Evaluate the Effects of the Massachusetts Reporting System

Principal Investigator: Nancy Ridley, M.S.
Associate Commissioner, Massachusetts Department of Public Health
Co-Investigators (alphabetically):
Paul Dreyer, Ph.D.
Massachusetts Department of Public Health
Arnold M. Epstein, M.D., M.A.
Department of Health Policy and Management, Harvard School of Public Health
Paula Griswold, M.S.
Massachusetts Coalition for the Prevention of Medical Errors
Lucian L. Leape, M.D.
Harvard School of Public Health
Eric C. Schneider, M.D., M.Sc.
Department of Health Policy and Management, Harvard School of Public Health
Joel Weissman, Ph.D.
Institute for Health Policy, Massachusetts General Hospital
Other Research Team Members (alphabetically):
Dragana Bolcic-Jankovic, M.A.
Center for Survey Research, University of Massachusetts – Boston
Brian R. Clarridge, Ph.D.
Center for Survey Research, University of Massachusetts - Boston
Jo Ann David-Kasdan, R.N., M.S.
Institute for Health Policy, Massachusetts General Hospital
Sandra Feibelmann, M.P.H.
Institute for Health Policy, Massachusetts General Hospital
Doris Hanna, R.N., C.P.N.P., Sc.D.
Massachusetts Coalition for the Prevention of Medical Errors
Katherine Howitt, M.A.
Department of Health Policy and Management, Harvard School of Public Health
Leslie Kirle, M.P.H.
Massachusetts Hospital Association
Jean Pontikas
Massachusetts Department of Public Health
Saul N. Weingart, M.D.
Center for Patient Safety, Dana-Farber Cancer Institute
Jie Zheng, Ph.D.
Department of Health Policy and Management, Harvard School of Public Health
Staff:
Catherine L. Annas, J.D., Project Director
Massachusetts Department of Public Health
Carla M. Cicerchia, Project Coordinator
Massachusetts Department of Public Health
Benyamin Suryanto, Computer Analyst
Massachusetts Department of Public Health
Christy Angiulo, Administrative Assistant
Massachusetts Department of Public Health
Organization: Massachusetts Department of Public Health
Dates of Project: 09/30/01-09/29/06
Federal Project Officer: James Battles
Supporting Agency: Agency for Healthcare Research and Quality
Grant Award Number: 5 U18 HS11928

Abstract
Purpose: Aim 1: Revise Massachusetts Mandatory Reporting System (MARS) data collection tool and coding system, and compare events with NQF list; Aim 2: Develop two voluntary safe practice models; Aim 3: Survey hospital leaders regarding reporting systems and disclosure policies; Aim 4: Survey discharged Massachusetts hospital patients on hospital experiences and disclosure policies, with chart review follow-up.
Scope: MARS (Aims 1, 2, 3 and 4); reporting systems in Pennsylvania, Florida, Colorado, Georgia, and Texas (Aim 3). Participants: 58 Massachusetts hospitals (Aim 2), 320 hospitals from 6 states (Aim 3), 2582 recently discharged patients surveyed, and 998 chart reviews (Aim 4).
Methods: Data Sources: MARS (Aims 1 and 2); participating Massachusetts hospitals (Aims 2, 3 and 4); hospitals leaders in 6 states (Aim 3); recently hospitalized patients and chart reviews (Aim 4).
Results: Aim 1: Of 760 MARS incidents, 66% met some NQF criteria. Aim 2: 58 Massachusetts hospitals participated (88%). Aim 3: Hospital leaders think mandatory reporting discourages adverse event reporting in their hospitals (68%); among the 86% that had a disclosure policy, 98% said serious injuries that were believed to be the result of error were disclosed to patients.
Key Words: Patient safety; reporting systems; medical errors: safe practices.

Introduction. The Massachusetts Department of Public Health (DPH) received this 3-year, $4.5 million Cooperative Agreement from AHRQ in 2001. In both 2004 and 2005, AHRQ approved no-cost extensions that brought the close of the project period to September 29, 2006. The Department was joined by the following research partner organizations: Center for Survey Research at the University of Massachusetts Boston (CSR), Harvard School of Public Health (HSPH), Institute for Health Policy at the Massachusetts General Hospital (IHP), Massachusetts Coalition for the Prevention of Medical Errors (Coalition), and Massachusetts Hospital Association (MHA). The research team received input from a Technical Advisory Committee (TAP) with the following members: Richard T. Moore, Massachusetts State Senator and Senate Chair of the Legislative Committee on Health Care Financing; Jill Rosenthal, National Academy for State Health Policy (NASHP) in Portland, Maine; and Dr. Mary Anna Sullivan, Lahey Clinic in Burlington, Massachusetts. The research team had seven meetings with the TAP during the project. Trish Riley of NASHP was originally named to the TAP but was replaced by Jill Rosenthal when she took a leave of absence from NASHP.

Aim 1: Improving the Massachusetts Mandatory Reporting System
Purpose. This project was performed under the leadership of Drs. Arnold Epstein and Eric Schneider and their research team at HSPH. Aim 1 evaluated DPH's mandatory reporting system, known as MARS, by systematically collecting data from reports of adverse incidents submitted by hospitals. The goal was to collaborate with staff at the DPH to identify enhancements to the reporting system's functionality and utility. More specifically, Aim 1 focused on revising and modifying the MARS coding system and data collection form by evaluating the content and characteristics of a representative sample of incident reports made by hospitals during 1999-2004. Also, as part of this analysis, hospital event reports captured under the Massachusetts system were examined and compared within the context of recommended national voluntary consensus standards for serious reportable events. Finally, the potential for developing and implementing an electronic web-based reporting system in Massachusetts was explored.

The Institute of Medicine's (IOM) groundbreaking report, *To Err is Human*, recommended statewide serious incident reporting by acute care hospitals to motivate them towards greater accountability and improved safety. By DPH regulation, all licensed healthcare facilities must report incidents of fire, suicide, serious criminal acts, pending or actual strikes, serious physical injury resulting from an accident or unknown cause, and "other serious incidents that seriously affect the health and safety of patients" to its Division of Health Care Quality (DHCQ). Certain incidents require immediate reporting via telephone to MARS intake staff, but others can be reported in writing within 7 days, by mail or facsimile. After review by clinical intake staff, the reports are then categorized for onsite follow-up in accordance with an

analysis of severity and whether issues uncovered may be the result of systemic deficiencies. A narrative investigation report is prepared and, if deemed necessary, a statement of deficiencies is developed.

Scope. Although a national mandatory reporting system has yet to be implemented, in 2002 the National Quality Forum (NQF) compiled and endorsed a list of 27 adverse incidents known as "never events" that should be publicly reported. These events represented incidents that are serious, usually preventable, clearly identifiable and measurable, and of significance to both consumers and healthcare providers. The events were grouped into six categories or types of incidents: surgical, product or device, patient protection, care management, environmental, and criminal.

The original plan was to sample events before and after introduction of a new web-based reporting system. For reasons detailed below, it proved infeasible to implement the web-based reporting system during the period of the project. With permission of the project officer, we modified the objective to study an important policy question raised by the introduction of the NQF reporting standard during the period of the project: should Massachusetts consider adopting the so-called NQF "never-event" reporting standard in place of its current reporting system?

