# Massachusetts Coalition
# for the
# Prevention of Medical Errors

## Final Report
## of
## The Accountability Project

***Presented to***
***The Betsy Lehman Center***
***for Patient Safety***
***and Medical Error Reduction***

**May, 2007**

## Executive Summary

The Massachusetts Coalition for the Prevention of Medical Errors undertook the Accountability Project to encourage hospitals and regulatory agencies in the Commonwealth of Massachusetts to partner on the establishment of a better way to investigate and report medical errors. Funding for the Project was provided by the Betsy Lehman Center for Patient Safety and Medical Error Reduction. A workgroup consisting of hospital-based patient safety experts, regulatory leaders in Massachusetts, regulatory board attorneys and representatives of consumers and state healthcare organizations conducted an analysis of the current Massachusetts regulatory system, which included interviews with key stakeholders and former patients and families, and developed a set of principles that could guide the development of an improved and better integrated regulatory system. A small test of a change was conducted to assess elements of a proposed new process designed by the Workgroup to investigate and report an adverse event. The Workgroup proposes a number of options to improve the current system which are delineated for further study and adoption.

There is not universal agreement among members of the Workgroup and key stakeholders about the best structure and process for an improved integrated system to analyze and report adverse events. It is the hope of all involved in the Accountability Project that the deliverables contained within this report will assist healthcare and public policy leaders in Massachusetts to commit to an agenda where all entities continue to energetically work together to build safe healthcare systems. The citizens of the Commonwealth of Massachusetts and the clinicians who deliver health care to them deserve nothing less.

**Introduction**

A series of papers published from the Harvard Medical Practice Study in 1991 reported that errors in hospital care were at least partly to blame for 98,000 deaths in the United States each year (1, 2). A subsequent report, issued by the Institute of Medicine (IOM), entitled "To Err is Human: Building a Safer Healthcare System" in November, 1999 validated these findings and captured the attention of both the lay public and professionals worldwide (3). While the IOM report was heard as the clarion call to the Patient Safety movement nationally, there was considerable activity related to patient safety already occurring in Massachusetts. A number of publicly reported medical errors, including the high profile death of journalist Betsy Lehman, had raised concerns about the Massachusetts health care delivery system and the processes which existed to investigate and report medical errors. Attempting to address these problems, the Massachusetts Department of Public Health clarified regulations for reporting and the Board of Registration in Medicine reissued an oncology advisory issued a year before. Consistent with activity in several other states where diverse groups were coordinating efforts to build public/private patient safety coalitions to enhance patient safety, a group of health care leaders in Massachusetts formed to lay the groundwork for the Massachusetts Coalition for the Prevention of Medical Errors (Coalition) (4). The original members of the Coalition included leaders from the Department of Public Health, the Board of Registration in Medicine, the Patient Care Assessment Committee, the Massachusetts Hospital Association, and the Massachusetts Medical Society.

The landmark studies of the epidemiology of medical errors, coupled with the learning generated from the events in Massachusetts, pierced the myth that clinicians are

infallible and dispelled the traditional notion that sanctioning or removing flawed practitioners while making no changes to the practice system assured patient safety. It became generally accepted that medical mistakes are rarely isolated events, but rather are frequently part of larger system problems that set up the adverse event or enable it to occur. The ubiquitous nature of problems with quality and safety in American healthcare and the disparity which exists between the care that is actually provided and the care that should be provided has been well documented (5). The surest way to keep patients safe is to bring about effective and lasting safety improvements by the prompt and impartial recognition, analysis and correction of system failures.

The Accountability Project (Project) of the Massachusetts Coalition for the Prevention of Medical Errors was initiated in 2002 and sought to encourage hospitals and the regulatory system in Massachusetts to partner to find a better way to investigate and report medical errors that would address individual as well as system accountability, improve the learning which can come from mistakes, decrease confusion and redundancy in reporting, protect the public from unsafe practitioners and unsafe systems and, most importantly, increase the safety and sense of trust and well-being of all consumers and specifically patients and families receiving healthcare in Massachusetts.

What the Project proposes is a model built on the premise that all hospitals and regulatory entities in the Massachusetts healthcare system hold the dual responsibility for assuring accountability and learning from medical error at their core. The model includes:

- Definition of the elements of accountability that acknowledge the responsibilities of system leaders and clinicians in the course of providing care, as well as responsibilities after an event occurs.

- An environment of accountability and learning that invites, stimulates and supports the reporting of incidents and medical errors by patients and their families, consumers, and all who work within the healthcare system;
- Prompt and reliable response to events reported internally within hospitals and externally to appropriate regulatory and accrediting agencies within a codified structure where all can openly discuss their understanding of what happened without fear of reprisal or harm;
- Public reporting of The National Quality Forum's (NQF) List of Serious Reportable Events in Healthcare (6), along with other events designated as reportable in Massachusetts through the Department of Public Health;
- A confidential multidisciplinary reporting process, through the Patient Care Assessment Committee of the Board of Registration in Medicine, which uses the best professional judgment of patient care experts to oversee the hospitals' safety systems and assures that necessary improvements are made;
- Preparation of an annual plan by the Betsy Lehman Center for Patient Safety and Medical Error Reduction which integrates information about patient safety issues obtained from a number of sources throughout the Commonwealth and prioritizes those issues for action;
- Assurance to the public that, in the case of an adverse event, both healthcare systems and regulatory bodies understand together what went wrong, agree on improvements, and guarantee implementation to insure that the event will not happen again.

