



Serious Reportable Events in Massachusetts Acute Care Hospitals:

January 1, 2008 – December 31, 2008

A report by the
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality

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Executive Summary

This report presents patient safety data that Massachusetts hospitals reported to the Department of Public Health during calendar year 2008 pursuant to the recommendation of the Commonwealth's Health Care Quality and Cost Council that the Department provide a hospital specific report in March of 2009.

Massachusetts acute care hospitals reported 338 serious reportable events (SREs) in 2008. More than 68 percent (231) were environmental events, with falls as the leading category (224 events). Sixty-two surgical events were reported (18 percent of the total), and care management events comprised 8 percent of the total (26 events). The remainder were criminal events (11 events, 3 percent of the total), product or device events (5 events, 1 percent of the total), and patient protection events (3 events, 1 percent of the total).

Non-acute care hospitals in Massachusetts reported 104 additional SREs, 84 percent of which are falls. However, the focus of this report will be the acute care hospitals. The systems at work in acute and non-acute hospitals are very different, as are the range of SREs that occur. Over three-quarters of the reported SREs took place in acute-care hospital settings and the types of SREs were more diverse than those in the non-acute settings. The non-acute SREs will be the subject of future reports.

In presenting data on the occurrence of SREs at individual hospitals, it is important to keep in mind the purpose of public reporting, which is ultimately to improve the quality of care; i.e., to eliminate SREs in Massachusetts. To that end, hospitals have been afforded the opportunity to share their programmatic responses to the SREs that they have experienced. It is our hope that these shared responses will spur improvement, so that in the not too distant future, Massachusetts patients will no longer experience SREs.

A. Introduction

The Department is pleased to present this first annual report on the status of serious events in Massachusetts hospitals using the Department's new National Quality Forum (NQF)-based reporting system.¹ Implemented on January 1, 2008, the system is based on the mandatory reporting by hospitals of twenty-eight (28) discrete adverse medical events grouped into six major categories:

- surgical,
- product or device related,
- patient protection related,
- care management related,
- environmental, and
- criminal

While the Department and the Massachusetts hospital industry have a decades-long history with respect to the reporting of medical errors and investigating incidents affecting patient safety, this NQF-based system is an entirely new reporting framework. It was developed over the course of 2007 in extensive collaboration with the Board of Registration in Medicine, the Massachusetts Hospital Association and numerous other stakeholders. Initial instructions and reporting forms were distributed to all chief executive officers and risk managers of Massachusetts hospitals in early December, 2007, and additional guidance and clarification were sent to all affected parties throughout the reporting period.² As such, we cannot over-emphasize that this is the first year of the data collection, and any conclusions are necessarily tentative.

While each reported SRE is reviewed by the Department and the respective hospital risk management personnel, lack of familiarity with the new reporting requirements and subjectivity in the interpretation of terms and criteria of reportable events by hospital staff underscore our caution about drawing any conclusions from the data during this first year. Apart from understandable inconsistencies in interpretation and classification, the number of reported incidents is simply too small to allow for any lessons to be derived regarding safety or quality at an individual hospital at this time.

When a second year of data is collected we will conduct further analyses of events sorted by race, ethnicity, age, and gender - and by other measures such as location of occurrence in hospital, time of day, protocols and procedures in place at the time of the event, and surgical specialty for example - to better serve the development of public policy and the expansion of a culture of best practices throughout the commonwealth's health care system.

¹ National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update*. Washington, D.C: National Quality Forum; 2007

² [#07-12-478 Hospital Reporting of Serious Incidents - 12/13/2007 \(PDF\)](#) and www.mass.gov/dph/dhcq

B. Background

Since the publication of the Institute of Medicine's landmark report *To Err is Human — Building a Safer Health System*³ in 2000, and the National Quality Forum's *Serious Reportable Events in Healthcare – A Consensus Report*⁴ in 2002, concerns over patient safety and medical errors have generated a wealth of public policy initiatives nationwide. In Massachusetts, the Department's Betsey Lehman Center for Patient Safety and Medical Error Reduction⁵ was established in 2004. Chapter 58 of the Acts of 2006 established the Massachusetts Health Care Quality and Cost Council⁶, and this summer the passage of Chapter 305 of the Acts of 2008, empowered the Council with a broad mandate to identify statewide goals for (1) improving health care quality and transparency, (2) containing health care costs, and (3) reducing racial and ethnic disparities in health care.