Methods. Researchers collected data on 800 incidents. After data cleaning and exclusion of ineligible incidents, the study sample consisted of a stratified, random sample of 760 incidents reported by 72 acute care hospitals in Massachusetts during 1999 to 2004 (after issuance of the 1998 circular letter clarifying the types of incidents considered reportable- DHCQ 12-98-385). Adjustments to the sample included under-sampling reported falls to insure inclusion of all rarer types of incidents. Half of the incidents were selected from the most recent 2-year period (2003-2004) to account for improvements in the handling and recording of incidents by DPH after 2002, with the other half selected from the period 1999-2002.

Data were abstracted from records of these hospital reported incidents in both summary electronic form and in paper files, housed within DHCQ. Because the format of the records was so variable among incidents, a structured, data abstraction tool was crafted that included a list of specific data elements and a list of codes for classification of the incidents. This data abstraction tool was also designed to serve as a prototype for a hospital reporting form to be developed in the future. A literature review was conducted to identify taxonomies and approaches to classifying and interpreting adverse events. Based on this literature review, a review of MARS, a review of systems developed in other states, and the NQF never-event specifications, a research taxonomy and incident codes were developed and embedded in the data abstraction tool. Besides classifying the incident type, the data abstraction tool was also designed to collect structured data about each incident. This structured data architecture was developed by qualitative review of a sample of incidents reported to the current system and through meetings between the research team and knowledgeable staff at DPH. Structured data included the date the incident occurred, the number of involved patients, the patient's age, gender, race, and functional status, type and severity of injury, whether or not the incident warranted further investigation by DPH agency staff, and whether or not corrective actions were taken. The data abstraction tool was disseminated to hospital executives through presentations by Eric Schneider and Paula Dreyer and to the MHA Clinical Issues Advisory Committee (CIAC) and they provided valuable feedback on its development.

Two research abstractors were trained to use the tool by independently abstracting the same sample of records and reviewing and resolving discrepant results. Abstracted records were entered into an electronic database for more detailed analysis. Abstractors also recorded a brief narrative summary of the incident too. To increase the uniformity of incident classification, an experienced nurse reviewer independently reviewed the abstracted data and narrative in order to sort them into one of three categories. The incident 1) conformed exactly to an NQF-defined never event; 2) was substantially similar to an NQF-defined never event, but differed on one or more details; or 3) was not consistent with an NQF-defined never event. For incidents that fell in either category 1 or 2, the associated never-event

was assigned. Two additional reviewers each independently classified a reliability sample of 140 incidents. The kappa statistic for agreement between reviewers on the specific incident was 0.72. Incidents that were serious, life-threatening, or fatal but did not fit into the NQF never-event category were analyzed for themes and classified based on these descriptive categories.

Results. Approximately 96% of the incidents reported by Massachusetts hospitals during 1999-2004 involved one or more patients. More than two thirds of patient-specific incidents involved a patient older than 65 years of age, and 60% involved women (Table 1). Nearly 90% of the incidents involved injury, with 21% classified as "life-threatening or fatal," and 56% were classified as "serious." To assess inter-rater reliability, two additional reviewers independently reviewed a sample of 140 abstracts, classifying each as conforming or non-conforming to the 2002 NQF specification. The kappa statistic for agreement between reviewers was 0.72 (95% CI 0.64 to 0.81).

Table 1. Characteristics of Serious Patient Safety Incidents Reported by Massachusetts Hospitals during 1999-2004

	%
Incidents Involving Patients	**95.7**
Age of Patient Involved (in years)	
0-18	6.1
19-50	16.4
51-65	10.3
>65	67.3
Gender of Patient Involved	
Male	40.6
Female	60.4
Severity of Injury	
None or insignificant	10.4
Significant	12.7
Serious	56.0
Fatal or life threatening	20.9
Incidents Not Involving Patients	**4.3**
All Massachusetts Incidents (N=760)	**100.0**

Table 2 shows that only 16% of the hospital reported incidents conformed to the 2002 NQF reportable event standard. Notably, there was no statistically significant difference in the percentage of NQF-conforming incidents among those with higher and lower severity of injury. Of those judged against the 2006 NQF reportable event standard, 59% of the incidents conformed. Compared to the low-injury-severity incidents, a statistically significantly higher proportion of the high-injury-severity incidents conformed to the 2006 NQF standard. Nearly all of the additional conforming incidents were a result of the inclusion incidents in which a patient fell and had a documented fracture. Other modifications to the NQF standard did not affect the percentage of conforming incidents. The hypothetical revisions to the 2006 NQF standard increased the percentage of conforming incidents to 70.9%. There was a corresponding increase in the proportion of high-injury-severity incidents that conformed to this hypothetical reporting standard.

Table 2. Percentage of Massachusetts Hospital Reported Incidents that Conformed to the NQF Reportable Event Standard Developed in 2002, the Revised NQF Standard Developed in 2006, and a Proposed Future Revision to the Standard

		Degree of Injury Associated with Incident		
	All Incidents 760 (100%)	Serious, life-threatening, or fatal injury 456 (73.5%)	Significant, insignificant or no injury 304 (26.4%)	
	%			*p-value**
NQF 2002 Reportable Event Standard	*15.8*	*14.8*	*18.5*	*0.219*
NQF 2006 Modification to Reportable Event Standard	*59.4*	*70.2*	*29.4*	*<0.0001*
Potential Future Revision to NQF Standard	*70.9*	*85.8*	*29.6*	*<0.0001*

* Chi-squared test comparing proportion of reportable incidents stratified by severity of injury

Table 3 shows the prevalence of incidents conforming to each category and type defined by the 2002 NQF reporting standard. The most common categories of incidents were "surgical events" (33%), "hospital environment events" (27%), "care management events" (22%), "criminal events" (11%), and "patient protection events (4%). The most commonly reported types of events were "retention of a foreign object" (22%), "medication errors" (18%), "patient death associated with a fall" (18%), and "sexual assault on the grounds of the hospital" (9%). For 10 of the NQF-defined event types, there was not a single reported occurrence during the 6-year period.

Table 3. Prevalence of Each Never-Event among Massachusetts Hospital Incidents Reported during 1998-2004, According to the 2002 NQF Reportable Event Standard (N=188)

NQF Event Standard (27)	*%*
1. Surgical Events	32.9
A. Surgery performed on the wrong body part	8.2
B. Surgery performed on the wrong patient	1.4
C. Wrong surgical procedure performed on a patient	0.9
D. Retention of a foreign object in a patient after surgery or other procedure	21.5
E. Intraoperative or immediately postoperative death in an ASA class I patient	0.9
2. Procedure or device events	3.4
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility	0.0
B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	1.4
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	2.0
3. Patient protection events	4.4
A. Infant discharged to wrong person	0.0
B. Patient death or serious disability associated with patient elopement (disappearance) for more than 4 hours	0.0
C. Patient suicide or attempted suicide resulting in serious disability, while being care for in a healthcare facility	4.4
4. Care management events	21.9
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	18.3
B. Patient death or serious disability associated with a hemolytic reactions due to the administration of ABO-incompatible blood or blood products	1.5
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	2.0
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0.0
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	0.0
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	0.0
G. Patient death or serious disability due to spinal manipulative therapy	0.0

5. Environmental events	26.6
NQF Event Standard (27)	*%*
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	0.0
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances[1]	0.4
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	5.2
D. Patient death associated with a fall while being cared for in a healthcare facility	18.7
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	2.4
6. Criminal events	10.7
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0.0
B. Abduction of a patient of any age	0.0
C. Sexual assault on a patient within or on the grounds of the healthcare facility	9.4
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility.	1.4
Total	100

*NQF event specification does not require involvement of a patient.