**History of the Project**

The Massachusetts Coalition for the Prevention of Medical Errors was established in 1998 to improve patient safety and reduce medical errors in Massachusetts. The impetus for the Coalition's development came from leadership efforts that were already in place through several state agencies and professional associations to address issues of public accountability, reporting, and learning. Realizing that interdisciplinary practice and collaboration are essential processes in error reduction, the Coalition's membership was designed to include regulators, providers, healthcare associations, professional boards and consumers who could work together to disseminate knowledge and information about the causes of adverse events and develop strategies for prevention. In 2002, the Coalition membership agreed to undertake the goal of defining and implementing a consistent, effective and fair process for evaluating system and individual accountability for medical errors in the Commonwealth. This initiative was called "The Accountability Project".

The Coalition commenced the Accountability Project initiative by conducting a literature review and bringing together approximately ninety-five officials, patient safety experts and patient representatives from the Massachusetts health care community and around the country to develop a vision for the Project and set initial priorities (7). In September 2003, a conference funded by the Agency for Healthcare Research and Quality (AHRQ), entitled *Enabling Safer Healthcare: a Statewide Effort to Align Perspectives on Accountability and Responses to Adverse Events – Part I,* generated the vision that "in the management of incidents/adverse events, all segments of the Massachusetts healthcare system utilize a jointly derived framework for accountability that is broadly viewed as just," along with the following goals:

1. Develop and broadly disseminate a common language and process to insure prospective and retrospective accountability across the healthcare system;

2. Encourage all parties to look collaboratively at errors that occur, focusing on a comprehensive review at the system level, prevention in the future, and learning;

3. Pursue opportunities to integrate the reporting of errors to various regulatory bodies;

4. Break down barriers across the state to encourage institutions to share lessons learned in order to minimize errors; and

5. Define a clear policy regarding human error, as well as system error, and explore how to address recurrent questionable performance, competency testing and training.

Another conference was held in November 2004 and generated the first version of an "Accountability Matrix", which describes best practices for clinicians, organizations and regulators to ensure a fair and just culture of safety and accountability as well as responsibilities of those stakeholders in responding to medical errors after they occur (Attachment 1).

In January 2005, funding for the Accountability Project came from The Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center), an entity established by the Massachusetts legislature in 2001 to serve as a clearinghouse for information about medical errors across the Commonwealth. The Lehman Center contracted with the Coalition to achieve the following deliverables:

1. A description of the current system of accountability in Massachusetts;

2. Proposed principles and process for an improved way to investigate and report medical errors, which includes a clearly stated vision, objectives and an Accountability Matrix defining best practices for clinicians, hospitals and regulators before and following an adverse event;

3. A conference where information learned in the course of the Project's work could be disseminated;

4. A final report of the Project's work for the Coalition and the Lehman Center; and

5. Publication and dissemination of findings to the professional community whose efforts are focused on improving patient safety.

A consultant was hired in March 2005 to manage the work of the Project. In May 2005, a Workgroup was convened consisting of hospital-based patient safety experts, regulatory leaders in Massachusetts, regulatory board attorneys, and representatives of major state healthcare organizations to begin analyzing the current system for reporting medical errors in Massachusetts and making recommendations for an improved process for investigating and reporting adverse events (Attachment 2). Two well-recognized leaders in the patient safety movement in Massachusetts, James Conway and Dr. Allan Frankel, were named to co-chair the Project, and along with Paula Griswold, Executive Director of the Coalition, and Eloise Cathcart, Project Consultant, constituted the Project's leadership team.

**The Workgroup**

The Workgroup met as a whole eight times from June 2005 to June 2006. The first three meetings focused on identifying the strengths and weaknesses of the current Massachusetts reporting system by discerning how it actually works. By December 2005, the Workgroup had begun to delineate the elements of an improved process to investigate and report an adverse event. That subject continued to be the focus of the Workgroup's agenda until June 2006. The Coalition's contract with the Lehman Center outlined that the scope of study would include only acute care hospitals in Massachusetts and the regulatory bodies most often involved with hospital error: the Department of Public Health's Division of

Health Care Quality; the Department of Public Health's Division of Health Professions Licensure, which houses the Board of Registration in Nursing and the Board of Registration in Pharmacy; the Board of Registration in Medicine, including both the Enforcement Division and the Patient Care Assessment Committee; and the Lehman Center. Masspro, the Quality Improvement Organization in Massachusetts, was invited to participate in the deliberations. The scope of the project included only hospital-reported events, not investigations arising due to complaints.

In addition to conducting the work described above, the Workgroup spent considerable time and thought learning about the ways hospitals and regulatory boards distinguish between individual and system accountability. While hospital leaders might earlier have believed that patient safety problems were the result of the behavior of individuals, safety science has highlighted the role systems play in errors. Recognizing that the sanction or removal of the involved clinician does not assure that a mistake will never happen again, these leaders have begun to undertake more rigorous and realistic internal assessments of their own policies, processes and systems surrounding an adverse event. By the same token, regulatory boards have recognized the limitations in their traditional approach of focusing solely on individual practitioners who have been reported to a board for disciplinary investigation because of some error or breach in the standards of safe practice. In addition to understanding how systems issues (e.g. resources, organizational structures and processes, level of collaboration, technology) might have contributed to the actual error, it is also important for hospitals and regulatory boards to understand the practitioner's intentionality and judgment in the situation being examined. The fact that it is impossible to accurately and fairly evaluate the practitioner's judgment and actions or prescribe effective remediation without understanding the context in which the actual event

occurred can no longer be ignored. The nature of investigations conducted by hospitals and regulatory boards has evolved from collecting information to build a case against the individual clinician to collecting information that can illuminate the understanding of what went wrong. This fact has significant implications for how hospitals collect and analyze information and report that information to regulatory bodies. It also changes the regulatory bodies' requirements for what constitutes an adequate report of an adverse event.

