are punished, reporting will not take place, and safety improvements will be impeded. The fear of malpractice liability, job loss and peer criticism has a chilling effect on provider willingness to openly acknowledge mistakes. This leads many to conclude that reporting of medical errors will most effectively support actual improvements in patient safety within a system that is confidential, non-regulatory, non-punitive, and voluntary—similar to the reporting system that has been successful in the aviation industry.

This report considers design elements and desired characteristics of a voluntary medical error reporting system and identifies the enablers and barriers to the success of such a system. The foundation for these design considerations was developed in two roundtable discussions held during 2000.

¹ Institute of Medicine, *To Err Is Human: Building a Safer Health System (Advance Copy)*, 1999: p. 81.

A. Claremont Roundtable—March 2000

In March 2000, patient and aviation safety experts and health policy leaders from around the country convened at the Claremont Graduate University for a discussion regarding the recommendations of the IOM Report, *To Err Is Human*. The report reveals that between 44,000 and 98,000 deaths occur each year due to errors at U.S. hospitals. The principle objective of the Claremont roundtable, sponsored by the Kaiser Permanente Institute for Health Policy, the National Quality Forum, and the Peter F. Drucker Archive and Institute, 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. The proposed strategy that emerged from the Claremont roundtable discussion builds on the experience of the NASA Aviation Safety Reporting System, which demonstrates that reporting of errors and near-misses can be used as a means to discover opportunities to improve safety.

B. NASA Roundtable—August 2000

“Design Considerations for a Patient Safety Improvement Reporting System” was the topic of a subsequent roundtable discussion conducted in August 2000. The Kaiser Permanente Institute for Health Policy, the NASA Aviation Safety Reporting System, and the National Quality Forum sponsored this discussion, held at the NASA Ames Research Center and a nearby conference center. The goal of the NASA roundtable discussion was to further develop the principles around reporting as a means to improve patient safety that were set forth earlier at the Claremont roundtable. NASA roundtable participants considered the design elements and desired characteristics of a voluntary medical error reporting system, and the potential relationship of such a system to existing reporting systems.

The primary questions addressed during the NASA roundtable were:

1. What information should be reported to improve patient safety, and to whom should it be reported (e.g., within institution versus outside of institution, errors² or adverse events³ versus near misses, local versus national)?
2. What are characteristics of a system that promotes voluntary reporting?
3. What are ways to enable these system features?
4. How would the following elements of a reporting system best be designed? (a) sponsorship and funding; (b) analytical process and expertise; (c) reporting of learning and public access to information.

² An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). Reasons, James T. *Human Error*, Cambridge University Press, 1990.

³ An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a “preventable adverse event.” Brennan, Troyen A; Leape, Lucian.; Laird, Nan M., et al. “Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study”, *N Engl J Med*. 324:370-376, 1991.

Information in this report is intended to build on the spirit and content of the discussions that occurred during the two policy roundtables and to inform the debate on this important topic. This report does not necessarily represent the views of all roundtable participants nor the endorsements of the organizations that they represent (see Appendix A and Appendix B for lists of participants).

II. NASA & VA Models

The National Aeronautics and Space Administration (NASA) Aviation Safety Reporting System (ASRS) and the U.S. Department of Veterans Affairs (VA) Patient Safety Reporting System (PSRS) are models that can contribute valuable design elements for a national voluntary reporting system for health care.

A. Aviation Incident Reporting—Valuable Information for Safety Improvement

The airline industry was highlighted in the IOM report, *To Err Is Human*, as a model from which the health care industry could learn. Since the release of the IOM report there has been considerable discussion about the potential transferability of the ASRS design elements to medical error reporting as a means to discover system vulnerabilities and improve patient safety.

ASRS is a national safety data resource that serves to identify aviation system vulnerabilities, generate research hypotheses, and provide unique human factors and operational insights. The program invites pilots, controllers, flight attendants, maintenance personnel, and others to report actual or potential discrepancies and deficiencies involving the safety of aviation operations.⁴ Over the last 25 years, ASRS has become a well-established, proven, and trusted program within the aviation industry. The effectiveness of the program in improving safety is, in large part, due to its voluntary, confidential and non-punitive reporting structure. Since the program's inception there has not been a single breach of reporter confidentiality.⁵

ASRS was created within NASA after an initial attempt by the Federal Aviation Administration (FAA) to establish a safety reporting system called the Aviation Safety Reporting Program (ASRP). ASRP was stalled by the civilian community's distrust of the system and their fear of reprisal if they reported mistakes.⁶ Subsequently, the FAA's ASRP was extended to establish the ASRS in 1976 under an agreement between the FAA and NASA to utilize ASRS as a third-party to receive aviation safety reports. The FAA provides most of the program's funding.

The mission of ASRS is to identify deficiencies and defects that are the precursors of accidents and fatalities in the airline industry (Figure 1). ASRS accomplishes this mission by providing information from which the aviation community can take corrective action. The information is also used for improving the current system and planning future system modifications.

⁴ NASA *Advisory Circular* 00-46D, February 26, 1987.

⁵ Statement of Linda Connell, Director, NASA Aviation Safety Reporting System, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, February 10, 2000.

⁶ National Health Policy Forum, *Improving Quality and Preventing Error in Medical Practice*, Issue Brief No. 753, from a discussion on March 15, 2000.

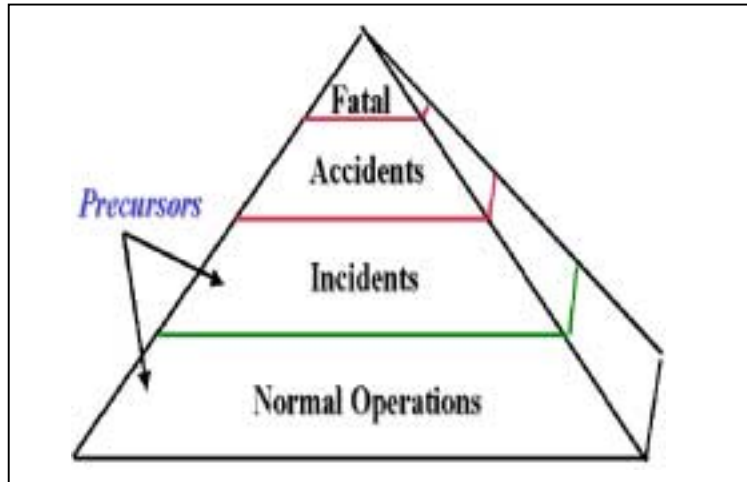


Figure 1. Accident Precursors. There is a general assumption that all aviation accidents are preventable. However, some industry safety experts question if all accidents have related precursors.