The level of investigation by DPH and the recording of corrective actions by hospitals were variable. Among the three NQF-based categories, those incidents meeting the NQF standard exactly (category 1) had the greatest percentage (45%) of onsite investigations, and those incidents that were substantially similar to the NQF standard (category 2) had the lowest percentage (9%) of onsite investigations. Thirteen percent of the incidents in the non-NQF grouping (category 3) never prompted an onsite investigation. In general, hospitals reported corrective actions for 40% of reported incidents.

The overall conclusion that arises from this analysis and comparison is that, if Massachusetts had adopted the strictly defined NQF standard and accompanying list of reportable events during the project research period of 1999-2004, a large proportion of incidents (up to 83%) would not have been reported. More important, those events that would have been excluded from mandatory incident reporting were often those that were serious, life-threatening, or fatal, which possibly was a suggestion of ongoing system problems that would have continued to remain undetected within the hospital. A larger percentage of these incidents were falls involving fracture, but not death of the patient, a category that was added by the NQF in the 2006 standard. Under this new standard, more of the incidents reported by hospitals would be considered reportable. These results suggest that the NQF could consider defining additional categories of serious incidents for inclusion in future revisions of the national standard.

The results also demonstrate that a systematic evaluation of reported incidents can be an important hypothesis generating tool for additional research and targeting of quality improvement initiatives. For example, during the project, we received queries about the prevalence of medication-related events and presented results to the coalition. Our results were also transmitted to the NQF committee that reviewed and revised the NQF reporting standard in 1996.

Web-based Reporting Developments. DHCQ has maintained an internally designed DOS-based database of all reported incidents at all Massachusetts licensed facilities since 1995, and it receives approximately 12 to 15 thousand incident reports annually. Incidents reported by hospitals can be delivered by phone, facsimile, or mail, with the information transcribed and entered into the Incidents/ Intake system.

In the early period of the AHRQ grant, DHCQ was considering modifying the current system to allow hospitals to make web-based reports of medication errors (eventually expanding to include the reporting of all reportable adverse incidents). Several internet technology (IT) vendors were contacted, and their product offerings and costs were reviewed toward accomplishing this goal. In September 2003, a company called Metatomix was chosen to do a proof of concept pilot to demonstrate the capabilities of its "Dashboard" product. The pilot required DHCQ staff to take a week's worth of data and load it through the dashboard, trying to test remote user security, connectivity, speed, and uploading of data from the internet. Four high-end computer users simulated remote facility data input (in place of hospital testers who would have had to been trained). In short, the pilot revealed that the current Massachusetts system would require many newly added features to make it fully productive and operational, which would lead to a major change in the current workflow.

In the past year, DHCQ has been analyzing different ways to leverage the existing internet technology development efforts within the larger state agency to identify areas where there might be a good fit for the medication error-web-based reporting system. The advantage of having a web-enabled medication error reporting system integrated with existing systems is that it would allow the designated user to input all the specific information regarding the actual incident, minimizing translation errors caused by data entry personnel. Although several options and/or new pilots have been discussed within DPH, no solutions that would meet the needs of the required type of reporting system have been identified. This quandary continues to be explored. A study is presently underway on how to analyze, recommend, and pilot test methodologies for the collection of data from hospitals on healthcare-associated infections (HAI). Results from this study could potentially lead to identifying an appropriate mechanism for the collection of medication error data from hospitals.

While the system's coding scheme was updated, DHCQ determined that it should not be used by hospitals until the web-based system was fully developed. Although the abstraction tool was presented to hospital executives (as mentioned above), it was not prudent to implement it during the project period.

Aim 2: Demonstration and Evaluation of a Voluntary Collaborative Statewide Best Practices Model to Reduce Errors

Purpose. The purpose of Aim 2 of the Department's Project was to:

- Develop a framework for application of the MHA/Coalition Best Practices Model to serious incidents identified through MARS and through a clinical consensus process;
- Use the framework to create two Best Practice Initiatives, including defining a set of best practices for each topic, disseminating them, and supporting their implementation; and
- Survey hospitals to evaluate the effect of dissemination and adoption activities on practice implementation.

Scope. This aim was led by the Coalition, partnering with MHA. Paula Griswold, Executive Director of the Massachusetts Coalition for the Prevention of Medical Errors, was the projects co-investigator. Her research team included Lucian Leape from Harvard Medical School as scientific advisor, Leslie Kirle from MHA, and project leaders for the two identified models: Gina Rogers for reconciling medications and Doris Hanna for communicating critical test results.

Methods.
Selection of Two Safe Practice Models. The selection of the two topic areas resulted from a comprehensive assessment of priorities among healthcare professionals statewide. First, the research team surveyed coalition members and other health providers, asking them "What keeps you awake at night?" They then combined the survey results into a list of 10 priority subjects.

The next step for the research team was to examine the existing literature and data on the various topics in order to apply the selection criteria of 1) frequency of harm to patients, 2) severity of harm, 3) existence of best practices, and 4) feasibility of best practices. Frequency of occurrence and severity of harm were obtained from reviewing the data on serious incidents reported to: DHCQ under the Massachusetts Mandatory Reporting System (MARS); The Joint Commission Sentinel Event Statistics; and two major malpractice insurance carriers in Massachusetts. From review of the literature and national models, the availability of tested safe practices for each issue was determined, and the evidence for effective implementation of the proposed practice was collected from reports and expert data.

A 17-member Advisory Committee, convened by the coalition, reviewed these data. Although surgical site infections and transfusion errors had initially been identified by the research team by using the criteria of frequency and severity of harm and the existence and feasibility of safe practices, they were eventually replaced by reconciling medications and communicating critical test results. This change was approved by Project Officer James Battles. Reconciling medications (RM) is the process of creating the most complete and accurate list possible of pre-admission medications for each patient and comparing the physician's admission, transfer, and/or discharge orders against that list. Discrepancies are brought to the attention of the physician and, if appropriate, changes are made to the orders. Any resulting changes in orders are documented. Communicating critical test results (CTR) focuses on timely and reliable communication of critical test results to the clinician who can take action. Critical tests results are any values/interpretations for which delay in reporting can result in a serious adverse outcome for a patient.

The two choices had high "resonance" with the group for several reasons: 1) Both topics were clinically important problems encountered in everyday practice and recognized as significant hazards; their solution would make a substantial impact on patient safety; 2) Solutions to these problems would require addressing fundamental issues of interdisciplinary communication and teamwork, which are recognized as crucial aspects of a culture of safety; 3) Impressive success in implementing the practices had already been achieved by a small number of institutions; 4) Implementation was perceived to not require major new investments in technology or additional staffing; 5) The practices should pay for themselves over time in efficiency gains and reduced adverse events.

