Roundtable Discussion:

Reporting as a Means
To Improve Patient Safety

Sponsored by

Kaiser Permanente Institute for Health Policy
The National Quality Forum
**Peter F. Drucker Archive and Institute**

Held at

Claremont Graduate University
Claremont, California

March 16-17, 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 the March 16-17, 2000 roundtable on "Reporting as a Means to Improve Patient Safety" held at Claremont Graduate University in Claremont, California. The report is being disseminated with the intent of informing the debate about this important topic. It is not a consensus document and does not necessarily represent the views of the participants or the endorsements of the organizations that they represent.

Background
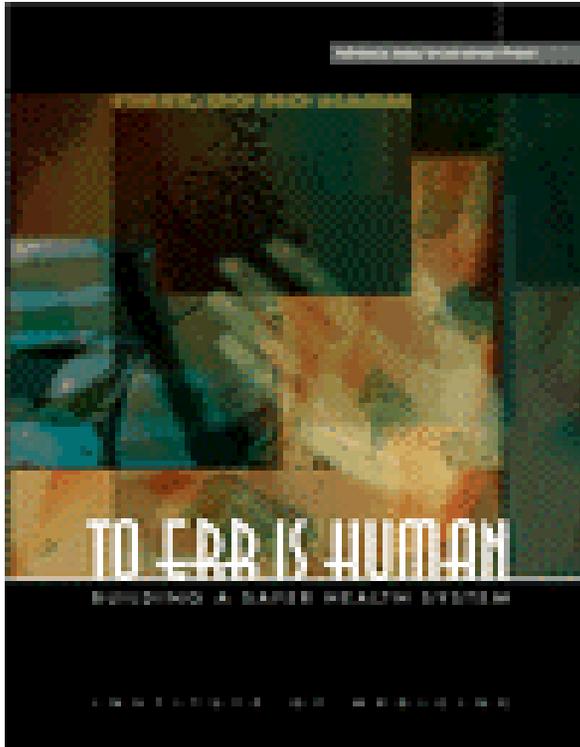
The recent Institute of Medicine Report "To Err Is Human" calls for both mandatory and voluntary reporting systems of medical errors. This recommendation is made as part of a comprehensive strategy to improve patient safety by creating an environment that encourages organizations to identify errors, evaluate causes, and take appropriate action to improve performance in the future. The report concludes that external reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them. Specifically, the IOM, the White House and Quality Interagency Coordination Task Force (QuIC) have recommended a nationwide state-based reporting system to provide for the collection of standardized information.

Policy Roundtable

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?

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, 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

DONALD PALMISANO, The National Patient Safety Foundation

SUSAN PENNEY, California Medical Association

MELISSA STEGUN, 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.*

Discussion Overview

INITIAL FOCUS—The Roundtable participants focused initially on understanding the IOM and Administration recommendations related to reporting as a means to improve patient safety.

EXISTING MODELS—The Aviation Safety Reporting System (ASRS) was presented to the Roundtable participants as a model that could lend effective design elements to health care. Participants were also informed of the key strategies of the VA Patient Safety Program's internal error reporting system.

DESIGN PRINCIPLES—Considerable time during the Roundtable was spent identifying the design principles of reporting systems with the goal of finding the most effective approaches to improve patient safety while promoting public trust. Underlying the principles is significant evidence that if individuals who report errors are punished, reporting will not take place.

PROPOSED PATIENT SAFETY REPORTING SYSTEM—The process of evaluating experience and design principles led to a recommended patient safety reporting system with confidential reporting to a non-regulatory entity as its centerpiece.

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 alert messages concerning potential hazards and important occurrences and 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 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 all

Proposed Strategy

The proposed strategy to improve patient safety through reporting builds on reporting system design elements from the Aviation Safety Reporting System (ASRS), the VA system and other existing systems. The strategy contains the following key elements:

1. All patients should be informed when they have been injured while receiving care.

2. Reporting on the implementation of effective safety practices by institutions should be established and made public.

3. Confidential reporting to a non-regulatory national entity should be the primary vehicle to collect information on adverse events and near misses and promote learning about them. Such a voluntary system should have strong confidentiality protections, provide incentives for reporting and create an effective basis for patient safety system improvement.