ASRS is the first line of defense against accidents in the aviation industry. ASRS receives close call reports, analyzes safety concerns, and issues early warnings of potential accidents. Reports coming into the system are from the people participating in the aviation system. ASRS has found that incident reporting provides rich, dynamic safety information. The narrative report, written by the incident reporter, expresses a first-hand view from the unique perspective of the frontline user. ASRS administrators have noted that the realistic descriptions of human performance that are contained in reports enhance human factors research and learning.

The ASRS program is based on voluntary, confidential, and non-punitive reporting. Pilots, air traffic controllers, flight attendants, maintenance personnel, and others are invited to voluntarily 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 from disciplinary action in the case of a potential violation of federal air regulations. The FAA considers the filing of a report to be indicative of a constructive attitude on the part of the incident reporter.⁷ Therefore, the FAA will not impose penalties upon individuals who complete and submit written incident reports to ASRS within 10 days after the violation if:

1. the violation was inadvertent and not deliberate;
2. the violation did not involve a criminal offense, accident, or action which discloses a lack of qualification or competency; and
3. the person has not been found in any prior FAA enforcement action to have committed a violation for a 5-year period prior to the date of the incident.

The key factors of the ASRS program's success are the continuing trust that it has established by holding the reports it receives in strict confidence and the provision of useful information to the field that improves safety. Another key success factor for ASRS is the balance of power between NASA, the FAA, and the aviation community. An advisory committee, comprised of

⁷ Federal Aviation Administration "Advisory Circular 00-46D", FAR 91.25, Facility Ops. and Admin. Handbook 7210.3M, <http://asrs.arc.nasa.gov>, February 1987.

representatives from the aviation community, including NASA and FAA, meets periodically to evaluate and advise ASRS operations.⁸

As the program administrator, NASA fulfills leadership responsibilities over ASRS in the following ways:

- oversees all ASRS operations and compliance with legal requirements;
- maintains program confidentiality, timeliness, and independence;
- assures integrity of policies, procedures, and critical safety alerting process; and
- evaluates proposed ASRS system improvements and innovations.⁹

ASRS receives an average of 2,900 reports per month or approximately 725 per working week. As of year-end 1999, the total report intake has been over 460,000 reports (Figure 2).¹⁰ The vast majority of reports are received from air carrier and general aviation pilots.

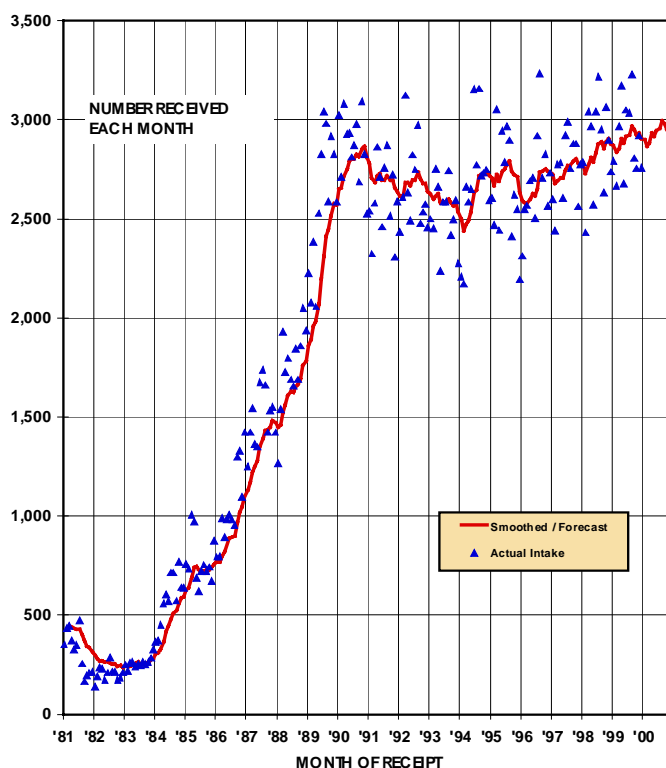


Figure 2. Incident Reporting Volume. ASRS has experienced a 60% increase in the volume of reports since 1988.

The annual operating budget of ASRS is approximately \$2.4 million. If one divides the ASRS operating budget by the annual report intake, the average cost per report received is approximately \$70. This funding level covers all aspects of the program including report

⁸ Ibid.

⁹ “Aviation Incident Reporting—Valuable Information for Safety”, a presentation by Linda Connell, Director, NASA Aviation Safety Reporting System at the “NASA Roundtable”, August, 2000.

¹⁰ “Aviation Safety Reporting System Program Overview”, Updated Through Fourth Quarter 1999, <http://asrs.arc.nasa.gov>.

processing, alerting messages, data dissemination functions, special studies, and publication activities.

All reports submitted to ASRS are initially reviewed by two expert analysts. Each report is screened against established criteria as part of the reporting system's triage process to determine if the report warrants full processing, analysis and database input. Currently, approximately 25-30% of reports receive full processing and are put into the database.

The subset of reports that receive full processing generally fall into four categories: 1) aviation hazards that require immediate alert messaging; 2) priority safety concerns that have been targeted for data collection; 3) random sample to ensure that the database is representative of all incidents reported; and 4) reports that, based on the discretion of the expert analyst, represent a new or unique learning opportunity. Report processing and analysis is the most costly service that ASRS provides. The proportion of reports that receive full processing for input in the database is monitored throughout the year and adjusted periodically based on available resources.