For each practice, the research team convened a stakeholder group that reviewed the literature and developed models for implementation of best practices. The groups were chaired by experts who had previously led implementation of the practice in hospitals (David W. Bates for CTR and Clark Fenn and Frank Federico for RM). The practices were implemented in all types of hospitals in the Commonwealth: teaching and community, urban and rural.

Enlisting Hospitals. An invitation letter was sent to the chief executive officer (CEO) of each hospital in the state explaining the practices and how they were selected and inviting them to participate in the project. The MHA Board of Trustees voted to make implementation of the two practices its "Flagship safety initiatives" for the year and called on all hospitals to participate in one or both of the initiatives. Hospital CEOs were asked to demonstrate their commitment by signing a "pledge of participation" form. Enrollment was tracked, and follow-up with hospital CEOs occurred through direct email communication, individual telephone calls, routine staff onsite visits, advisories, and bulletins.

Finally, a special program was held for hospital leaders to inform them of the projects. At this briefing, the national expert leaders described the practices and their successful experiences, answered questions, and outlined the requirements for participation.

Facilitating Implementation – The Collaborative Model

The research team used a collaborative model to implement the practices. Each hospital was invited to participate in both collaboratives, either simultaneously or sequentially. Hospitals were asked to form multidisciplinary teams, secure support from the CEO, and commit to four collaborative meetings.

Separate meetings were held for each collaborative. At the initial meeting, teams from the participating hospitals gathered for a day-long orientation session. National experts made presentations that described the details of the practices, the rationale behind them, and their experiences with implementation. Next, process experts described the "PDSA" rapid cycle change methodology for implementing new practices.

Participants were provided with a *toolkit* containing safe practice recommendations, a change package, and implementation strategies. The safe practice "change package" consisted of a detailed explanation of the rationale behind each of the subpractices and recommendations for what was needed to carry them out. It addressed such issues as the roles for each participant, development of measures, preliminary data collection, etc. A set of sample tools, implementation tips, and reference materials were also provided.

The importance of engaging leadership and involving all stakeholders, particularly physicians, was emphasized. Teams were advised to identify early clinical "champions" and were given suggestions of strategies for enlisting support of clinicians and for dealing with "pushback." Members of teams from hospitals that had implemented the practices provided practical advice on getting started and on implementation strategies.

Teams were instructed to collect baseline data and begin their first tests of changes within a few days. They were advised to have frequent meetings and to file reports with their CEO and with the coalition project staff monthly. A listserv was set up to exchange information and answer questions. In addition, the project director was available for telephone consultation for the two sets of safe practices.

Three additional meetings were held for each Collaborative over the next 18 months. Teams presented reports on their progress and shared observations on problems and strategies used to overcome them. Process experts and colleagues from other teams commented on reports and provided advice on changes that could be made to aid progress.

Continuing hospital interest in the Collaboratives was actively encouraged by MHA through publicizing success stories and lessons learned in its communications targeted at hospital leaders and through poster boards prominently displayed at the MHA annual membership meeting. At its 2004 annual meeting, the MHA Board of Trustees received and disseminated to every hospital participating in the initiatives a status report showing where their team stood in comparison to all participating hospitals.

Evaluation. Based on team reports, the research team rated success in implementing the practices using the following assessment scale: 1 = Planning only, 2 = Testing changes, 3 = Partial implementation, 4 = Fully implemented in some areas, 5 = Fully implemented throughout the institution.

To evaluate the impact of the various factors responsible for hospital team success, surveys of team leaders and CEOs were carried out at the end of the project. Respondents rated a) factors that contributed to an institution's decision to participate, b) organizational and administrative factors that facilitated implementation, including the role of the Collaborative, c) data collection and use of the rapid cycle improvement model, d) implementation and measurement details for each practice, and e) barriers to implementation. Forty-four CEOs completed the evaluation, for a response rate of 76%. As for the hospital teams, 42 Reconciling Medication team members completed the survey, for a response rate of 84%, and 34 CTR team members completed the survey, for a response rate of 85%. Although the research team originally planned to survey 100 hospitals nationwide to compare rates of adoption of

evidence-based best practices with Massachusetts hospitals, this part of the project was eliminated due to the 5% cut by AHRQ in the total award amount.

Results

Hospital participation. Of the state's 66 acute care hospitals at the time, 58 (88%) participated, 50 enrolled teams for RM, and 40 enrolled teams for CTR; 32 hospitals sent teams to both.

Response rates to the surveys were high:

- Hospital CEOs = 76% (44 of the 58 acute hospitals participating)
- RM Hospital Team Members = 84% (42 of the 50 Collaborative participants)
- CTR Hospital Team Members = 85% (34 of the 40 Collaborative participants)

Numerous factors were perceived by respondents to influence them positively toward participating in the Collaboratives. Factors with highest impact (rated as "some" or "a lot" by 90% or more of CEOs and team leaders) included the sense that the recommendations were likely to work, access to experts, the opportunity to learn from peers, and availability of a set of implementation strategies.

Surveys of hospital CEOs and team leaders indicated that endorsement by the Coalition and MHA leaders as well as evidence provided at the Coalition/MHA Leadership Briefing were important factors in the decision to participate, as were interest in the topic among clinical leaders and the intrinsic appeal of the practices. Features of the Collaborative that were attractive were low cost, access to experts, learning from peers, and the availability of materials.

Interviews with quality leaders in all of the hospitals that did not participate revealed they were small hospitals (7 of the 8 had fewer than 50 beds) in small communities or distant from the Collaborative meeting sites. Two were geographically isolated. Most were unable to muster the resources and personnel to do the project. Several have been facing significant financial constraints (negative margins) as well as staffing issues, such as overburdened quality directors who also covered for other vacant positions. Several cited competing priorities, particularly the upcoming Joint Commision surveys.

Implementation. The teams varied widely in their success at implementing both of the safe practices; 10% to 15% were unable to get beyond the planning stage. However, 50% of RM teams and 65% of CTR teams implemented the practices partially or fully during the Collaborative term.

Elements of the Collaboratives that teams reported as especially helpful were hearing about the practices from national leaders, learning from peers, having specific recommendations and a toolkit for implementing each practice, and guidance in developing measurement protocols.

Surveys showed that teams found implementing the recommended practices difficult (91% of RM and 75% of CTR indicated some or a lot of difficulty). Major barriers expressed by RM respondents included getting people to change, complexity, staffing time required, difficulty achieving clinician buy-in, and competing priorities. For CTR, fewer teams perceived serious barriers, with only getting people to change, complexity and competing priorities cited by a majority. Surprisingly, costs were not cited as a problem by the vast majority of teams or by the CEOs.

Responses to questions about project features known to facilitate implementation gave some insights into why many teams had problems. One reason was that most teams met infrequently - a minority met only monthly to analyze data to assess progress. Finally, about one in five teams did not use PDSA cycles.

Hospital support varied considerably. Hospital leaders did not ensure that staff resources were freed up during the testing and implementation phases of these practices. Only 54% of RM teams and 35% of CTR

teams set aside dedicated staff time for this work. Additionally, they did not assign a senior administrator to support the project in 50% of RM teams or 23% of CTR. Physicians were minimally or not at all involved in 63% of RM teams and 41% of CTR teams.