Informed by the work of Reason and Marx and the concept of practice responsibility (Attachment 3), and building on the practical knowledge and experience of some of its members, the Workgroup enhanced a root cause analysis (RCA) tool (Attachment 4); originally developed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which could be used to collect and organize information necessary for system learning after an adverse event (8, 9, 10, 11). The RCA tool was designed to bring about a shared understanding of what happened, why the event happened and what could be done to prevent it from happening again. It was the belief of the Workgroup that an effective, codified organizational process for root cause analysis is a central part of a robust patient safety program which, in turn, is an essential component of a culture of safety.

Recognizing the interdependence of regulatory boards and employers in assuring the continued competence of clinicians actively engaged in clinical practice, the Workgroup also discussed ways to enhance collaboration between hospitals and regulatory agencies and the ways in which regulatory bodies might actually drive safety in their own right. They examined the Citizen Advocacy Center's (CAC) Practitioner Remediation and Enhancement Partnership (PREP), a pilot project funded by Health Resources and Services Administration (HRSA) and administered by CAC in cooperation with the Administrators in Medicine (AIM) and the National Council of State Boards of Nursing (NCSBN) (12). The program

offers a framework in which state medical and nursing boards work with hospitals and other health care organizations to identify, remediate and monitor health care practitioners with knowledge and skill deficiencies that cause concern but do not rise to the level of precipitating disciplinary action. Working together in a non-punitive way, clinicians, hospitals and licensing boards can identify and correct individual practitioners' clinical deficiencies and may discover systemic issues that jeopardize patient safety in the process.

The Workgroup also reviewed initiatives similar to this Accountability Project underway in other states. These include the Minnesota Alliance for Patient Safety, a collaborative among the Minnesota Hospital Association, professional regulatory boards and the Minnesota Department of Health; a pilot program underway at the North Carolina Board of Nursing wherein this board actively collaborates with hospitals in addressing practice deficiencies and remediation of nurses who come to the board's attention; and the Just Culture principles from the Dana Farber Cancer Institute (Attachment 5); and practices at the M.D. Anderson Cancer Center in Houston. The Workgroup also examined the newly revised "Model Principles for Incident-Based Peer Review for Heath Care Facilities" of the Massachusetts Medical Society, which are intended to assure that the statutorily driven peer review processes for physicians in Massachusetts meet the goal of quality improvement while being fair, transparent and credible. (Attachment 6)

**Meetings with Key Stakeholders**

As the Workgroup proceeded in its deliberations, a parallel set of meetings among key stakeholders and the Project Leadership Team occurred (Attachment 7). The purpose of these individual meetings was to ascertain stakeholders' understanding of how the current system works, what the role of their particular agency is in the current regulatory framework,

and to elicit ideas for improvement to the current process. It was recognized that in order to accomplish the transformation in state healthcare policy that an improved system for accountability could bring about, it was important to determine the readiness of key stakeholders to buy in to the vision while being assured that their particular concerns and perspectives were understood and respected.

**Focus Group Meeting with Former Patients and Families**

In addition, a focus group of former patients and families who had either participated in the Medically Induced Trauma Support Services (MITSS) or contacted state regulatory agencies around an incident of unsatisfactory care met to describe the circumstances of their particular experience and offer recommendations for improvement in the healthcare and regulatory systems. The group's major concerns centered around poor or absent communication between them and their healthcare providers, lack of acknowledgement to them that something had gone wrong with their care or that of a family member's, a fear of retribution if they expressed their discomfort with care and a sense of being unheard or dismissed by those to whom they entrusted their care. They also discussed ways in which hospitals appear to shield themselves from a patient's dissatisfaction with care, and they described their perceptions of the lack of helpfulness from "patient advocates" whose ultimate responsibility was to the employing hospital. Participants noted that staff at DPH/Health Care Quality Division were compassionate and attentive and provided guidance to them about how to process a complaint. The final report from DPH/HCQ, however, was often disappointing to them because it was a succinct "clinical report of what happened" when their hope had been for a full explanation of what went wrong with assurance that the event would never happen again to them or someone else (Attachment 8).

**Assessment of the Current Massachusetts Regulatory System**

Within the current system, the Massachusetts Department of Public Health's Division of Health Care Quality is mandated by state and federal statutes to license and certify healthcare facilities in Massachusetts and investigate complaints about care provided in those facilities. The DPH/HCQ always responds to the report of an adverse event by conducting an official review which may occur at the hospital or off site. The ultimate sanction of DPH/HCQ is to suspend or revoke a facility's operating license. Presently, the DPH/HCQ commonly makes referrals to professional licensing boards about practitioners involved in adverse events.

There are several regulatory boards housed in one of three entities: the Department of Public Health/Division of Health Professions Licensure, the Office of Consumer Affairs and Business Regulation, and the Board of Registration in Medicine. All regulatory boards exist to assure the on-going competence and good moral character of clinicians who seek to practice in a specialty within the particular board's jurisdiction.