Members of the aviation community have visible evidence that they are helping to improve aviation safety by reporting to ASRS. The ability of ASRS to convert aviation incident reports into constructive output is demonstrated by the variety of products made available to the aviation community.¹¹ The ASRS program provides feedback in the form of reports that summarize research and analysis, alert messages, an on-line database, a monthly safety newsletter, and a quarterly 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 through a link to the FAA web site (NASDAC), on a CD-ROM, or through an established ASRS search request process.

B. VA Voluntary Reporting System Venture with ASRS

The Department of Veterans Affairs (VA), which operates 172 medical centers across the country and serves more than 3 million veterans per year in its health care system, has become a national leader in efforts to reduce medical errors. The VA's focus on patient safety and quality assurance has resulted in measurable improvements that have been achieved through the application of new technologies and process redesign.¹²

The VA is working with NASA to implement a de-identified, voluntary Patient Safety Reporting System (PSRS) initiative as a complementary mechanism to its internal mandatory reporting system. The internal adverse event and close-call reporting program, launched in 1999, allows for the determination of root causes and captures corrective actions for implementation. The VA leaders have found value in the internal reporting system, as it provides specific corrective actions that can be applied to a specific circumstance in a specific location, but they sense that incidents may be underreported due to employees' fear (in some cases) or other reasons. The voluntary PSRS will enable de-identified reporting in a system that acts as a 'safety valve' to

¹¹ Statement of Linda Connell, Director, NASA Aviation Safety Reporting System, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, February 10, 2000.

¹² The National Coalition on Health Care and The Institute for Healthcare Improvement, "Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines of Medicine", February 2000.

allow learning to take place from otherwise unknowable events, although only the vulnerabilities are revealed, not the specific corrective actions.¹³

The PSRS prototype is being developed through an interagency agreement between the VA and NASA. The reporting system will be operated by NASA and modeled after the Aviation Safety Reporting System. The information from PSRS will serve a different purpose from the VA's internal reporting system. It is hoped that PSRS will identify previously undetected and/or under-recognized system vulnerabilities. Unlike ASRS, PSRS will focus on adverse events, as well as close calls and general safety reporting. The near-term milestones for the reporting system are to develop a reporting form and promotional materials for testing in two VISNs (Veterans Integrated Services Networks) with continued rollout to the remainder of the VA in 2001-2002.

The three guiding principles of PSRS are (1) voluntary participation, (2) de-identification and confidentiality protection, and (3) non-punitive application.¹⁴ PSRS is being designed strictly as a tool for learning.

The partnership between the VA and NASA will center on five primary operational functions:

- 1) receipt, de-identification, and processing of incident and safety-related event reports;
- 2) analysis and interpretation of data;
- 3) issuance of alert messages as required;
- 4) dissemination of de-identified reports and other information; and
- 5) program evaluation and review.

Reports will be submitted to NASA, which will oversee all PSRS operations and maintain confidentiality and assure de-identification of the reporting system. Under the terms of the partnership agreement, the VA may not review any report or data until it has been de-identified. The NASA/VA collaboration on PSRS will serve as one laboratory to test voluntary medical error reporting for the nation.

The potential disclosure of the reporter's identity is a risk that could undermine the credibility of PSRS within the VA system. Therefore, a decision has been made not to maintain the reporter identity in a database, consistent with the long-standing policy of the ASRS. NASA protects the identity of the VA reporter and any third-party references through the Privacy Act and established exemptions to the Freedom of Information Act. In addition, records created for the VA as part of a medical quality assurance program, such as patient safety reports, have additional protections beyond those of other government agencies.¹⁵ Moreover, the peer review protections applicable to the VA shield the data from discovery. Once an incident report is de-identified, and is virtually anonymous, the VA's concerns for protecting the de-identified information from disclosure are virtually eliminated. Although federal law appears to provide

¹³ Jim Bagian, MD, PE, John W. Gosbee, MD, and Caryl Z. Lee, RN, MSN, "Partners in Prevention: The VA-NASA Patient Safety Reporting System", *Federal Practitioner*, V18 N3, March 2001.

¹⁴ "Patient Safety Reporting System", a presentation by Jim Bagian, MD, PE, Director, VA National Center for Patient Safety at the "NASA Roundtable", August, 2000.

¹⁵ 38 United States Code (USC) 5705 provides that records and documents created by the VA "as part of a medical quality-assurance program" are "confidential and privileged and may not be disclosed to any person or entity", with certain exceptions.

the VA considerable protection against the discovery and disclosure of data, these unique legal shields are not afforded to non-VA hospitals.

III. Mandatory and Voluntary Reporting Systems

Most stakeholders in the health care industry would agree that there is an important role for reporting of adverse medical events and safety hazards. However, there are widely divergent views and strong sentiments regarding the appropriate role and scope of mandatory reporting systems. With the attention of the media, the public, and policymakers focused on medical errors, it is important to acknowledge the distinction between mandatory systems (primarily focused on accountability) and voluntary systems (primarily focused on learning) as they relate to patient safety.

A. Mandatory Reporting

Mandatory reporting systems operate at the institutional and/or government level and typically focus on the identification of the most serious adverse events and/or issues related to criminal activity, gross negligence, or professional misconduct, although some systems include close calls. A number of mandatory systems currently exist; they focus primarily on holding medical care providers and institutions accountable for the quality and safety of the care that they provide. In addition, manufacturers of medical products are required by law to report errors, adverse events, and product quality deviations to the U.S. Food and Drug Administration (FDA). The FDA's program also requires hospitals to report device-related injuries to manufacturers and device-related deaths directly to the FDA.

In 2000, fifteen states (Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington) required mandatory reporting of adverse events from general and acute care hospitals.¹⁶ The focus, structure, and operation of state reporting systems vary significantly. Types of adverse events required to be reported in state mandatory reporting systems also vary significantly and include: unexpected deaths, wrong site surgery, major loss of function, and errors in medication.¹⁷ The levels of participation and utility of mandatory state reporting systems are highly variable; in fact, it will be important to conduct research to fully understand how they function and their impact.