Consistent with this mandate, the statute requires the Department to collect such hospital-specific data on adverse medical effects and medical errors as it may require and to convey the information collected to the Betsy Lehman Center and to the Health Care Quality and Cost Council for publication. A facility failing to comply with the Department's requests for information may be fined up to \$1,000 per day per violation, have its licenses revoked or suspended, or both.

In addition, the legislation directs the Department to promulgate regulations prohibiting a health care facility from charging or seeking reimbursement for services provided as a result of the occurrence of a serious reportable event. According to the legislation a health care facility may not charge or seek reimbursement for a serious reportable event that the facility has determined, through a documented review process, and under Department regulations was preventable, within its control, and unambiguously the result of a system failure based on the health care provider's policies and procedures. As of March 2009, these regulations have been drafted and are going through a public comment period.

The objectives underlying the development of the Department's NQF-based reporting system, however, are not focused on regulating these events or punishing hospitals involved. Rather, the goal is to gain a greater understanding of why events happen and how they can be prevented in the future. In that spirit, as part of this public reporting process, hospitals are able to share with the public additional information about their specific SREs and corrective steps taken as part of a document on the Department's website⁷.

As hospitals and their staffs become increasingly proficient with the reporting, the Department will work with them to compile and communicate best practices. There is little question among the stakeholders that the imposition of consistently high levels of inquiry, accountability, and transparency will foster the system-wide patient safety improvements that need to take place.

³ Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human – Building a Safer Health System*. Washington, DC: National Academy of Science Press; 2000

⁴ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002

⁵ mass.gov/dph/betsylehman

⁶ www.mass.gov/hqcc

⁷ www.mass.gov/dph/dhcq

C. MDPH/NQF Listing of Serious Reportable Events⁸

The Department's reporting requirements are based on the National Quality Forum's (NQF) categorization of serious reportable events. NQF serious reportable events are adverse events that are of concern to both the public and healthcare professionals and providers; clearly identifiable and measurable, and thus feasible to include in a reporting system; and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.⁹

NQF Serious Reportable Events:

1. Surgical Events

- A. Surgery performed on the wrong body part
- B. Surgery performed on the wrong patient
- C. Wrong surgical procedure performed on a patient
- D. Unintended retention of a foreign object in a patient after surgery or other procedure
- E. Intraoperative or immediately postoperative death in an ASA Class I patient

2. Product or Device Events

- A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. Patient Protection Events

- A. Infant discharged to the wrong person
- B. Patient death or serious disability associated with patient elopement (disappearance)
- C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

4. Care Management Events

- 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)
- B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- 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
- E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- G. Patient death or serious disability due to spinal manipulative therapy
- H. Artificial insemination with the wrong donor sperm or wrong egg

⁸ National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update*. Washington, D.C: National Quality Forum; 2007

⁹ NQF website: <http://www.qualityforum.org/projects/completed/sre/>

5. Environmental Events

- A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- 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
- C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

6. Criminal Events

- A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- B. Abduction of a patient of any age
- C. Sexual assault on a patient within or on the grounds of a healthcare facility
- 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 a healthcare facility

D. Massachusetts Experience: 2008

Beginning January 1, 2008 all licensed hospitals in Massachusetts have been required to report any occurrence of a serious reportable event within seven days of occurrence. For reporting purposes, in cases where hospitals have merged or otherwise combined operations (for example North Shore Medical Center – Salem and North Shore Medical Center – Union; Berkshire Medical Center – Berkshire and Berkshire Medical Center – Springfield; or Southcoast Hospitals Group, which operates three formerly independent facilities in three localities under a single license) each campus is required to report separately, consistent with similar data reporting requirements elsewhere in the Department.

The complete set of materials including reporting forms, guidelines, criteria and definitions provided by the Department to the reporting hospitals may be found on the Department's website under Hospital Circulars/Reporting Serious Incidents¹⁰. Hospitals were instructed to provide the following data elements on standardized forms provided for each incident of a serious reportable event. These twenty-two patient and event descriptors form the backbone of the Department's SRE reporting system.