The Board of Registration in Medicine houses two entities: the Enforcement Division, which carries out the mandate common to other regulatory boards, and the Patient Care Assessment Committee (PCAC). The PCAC came into existence in 1986 when the Massachusetts legislature passed the Medical Malpractice Reform Act. The PCAC is statutorily authorized to oversee mandated programs of quality assurance, risk management, utilization review, peer review and credentialing in any setting where medicine is practiced. Despite its location within the Board of Registration in Medicine and its funding, which comes predominantly from fees paid by physicians for initial licensure or relicensure, the PCAC is primarily focused on the function of the healthcare organization rather than on

individual practitioners. The PCAC review processes examine the organization's executive and medical leadership structures and functions and the activities of *all* hospital employees. As a byproduct of this systems evaluation, individuals may be deemed culpable, but this is not the purpose of the PCAC evaluation. Satisfactory participation by a healthcare setting in the PCAC program is a condition of hospital and physician licensure. (M.G.L. c. 111, §203, and M.G.L. c. 112, §5; .243 CMR 3.00 et seq.)

A summary assessment of the current Massachusetts regulatory system was derived from the analysis of the Workgroup and the discussions with key stakeholders and former patients and families. It was noted that the regulatory programs have made improvements in recent years, some quite significant, but there are issues that remain. While everyone was able to identify problems and a sense of frustration with aspects of the current system, there was an overwhelming commitment to quality, patient safety and protection of the public, a legacy of important work to date, as well as openness to a new vision. The following broad statements, while not occurring in every case or in every setting, represent the views of the Workgroup, key stakeholders and former patients and families:

1. There is perceived underreporting of medical errors in the Commonwealth of Massachusetts. Healthcare institutions underreport medical errors because they do not have reliable systems to identify and analyze adverse events, and clinicians can be reluctant to report them within the organization. This may be exacerbated by the $20,000 charitable immunity cap on hospitals in Massachusetts, which leaves physicians and nurses fearful that reporting an error may result in their facing a malpractice suit since the liability of the hospital is so limited.

2. Hospitals that have instituted vigorous internal patient safety programs describe the complexity of reporting requirements, which can create confusion about the

appropriate regulatory agency or agencies to which the report needs to be made, the expected content and timing of reports, the format for the report, and what happens after the report is made. Similar information about a single adverse event can be requested by different regulatory bodies, resulting in redundant work efforts by staff. These hospitals cite the significant human and financial resources that are necessary to meet the requirements of the current system.

3. As they operate under existing statutory authority, the regulatory boards have different requirements for mandatory reporting and little coordination of work processes and information management.

4. In addition to these agencies, there are other organizations where complaints, concerns or occurrences related to patient care can be addressed. These agencies are often independent, and it is not unusual for multiple agencies to be investigating the same issue at the same time (Attachment 9).

5. Clinicians and hospitals reported a lack of understanding of criteria by which their actions are evaluated, believe the criteria may change from one situation to the next, and there is no assurance that people investigating adverse events are experts in the clinical areas being reviewed or have a sufficient understanding of human factors science.

6. Regulatory agencies follow different mandates, and therefore their processes and findings are uncoordinated. Regulatory bodies may receive different information about the same event at different times. Findings may be reported to the hospital at different times by different agencies and can, in theory, conflict with one another. The regulatory entities have different legal access to descriptive information surrounding an adverse event. For example, the Board of Registration in Medicine

has subpoena power so hospitals tend to comply with requests for information. The Board of Registration in Nursing does not have subpoena power prior to the issuance of an order to show cause (the initiation of a disciplinary/adjudicatory proceeding). The board must rely on information that is self-reported by the involved nurse or is submitted voluntarily by the hospital in response to the board's request during the investigatory phase when it is making a determination about whether an adjudicatory or disciplinary proceeding should be initiated. Only after the decision is made to initiate such a proceeding is the Board of Registration in Nursing able to subpoena hospital information. The result is that decisions may be based on incomplete information. The Board of Registration in Pharmacy regulates the practice of pharmacists and pharmacy technicians at in-hospital pharmacies (in addition to community retail pharmacies) and has the authority to request information from hospitals.

7. Some investigations are confidential, while others are public. There is an active debate which events should be publicly reported and which should remain confidential.

8. There is no established process for patient safety issues derived from hospital or regulatory system review to be referred to the Lehman Center for further study.

9. There is a tension between public accountability and reporting and peer review protection.

10. In general, hospitals do not have the infrastructure or processes which allow patients and families to have input into decisions affecting their own care or into hospital policies and practices. Generally, there are not transparent or codified

processes in place by which providers and families can know what to expect and what to do when an adverse event occurs.

**Principles of an Improved Integrated Regulatory System**

The Workgroup then proceeded to identify a set of principles upon which an improved integrated system for assuring accountability, protection of the public and a fair and just culture could be based. These principles could serve as guidelines for all hospital and regulatory systems structures and processes:

1. Healthcare settings should have strong and highly effective systems to assure accountability and learning from adverse events and near misses.
2. Clinicians should readily demonstrate accountability for providing safe and effective patient care.
3. Hospital governing boards and executive leadership should ensure that processes that are easily accessible exist for patients and families to address concerns about their care. Patient and family advisory councils should be embedded into the infrastructure of hospitals so that the voice of the patient and family is heard in all hospital policies and decisions.
4. All adverse events in Massachusetts should be reviewed within an integrated system which actively and intentionally supports accountability and learning, and focuses on quality and patient safety and protection of the public.
5. As part of the process of investigating adverse events, patients and their families should be informed about what happened, provided support and given information to demonstrate that their concerns are being addressed.