As a way to deal with this diversity in state reporting systems, the National Quality Forum (NQF), a not-for-profit organization created to develop and implement a national strategy for health care quality measurement and reporting, is carrying out a project sponsored by the federal government to identify serious, egregious, and preventable healthcare errors that should never occur—events that they call “never events.” This project, which began in December 2000, will identify and develop consensus on a core set of patient safety measures related to avoidable, serious adverse events in hospital care. The core measures, in turn, will enable more standardized data collection and reporting of these events within and across states. The results

¹⁶The National Academy for State Health Policy, *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*, April 2000.

¹⁷ *Ibid.*

of this NQF effort will help inform states and the federal government about what should be reported in mandatory systems.

A survey of states conducted in February 2000 by the National Academy for State Health Policy (NASHP) explored current state activities to assess and address the issue of medical error reporting. The principal purpose of the survey was to determine the extent to which states require the reporting of serious adverse events attributable to errors in hospital settings.¹⁸ All 50 states and the District of Columbia responded to the survey. The survey found that the most frequent use of data from reports is aggregating data to identify trends, which was reported in 10 states with mandatory reporting. Nine states administer sanctions and assure corrective action. Eight states issue public reports. In another study of state-based reporting programs by NASHP, several states expressed concerns that their mandatory reporting systems suffer underreporting from hospitals.¹⁹ Using medical error reporting data to affect actual improvement in public safety also continues to be an issue with which states are grappling.

Opponents of mandatory reporting argue that the threat of punishment discourages reporting, discussion, analysis, and improvement. They argue that rather than focusing on the rate or frequency of errors, reporting systems should concentrate on gaining knowledge about the root causes of mistakes to avoid their repetition. Approaches that focus on punishing individuals instead of changing systems provide strong incentives for people to report only those errors that they cannot hide.²⁰ Given the Institute of Medicine's recommendation to build a mandatory, national system of state-based reporting, an evaluation of existing state systems is particularly important. Questions to examine in such an evaluation include: What impact do mandatory reporting systems have? Are there design elements of mandatory systems that make a difference? For this analysis, five to six markers (e.g., unanticipated death, suicide of a patient, wrong site surgery) could be used to compare the rate of incidence in states with and without mandatory reporting systems. An alternative or complementary approach might be to compare the responses to survey questions regarding patient safety orientation among providers in states that mandate reporting versus providers in states that do not.²¹

In February 2001, the Agency for Healthcare Research and Quality (AHRQ) released a request for grant applications in support of research that will evaluate reporting system strategies and safety interventions. In particular, AHRQ is interested in research projects that will assess reporting systems that publicly disclose information on errors or risks, in comparison with reporting systems that focus on learning from incidents for the purpose of error prevention.²²

¹⁸ Ibid.

¹⁹ The National Academy for State Health Policy, *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*, January 2001.

²⁰ Statement of Lucien Leape, M.D. before the U.S. Senate Committee on Health, Education, Labor and Pensions, January 25, 2000.

²¹ Testimony of Robert M. Crane, Senior Vice President, Kaiser Foundation Health Plan, Inc. and Director, Kaiser Permanente Institute for Health Policy presented at The National Summit on Medical Errors and Patient Safety Research, September 11, 2000.

²² Agency for Healthcare Research and Quality, "Request for Application: Improving Patient Safety: Health Systems Reporting, Analysis, and Safety Improvement Research Demonstrations", Release date: February 2, 2001.

B. Voluntary Reporting

Many believe that significant progress toward safety improvement and learning from errors will occur most successfully within voluntary event reporting systems.²³ The purpose of a voluntary medical event reporting system is to gather information, identify system vulnerabilities, and develop solutions. To improve patient safety, voluntary reporting systems need to serve as tools for learning rather than accountability systems. Successful safety improvement efforts rely on voluntarism, collaboration, and trust, which are characteristics most closely aligned with a voluntary and confidential reporting system model.

Reportable occurrences in a voluntary system should include any adverse events, close calls (“near hits”), and hazardous conditions that could lead to error. Reports to voluntary systems, such as the US Pharmacopeia Medication Error Reporting program, typically come from front-line practitioners or others close to the event, who can best describe the specific conditions that led to the incident.²⁴

IV. Design Characteristics

The desired characteristics of a voluntary patient safety improvement reporting system evolved from the synthesis of discussions at the Claremont and NASA roundtables and build on design elements from the Aviation Safety Reporting System (ASRS), the prototype VA Patient Safety Reporting System (PSRS), and existing voluntary reporting systems in health care. These systems have recognized that the ultimate purpose of reporting should be to (1) identify errors and system vulnerabilities and, (2) learn from those errors to prevent future adverse events. The underlying, fundamental issue is that information gathered through a voluntary reporting system should not be used for punitive purposes. The threat of punishment discourages reporting, discussion, analysis, and improvement. The 11 key design elements that follow build on this recognition and promote the development of a culture of continuous quality improvement in health care.

1. Voluntary reporting by individuals and institutions to a non-regulatory, national entity should be the primary vehicle, external to institutions, used to collect information for the purpose of learning from adverse events, close calls (“near hits”), and hazardous conditions that could lead to error.

Because the primary purpose of the voluntary reporting system is to improve safety and reduce the future occurrence of errors, it is important to create a climate in which providers and health care workers feel comfortable to report. The cultural barriers to reporting (e.g., blame, shame and fear of reprisal) must be dramatically reduced to encourage reporting. Individuals should have assurances that reports will not be used by their employer, a regulator, or the tort system to take punitive action against them.

²³ The notion that safety improvement and learning from errors will occur most successfully within voluntary reporting systems was generally acknowledged among participants at the August 28-29, 2000 NASA roundtable *Design Considerations for a Patient Safety Improvement Reporting System*.

²⁴ Institute for Safe Medication Practices, “Discussion Paper on Adverse Event and Error Reporting in Healthcare”, January 23, 2000.