The importance of leadership engagement is demonstrated by one of the most successful hospitals. Each month, the project team leader met in a "huddle" (15 minutes) with the administrators responsible for the departments affected by the proposed changes. These huddles were initiated early in the project and occurred consistently throughout. The hospital leaders regularly reviewed project data, assumed responsibility for overcoming challenges and barriers within their areas of accountability, and provided direction and support for the implementation team. These leaders provided critical links to the Patient Safety Committee, the Medical Executive Committee, and the hospital Board.

The Collaborative Process. A survey of the hospitals participating in these Collaboratives was conducted. Results are from hospital CEOs and hospital team leaders associated with the RM and CTR initiatives:

Leadership View of Coalition Impact on Implementation: CEOs (94%) felt strongly that the coalition's ability to produce a specific set of implementation strategies was important in the implementation of changes. Ninety-one (91%) of the CEOs felt that the coalition's access to experts was important in the implementation of changes and 88% of the CEOs felt that the coalition's endorsement of best practices was important in deciding to implement the best practices.

Safe Practices: A large percentage, 95%, of the RM team leaders and 91% of the CTR team leaders felt that the coalition's safe practice recommendations made either a large or moderate contribution in the hospital's ability to implement safety changes.

Materials Provided: The toolkit materials provided by the coalition made a large or moderate contribution to their ability to implement changes, said 93% of the RM team leaders, as did 82% of the CTR team leaders.

Long-Term Improvements for Patient Safety: All the CEOs (100%) said the RM initiative has a large or moderate impact to long-term improvements for patient safety, and 93% of the RM team leaders felt this way. Additionally, 91% of the CEOs reported that the CTR initiative has a large or moderate impact to long-term improvements for patient safety, and 91% of the CTR team leaders reported the same.

The research team identified five aspects of the Collaborative model that would be modified in future projects: 1) establish clear requirements for participation including an executive sponsor as a member of the team; 2) have greater hospital leadership engagement, including a requirement of more frequent review of project results; 3) ensure sufficient use of measures; 4) ensure appropriate implementation of rapid cycle improvement changes in the hospitals (survey analysis revealed that many teams did not follow the PDSA method for rapid-cycle change); and 5) have additional staffing to support the needs of each collaborative.

Future Application of the Collaborative Approach for Patient Safety Goals. The effectiveness of the process used to identify high-priority patient safety topics was confirmed when The Joint Commission incorporated both topics in their National Patient Safety Goals in the summer of 2004. The toolkits that were developed and refined by the Massachusetts hospitals participating in the Coalition Collaboratives are now available for free on the Coalition's website to all health care organizations working to comply with these goals. Though it was not a part of the initial study design, this process of developing, testing, and refining a toolkit with implementation strategies that is to be made available in the public domain to support organizations working to meet safety requirements is a valuable approach that should be considered for future funding.

Aim 3: Survey of Hospital Leaders

One of the aims of the project was to survey hospital leaders in six states on patient safety issues as a way to identify the major barriers to reporting of medical errors. To achieve this goal, DPH contracted with researchers at the IHP, HSPH, and CSR to write and administer this survey.

The goals of the hospital leader survey included: 1) assessing the strengths and weaknesses of operational and substantive components of state reporting systems, and identifying barriers to internal and external reporting; 2) assessing how hospitals are implementing the patient disclosure standard from The Joint Commission; and 3) generating recommendations for state and local stakeholders to improve the rates of reporting and establish meaningful best practices in the area of patient disclosure.

Methods. The respondents to this questionnaire included hospital leaders: Chief Executive Officers (CEOs), Chief Operational Officers (COOs), Chief Medical Officers (CMOs), Risk Managers, and Patient Safety Officers at 320 hospitals from six states (MA, CO, FL, PA, GA, TX). Some Risk Managers also served as their hospitals' legal counsels. Therefore, the insights of legal counsels were also captured through some of the interviews. The states were chosen because they span the continuum of reporting from voluntary to mandatory, and from confidential to non-confidential.

The hospitals were selected from hospital association lists or from the *AHA Guide to Hospitals 2001-2002.* All 76 acute care hospitals in Massachusetts were contacted. Fifty acute care hospitals were selected at random from each of the remaining five states. Rehabilitation facilities, psychiatric facilities, children's hospitals, nursing homes, and Veterans Administration/military hospitals were excluded from the sample of hospitals. When there were multiple campuses of a hospital system with the same set of hospital leaders, one of the campuses/hospitals was chosen to avoid duplication of interviews.

Survey Administration and Confidentiality. The names and positions of the hospital leaders chosen for the survey were confirmed with the appropriate state hospital association and/or hospital administrative assistants to the hospital leaders. Hospital leaders were sent their hospital association's endorsement letter, a letter from the research team, and a fact sheet about the survey prior to being contacted by phone. Professional interviewers conducted computer-assisted telephone interviews at the central phone facility at CSR. Interviews took, on average, 20 minutes to complete. Twenty cognitive interviews took place with selected subjects, who were each paid $100 for providing detailed feedback on the questionnaire. CSR was responsible for training and maintaining quality control of all aspects of the data collection.

This protocol was reviewed and approved by the Institutional Review Boards (IRBs) of DPH, the Massachusetts General Hospital, HSPH, and the University of Massachusetts. Participation was voluntary, and all responses were completely confidential. No individual respondent or individual hospital was or will be identified. After data collection was completed, CSR "anonymized" the data (i.e., destroyed all identifying information). A complete firewall was always present between the survey research firm and all non-academic personnel (i.e., hospital associations and the Massachusetts DPH).

Results. In total, 203 CEOs and COOs were surveyed, for a response rate of 63%.

Attitudes about Mandatory Reporting. Hospital leaders were asked their opinions regarding mandatory reporting of Patient Safety Incidents (PSIs). Sixty-five percent of respondents in the six states think mandatory reporting laws discourage the reporting of PSIs internally within hospitals. Furthermore, 76% of respondents overall believe mandatory reporting laws encourage lawsuits against the hospitals. Forty-three percent of respondents, overall, think that mandatory reporting systems have no effect on patient safety. Fifty-two percent of respondents think that mandatory reporting systems have no effect on the willingness of staff to report medical errors and other PSIs to their hospital administration.

Eighty-three percent of respondents in all of the states believe that keeping confidential both the name of the hospital and individuals involved in a patient safety incident would reduce actual hospital errors the most.

Structures. According to 95% of respondents, nurses report the most PSIs to their hospital's internal system. Seventy-seven percent of respondents said that patient safety is always or usually on the agenda at special board meetings, and 77% of respondents report it is also always or usually on the agenda at Executive Committee meetings.

Internal Reporting Systems. Respondents were then asked about the frequency and the types of errors that are reported to their hospital's current internal reporting system. In all six states, 88% responded that errors that cause serious harm always or usually show up through their hospital's current internal reporting system. Of errors that cause minor harm to the patient, 80% of respondents said that these errors always or usually show up through their hospital's current internal reporting system. Seventy-eight percent of respondents overall said that near misses usually or sometimes show up in their hospital's current internal reporting system. Seventy-eight percent of respondents reported that errors that cause no harm usually or sometimes show up in their hospital's current internal reporting system. Seventy-two percent of respondents reported that errors that cause no immediate harm usually or sometimes show up in their hospitals' current internal reporting system. Some respondents said that errors that cause no harm or no immediate harm would rarely show up.

