

Roundtable Discussion:

Design Considerations for a Patient Safety Improvement Reporting System

Sponsored by

**Kaiser Permanente Institute for Health Policy
NASA Aviation Safety Reporting System
The National Quality Forum**

Held at

NASA Ames Research Center
Moffitt Field, California

August 28-29, 2000

Purpose and Disclaimer

The information about patient safety reporting systems presented in this summary report is intended to capture the spirit and content of the discussion that occurred during a roundtable on “Design Considerations for a Patient Safety Improvement Reporting System” held at the NASA Ames Research Center and a nearby conference center on August 28 and 29, 2000. The report is being disseminated with the intent of informing the debate about this important topic. It does not necessarily represent the views of all participants nor the endorsements of the organizations that they represent.

Background



The 1999 Institute of Medicine Report “To Err Is Human” calls for both mandatory and voluntary systems for reporting medical errors. This recommendation was made as part of a comprehensive strategy to improve patient safety by creating an environment that encourages organizations to identify errors, evaluate causes, and take appropriate action to improve performance. The report concludes that adverse event reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them.

Claremont Roundtable—March 16 & 17, 2000

Patient and aviation safety experts and health policy leaders from around the country convened at the Claremont Graduate University on March 16-17, 2000 for a Roundtable discussion on the recommendations of the IOM Report, “To Err Is Human”. The Roundtable was cosponsored by the Kaiser Permanente Institute for Health Policy, the National Quality Forum, and the Peter F. Drucker Archive and Institute.

Roundtable Discussion Focus

- How can reporting contribute to dramatic improvements in patient safety?
- What design elements are crucial for the operation of a successful patient safety reporting system?

NASA Roundtable–August 28 & 29, 2000

“Design Considerations for a Patient Safety Improvement Reporting System” was the topic of a second roundtable discussion conducted on August 28 and 29, 2000. This discussion was held at the NASA Ames Research Center and a nearby conference center. The goal of this discussion was to further develop the principles espoused at the Claremont roundtable earlier in the year by specifically considering 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.

Roundtable Discussion Focus

1. What information should be reported to improve patient safety, and to whom should it be reported?
2. What are the characteristics of a system that promotes reporting?
3. How would the following elements of a voluntary reporting system best be designed?
 - (a) sponsorship and funding;
 - (b) analytical process and expertise;
 - (c) reporting of learning and public access to information.

Roundtable Participants*

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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.*

Discussion Overview

NASA & VA MODELS—The NASA Aviation Safety Reporting System (ASRS) and the VA Patient Safety Reporting System (PSRS) were presented to the roundtable participants as models that could contribute experiential information about the design of a national voluntary reporting system.

WORKING THE DESIGN ISSUES—Roundtable participants discussed the policy and operational aspects of a voluntary safety improvement reporting system's design features.

EXISTING REPORTING SYSTEMS—Representatives from the Medication Error Reporting (MER) Program, MedMARx, and the ECRI International Medical Device Reporting System described how their reporting programs function. Participants considered how these and other existing systems might impact a new voluntary system.

POINTS OF AGREEMENT—Participants identified areas of agreement and issues that require further discussion.

Mandatory & Voluntary Reporting

While there was agreement on the importance of reporting, the roundtable participants expressed divergent views about the appropriate role and scope of mandatory and voluntary medical error reporting systems.

MANDATORY systems can 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 include close calls. A number of mandatory systems currently exist; they are primarily systems that focus 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.

VOLUNTARY reporting is an integral component of learning systems that are focused on reducing the occurrence of errors and improving patient safety by identifying system vulnerabilities. Reportable occurrences in the voluntary system should include any adverse event, close call (“near hit”), and hazardous condition that could lead to an undesirable patient outcome. The focus of the roundtable discussion was on this type of safety improvement reporting system.

NASA Aviation Safety Reporting System (ASRS)

A reporting model with applications to medical care

- Successful and trusted, voluntary, confidential, non-punitive, safety program and reporting system with 24 years of operational experience.
- Collects, protects and uses incident data to improve the National Aviation System. Identifies deficiencies for correction by appropriate authorities. Issues “alerts” (i.e., messages concerning potential hazards) and important occurrences and a monthly newsletter. Supports aviation system policy, planning and improvement and strengthens the foundation of aviation human factors research.
- Over 36,000 voluntary reports submitted annually by pilots, air traffic controllers, flight attendants, maintenance workers, and other aviation personnel with knowledge of actual or potential hazards to safe aviation operations.
- In exchange for the unique and valuable information they provide, reporters are guaranteed confidentiality and limited immunity. All identifying information is removed prior to entering final (or completed) reports in database.
- Reports are not used for enforcement. Fines and penalties for unintentional violations of Federal Aviation Regulations are waived when reports are submitted within 10 days of the occurrence. (However, accidents and criminal activities are not protected and should not be submitted to ASRS.)
- De-identified database is available to everyone.