6. The process for investigating adverse events should be fair and just, informed by human factors science, and should include timely support for the caregiver and remediation of the caregiver when appropriate.
7. Situations that impair a clinician's ability to practice safely (e.g. substance abuse, mental or behavioral issues, medical illness, or deficits in knowledge and skill) should be addressed promptly and respectfully. The system should have safeguards which prevent an unsafe practitioner from moving from one institution to another.
8. Standardized approaches should be used in the analysis of adverse events and near misses. This may include a common language (e.g. The NQF List of Serious Reportable Events in Healthcare), standardized tools (e.g. root cause analysis format), accountability algorithms, and principles of peer review.
9. Reviewing bodies should be composed of expert practitioners from all involved disciplines who are knowledgeable about human factors science.
10. The ideal system would reconcile the disparate goals of accountability and learning. Accountability requires public disclosure and review. Confidential review is often appropriate for learning, regardless whether cases are individual or aggregate; confidential review will provide greater access to information from the facility, such as peer-review protected information.
11. Comprehensive reporting should be done once and there should be no duplication of effort. The investigation of an adverse event should be done in a coordinated way, and recommendations to the organization ought to be consistent and made in a timely manner even though different regulatory bodies may be involved. The decision-making framework used by reviewers should be publicly available and understood.

12. Organizational structures and relationships should be designed to support an integrated system of accountability and learning.

**Lessons Learned from a Small Test of Change**

An initial small test of change was conducted to test a proposed new model designed by the Workgroup to investigate and report an adverse event . (The initial test was conducted with the DPH/Health Care Quality Department. Circumstances prevented the PCA Division from participating, but a test with PCA, and other organizations, would be valuable in the future.)

The proposed improved process establishes a scheduled meeting between DPH/HCQ and the hospital in lieu of an unannounced visit. This planned meeting affords the hospital sufficient time to conduct a comprehensive and thorough root cause analysis of the adverse event. The integrated collaborative process brings the two entities together to openly discuss and question the circumstances surrounding the event, so that both parties can be satisfied that a complete understanding about what happened has been reached, along with why the event happened and what actions the hospital has put into place to assure that the event will not happen again. The process preserves the prerogative of the DPH/HCQ reviewers to obtain more information if they are unsatisfied with what the hospital has put forth. In addition, the planned meeting eliminates the time lost for both the DPH/HCQ reviewer and the hospital, which is created when records need to be retrieved and staff summoned for an unannounced visit.

The steps in the proposed improved process are delineated below:

- The hospital recognizes that an adverse event has occurred and takes immediate steps to insure the safety of the patient, family and staff. Hospital leadership makes

an initial assessment of the event to determine what happened, that all are safe and that any obvious causative factors have been addressed.

- Within 48 hours, the event is reported to the DPH's Division of Health Care Quality (DPH/HCQ).
- A meeting between the hospital and DPH/HCQ is scheduled within 21 days.
- The hospital conducts a comprehensive and thorough root cause analysis (RCA) before the meeting which includes all clinical staff involved in the event. The hospital develops a proposed improvement plan to assure that the event will not happen again. The plan reflects the comprehensive assessment and improvement process that has been underway since the event was discovered.
- The meeting to review the RCA and improvement plan is co-chaired by a member of the hospital and DPH/HCQ.
- At the meeting, the RCA and the improvement plan are reviewed. Both parties may agree that the information is adequate or that additional information needs to be collected. The DPH/HCQ may decide to conduct additional interviews or review additional records. Root causes and the improvement plan are agreed upon along with a mechanism to track and insure the hospital's follow through.
- After agreement on the RCA and the improvement plan for the hospital, the Reason algorithm is applied to distinguish between individual and system accountability. If there might be individual accountability of a reportable nature, the information would be referred to the appropriate regulatory board.

The Brigham and Women's Hospital, a major Harvard teaching facility in Boston and a member of the Partners Healthcare System, and the DPH/HCQ tested the hypothesis that a scheduled meeting between the two entities to review the completed RCA tool would be

perceived by hospital patient safety leaders, DPH/HCQ reviewers and hospital staff as preferable to the unannounced visit which currently occurs. It was hoped that the learning and process improvement which ensued could be an initial step in transforming the current Massachusetts system. The case which was reviewed involved a programming error with an implantable pump which occurred despite several checks of the procedure, and no harm reached the patient.

While the DPH/HCQ reviewers were satisfied with the RCA and the hospital's plan for improvement, both reviewers thought that the severity level of this case did not call for an in-depth on-site review. There was agreement that application of the Reason algorithm to the events surrounding the error did not raise the potential for individual accountability that would require reporting to the respective regulatory board(s). The physician involved in the review process volunteered that preferred this method to previous ones in which he had participated. The hospital intended to report the event to the PCAC at the end of the quarter. It was agreed that the process should be repeated by selecting a case of sufficient magnitude and severity that would predictably have more value to DPH/HCQ and fit more closely with the Division's regulatory mandate.

A separate meeting occurred with members of the three regulatory boards of Medicine, Nursing and Pharmacy to apply the Reason Algorithm to an actual redacted case. The intent was to explore whether this algorithm would be useful to the boards in differentiating between individual and system accountability in the case of an adverse event (Attachment 10). This meeting highlighted the issue that the systems context of the event is not fully available to the Board of Registration in Nursing in its deliberations about whether to initiate an adjudicatory hearing. This was identified as a concern since the application of the algorithm requires information about the system contributions to the event.