The airline industry's success with voluntary reporting can be attributed, in part, to reporting to a non-regulatory entity with confidentiality protections. In addition, the system provides incentives in the form of a limited immunity. Such a system should be the primary vehicle for external reporting of medical errors. Those in the health care industry should carefully study the elements of the ASRS and other successful systems 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
- Reporters are guaranteed confidentiality and de-identification
- Reporters have incentives to report due to the provision of limited immunity²⁵ to regulatory action
- Identifies improvement opportunities and issues alerts
- The de-identified database is broadly available for review and analysis

Unlike the ASRS, yet in line with the VA's PSRS, the scope of events reported to a voluntary safety improvement reporting system should not be limited. The reporting system should capture errors, adverse events, and close calls to identify a broad range of safety concerns (both potential and actual experience). The system should encourage reporting of 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 safety improvement reporting system.

The aviation industry has demonstrated the advantages of a single, national voluntary reporting system. A national reporting system enables economies of scale, offers the best opportunity to identify low-volume events, and facilitates the development of adequate expertise for analysis. While reporting to a national entity is not essential, this approach could have similar advantages in health care.

2. The system should have strong confidentiality protections and afford evidentiary privilege to reported information to protect against discovery and disclosure.

Protection of data against disclosure and discovery in litigation is a fundamental component of any successful voluntary event reporting system. Individuals and institutions need to have assurance that they will not incur punitive action as a result of submitting a report to the system. 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

²⁵ The FAA will not use information that has been filed with the ASRS in an enforcement action, and will waive fines and penalties for unintentional violations of federal aviation regulation that are reported within 10 days of their occurrence and meet other conditions of limited immunity. Accidents and criminal activities are not protected.

protecting patients. In such a culture and environment, it is difficult for providers to acknowledge mistakes.

States generally have statutory protections for the processes and information involved with quality assurance and peer review within health care institutions. However, these protections are often lost when information is shared outside of the health care institution. Protections similar to those afforded by state peer review statutes need to be extended to the entity that receives and compiles patient safety incident reports. For the purpose of this report, such an entity will be referred to as a “host” agency. Legislation to protect information reported to the host agency will likely be the system keystone. At the same time it is acknowledged that it is impossible to truly protect data from all forms of discovery. For example, a legislative committee could subpoena reports held by the host agency, if it so desired.

A reporting system model might be structured such that an individual or institution would complete and submit an incident report form, disclosing their identity, to the host agency of the system. Information identifying the reporter is desirable to allow follow-up with the reporter to complete the analysis of the report. The report would be de-identified—stripped of names, dates, times, and any other identifying information—after the identifying information was no longer needed for report follow-up. Incident reports submitted to the system would be vulnerable to breach of confidentiality or discovery from the time they are received by the host agency only until the time they are de-identified. It is conceivable that an attorney for a plaintiff could attempt to subpoena individual reports held by the host agency. If a suit were filed immediately after an event, and the reporting system received notification and/or a subpoena related to the suit prior to de-identification of the report, the host agency would be precluded from stripping the identifiers²⁶.

After a report is de-identified, it would be entered into a database and the original report destroyed. At this point, all database entries are essentially anonymous. For all practical purposes the information in the database would be inadmissible evidence, because it is hearsay (a report of a report) and it could not be attributed to specific actual events.²⁷ Moreover, in all likelihood the database would contain only a subset of all reports submitted to the host agency. Reports that are highly duplicative or that contribute insignificant value for learning might be routinely destroyed after appropriate review, and might not be included in the database. Such a policy would provide further protection, as an attorney representing a plaintiff could not determine conclusively that a report of a specific incident was contained within the de-identified database. However, any policy that authorizes the routine elimination of highly duplicative records should be supported by mechanisms to identify incident trends prior to the destruction of data.

It is important to acknowledge that the success of ASRS in maintaining data confidentiality protections may be in part attributed to the fact that the FAA is the single national regulator for the aviation industry. Obtaining protection and privilege for event reports in a national

²⁶ Gaba, David M., MD, *Analysis of the NASA Aviation Safety Reporting System for a Model for Safety Reporting in Anesthesiology*, 1992.

²⁷ The opinion of William Reynard, an aviation attorney and former Director of the NASA ASRS, as reported by David M. Gaba, MD in *Analysis of the NASA Aviation Safety Reporting System for a Model for Safety Reporting in Anesthesiology*, 1992.

health care industry that is subject to the regulations of 50 different states would be much more difficult. Federal legislation could provide uniform protections and, in fact, bills have been introduced in Congress to do so.

3. The system should be complementary to other mandatory and voluntary reporting systems that are in place.

There are several established public and private reporting systems that cover adverse medical events, including care in institutional settings, drugs, devices, vaccines, biologics and blood. The reporting systems listed in Table 1 below differ in their purpose and objectives. For additional information on these reporting systems, refer to the Kaiser Permanente Institute for Health Policy Web site (<http://www.kp.org/ihp>).

Table 1. Existing Medical Event Reporting Systems

	Adverse Events²⁸	Drugs	Devices	Vaccine	Biologics	Blood
U.S. Food and Drug Administration		✓	✓	✓	✓	✓
Joint Commission on Accreditation of Healthcare Organizations	✓					
Medication Error Reporting (MER) Program		✓				
MedMARx		✓				
ECRI International Medical Device Reporting System			✓			
State Adverse Event Tracking (Multiple States)	✓					

When a new voluntary safety improvement reporting system is established, individuals and/or institutions that report should not, where practical, be required to duplicate their effort in order to provide information to multiple voluntary reporting systems. Mechanisms for sharing information among voluntary reporting systems are needed. To a limited degree,

²⁸ FDA, MER, MedMARx, and ECRI routinely receive reports of adverse events in their respective areas of concentration.

existing reporting systems are now sharing incident reports and/or adverse event data. The U.S. Food and Drug Administration, which maintains reporting programs for drugs, therapeutic biological products, blood and blood components, vaccines, and medical devices, currently shares adverse event data with the ECRI International Medical Device Problem Reporting System (ECRI) and with US Pharmacopeia (USP).²⁹ Two national medication error reporting programs, the Medication Error Reporting program and the MedMARx program, receive reports related to medical devices (though limited to medication administration devices), vaccines, biologics and blood, as well as drugs. ECRI's International Medical Device Reporting System also receives reports related to vaccines, biologics, blood, and drugs when related to medical devices. ECRI, the Medication Error Reporting program, and MedMARx have an agreement to share reports.