VA Patient Safety Reporting System (PSRS)

- PSRS is a prototype medical error reporting system being developed through an interagency agreement between NASA and Department of Veterans Affairs.
- This initiative is a voluntary, confidential and de-identified patient safety reporting system designed as a complementary mechanism to VA's internal mandatory patient safety improvement reporting system. PSRS will identify previously undetected and/or under-recognized system vulnerabilities.
- The partnership between VA and NASA will explore five primary 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
 4. Dissemination of de-identified reports and other information
 5. Program evaluation and review
- Reports will be submitted to NASA, which will oversee all PSRS operations and maintain confidentiality of the reporting system. VA may not review any report or data until it has been de-identified.
- PSRS is strictly a tool for learning, increasing awareness, and enabling solutions.
- The near-term milestones are to develop a reporting form and promotional materials for testing in 2 VISNs (Veterans Service Integrated Network) by early next calendar year (2001).

Optimal Design Characteristics

The proposed voluntary patient safety improvement reporting system builds on design elements from the Aviation Safety Reporting System (ASRS), the prototype VA Patient Safety Reporting System (PSRS), and existing reporting systems in healthcare. The proposed system includes the following key design elements:

1. Voluntary reporting by individuals and institutions to a non-regulatory national entity should be the primary vehicle to collect information for the purpose of learning from adverse events, close calls (“near hits”), and hazardous conditions that could lead to error.
2. The system should have strong confidentiality protections and afford evidentiary privilege to the reported information to protect against discovery and disclosure of data.
3. The system should be complementary to existing reporting systems.
4. There should be public access to a de-identified database (i.e., de-identified patient, provider, institution, and person reporting).
5. Expert analysis of the reports is essential to glean the most benefit from them. Potential sources for this expertise may be obtained through existing organizations that possess the requisite knowledge as well as through the development of dedicated resources that can perform the data analysis, promote learning from the data, and develop recommendations.

Optimal Design Characteristics

(continued)

6. The system should be enabled through federal authorization and funding.
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 reporting system.
8. Individuals or institutions reporting to the system should be guaranteed confidentiality, but should not be anonymous. Follow-up with the reporter may be necessary to obtain additional information about the incident in order for a full analysis to be completed.
9. Reports should be de-identified of the name and any other information that may identify individuals and or institutions as early as possible after the utility of identification of the report is achieved.
10. Routine feedback (e.g., alert notices, newsletters) should be provided to the healthcare community.
11. The reporting system should be broadly understood and easy to use.

System Enablers

- Legal protections against discovery and inappropriate disclosure of data should be established to protect individuals and institutions that report.
- A strong ethical imperative for reporting of errors should exist within the healthcare community. A non-punitive culture is also a desired enabler; however, it does not currently exist to support the ethical imperative for reporting.
- Incentives for timely reporting should be established and promoted (these incentives could mitigate reporter liability, in the event of a legal claim).
- The federal government should authorize and provide financial support to initiate the safety improvement reporting system.
- Ongoing funding for the system should be secured from the government and the private sector.
- The safety improvement reporting system would not preclude patients who have been harmed from seeking recourse through existing mechanisms.

