

Report to the Hawaii State Legislature

by

The Patient Safety Task Force

of

The Healthcare Association of Hawaii

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Introduction

During the 2002 session the Hawaii State Legislature adopted H.C.R. No. 190, which requests the Patient Safety Task Force (PSTF) of the Healthcare Association of Hawaii (HAH) to submit a report of its efforts to reduce medical errors. The resolution recognizes the critical importance of creating a collaborative atmosphere in which people are willing to discuss problems with the intent of developing solutions to prevent errors in the future. The undesirable alternative is to create a punitive system of identifying and blaming individuals that results in the concealment of medical errors. This report is submitted in response to H.C.R. No. 190.

The PSTF was established by HAH in 2001 to take a proactive approach to address national and local concerns about patient safety. The mission of the PSTF is to bring representatives from all aspects of healthcare together in an open and blame-free environment to hold frank and full discussions about issues affecting patient safety in order to improve the quality of care delivered. The objectives of the PSTF are to:

- (1) Develop a plan for identifying, analyzing, and evaluating factors that affect patient safety;
- (2) Identify and recommend the utilization of best practices to improve the delivery and quality of health care; and
- (3) Promote community awareness through education and advocacy.

The PSTF agrees with H.C.R. No. 190 in that the system for reporting medical errors must be collaborative rather than punitive. With this in mind the PSTF has adopted an overall strategy to improve patient safety and has taken the initial steps to implement it.

The membership of the PSTF was originally limited to representatives of health care organizations. That membership has recently been expanded to include representation from nurses, physicians, pharmacists, consumers, and the State Department of Health.

Background

Patient safety has become a major concern of the general public and of policymakers at the state and federal levels. This interest has been fueled by news coverage of victims of serious medical errors and by the publication in 1999 of a report by the Institute of Medicine (IOM) entitled, "To Err is Human: Building a Safer Health System." In this report, the IOM highlighted the risks of medical care in the United States and shocked many Americans by its estimates of the magnitude of the number of deaths resulting from medical errors -- 44,000 to 98,000 deaths per year -- although these estimates were later revised downward by a subsequent study.

Beyond the cost of human lives, preventable medical errors exact other significant tolls, such as the expense of additional care necessitated by errors, lost income and household productivity, and disability. For hospitals alone, these costs are estimated at between \$17 billion and \$29 billion. Errors are also costly because they result in a reduced level of trust in the healthcare system by patients and diminished satisfaction for both patients and health care professionals.

The IOM report concluded that the majority of medical errors do not result from individual recklessness or the actions of a particular group. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Thus, mistakes can most effectively be prevented by re-designing the health system at all levels to make it safer. In short, conditions must be created that discourage people from making errors and encourage them to act in ways that ensure safety. Of course, even within an improved system, individuals must continue to be vigilant, and they must be held responsible for their actions.

Researchers now believe that most medical errors cannot be prevented by perfecting the technical work of individual doctors, nurses, or pharmacists. Improving patient safety often involves the coordinated efforts of multiple members of the health care team. In this regard, approaches from outside the health care industry have been reviewed for possible application to health care, specifically, practices from commercial aviation, nuclear safety, aerospace, human factors engineering, and organizational theory. Such practices include root cause analysis, computerized physician order entry and decision support, automated medication dispensing systems, bar coding technology, aviation-style preoperative checklists, promoting a "culture of safety," crew resource management, the use of simulators in training, and integrating human factors theory into the design of medical devices and alarms. After reviewing practices in different industries, the PSTF has determined that the most useful model is the one used in the aviation industry.

Key Issues

The Aviation Safety Reporting System as a Model for Hawaii

The health care industry is similar to the aviation industry in that they both involve high risks. The aviation industry has had a long history of incident reporting, analysis, and risk reduction. The Aviation Safety Reporting System (ASRS) is a successful and trusted, voluntary, confidential, non-punitive, safety program and reporting system with 25 years of operational experience. It provides incentives for people to report, ensuring that a sufficient number of reports are submitted so that a broad view of safety issues can be developed. It also ensures that enough relevant information is included in the reports, thereby enabling situations and conditions to be examined and appropriate changes made to effectively reduce risks. The system provides feedback to the operational community (which is both an incentive to report, and a risk reduction strategy in itself) as well as to regulators. The ASRS publishes alerts, and its de-identified database is available to all.