Ninety-one percent of respondents across the six states said their hospital has a policy to protect individuals who report errors or incidents. When asked why they believe these policies exist, 81% said to protect individuals who are responsible for the error. Most respondents rank the following as very high or high priority when patients are harmed: to find out about root cause (96%), to identify hospital procedures (91%), to protect staff from negative consequences (90%), and to find out who was at fault (64%). The last category is less of a priority for some respondents.

State Reporting Systems. Respondents are consistent about their views regarding how and what to report. Thirty-eight percent of respondents reported that directors of risk management departments decide if an internally reported patient safety incident should be reported to the state agency (DPH, HFD, AHCA, DOH). The questions in this section were only asked of respondents in MA, CO, FL, and PA, because they have mandatory reporting systems. Seventy-one percent of the respondents find the criteria for what to report to the agency very clear or clear enough, and 84% find it very easy or easy enough to file a report. Seventy-eight percent of respondents think their hospital only has moderate or little discretion in deciding what needs to be reported to the agency. To improve the agency's internal reporting system, the two most common suggestions were clarifying how and what to report and providing feedback across hospitals within the state.

Respondents were also asked about the process by state agencies to follow-up on reported events. Despite the burden of onsite investigations, hospital leaders give state agency investigators very high or high marks on understanding hospital issues (61%), clinical qualifications (54%), discovering issues that would prevent future PSIs (71%), and being able to assess hospital compliance with Medicare conditions of participation (70%). Respondents think investigators are less interested in assigning blame for reported incidents (35%). Though there is consistency among hospital leaders about onsite investigations, their opinions vary about the role the state agency has in disclosure of PSIs.

Seventy-four percent of respondents say there are circumstances under which the state agency should not disclose any information of the PSI to the press. Almost all respondents think the agency should disclose information to the family on a reported PSI that is about to be released to the press. Of respondents that support such disclosure to affected patients and their families, 68% think only certain incidents should be

shared. Yet, if the patient or family makes the request for disclosure of information, 72% of respondents support disclosure. When there may be harm to the patient, 64% of respondents support disclosure. Ninety-seven percent of respondents believe the hospital where the incident occurred should be the source of disclosure of information to the patient or family affected.

Hospital Patient Disclosure Policies. Eighty-eight percent of respondents across the six states confirmed their hospital has a policy to disclose unanticipated outcomes and other PSIs to patients and their families. Ninety-eight percent of hospitals' policies recommend disclosure in case of serious injuries believed to be the result of errors and 80% of respondents said their hospital has such a recommendation for minor injuries as well. Sixty-five percent of respondents said their hospital even recommends disclosure of injuries not believed to be the result of errors. However, 60% of respondents said there is no policy for disclosing if the errors do not result in harm to patients.

Sixty-six percent of respondents said the hospital policy addresses apologizing to patients when an error or incident occurs. Fifty-six percent of respondents believe an aggressive policy of informing patients would increase patient confidence in the hospital. Forty-five percent of respondents said such a policy would increase the reputation of the hospital.

Vignettes. The purpose of the vignettes used in the survey was to give hospital leaders the opportunity to evaluate a hypothetical scenario. Overall, the respondents identified the scenarios as PSIs and medical errors. As the scenarios become less severe, the number of respondents who said the incident would come to their attention lessens. Consistently, as scenarios become less severe, the frequency that the incident is always or usually reported to the state agency decreases. Similarly, as the scenario becomes less severe, the frequency that someone from the hospital always acknowledges to patients or to the family members that an incident has occurred decreases.

Conclusions. Whether there is a mandatory or a voluntary reporting system in place, these six states have shown that patient safety is an important issue. In 2001-2002, 83% of the respondents say their hospitals have run seminars and workshops to help staff learn about the disclosure to patients of errors, unanticipated outcomes, or other PSIs.

Aim 4: Survey of Recently Hospitalized Patients in Massachusetts

Purpose. The goals of the patient survey were to 1) estimate the rate at which hospitalized patients perceive that suboptimal care, errors, or injuries from care occurred during their hospital stay; 2) measure perceptions and attitudes of patients as to whether information on such events was or should have been disclosed to them by caregivers or hospital personnel; and 3) determine whether patients are able to accurately report that an adverse event (AE) occurred, using chart review as the gold standard.

Scope. The respondents to this patient survey included adult patients that were hospitalized for either medical or surgical treatment in Massachusetts between April 1, 2003, and October 1, 2003.

Methods and Sample Design. A two-stage probability sample was drawn, selecting hospitals and then selecting patients within the selected hospitals. The goal was to select a sample of approximately 6000 unduplicated patients who had stayed in a hospital overnight and been discharged alive, with the expectation that this would yield interviews with approximately 3000 patients.

The research team obtained the list of 80 Massachusetts acute care hospitals from DPH. Relevant data included hospital name, number of discharges, and hospital ID number assigned by DPH. Nine hospitals were then excluded as non-eligible either due to duplication (one hospital), specialty hospital status (five hospitals - pediatrics, cancer, eye and ear, hospice), closure (two hospitals), or no longer an acute care hospital (one hospital). This left the research team with 71 eligible Massachusetts hospitals.

In the first stage, these 71 hospitals were grouped into four strata, based on hospital size. Stratum 1 included the five largest Massachusetts acute care hospitals. These were selected with certainty because they collectively represent about one quarter of all Massachusetts discharges. There were exactly 22 hospitals in each of the other three strata, which were arranged in decreasing order by number of discharges. Five hospitals were randomly selected from each stratum. Thus, the rate of sampling patients within hospitals in strata 2-4 is slightly over four times the rate of selection in Stratum 1. Sampling in this way assured that the sample would be self-weighting, except to the extent that they might want to adjust for differential non-response.

Once selected, hospitals were asked to sample their live medical-surgical discharges during the research team's specified 6-month period. The research team excluded discharges for patients under the age of 18. The hospital's medical records department then either 1) provided the research team with a file from which they could sample or 2) selected a random sample using the research team's specifications. The research team then obtained the names and contact information for the selected patients.

For the second stage of the sample, the research team identified the rate at which patients would be selected from the discharge list based on a desired sample of 6000. Those discharged from the largest hospitals were selected at that rate, and those in the strata of smaller hospitals were selected at 5/22 of the overall rate, thereby making the selection rate of patients approximately constant for the state as a whole.

The research team communicated with the medical record or health information departments at each of the hospitals to generate a list of randomly selected adult medical/surgical patients who met the criteria of the study. The research team initially asked each hospital for a list of discharges that would yield a sample of 7200 patients. In the case of two of the largest hospitals, they doubled the number of medical/surgical patients so they could select patients for the pretest. Therefore, they took a subsample as needed from the discharge samples provided by the hospitals to yield a sample based on the aforementioned rates. In order to do this, they took each sample list of discharges provided by hospitals; after cleaning the list of cases that were without a permanent address, with a residence out of country, or that were discharged to psychiatric institutions, they assigned each case a random number.