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

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

Proposed Strategy

This proposed strategy builds on the IOM recommendations but differs from them in four ways:

- Emphasizes the importance of disclosing errors to patients when care processes creates injury

- Emphasizes that patient safety improvements can best be achieved through a national voluntary, confidential and protected reporting system that is non-regulatory

- Recommends that public reporting focus on the implementation of effective safety practices by institutions and not on the number of errors reported

- Recommends incentives for persons to make timely reports. Such incentives could include providing protection for individuals reporting errors and making events that are reported eligible for reformed tort processes in the event of a claim

9

Proposed Elements

1. ## All patients should be informed when they have been injured while receiving care

   – Health care providers have a professional and ethical obligation to inform patients and their families about events that cause injuries. *The American College of Physicians--American Society of Internal Medicine (ACP-ASIM) acknowledges that physicians have a professional 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.*

   – This is an important step in being able to identify causes and develop solutions to prevent such injuries to other patients.

Proposed Elements

2. Reporting on the implementation of effective safety practices should be established and made public

   – The most significant improvements in patient safety occur within institutions as a result of appropriate priorities, structures and processes.

   – 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.

   – The public should receive information on institutional progress in adopting patient safety "best practices".

   – This type of information is more meaningful than reporting the number of adverse events and would inform patients about their health care organization's patient safety practices.

Proposed Elements

3. Confidential reporting to a non-regulatory national entity for adverse events and near misses

- Reporting should be encouraged from all stakeholders. Individuals submitting reports are assured confidentiality.

- Reporting should be easy, yet structured to capture adequate detail.

- Reports should be confidential, non-discoverable, and inadmissible. Following analysis reports should be de-identified and put into a publicly available database.

- Intentional unsafe or grossly negligent acts should not be included in this reporting system: any events that result from a criminal act, purposefully unsafe act, impaired individuals, or abusive conduct should continue to be reported to legal and regulatory channels—not the voluntary reporting system.

- Reports should be analyzed and used exclusively for quality and safety improvement—not punishment.

- The de-identified national database should be broadly available for analysis.

Proposed Elements

3. Confidential reporting to a non-regulatory national entity for adverse events and near misses (continued)

– The national database should be a useful tool for regulators and accrediting bodies to keep up with new developments related to patient safety effective practices.

– Incentive should be provided for persons to make timely reports. Such incentives could include providing protection for individuals reporting errors and making events that are reported eligible for reformed tort processes in the event of a claim (e.g., application nationally of California MICRA standards or no-fault compensation approach to injured patients).

– The entity receiving reports should analyze the reports, maintain a data repository, and issue safety alerts to improve the quality and safety of the health care system.

– Potential entities to carry out this role include NASA's Aviation Safety Reporting System (ASRS) or a public-private partnership such as the National Quality Forum.

Proposed Elements

4. Existing state mandatory reporting systems should focus on errors related to significant licensing violations

   – Existing mandatory state reporting should focus on areas of significant established regulatory standards and provide adequate confidentiality to support reporting

   – Additional state law in this area should be based on the evidence about the effectiveness of state mandatory reporting impact on improving patient safety. Priority should be placed on developing this evidence.

Proposed Elements

5. A National Center for Patient Safety should be established

   – The national center for patient safety should be established as a non-regulatory organization.

   – The national center should sponsor research on patient safety, identify effective practices to promote patient safety, and monitor progress on achieving goals.

Proposed Patient Safety Reporting System

Legend:

——————— Event Reporting

– – – – – "Best Practice" Reporting

·········· Learning

16
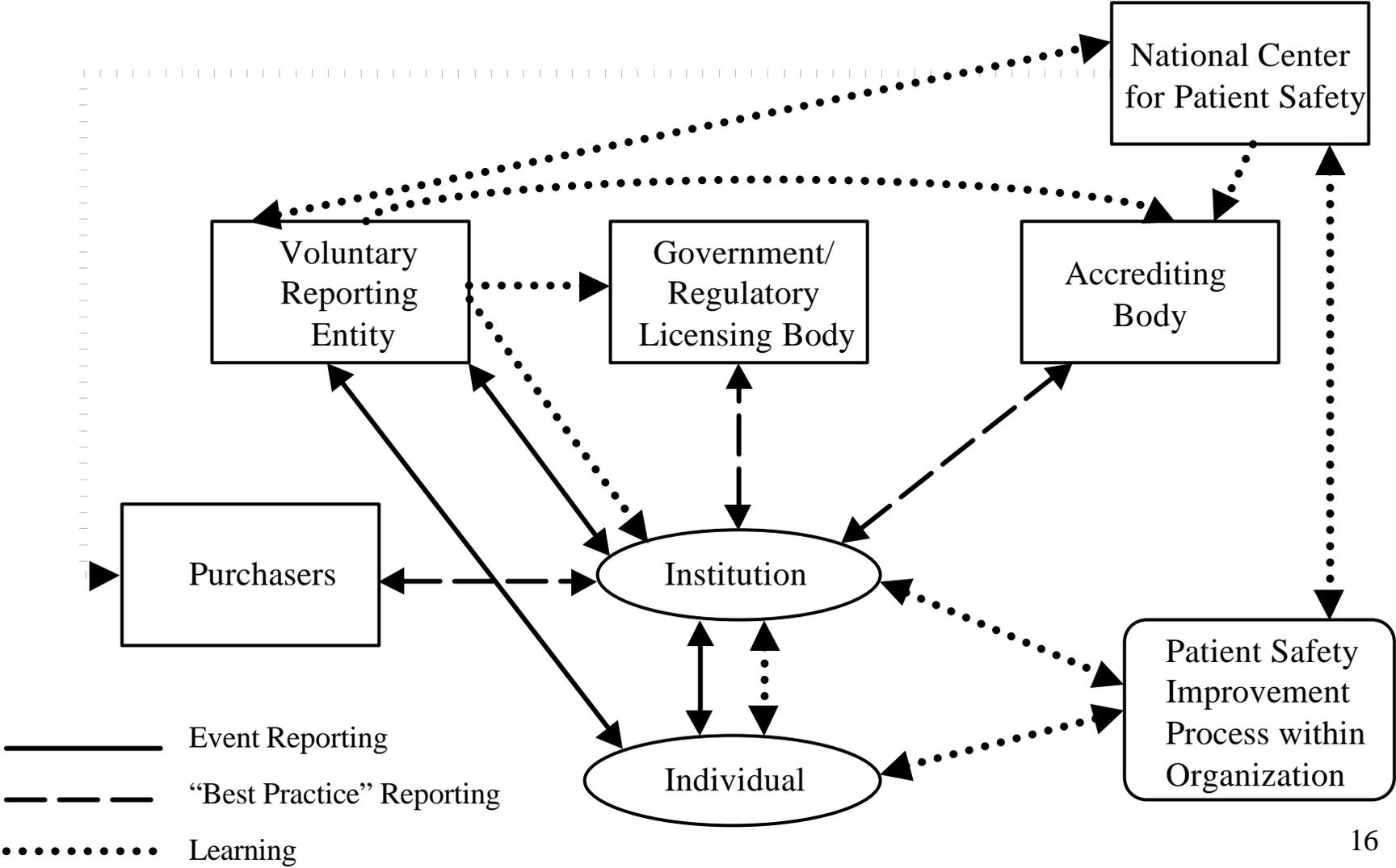
Error Reporting System Design Principles

Primary Goals of a Patient Safety Reporting System

- •Improve patient safety

- •Enhance public trust

By improving patient safety, public trust will be enhanced.

Design Principles: Public Trust

- Patient safety is the first priority.

- The health care system demonstrates its interest and actions in improving patient safety.

- Patients are treated as partners in the effort to reduce medical errors.

- Credible control systems and a credible reporting system are implemented.

- The information reported is used to improve patient safety.

- The public receives information on institutional progress in adopting patient safety "best practices".

Design Principles: Patient Safety*

- Patient safety is viewed as a top priority.

- Reports are used for prevention not punishment (i.e., non-punitive).

- The purpose of the reporting system is clear to all stakeholders.

- Reports are accepted from all stakeholders.

- Reporting of adverse events and close calls is encouraged.

- Reports are confidential (i.e., non-discoverable, inadmissible, de-identified).

- The system captures appropriate detail and is easy to use.

- Reports are analyzed by experts and effective corrective actions are identified.

- System vulnerabilities are identified.

- Reporters and stakeholders receive timely feedback.

- System testing occurs before there is a large scale roll-out of new initiatives.

- Incentives are provided to report errors and adapt successful safety practices.

* Builds on Quality Interagency Coordination Task Force (QuIC) recommendations

Potential Next Steps

- Prepare and distribute Roundtable results
- Discuss model and principles with others
- Develop coalition of supportive organizations
- Work with The National Quality Forum on patient safety reporting
- Organize experts to develop detailed design of proposed patient safety reporting system and potential pilot
- Identify legislative action needed to implement