The ASRS system focuses on incidents, not accidents—using the same rationale that hospitals now use to focus on “near misses” or potential hazards, rather than wait for the accident to occur. However, the aviation model goes one step further by relying on expert analysis. The analysts are domain experts who serve to gain the respect of those who make the reports, and to ensure the maximum quality of report information and analysis. Reports are confidential yet not anonymous, so they allow for follow-up with the person reporting to get the best information possible.

The ASRS is the most advanced model of error reporting among all industries. It includes credible control systems and a credible reporting system. The application of the ASRS model to state and national medical error reporting is supported by the National Patient Safety Foundation and the Veterans Association’s National Center for

Patient Safety. The healthcare community, regulators and legislators would demonstrate to the public that patient safety is the first priority by adopting the ASRS model.

Voluntary reporting versus mandatory reporting

ASRS is founded on the concept of voluntary reporting, with an emphasis on improving the system rather than blaming individuals. ASRS recognizes that, when errors are identified, a collaborative atmosphere is needed to determine how the system can be changed to prevent errors in the future. ASRS understands that a collaborative atmosphere cannot co-exist with a punitive approach that emphasizes blame.

The PSTF rejects mandatory error reporting because it focuses on punishing individuals rather than promoting strategies to reduce risk or to warn others of a risk. Mandatory reporting systems are designed to identify “bad” practitioners and facilities and to punish them. Practitioners who are forced to report errors are less likely to provide in-depth information because the primary motivation of many would be self-protection, rather than helping others avoid the same tragedy. An emphasis on punishing individuals, rather than changing the system that led to the error, is a powerful deterrent to reporting. Furthermore, errors are caused most often by system flaws rather than individual mistakes. It is not usually clear who, if anyone, is “at fault.” As such, a reporting system that requires the individual “at fault” to report the error would result in many errors not ever being reported. Non-punitive, confidential reporting provides more valuable information about errors and their causes than mandatory programs.

Voluntary reporting provides frontline practitioners with the opportunity to tell the complete story without fear of retribution. The depth of information contained in these stories is key to understanding the error. Voluntary systems also encourage practitioners to report hazardous situations and errors that may not cause harm, but have the potential to do so. In a mandatory reporting system it is not feasible to require reporting of “near misses.” As a result, critical information about the hazardous situation is absent in most cases and any subsequent error prevention strategies are much less likely.

PSTF Activities

In developing a strategy to improve patient safety, the PSTF reviewed many reports from such sources as the National Academy for State Health Policy, the Institute for Safe Medication Practices (ISMP), the National Patient Safety Foundation (NPSF), the Veteran’s Administration’s National Center for Patient Safety (VA NCPS), and the Agency for Healthcare Research and Quality (AHRQ). (Please see the list of references on page 9. A concise, insightful article that appeared recently in the New England Journal of Medicine, entitled, “Reporting of Adverse Events,” by Lucien L. Leape MD is included in the appendix beginning on page 11.)

The PSTF strategy for improving patient safety involves improving policies, procedures, and structures within health care organizations, as well as educating consumers so that they are more aware of what they can do to help ensure their own safety. The PSTF has made efforts to educate health care organizations about “best practices” and to educate the general public so that they can be more involved with improving safety for themselves. In addition, the PSTF is developing a recommendation for creating a new agency to receive reports from health care organizations, to analyze them, and to feed

back recommendations for improving safety to all health care organizations. Furthermore, the PSTF is in the process of developing a more comprehensive educational campaign. To date, the PSTF has accomplished the following:

Systems focus

Health care organizations have an inherent commitment to relieve suffering and improve quality of life. The PSTF believes that by identifying, analyzing and evaluating factors that affect the optimal delivery of care, best practices can be identified and recommended to organizations for implementation or adaptation within their particular environment. The PSTF believes that consistent utilization of best practices within the complex systems that comprise the organization and delivery of health care in this nation will result in fewer medical errors and improved patient care and outcomes. Through representation on the PSTF, member organizations have been educated regarding this “systems thinking” approach to patient safety. In addition, national guidelines and tools published by the American Hospital Association and Veterans Association have been distributed via the PSTF to all hospitals for implementation.