Data Elements Reported

Identification

- Name - Age; Sex; Admission Date
- Ambulatory Status.
- ADL Status
- Cognitive Level
- Mentally Retarded/Developmentally Disabled

Report Detail

- Serious Reportable Event Text Description (From Pick List)
- DPH Occurrence Type
- Type of Harm
- Body Part Affected
- Patient's Activity at Time of Occurrence
- Place of Occurrence
- Equipment, If Any, Being Used At Time of Occurrence
- Safety Precautions in Place
- Narrative of Event
- Corrective Measures Narrative
- Notification
- Staff Person In Charge Of Facility At Time Of Occurrence
- Witness Information
- Accused Information

To improve consistency of reporting, each quarter a list of the most current quarter's SREs is sent to the hospitals to ensure that the incidents captured reflect the hospitals' understanding of what they have reported. Hospitals then have the opportunity to raise any questions about the information they have received. If a hospital does not believe an incident to be an SRE, the Department will work with them to make a determination. This process has been especially important in this first reporting year, as hospitals develop and refine their identification and reporting processes. As reported in the

¹⁰ mass.gov/dph/dhcq/hcqskel.html

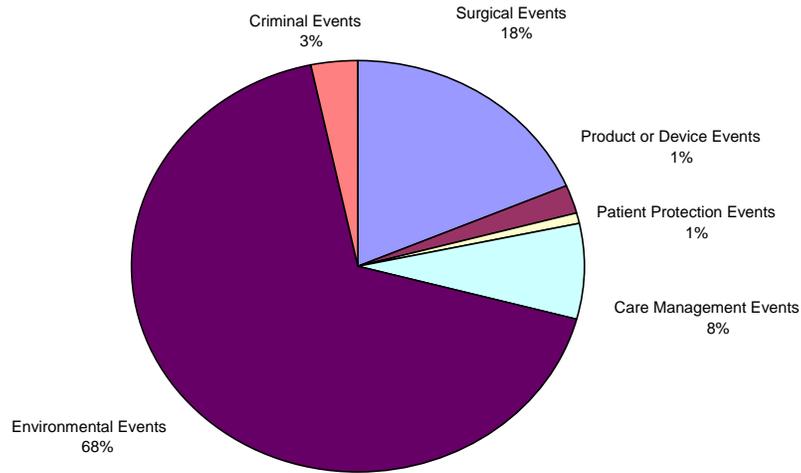
following table, Massachusetts acute care hospitals in 2008 reported three hundred and thirty-eight (338) serious reportable events to the Department. Falls were by far the most common event reported representing 66% of the total. The next three most common events comprised an additional 20% of the total: retained foreign objects (9%), wrong site surgeries (7%) and medication errors (4%). To date there is not enough data to support significant stratification and analysis.

Table 1
Massachusetts Acute Care Hospital SREs by Number and Percentage:
January through December, 2008.

Event	Count	Percent
Fall	224	66%
Retained Foreign Object	32	9%
Wrong Site Surgery	24	7%
Medication Error	12	4%
Stage 3 or 4 Pressure Ulcer	12	4%
Sexual Assault	11	3%
Burn	6	2%
Wrong Surgical Procedure	5	1%
Device Malfunction	3	1%
Suicide/Suicide Attempt	3	1%
Air Embolism	2	1%
Wrong Patient Surgery	1	0%
Maternal Death / Disability	1	0%
Hyperbilirubinemia in Neonate	1	0%
Restraints/Bedrails	1	0%
Death < 24 Hours ASA 1 Patient	0	0%
Contaminated Drugs or Device	0	0%
Infant Discharged to Wrong Person	0	0%
Elopement	0	0%
Transfusion Error	0	0%
Hypoglycemia	0	0%
Spinal Manipulation	0	0%
Artificial Insemination Error	0	0%
Electric Shock	0	0%
Oxygen or Gas Error	0	0%
Physical Assault	0	0%
Abduction	0	0%
Impersonation of Health Professional	0	0%
Total	338	100%

Combining the reported events into their six NQF categories yields the following distribution:

Figure 1
Distribution of Serious Reportable Events in
Massachusetts Acute Care Hospitals:
January 1, 2008 - December 31, 2008 (N=338)



Serious Reportable Events by Hospital

In this report, SREs are identified by individual hospital, rather than simply in aggregate. However, it is misleading to draw any conclusions about the overall quality of care at an individual hospital based on a raw number or types of SREs reported by that hospital.