**Options to Achieve an Improved Integrated System**

In order to achieve an improved and better integrated system, the Workgroup offers the following options for further study. The options are derived from the collective expertise, experience, wisdom and thoughtful deliberation of the Workgroup, and it is hoped that further analysis will lead to agreements on implementation. It is well recognized that strong leadership and clear direction will be required to move from the current state to an improved environment for patient safety (13).

**Agency Roles**

DPH/Health Care Quality Division

1. Establish that cases reported by law to DPH/HCQ for public accountability are transparent
2. The NQF Serious Reportable Events in Healthcare plus other events required by Massachusetts law would be reported to DPH/HCQ.
3. DPH/HCQ would publish an annual report that lists all hospitals and their reported Serious Reportable Events in Healthcare by category and number.

Regulatory Boards

4. For regulatory boards, insure that codified processes are implemented to differentiate individual and system accountability. Oversight of all licensed health professionals should occur in consideration of the systems context of the event, and the review bodies should include expertise in safety science.
    - Review of the clinical practice of specific physicians should be conducted by their peers.
    - Review of standards of care of specialists should be confirmed by review by appropriate specialty societies.
5. Remediation should address the real causes of substandard care and patient harm and result in a change in the clinician's practice.
6. Ensure that hospitals and regulatory boards work effectively and efficiently in a formalized way to assure continued competence of all practicing health care professionals. Consider implementing approaches based on the Practitioner Remediation and Enhancement Partnership model

Patient Care Assessment (PCA) Program

7. Events reported within the purview of PCAC are confidential.
8. PCAC would focus on evaluation and monitoring the hospitals' quality and safety systems and assuring that necessary improvements are made.
9. Expand the PCAC structure and processes so that the review body is multi-disciplinary and has greater expertise in safety science.

10. PCAC could be available to hospitals for consultation in the RCA process.

Betsy Lehman Center for Patient Safety and Medical Error Reduction

11. The Lehman Center shares lessons learned, and creates a library for ongoing access by providers and consumers.
12. The Lehman Center identifies priorities for research and best practices. The center conducts that work in consultation and coordination with provider organizations, consumer groups and other agencies.

**Education/Expanding Shared Learning**

13. Institute a core curriculum in safety, reporting, and a fair and just culture that is widely available, continuously updated and user-friendly, and require participation by all clinical staff, hospital leadership and regulatory bodies within the Commonwealth.
14. Reports to DPH/HCQ and PCAC, and reviews by regulatory boards should identify lessons to be shared with other hospitals and providers; these agencies could share these lessons directly with all health care providers. In addition, these lessons, along with priorities for research and development of best practices for safety, are all passed on to the Lehman Center, which provides ongoing access to those lessons.

**Patients, Families, and Caregivers**

15. Hospitals should be accountable for implementing the recommendations put forth in the document *When Things Go Wrong: Responding to Adverse Events – A Consensus Statement of the Harvard Hospitals* to insure that patients, families, caregivers and hospital leaders appropriately address concerns about care (15)

**Coordination**

1. Institute use of a standardized RCA tool and root cause analysis process throughout the Commonwealth. The standardized Root Cause Analysis tool could be adopted as best practice by the Lehman Center, which would then offer training to hospitals throughout the Commonwealth.
2. Standardize taxonomy used in all reported information so that data generated by regulatory Boards, DPH and the Massachusetts QIO on similar issues lend themselves to common interpretation, by all governmental entities with access to the data and by a peer-review protected QIO.
3. Establish a process to eliminate the rework which occurs with redundant and duplicative reporting.
4. Continue small tests of change to identify improvements to the current processes.
5. Establish a process by which all principals of the Massachusetts regulatory system routinely come together to discuss key issues.
6. Attention should be given to findings from a study planned by researchers at the Harvard School of Public Health to identify which events are currently reported to DPH/HCQ and which are reported to the PCAC (14).

**Conclusion:**

The Workgroup of the Accountability Project has taken a focused look into the culture of healthcare in the Commonwealth of Massachusetts. The current system benefits from the proud legacy embedded within the state's hospitals, across its regulating and accrediting bodies, and throughout its professional associations to provide the best care to those who seek it. At the same time, there is no question that the highest quality and safest healthcare for Massachusetts citizens is not reliably assured.

There is an awesome potential which could be realized if all the entities in the Massachusetts healthcare system worked collaboratively to willingly share knowledge of best practices to keep patients safe. This report, describing the work of the Accountability Project, makes the case that significant benefits could accrue to the citizens of the Commonwealth from serious partnerships among the state's hospitals and regulatory bodies designed to build safe healthcare systems.

Accountability stands as an important reminder that our moral choices, rather than simply legal, professional or economic, should guide our public policies when dealing with error in medicine (16). Our ethical mandate as a healthcare community demands that we individually and collectively commit to this agenda. Those among us who need healthcare and those who deliver that care deserve nothing less.