Best Practices

The most significant improvements in patient safety occur within institutions as a result of appropriate priorities, structures and processes. PSTF members are provided with information regarding national sources for patient safety best practices. For example, the PSTF has identified and shared member organization best practices in the following areas:

- (1) Falls prevention;
- (2) Reducing risk of medication errors; and
- (3) Surgical site verification

Education

To date, the PSTF has educated member organizations and CEOs via membership, presentations to the HAH Board of Trustees, and dissemination of materials/tools, such as the AHA/VA toolkit. The PSTF is developing specific education programs for the public, physicians, nursing and pharmacy professionals, including those in training. PSTF member organizations participated in National Patient Safety Awareness Week by distributing information to patients, visitors, and staff about what they can each do to reduce the risk of medical error.

Disclosure of Adverse Events

All patients, and/or family members as appropriate, should be informed when they have been injured while receiving care. Healthcare providers have a professional and ethical obligation to inform patients and their families about events that cause injuries. The PSTF is assisting all Hawaii healthcare organizations to establish policies and procedures to ensure disclosure of every adverse event to patients/families. The PSTF offers a forum for healthcare organizations to share and learn from each other about the development and implementation of disclosure practices. In addition, the PSTF is developing an education program for physicians and other healthcare professionals

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

Recommendation

To support health care organizations in improving patient safety, the PSTF recommends that Hawaii adopt ASRS as a model for health care in Hawaii. Consistent with this recommendation, the PSTF endorses the concept of a non-regulatory agency that would receive confidential reports of adverse events and “near misses” or “close calls.” This agency would be staffed by experts to analyze the reports received from health care organizations, maintain a data repository, make recommendations for changes in policies and procedures to the reporting organizations, and issue safety alerts to all health care organizations to improve the quality and safety of health care in the state.

However, any event that results from a criminal act, a purposefully unsafe act, an impaired individual, or abusive conduct would continue to be reported through existing legal and regulatory channels. Existing state regulatory agencies would continue to focus on errors related to licensing violations. The proposed agency would not receive reports of intentionally unsafe or grossly negligent acts.

The proposed agency would analyze reports exclusively for systems change to improve quality and safety, and not for the punishment of individuals. Incentives would 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.

All stakeholders should be encouraged to make appropriate reports. Reporting should be made easy, yet sufficiently structured to capture adequate detail. Reports should also include descriptions of what organizations are doing to prevent re-occurrences. Individuals submitting reports should be assured confidentiality.

After reviewing error reporting systems in states throughout the nation, the PSTF has determined that Minnesota has the most appropriate model that can be adapted to Hawaii’s particular situation. In addition to assigning error reporting functions to an agency, the adoption of the Minnesota model would require amending Hawaii’s statutes to assure that reports to the agency are confidential, non-discoverable, and inadmissible in potential court cases. It should be noted, however, that de-identified report analyses would be made available to the public.

Conceptual design

In order to encourage high volume and high quality reporting, the PSTF proposes an error reporting system that would be non-regulatory, confidential, and non-punitive. Such a system would be in keeping with:

- (1) Patient safety standards established by the national Joint Commission on Accreditation of Healthcare Organizations for error reporting and promoting a culture of safety;
- (2) Recent proposed federal legislation; and
- (3) VA NCPS, NPSF, and ISMP position statements and practice.