Further consideration should be given to approaches to minimize the reporting burden on individuals and institutions through the sharing of data across reporting systems. The de-identified data that are subsequently generated by the safety improvement reporting system could be shared with a broader array of organizations without compromising confidentiality.

4. There should be public access to a de-identified database (i.e., de-identified patient, provider, institution, and person reporting).

There is a need for some form of public disclosure of data from the safety improvement reporting system, although the method and degree of disclosure need further consideration. The primary reason for making the de-identified database publicly accessible is to enable a broad array of organizations to conduct research and facilitate improvement in patient safety.

Public access to the reporting system database is a viable option only if reporter confidentiality can be guaranteed. The reports selected for input into the safety improvement reporting system database should be de-identified of information that might assist in or establish the identification of individuals or institutions filing the reports and the identities of parties named in the reports. The analysts who de-identify reports should also ensure that any other information that may potentially disclose the identity of individuals or institutions involved in the report (such as a unique medical procedure conducted at only one facility or unique physical characteristics of an individual) is deleted. Caution must be exercised to ensure that key contextual information, crucial to learning from reported incidents, is not lost in the de-identification process.

The layperson is unlikely to find much utility in the individual de-identified incident reports contained in the safety improvement reporting system database. The public wants information to assure them that progress is being made in improving the safety of the healthcare delivery system. Through mechanisms beyond the scope of the safety improvement reporting system, the public should be informed of the safety of the health care delivery system and the safety practices which health care organizations have adopted.

²⁹ FDA data is publicly available. FDA shares data with ECRI and USP in a format that allows these organizations to more readily load and analyze the data on their internal computer systems.

This information will assist patients in comparing institutions and create an incentive for providers to implement system improvements.

5. Expert analysis of the reports is essential to glean the most benefit from them.

The host agency of the safety improvement reporting system should compile the reports, organize the analysis of the data, and conduct a preliminary analysis for trend identification in order to provide safety alert messages to the medical community. A single, core, national reporting system staff is recommended for this function. The multidisciplinary, analytic staff of the host agency would require a combined knowledge of human factors and current medical practice. The analytic staff should have a current knowledge of the medical content that is applicable to the incidents they are reviewing, such that they can understand and interpret the reports. A multidisciplinary team approach, involving physicians, nurses, human factors experts and other is recommended.

Selected expert entities could contract with the safety improvement reporting system to expand the analytical capacity of the system. Potential sources for this expertise may be obtained through existing organizations that possess the requisite knowledge and through the development of dedicated national resources that can perform the data analysis, promote learning from the data, and develop recommendations. Rather than placing responsibility with a single entity for data analysis and the development of safety recommendations, a network of expert organizations could be established. Existing voluntary reporting systems, medical specialty societies, private health care delivery systems, and private patient safety organizations may be well-equipped to analyze the data to identify learning opportunities. If such an approach is taken, legal privileges that protect incident reports against disclosure and discovery must extend beyond the host agency to protect other entities providing analytic services to which reports are referred before de-identification.

The focus of the analytic processes should be on gaining new insights about adverse events, understanding the cause of errors, and identifying successful safety practices to share and have implemented within the health care community.

6. The system should be enabled through federal authorization and funding.

Despite the compelling public interest in having such a system, it will be challenging to find sufficient funds in the existing flow of private sector resources to establish a safety improvement reporting system. Federal funding will be important to initiate the voluntary reporting system. A combination of government and private sector funds might be employed for the long-term financing of the system. Federal authorization is necessary to extend protections to the reporting system against data discovery and disclosure in a consistent manner across all states. Federal authorization will also give the system legitimacy and currency as perceived by stakeholders in the health care industry. (Federal funds were used for the start-up and ongoing operation of ASRS and have been used to initiate other programs such as the Professional Standards Review Organizations—the forerunners of current Professional Review Organizations which are responsible for conducting health care quality improvement activities. Several of the health care error reporting legislative proposals introduced in the 106th Congress include authorization of substantial sums for proposal implementation.)

7. Individuals and institutions should be instructed to report complaints of criminal activity, gross negligence, or professional misconduct to the appropriate regulatory agency and not to the voluntary safety improvement reporting system.

Incidents in health care settings involving criminal activity, gross negligence, or professional misconduct are under the jurisdiction of state regulatory agencies, law enforcement authorities, or authorities for a particular clinical service. These authorities should assure the public that appropriate action will be taken with regard to providers who (1) are not appropriately accredited, licensed or credentialed; (2) are abusive to patients; (3) provide care while impaired by alcohol, drugs, physical disability or mental disability; (4) act intentionally to cause patient harm; (5) practice with gross incompetence or gross negligence; or (6) engage in a criminal act by providing or failing to provide care.

Incident reporting forms must clearly instruct the individual or institutional reporter not to submit complaints involving criminal activity, gross negligence, or professional misconduct to the safety improvement reporting system. If, however, reports received by the system are determined to contain complaints of criminal activity, gross negligence or professional misconduct, they should not be disclosed to regulatory authorities by the host agency. Individuals who report such complaints should be contacted by the host agency and informed of avenues that they can take to address their concerns to the appropriate authority. The safety improvement reporting system should not put its analysts in the position to pass judgment on incidents potentially involving gross negligence or professional misconduct.

8. Individuals or institutions reporting to the system should be guaranteed confidentiality, but should not be anonymous.

As mentioned previously, incident reports submitted to the safety improvement reporting system should be non-discoverable and inadmissible in court or other proceedings prior to de-identification. 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. Another concept borrowed from aviation safety reporting is that reporters should not be anonymous. Follow-up with the reporter prior to de-identification may be necessary to obtain additional information about the event in order to gain a more complete understanding of the circumstances.