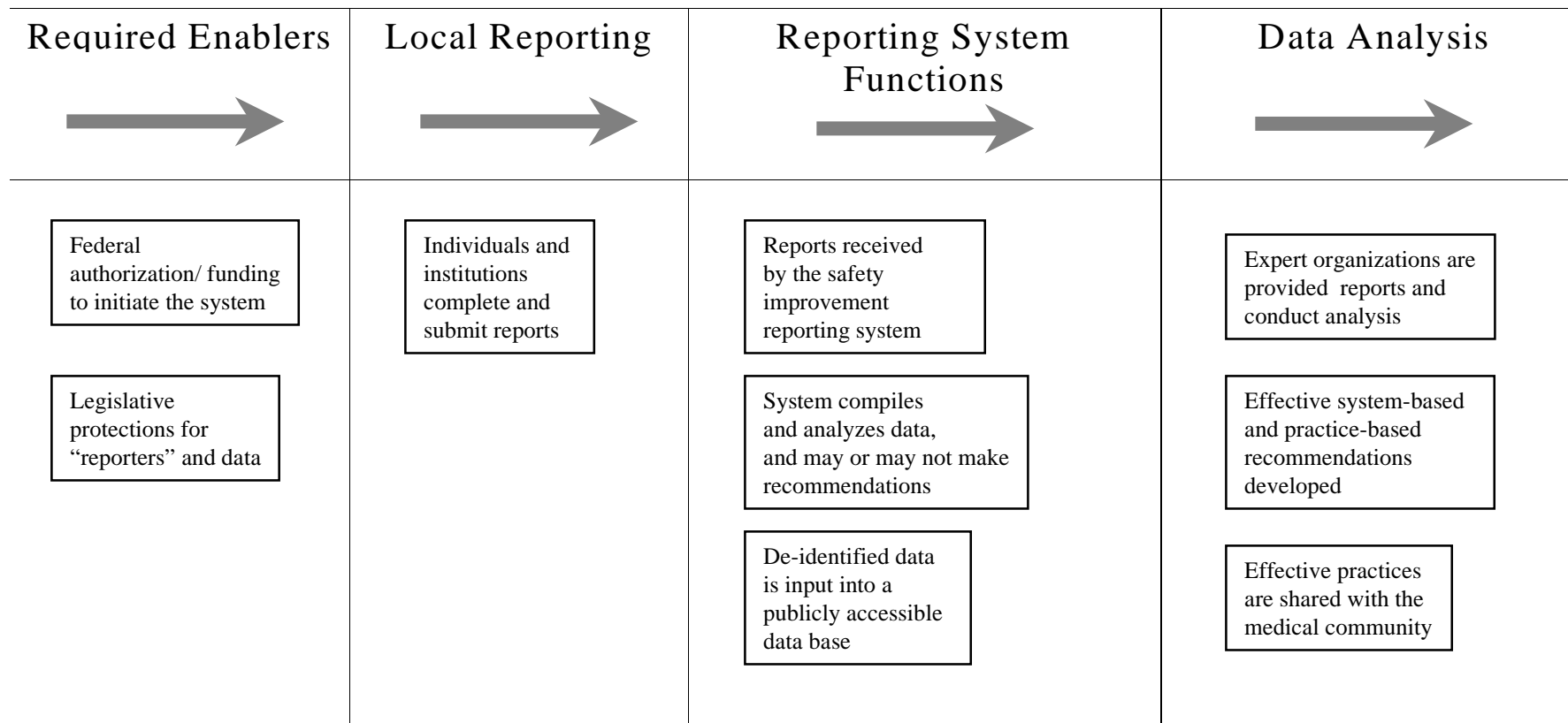
Analytical Process and Expertise

- The safety improvement reporting system should compile and organize the analysis of the data.
- A combined knowledge of human factors and current medical practice would be required by the multidisciplinary analytical staff of the safety improvement reporting system.
- Selected expert entities could contract with the safety improvement reporting system as a means to expand the analytical capacity of the system.
- De-identified data could be made available from the database to a broad array of organizations for the purpose of furthering research and improvement in patient safety.

Complementary to Existing Systems

- Individuals and/or institutions that report should not 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.
- Consideration should be given to using existing voluntary reporting systems as expert organizations to analyze reports in their areas of expertise for the safety improvement reporting system.
- Legal privileges that protect incident reports against discovery and disclosure must be extended to the entities providing analytic services and to whom reports are referred before de-identification.

Voluntary Safety Improvement Reporting System



Roundtable Participants Explored Desired Relationships to Existing Reporting Systems

	<u>Adverse Events</u>	<u>Drugs</u>	<u>Devices</u>	<u>Vaccine</u>	<u>Biologics</u>	<u>Blood</u>
U.S. Food and Drug Administration		✓	✓	✓	✓	✓
JCAHO	✓					
Medication Error Reporting (MER) Program		✓				
MedMARx		✓				
ECRI International Medical Device Reporting System			✓			
State Adverse Event Tracking (Multiple States)	✓					

Note that the Medication Error Reporting (MER) Program and the MedMARx program receive reports on devices (though limited to medication administration devices), vaccines, biologics and blood, as well as drugs. The ECRI International Medical Device Reporting System receives similar reports when related to devices. The organizations that sponsor these reporting systems have an agreement to share these reports.

Current State-Based Mandatory Reporting of Serious, Adverse Events

- Fifteen states (Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington) require from hospitals mandatory reporting of adverse events as defined by the IOM or by the state in a way that encompasses part or all of the IOM definition.
- Thirteen states require mandatory reporting from ambulatory care centers. Twelve states require reporting from psychiatric hospitals.
- Six states (Iowa, Kentucky, Maine, Missouri, North Dakota, New Hampshire) have legislation pending to require reporting of medical errors or adverse events.
- Types of adverse events already required in state mandatory reporting systems include: number of unexpected deaths, wrong site surgery, major loss of function, error in medication, and defective process not resulting in harm.

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

Issues for Further Consideration

1. While roundtable participants agreed that there is a need for some form of public disclosure of data from the safety improvement reporting system, the method and degree of disclosure needs further consideration.
2. The structure of the proposed system is national. However, questions were raised about the desirability of aggregating data at the sub-national level.
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 effective mechanisms to provide effective, timely, and accurate error reduction information to the healthcare community.

Recommended Actions

1. Seek legal protections from Congress for the voluntary safety improvement reporting system
 - Protections for information against discovery and disclosure
 - Protections for individuals from punishment and reprisal
 - Safeguards for patient confidentiality
2. Expand testing of the VA's prototype voluntary Patient Safety Reporting System (PSRS)
 - Identify a small number of private sector test sites to participate in the VA's PSRS
 - Explore the operational and legal issues for private sector participation in PSRS
3. Seek federal authorization and funding to test a prototype for a national voluntary reporting system
4. Initiate evaluation of established reporting systems
 - Assure that reporting systems have desired impact
 - Create a process of continuous learning and improvement