A private agency should have the responsibilities for receiving and analyzing error reports, distributing risk alerts, and publishing summary reports. Ideally, the new agency would have the following characteristics:

- (1) Independence from regulators;
- (2) Ability to ensure confidentiality and to issue de-identify reports;
- (3) Expertise in patient safety analysis, such as human factors and root cause analysis;
- (4) Ability to “index” reports
- (5) Ability to provide summary reports to the public and to provide feedback to those who provide the initial reports;
- (6) Ability to receive and organize narrative reports from a variety of data submitters.

The PSTF has considered whether a new agency should be created or an existing agency assigned the responsibilities for receiving and analyzing error reports. In consideration of a variety of factors, the PSTF finds that a new agency is not needed. Instead, the PSTF recommends that these responsibilities should be assigned to the Hawaii Health Information Corporation (HHIC), an existing private non-profit agency that currently receives other types of data from hospitals and issues reports to the hospitals, State government, and the public. HHIC is the existing agency that most closely fulfills the above characteristics. Preliminary discussions have been held with HHIC, which has indicated a willingness to incorporate these new responsibilities.

The PSTF recommends funding the new error report function from private sources. During the coming year the PSTF will work with HHIC to develop a budget and identify potential funding sources, such as federal grants. The PSTF will also establish a timeline for implementation and develop performance measures to determine effectiveness. It should be noted that the State currently shares in the oversight of HHIC because of provisions authorizing the Director of Health or a representative to be a member of the board of directors of HHIC. The PSTF will also propose a bill for consideration in the 2004 session to amend Hawaii statutes to ensure confidentiality in error reporting.

2003 Goals

In 2003 the PSTF will develop the specifics needed to create an error report function within HHIC. The PSTF will also continue its education function. Specifically, the 2003 goals of the PSTF are to:

- (1) Fully develop a proposal to establish an error report function within HHIC, including a budget, timeline for implementation, and bill to amend State statutes to protect information provided in reports.
- (2) Develop and implement a comprehensive patient safety education program.

- (3) Continue identifying and disseminating patient safety best practices among member organizations via the PSTF forum.
 - (a) Ensure that member hospitals are analyzing staffing (not only adequate numbers of staff, but staff competency and skill mix as well) in relation to patient outcomes. Member healthcare organizations will be asked to incorporate a staffing analysis into their error reporting/analysis process, as appropriate, and staffing effectiveness will be a focus for the PSTF forum.
 - (b) In response to recent national attention to infections in healthcare organizations, the PSTF will include infection prevention as a topic for the PSTF best practice forum and for public education. For example, the PSTF could provide patients with information about what they can do to prevent infections from developing in the hospital setting.

References

- (1) Cohen MR. Why error reporting systems should be voluntary: they provide better information for reducing errors. *BMJ*. 2000;320:728-729. An examination of the reporting systems and barriers to widespread reporting. The latter includes fear or repercussion, that medical error reflects on competence, and legal discovery.
- (2) Cost Implications of State Medical Error Reporting Programs: A Briefing Paper, May 2001.
- (3) Institute of Medicine: *To Err Is Human: Building a Safer Health System* Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors; Committee on Quality of Health Care in America, Institute of Medicine.
- (4) Lessons from the Aviation Safety Reporting System, Charles Billings MD, Chief Scientist (retired), NASA Ames, April 2001.
- (5) National Academy for State Health Policy: *State Responses to the Problem of Medical Errors: An Analysis of Recent State Legislative Proposals*, February 2002.
- (6) National Patient Safety Foundation: Helmreich RL, Musson DM, Sexton JB. Applying aviation safety initiatives to medicine. *Focus Patient Safety*. 2001;4:1-2. A description of how aviation's approach to managing threat and errors can be applied to medicine.
- (7) Patient Safety and Medical Errors: A Roadmap for State Action, March 2001.
- (8) Reporting as a means to improve patient safety: roundtable discussion. March 2000.

Appendix

The appendix consists of an article entitled, "Reporting of Adverse Events," by Lucian L. Leape, a physician who is a recognized expert in the field of patient safety. The article appeared in the November 14, 2002 issue of the New England Journal of Medicine.