9. Reports should be de-identified prior to entry into the database.

The report should be de-identified of the name and any other information that may identify individuals and/or institutions after a period of time during which the host agency can perform follow-up to obtain additional information about the incident to file a complete report. During the de-identification process, the staff of the safety improvement reporting system need to be sensitive to parameters beyond names that could potentially pinpoint an individual or institution in a report. For example, a unique service or procedure cited in a report could link an institution to a reported incident. Public disclosure of health system, facility or individual identity would undermine the incentive to report that confidentiality provides.

10. Feedback should be provided to the health care community.

Feedback in the form of safety alerts, newsletters, and articles in professional journals should be provided to the health care community from the safety improvement reporting system. It is important to recognize that a wealth of information is currently available from a variety of sources about healthcare systems defects that could enable the prevention of errors and adverse events. Emphasis must be placed on better dissemination and synthesis of learnings and the adoption of evidence-based safety practices to prevent future errors.

A variety of organizations have been suggested as the entity to take the lead in promoting and facilitating the use of safety information in the health care community. The IOM report suggested that a National Center for Patient Safety, housed within the Agency for Health Care Research and Quality, could play a leadership role in communication activities to improve patient safety.³⁰ AHRQ recently renamed its Center for Quality Measurement and Improvement as the Center for Quality Improvement and Patient Safety (CQuIPS) which conducts and supports research on the measurement, improvement, and reporting of health care quality and the enhancement of patient safety. Specifically, CQuIPS will seek to integrate patient safety activities into broader AHRQ activities, conduct research on how to reduce medical errors, convert those research findings into improved practices, and help educate patients about safety issues.³¹

In carrying out its activities, the National Center for Patient Safety should collaborate with various groups involved in education and dissemination such as the National Patient Safety Foundation. In addition, the sponsors of existing voluntary reporting systems (e.g., ECRI, US Pharmacopeia, VA, and the Institute for Safe Medication Practices) are currently disseminating safety information in their areas of expertise. A logical, first step would be to sketch out a prototype national system for obtaining, exchanging, and implementing “best practices” in patient safety.

11. The reporting process should be broadly understood and forms should be available and user-friendly.

The report submission forms should be readily available to health care professionals in their work place and from labor unions, professional societies, and the Internet. The system should employ a uniform, user-friendly reporting format that includes clear and simple instructions. The safety improvement reporting system should be highly visible and clearly understood by providers and other health care workers. Communication to all stakeholders should emphasize that quality and safety improvement is the mission of the reporting system.

³⁰ Institute of Medicine, *To Err Is Human: Building a Safer Health System* (Advance Copy), 1999: p. 60.

³¹ *Federal Register*: January 24, 2001 (Volume 66, Number 16), Federal Register Online via GPO Access [wais.access.gpo.gov].

V. System Enablers

The following are general considerations including legal, cultural, and operational factors that will impact the implementation and ultimate success of a voluntary safety improvement reporting system.

Legal Protections

The confidentiality of reported data must be protected so that physicians and other health care professionals are encouraged to report 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, law suits, or reprisals, will discourage health care professionals from voluntarily reporting close calls and adverse events.³² Legal shields against discovery and inappropriate disclosure of information submitted to the safety improvement reporting system are the critical determinant of the operational success of the program. Action will be required by either Congress or state legislatures to provide evidentiary privilege to information reported to the safety improvement reporting system in order to protect the data against disclosure and discovery in litigation. The privilege will be required by the host agency of the safety improvement reporting system and any expert organizations that perform analysis of data prior to de-identification. In the event that the host agency is a government entity, an exemption from legal discovery and the Freedom of Information Act may also be required to create a disclosure prohibition.

Ethical Imperative

A strong ethical imperative for reporting errors is needed within the health care community. A non-punitive culture is a desirable enabler; however, this culture does not currently exist to support the ethical imperative for reporting. Health care providers should incorporate the principle “first, 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. Ideally, the driving force for submitting a report to a safety improvement reporting system is a sense of altruism and interest in preventing future adverse events. Moreover, health care providers have a professional and ethical obligation to inform patients and their families about errors in the care process that cause injuries.³³

Incentives

Incentives for timely reporting would increase the likelihood of participation in the reporting system. Again, looking to the experience of the aviation industry, the guaranteed limited immunity provision in the ASRS program was a prime motivation for aviation professionals to submit reports in the initial launch of the system. Through this immunity provision, the FAA will not use information reported to ASRS in an enforcement action, and will waive fines and

³² 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.

³³ The American College of Physicians—American Society of Internal Medicine, acknowledges that “physicians have 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. American College of Physicians—American Society of Internal Medicine Ethics Manual, 1998, pages 8-9.

penalties for unintentional violations of federal aviation regulations if the incident is reported to ASRS within 10 days of its occurrence and meets other conditions of limited immunity. Aviation accidents and criminal acts are not protected.

Similar incentives and protections could be developed within a safety improvement reporting system in health care. One such incentive would make individuals and organizations reporting adverse events and errors eligible for reformed tort processes in the event of a claim. For example, California Medical Injury Compensation Reform Act (MICRA) standards could be applied 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.³⁴ 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.³⁵

Meaningful incentives could be an important factor in driving the initial momentum of a safety improvement reporting system. Over time, altruism and the opportunity to improve the system may be sufficient motivation for reporters.

Authorization and Funding

The federal government has a vital role to play in supporting tests of methods to identify and learn from medical errors to enhance patient safety. The federal government should authorize and provide financial support for a reporting system, perhaps starting with a demonstration project to test the design concepts of a safety improvement reporting system on a small scale before larger-scale rollout. Again, it is important to note that AHRQ is seeking applications for demonstration and evaluation projects related to various methods of collecting and using information to increase patient safety.³⁶ Ongoing funding for the safety improvement reporting system should be secured from the federal government and the private sector.