They sorted by the random number and then selected first the number of discharges they needed from each hospital based on the application of the above sampling rate. In the case of duplicated patients (when the same patient had more than one hospital experience during the 6-month period), they took the first hospital experience on the random list and deleted the others. That was the hospital experience about which the selected patient was interviewed. Only CSR received the list of names and contact information of the randomly selected, potential participants from the hospital medical records departments.

Of the original 20 hospitals initially selected, five declined or did not respond about their willingness to participate in the research study. In addition, among their selected replacements, three replacement hospitals also declined to participate. The reasons for declining included five that said that they had only a limited number of staff or could not commit the time to have the hospital participate; one hospital said that it was focusing on internal projects, and two did not respond to multiple phone calls, emails, and fax follow-up attempts.

IRB Process/Issues. The research team submitted applications to the Institutional Review Boards (IRBs) at each of the original 20 hospitals. Some of the hospitals shared an IRB because they were part of the same hospital system. Letters of support for the research study from the hospital CEOs/Presidents and DPH accompanied the IRB applications to each of the hospitals.

Of these 20 hospitals, 16 approved the research study. At two hospitals, part of the same hospital system, IRB approval was obtained but executives changed their minds about participating. At another two hospitals, which also shared a hospital system, the IRB rejected the research study twice due to concerns over the sensitivity of the information and fear of negative media attention of any results the research team might find. Despite several attempts to prove the research study otherwise valid, including the approval at 16 other hospitals in Massachusetts, this brought the number of hospitals that declined participation in our study after IRB consideration to four. In order to prevent further delay, the research team did not replace these four hospitals.

This protocol was also reviewed and approved by the IRBs of DPH, the Massachusetts General Hospital (MGH), HSPH, and CSR at University of Massachusetts. The project also received designation as a public health research project under MGL 111:24A, providing confidentiality protections to information collected as part of the study. Hospital and individual participation was voluntary, and all responses were completely confidential. No individual respondent or individual hospital was or will be identified. After data collection was completed, CSR "anonymized" the data (i.e., destroyed all identifying information). A complete firewall was present between the survey research firm and all non-academic personnel (i.e., the Massachusetts Hospital Association and DPH). Though DPH staff had knowledge of which hospitals participated in the research study, they had no access to any hospital-specific or patient-specific data.

In order to get the needed information from hospitals (patient name, mailing address, telephone number, admission and discharge dates, discharge status, age/date of birth, gender, and medical record number), the researchers sought a temporary waiver of the consent requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR Part 164.512(i)). Upon showing that 1) the use of the requested data posed only minimal risk to the privacy of the individuals involved; 2) the research could not practicably be conducted without the waiver; and 3) the research could not practicably be conducted without access to and use of the information, the researchers were awarded temporary waivers.

These waivers were temporary because they only disclosed information that allowed the team to send a letter and fact sheet to the potential participants and to make the initial telephone call contact. Once the person was reached on the telephone, the interviewer was required to obtain verbal authorization to participate in the interview (and at the end, verbal authorization to use the information shared in the interview). In addition, as required under the HIPAA Privacy Rule, a Business Associate Agreement was established between the MGH researchers and CSR, and between the MGH researchers and each hospital, in order for the hospitals to release the requested data.

Focus Groups. The original research plan submitted specified two initial focus groups for this aim, with seven or eight participants in each to pretest the patient survey. CSR held two focus groups each with 10 recently hospitalized patients for this task. They were paid $40 in appreciation of their time to provide detailed feedback on the questionnaire. CSR was responsible for training and maintaining quality control of all aspects of the data collection.

Important lessons learned were that most patients do not understand the term "adverse events," and they are not familiar with certain clinical terms (e.g., postoperative, deep vein thrombosis) that physicians used to describe complications. As a result, the research team took a closer look at the medical jargon and the use of terms in the telephone survey. They decided to use the phrase "negative effects" instead of "adverse events." Also, the term "complications" was used instead of medical error or mistake.

The first part of the survey included questions about four common hospital treatment scenarios, including medicines patients were taking prior to the hospitalization and which were administered in the hospital, new medicines given in the hospital, diagnostic tests, and surgery. The second half of the survey asked

patients about 11 medical or surgical complications or injuries, including heart attack, uncontrolled bleeding, rash, and injury from a fall. If the patient reported one of these complications, they were asked one of the four care scenarios of questions.

Survey Administration. Each potential participant received a letter and a fact sheet about the survey prior to being contacted by phone. Patients had the opportunity to call an 800 number at CSR to opt out of the research study if they did not wish to be contacted.

Professional interviewers conducted the computer-assisted telephone interviews at the central phone facility at CSR. On average, the interviews took 25 minutes to complete. Before the interviewer asked any survey questions, the interviewer asked the patient if he/she still consented to participating in the survey. This was the second opportunity for the patient to opt out of participating. At the end of the survey, the patient was asked if he/she agreed to allow their answers to the interview to be analyzed by the research team. This gave the patient a third opportunity to opt out by discounting his/her interview. At the end of the telephone interview, if the patient allowed their responses to be analyzed, he or she was asked if the research team could review their medical record for the particular hospitalization about which they were interviewed. If the patient agreed, then CSR mailed that patient the hospital's medical record release form to sign and return to CSR. Only if a signed medical record release form was received did the research team's nurse reviewers have permission to request and review that patient's medical record for the particular hospitalization.

Chart Review. The methodology used in the Harvard Medical Practice Study, similar to the California Medical Insurance Feasibility Study, was used as a model to identify AEs. However, the research team counted injuries regardless if prolonged hospitalization or disability at discharge occurred. A pre-specified list of adverse events and an evidence-based clinical case definition for each AE was created. The categories included AEs that were common, potentially preventable, and possibly severe. The list included: adverse drug events, acute postoperative myocardial infarction, bacteremia, perioperative bleed, deep vein thrombosis, fall, nerve injury, organ injury, pneumonia, pneumothorax, pressure sore, sepsis, shock, urinary tract infection, postoperative wound infection, and other.

Three nurse reviewers underwent two days of training. They were asked to enter into a password-protected Access data collection tool the discharge diagnoses, to verify the length of stay, and to identify the comorbidities for the purposes of assigning a Charlson score. They were also asked to confirm that the patient spent part of their stay on the medical/surgical unit of the hospital. A summary of the patient self-reported AE was provided in the data tool. Reviewers had to confirm that the patient's medical chart reflected that an AE occurred. The adverse event was assigned to one of 19 categories.

The nurses prepared case summaries for those with adverse event that met the clinical case definitions, which were sent to two physicians for review. To identify chart events, the two physician reviewers independently assessed the case summaries and then discussed disagreements to reach a joint review decision. No cases required a third reviewer for unresolved disagreements.

Chart Re-Review. All patient-reported survey events were put into a "virtual envelope" field in the nurses' computerized chart review tool. Once the nurses completed the initial chart review, they were instructed to "open the envelope." If the patient had reported an event and the nurse had not recorded it, she assessed whether the reason was that she had found evidence for the event but it did not meet the clinical case definition as specified in the tool (Yes, No, Not Sure). If she answered "no" or "not sure," she was instructed to re-examine the record and look for evidence of the event. If evidence was found and it met criteria, the nurse passed it on to the physician reviewers along with the other adverse events found in the chart. If evidence was found, but the event did not meet criteria, it was not passed on to the physician reviewers.