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## Attachments

1. Accountability Matrix
2. Accountability Project Workgroup Members
3. Frameworks for Patient Safety Science
4. RCA Tool
5. Dana Farber Cancer Institute Principles of a Fair and Just Culture
6. "Model Principles for Incident-Based Peer Review for Heath Care Facilities" of the Massachusetts Medical Society
7. List of Key Stakeholders Interviewed
8. Report of the Former Patient/Family Focus Group[
9. Reporting Inventory
10. Reason Algorithm
11. List of Coalition members

*Attachment 3:* Frameworks for Patient Safety Science

The Workgroup studied the work of James Reason, a British physician who is a renowned leader in the science of human errors (6). Reason posits that serious errors are more often the result of system flaws that are usually hidden within the system than of a single individual doing something explicitly inept. He introduced terminology and processes which describe the multiple phenomena associated with an adverse event. According to Reason, the *sharp end* is the point of vulnerability in a system where expertise is applied, errors are experienced and failure is visible. It is the place where the collective professional capabilities of the organization rest in the hands of one or more practitioners working in a highly dynamic and changeable environment where successful outcomes may be routine but cannot be assured. By contrast, the *blunt end* is the work of management, governance, regulation, suppliers, payors and purchasers. Flaws in the extensive infrastructure of knowledge, investment, performance history and invested capital can be instantly revealed by the human mistakes of someone working at the *sharp end*.

*Active failures* are unsafe decisions, acts or omissions committed at the sharp end, while *latent failures* occur at the blunt end and are difficult to associate with individual practitioners. *Latent failures*, often inadvertently introduced into the system as a consequence of other decisions and system changes, may be hidden in work processes and reflect high-level decisions and organizational culture. To understand error it is essential to have stories both from the *sharp end*, often more dramatic and sensational, and the *blunt end*.

Reason's "*Swiss Cheese Model of Accident Causation"* is a useful tool for deconstructing error by describing how faulty systems and multiple aligned errors, rather than the error of a single individual, create the conditions for harm to reach the patient. Reason also described

a structured algorithmic approach to distinguish individual and system accountability. Reason's *Unsafe Acts Algorithm* facilitates the comprehensive investigation of an adverse event by focusing on key issues and bringing out systemic functions that must be examined. The algorithm is also a codified method that leads to fairness and openness for staff. The issue of *hindsight bias*, the influence in perception of an event that comes with knowing the outcome, is always present and cannot be avoided but must be accounted for in the analysis of an error. *Hindsight bias* occurs when observers of past events exaggerate what others should have been able to anticipate in foresight.

The Workgroup also studied the work of David Marx, a human error management consultant who assists hospitals, air carriers and regulatory bodies to develop safety-supportive enforcement and disciplinary systems (7). Like Reason and other patient safety experts, Marx supports the belief that errors are most often the result of system problems. He coined the term "Just Culture" to describe a work environment that emphasizes learning rather than blame, where any employee can openly discuss errors of commission or omission, process improvements and/or systems corrections without fear of reprisal. Marx's work examines responsibility for system and individual performance surrounding risk-taking behavior and the role of punishment in building safe systems. In addition, Marx's work provides a useful framework for establishing the clinician's intentionality in situations of medical error. He proposes managing risk in terms of three behaviors:

- *Human error* which occurs when someone should have done other than what they did, and in the course of that conduct, inadvertently caused or could have caused an undesired outcome. Implicit in this definition is that the practitioner did not intend to commit a risk-taking act or to induce harm in any way; he or she simply made a mistake. This behavior should be managed through changing processes and

procedures, instituting training methods and changing systems design and the clinician should be consoled.

- *At-risk behavior/unintentional risk-taking* which occurs when a person deviates from a prescribed path in a manner that creates a substantial and unjustifiable risk, but does not recognize the risk or believes it to be justified. This clinician should be coached to choose healthy rather than at-risk behaviors and helped to understand the consequences of each.
- *Reckless behavior/intentional risk-taking* occurs when a person consciously disregards a visible significant risk, putting the patient and him or herself in harm's way. This situation may call for disciplinary action and may result in termination of that individual's employment.

Another way of understanding individual accountability within a systems context is expressed in the notion of "practice responsibility" (8). Practice responsibility refers to the ethical mandate of licensed clinicians to assure themselves, the public and each other that the care they provide is based on valid current science and technology and the safest practices, and occurs within an inviolable trust relationship between the clinician and patient. In return, the public entrusts the health-care professions with the responsibility of "self-regulation," and review of a clinician's performance by peers is one time-honored way of fulfilling that trust. The Workgroup examined the newly revised "Model Principles for Incident-Based Peer Review for Heath Care Facilities" of the Massachusetts Medical Society, which are intended to assure that the statutorily driven peer review processes for physicians in Massachusetts meet the goal of quality improvement while being fair, transparent and credible. (Attachment 6)

*Attachment 8:* Report of the Former Patient/Family Focus Group

Massachusetts Coalition for the Prevention of Medical Errors

**Accountability Project Patient/Family Focus Group Meeting**

June 29, 2006

10:00 – 11:30 am

## Report

As one important step in obtaining feedback and guidance from key stakeholders, a focus group of former patients and families met on Thursday, June 29 from 10:00 am – 11:30 am. Invitations were extended to individuals identified in three ways: because of their participation in the Medically Induced Trauma Support Services (MITSS), because they were suggested by the Board of Registration in Medicine, or because they had contacted the Department of Public Health Division of Health Care Quality (DPH/HCQ) around an incident of unsatisfactory care. The final group consisted of eight members. Stephanie Buia, a facilitator not involved in the ongoing work of the Accountability Project (Project) managed the group process. Paula Griswold and Eloise Cathcart welcomed the group and briefly explained the work of the Project and of the Massachusetts Coalition for the Prevention of Medical Errors (Coalition).