Recourse for the Injured

The safety improvement reporting system should not preclude patients who have been harmed from seeking recourse through existing mechanisms. To ensure public support for a voluntary reporting system, consumers need evidence that the voluntary reporting system is not protecting the professional misconduct or negligent behavior of providers. The public will need assurance that the voluntary reporting system will in no way impede their ability to seek recourse if they or a member of their family are injured while receiving care, whether or not it was reported to the voluntary system.

³⁴ Werner, M., American College of Physicians, *Beyond MICRA: New Ideas for Liability Reform*, 1995.

³⁵ Institute of Medicine, *To Err Is Human: Building a Safer Health System (Advance Copy)*, 1999: p. 95.

³⁶ Agency for Healthcare Research and Quality, "Request for Application: Improving Patient Safety: Health Systems Reporting, Analysis, and Safety Improvement Research Demonstrations", Release date: February 2, 2001

VI. Issues for Further Consideration

The following important design considerations for a safety improvement reporting system warrant a forum for additional discussion.

1. While most stakeholders would agree that there is a need for some form of public disclosure of data from a voluntary reporting system, the method and degree of disclosure needs further consideration.
2. The structure of the reporting system envisioned in this report is national. However, the desirability of aggregating data at the sub-national level also warrants further discussion, particularly in consideration of a pilot project.
3. A more detailed examination is needed to determine the relationship of the proposed safety improvement reporting system to existing voluntary reporting systems.
4. There is a need to explore and define the most useful mechanisms to provide effective, timely, and accurate error reduction information to the health care community.
5. There is a wealth of information about regularly occurring problems in the health care system that compromise patient safety. There should be a concerted effort to better disseminate and apply that existing information, as well as successful practices that can prevent adverse events.

VII. Recommended Next Steps

1. Seek legal protections from Congress for the voluntary safety improvement reporting system.

Error reporting is highly complex because of the legal issues involved. The effectiveness of any reporting system will greatly depend upon the degree to which information reported to the system is legally protected from discovery or use in civil litigation. There is general agreement that federal and/or state laws would need to be changed to safeguard reports received by the host agency from discovery and disclosure prior to de-identification. If state-based pilot projects are implemented, protections would need to be established in state laws. Further investigation is recommended concerning the scope and focus of the required legislation. Organizations such as the National Patient Safety Foundation, the VA, the National Academy for State Health Policy, or the National Conference of State Legislatures can play a positive role in efforts to draft model legislation and to advocate its passage.

2. Expand testing of the VA's prototype voluntary Patient Safety Reporting System (PSRS).

After the VA PSRS gains sufficient operational experience, a limited number of private sector health care institutions could participate in the system as a demonstration project to further test its features. Such a demonstration project is a crucial precursor to wide-scale rollout of a safety improvement reporting system in the private sector.

3. Seek federal authorization and funding to test a prototype for a voluntary reporting system.

Led by Senators Jeffords, Kennedy, Specter and others, a number of proposals were put forth in the 106th Congress to promote patient safety and raise awareness about an effective foundation for a national, adverse event reporting system. The attention of the 107th Congress should be focused on those legislative offerings with emphasis on confidentiality protections, authorization and the funding necessary for the initiation of an effective safety improvement reporting system.

4. Initiate evaluation of established reporting systems.

There is little, if any, research about the effectiveness of existing reporting systems to either hold health systems accountable or reduce preventable errors. A comprehensive evaluation of established mandatory and voluntary reporting systems is necessary to determine their impact and effectiveness. The February 2000 Report of the Quality Interagency Coordination Task Force (QuIC) to the President commits to carry out research to better understand the effectiveness of existing reporting systems to determine their effectiveness and to inform the development efforts of future reporting systems. In October 2000, The Agency for Healthcare Research and Quality (AHRQ) released a request for grant applications to build the knowledge base on the scope and impact of medical errors. Within this program, AHRQ is supporting research in the area of learning from medical error reporting which will be an opportunity to document the impact of existing reporting systems.

Entities such as AHRQ and The National Quality Forum can play an instrumental role in creating a process of continuous learning and improvement among error reporting systems.

VIII. Conclusion

Significant progress toward patient safety improvement and learning from errors will occur most successfully with voluntary event-reporting systems.³⁷ The ultimate purpose of a patient safety improvement system should be to identify system vulnerabilities and to learn from errors to prevent future adverse events. Further, voluntary and confidential reporting to a neutral third party will likely elicit greater participation in the system. Perhaps the most difficult challenges to error reporting are the cultural barriers that exist today in health care and the need for legal protection of the reported information and the reporter.

The 11 desired characteristics of a patient safety improvement reporting system build on design elements from the NASA Aviation Safety Reporting System (ASRS), the prototype VA Patient Safety Reporting System (PSRS), and other existing reporting systems in health care (e.g., Medication Error Reporting Program, MedMARx, and the ECRI International Medical Device Reporting System). These design elements offer important considerations for the framework of

³⁷ The notion that safety improvement and learning from errors will occur most successfully within voluntary reporting systems was generally acknowledged among participants at the August 28-29, 2000 NASA roundtable *Design Considerations for a Patient Safety Improvement Reporting System*.

a voluntary safety improvement reporting system for the United States. The strategy that emerges from this framework is founded on the premise that reporting of medical errors will most effectively support actual improvements in patient safety within a system that is non-punitive, 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. A test of these concepts is an important next step that can be achieved through further system design work and reporting system pilot projects.

The design characteristics highlighted in this paper emphasize the qualities of an optimal safety improvement reporting system, while leaving the myriad practical considerations to the system implementers, so as not to unnecessarily restrict flexibility to accomplish the ultimate goals of learning and error reduction. It is our hope that the lists of design considerations, system enablers, recommended actions and unresolved issues will serve as a springboard for further evaluation and discussion.

Appendix A: MARCH 16 & 17, 2000 ROUNDTABLE PARTICIPANTS

REPORTING AS A MEANS TO IMPROVE PATIENT SAFETY

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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.*

Appendix B: AUGUST 28 & 29, 2000 ROUNDTABLE PARTICIPANTS

DESIGN CONSIDERATIONS FOR A PATIENT SAFETY IMPROVEMENT REPORTING SYSTEM

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***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.*