Physician Review. There were two sets of physician reviewers for this part of the research study. All physician reviewers underwent one day of training. For the self-reported adverse events, two physicians reviewed patients' responses from the survey, in which they provided open-ended responses that described possible adverse events. The second set of physician reviewers was responsible for reviewing the nurse reviewer's case summaries of adverse events identified from the chart reviews.

All physician reviewers were asked to state if an adverse event, defined as an injury due to medical care during the hospital admission, was present in their clinical opinion They excluded incidents that were the result of the natural history of the patients' illnesses rather than a consequence of medical care, incidents that occurred before the hospital admission, or incidents in which no adverse event was identified.

They were also asked to determine the severity of the event, determine the preventability of the event, and rate how confident they were that the event occurred during the hospital stay. The physician reviewers classified each incident according to its severity (life-threatening, serious, significant, trivial or insignificant) using written guidelines. A serious incident affected an organ system function. Significant events resulted in patient symptoms, prolonged hospitalization, or laboratory abnormalities. Trivial or insignificant events include minor injuries of little clinical consequence such as nausea, dizziness, or itchiness.

Preventability was scored on a 4-point scale (definitely, probably, probably not, definitely not). Multiple reports of a single incident were coded only once. The reviewers also rated their confidence on a 4-point scale (little or none, modest, strong or virtually certain). They rated little or no confidence if there was insufficient information to adequately understand or to interpret the patient report and to describe scenarios that were not clinically credible.

Sample. The initial sample from the 16 hospitals consisted of 6003 patients. Of these patients, 144 were deemed ineligible from hospital discharge records because the patient was an OB/GYN, rehabilitation, or duplicate patient (same patient had >1 hospital experience during the 6-month period). This left 5859 patients who were eligible to go into the field, meaning they received the initial cover letter and fact sheet and received a screening phone call if they did not call the toll-free phone number to opt out of the research study. Upon screening, 960 additional patients were deemed ineligible because they were deceased, in nursing homes, resided out of state, or had not received medical-surgical services during the 6-month time period that the research team was examining. Therefore, 4899 patients were deemed potentially eligible for the patient survey. The research team was never able to confirm where 602 patients were located. An additional 131 patients could not be screened or interviewed because no one in the household spoke English. The total known eligible population was 4166 patients. This sample is close to the original 4200 sample predicted in the research plan. After the interview was completed and the patients agreed to have their medical chart reviewed for the particular hospitalization about which they were interviewed, 13 of the 4166 patients were excluded because it was discovered during chart review that they had not received medical/surgical services during their hospital stay. The final known eligible population for the patient survey was 4153 recently hospitalized patients.

Of the 4153 patients who were contacted, 757 of them refused to participate, another 548 were too ill to participate, and another 266 were unable to have an interview arranged after repeated phone calls. The total number of patients who completed the telephone survey was 2582, for a response rate of 62%. Although the research team originally expected to achieve a survey response rate of 70%, issues detailed above related to ineligible respondents brought that rate down. In addition, although the research team had originally planned to interview proxies if patients were unavailable, this approach was abandoned. After the survey was developed, the researchers decided that proxies would not be able to provide specific enough responses to be useful to the study.

Of the 2582 patients who participated in the telephone survey, 2028 agreed to have their medical record for that hospitalization reviewed. Of those 2028 patients, 1031 of them returned the signed medical record release form that was required before the research team could request the patient's chart for review. Because of confidentiality procedures requiring that patients "opt in" to the study rather than "opt out," chart review releases were lower than the original 2000 expected. Of the 1031 charts requested, the nurse reviewers were able to review 998 charts. (Twenty charts were not located; 13 patients were excluded, as they were not medical-surgical admissions.)

Results. Of 998 patients in the sample, 229 (23%) reported 308 events from the survey, and 105 (11%) patients were found to have 128 events based on the chart. Adverse drug events were the highest type of adverse event reported by patients and recorded in the medical record. Regardless of type of event, the chart and the patient survey agreed 77% of the time that an event occurred. For patients with serious or life-threatening events, the agreement between the patient survey and the chart increased to 94%.

Based on the survey and the physicians who reviewed the self-reported adverse events, women were far more likely than men to report adverse events ($p<.01$), but no significant differences occurred by chart review. The patient survey also found that younger patients were more likely than older patients to report adverse events. The longer patients stayed in the hospital, more patients reported having at least one adverse event. This was also true for the chart review.

As for the issue of whether the hospital disclosed an adverse event to the patient, approximately 50% said that someone from the hospital talked to them about the event. Those reporting such disclosure were more likely to say they were satisfied with their care and were more likely to rate the hospital's handling of the event as excellent or very good.

Length of Stay. Based on self-reports in the survey, 20% of patients who completed the phone survey stayed in the hospital for 1-2 days. Fifty-two percent of the patients stayed 3-5 days in the hospital, and 22% were in the hospital for 6-10 days. Only 5% of patients stayed in the hospital for 11 or more days.

When the 998 charts are reviewed, the largest percentage of patients still stayed in the hospital for 3-5 days. Almost another quarter (23%) were in the hospital for 6-10 days. Slightly less than a quarter (21%) of patients who stayed 1-2 days in the hospital. Also, 5% were in the hospital for 11 or more days.

Hospital Characteristics. More than three quarters of the patients (85%) received medical-surgical services at an urban hospital, whereas less than one quarter (15%) received care at a non-urban hospital. More than three quarters of patients (82%) received care at a private, not-for-profit hospital. Another 15% of patients received care at a private not-for-profit church hospital.

Thirty-four percent of patients received care from a major teaching hospital, whereas 27% received care at a minor teaching hospital. At least another third (35%) received care at a non-teaching hospital. Three percent of patients received care from a hospital where teaching status is not known. More than one third (41%) of patients received care at a large hospital (more than 301 beds). About half (45%) received care at a medium sized hospital. Only 11% of patients received care at a small hospital (fewer than 100 beds).

Conclusions. Patients may be able to serve as a useful source of information on adverse events during hospital stays, although they tend to identify events that are not documented in the chart, either because they are less serious or because clinicians are unaware of their existence. More research needs to be done focusing on the results of a survey with shorter recall, verification of the events disclosed, and understanding whether eliciting such reports affects the patient-doctor relationship.

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Aim 4:

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Products:

Aim 1:

- Abstraction tool for analyzing reported events.
- Proposed new coding list for Massachusetts Mandatory Reporting System.

Aim 2:

- Communicating Critical Test Results Resource Book.
- Reconciling Medications Resource Book.
- Website, including the safe practice models, getting started tips, toolkits and other resources. See http://www.macoalition.org/initiatives.shtml#2.
- Survey instrument for hospital Chief Executive Officers.
- Survey instrument for hospital team members.
- Implementation awards.

Aim 3:

- Survey instrument for hospital leaders.

Aim 4:

- Survey instrument of recently discharged patients.
- Chart review tool.