The participants were asked to respond to the following four questions to the degree that they were comfortable in doing so:

Question # 1: Can you describe your unsatisfactory healthcare experience or the experience you came to talk about?
Question # 2: Did you bring this situation to the attention of anyone at the hospital? If yes, to whom did you bring it and what happened as a result of that? If no, why not?
Question # 3: Did you report this situation to the Department of Public Health or to any other regulatory board? If yes, what happened as a result of that? If no, why not?
Question # 4: If you could repeat the experience and it went well, what would be different? What areas can you identify for improvement? What advice do you have for the Project?

There were several common themes which emerged from the rich discussion among the participants. One major issue was the communication or lack thereof between the group members and their caregivers. Terms that were used to describe those interactions were "insufficient" "confusing" and "crass". In some situations, there was simply no communication – no explanation of what had happened or about the plan of care. One group member said that for the five and a-half months following her father's adverse event, there was no explanation to the family about the plan for his care. In fact, there didn't even seem to be a plan as the various groups of medical specialists contradicted each other about what to do. When her father died, no one came in to his room to explain what would happen next. One participant said "it was easy to get lost" in the hospital processes. Another explained "all I wanted to do was understand what happened" in the case of an adverse event surrounding her care.

Most group members described a wish for a simple acknowledgement that something had gone wrong in their own or a family member's care. They were in agreement that such an acknowledgement or an apology was not an admission of wrongdoing by the physician. One member said "after two years, I finally got an apology from the doctor, which I had to work hard for." Another spoke of her continuing strong desire to have an apology even though it has been two years since the adverse event occurred.

The issue of fear of retribution was discussed. One group member said her family felt intimidated to ask the surgeon for a full explanation ( and apology?) even though several family members were health professionals. Members expressed fear that they wouldn't be allowed to visit, or that the care team would " take it out" on the patient. Another member said that when her physician learned she had contacted a hospital official, he asked "what was that about?"

There was discussion about the ways in which the hospital protects itself from a patient's dissatisfaction with care. Hospital attorneys and hospital policies were felt by the group members to be responsible for withholding information and cutting off dialogue between providers and patients. The group in general felt that patient advocates were unhelpful to them in addressing concerns about their care. Persons in these roles felt "more like PR (public relations) people" for the hospital, intent on protecting the hospital rather than advocating for the patient and family. Several members expressed their beliefs that patient advocates would never address issues with powerful physicians for the sake of dissatisfied patients, and that patient advocates are "on the hospital payroll, and who will jeopardize their job?" One member who "just wanted someone to talk with me about what happened" described that communication between her and the hospital's risk manager and patient representative abruptly ceased when they learned she had filed a complaint with DPH/HCQ and the Board of Registration in Medicine. Another participant said she wrote a letter to the president of the hospital describing her unsatisfactory experience, while acknowledging one member of the care team who had been supportive and helpful, and received a letter back saying "he was happy to hear that she was satisfied with her care".

Although the majority of participants had very negative experiences with the hospitals in which they received care and said their "faith in the system was non-existent," one member had an entirely different experience. She spoke of feeling very genuine concern by the physicians involved in her care who were very understanding, very accessible (to the point that one physician had given her a home phone number), and very present ("the doctor never looked at her watch while she was with me").

Most group members described the heavy burden of needing to deal in the moment with the untoward events which happened to them or to their family member. They

described the sense of being unheard or dismissed by those in whom they entrusted their care and the blatant fear or anger they felt as a result of how they were treated. They felt that, if a process existed by which they could seek remedy, it was invisible. It was not clear to whom they should or could go in their frightened and vulnerable states.

Some group members had contacted DPH/HCQ in an effort to satisfy their concerns about what happened to them. While there was general agreement that staff at DPH/HCQ were compassionate and attentive and provided guidance to them about how to begin a process of complaint and how to put things in writing, the final report was disappointing because it was a succinct "clinical report of what happened." The report was perceived as not very helpful to the participants when they had hoped for a full explanation of what had happened, and steps the hospital would take to prevent it from happening in the future. One member was told simply that "treatment and care were within established guidelines." Another member (describing an event that occurred in another state) wrote to the Insurance Commissioner out of frustration when she was unable to get her physician to speak with her about options for her complicated clinical condition following a medical error. She told of receiving a letter in return which "made me sound like a lunatic" and which suggested that she convene a meeting with her physician to discuss her concerns.

The group offered the following recommendations to be included in the Project's final report:

1. All hospitals should ensure continuity of the patient-clinician relationship. It should be clear to the patient and family at all times which physician and nurse are accountable for the patient's care and to whom the patient and family can turn with any question they have regarding care.

2. The process for expressing concern and dissatisfaction with care should be clearly described and accessible. Information about this process could be provided to the patient and family during the signing of consent forms.
3. Hospital governing boards and executive leadership should ensure that patient and family advisory councils are embedded in the infrastructure of hospitals so that the voice of the patient and family are heard in all hospital policies and decisions.
4. The best practices of patient-centered care should be widely publicized for all hospitals to embrace.
5. Hospitals should have programs available to address the emotional concerns of patients and families involved in medical errors, which include billing for care in question.
6. Patients and families have the right to be educated about all aspects of their care in language and terminology which they understand.
7. Medical care, including errors, should be documented in the patient's record; this information may be essential for future care.
8. The response of DPH/HCQ to patient complaints and inquiries should include more dialogue and exchange of information.
9. Ensure that the reporting system includes near-misses to increase learning about those situations which could harm a patient.
10. Create a clearinghouse which tracks numbers and types of medical errors and alerts hospitals and clinicians about high-risk situations.
11. Standardize the terms and process for clinicians reporting adverse events and near misses.