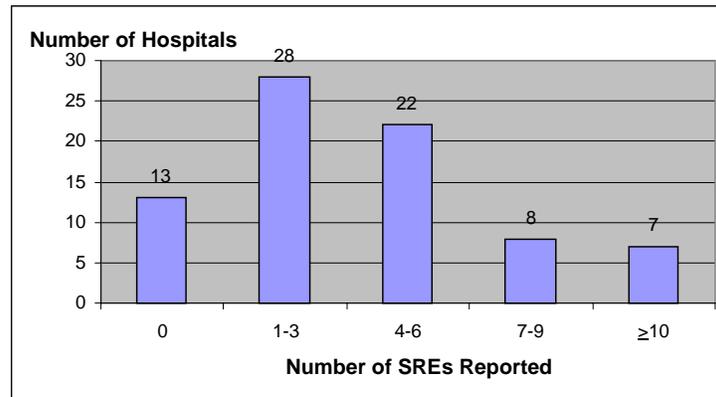
The raw number of SREs may not be an indicator of poor quality hospital care. Because the reporting requirements are relatively new, some hospitals may be more proficient in reporting, resulting in a higher number of SREs. A higher number of SREs may indicate a strong reporting culture, rather than a quality concern. Just as a higher number of SREs does not necessarily suggest poor patient care, a lower reported number does not necessarily suggest higher quality care.

The National Quality Forum itself makes the point that not all occurrences of SREs may be preventable. Despite hospitals' best efforts, particular circumstances may render particular SREs unavoidable. The long-term goal of SRE reporting is to minimize the number of these occurrences through increased awareness and development of robust systems for error trapping and prevention.

Table 2 shows the number of serious reportable events per hospital. Attachment A provides a complete listing of SREs by hospital by type. Attachment A also shows how hospitals have responded to the SREs that have reported. Over time, we expect that this database of responses will become a valuable resource for shared learning about best practices in reducing the occurrence of these events.

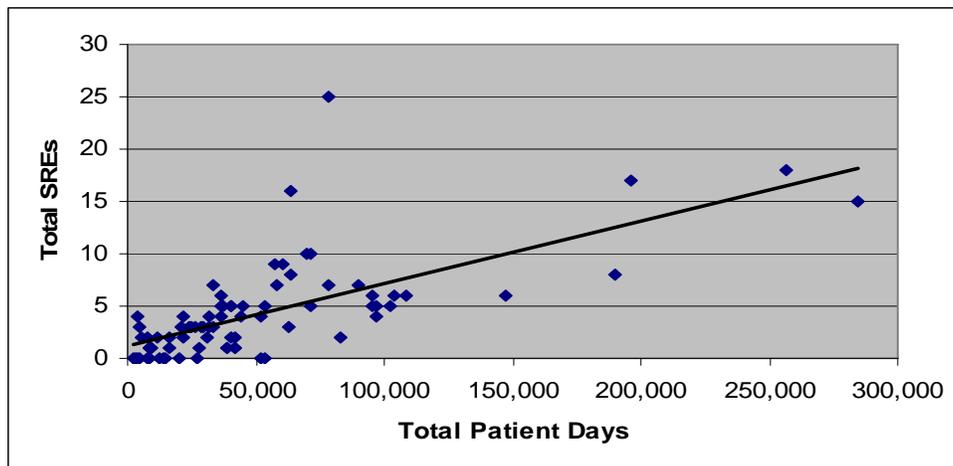
The number of events at each hospital ranges from 0 to 25. Figure 2 shows this distribution. 13 hospitals reported zero events, while 7 hospitals reported 10 or more events.

Figure 2
Frequency of SRE Reporting



Serious Reportable Events and Volume. One obvious explanation for variation among hospitals with respect to the number of reported SREs is volume. Figure 3 is a graph of SREs and patient days; each data point is a hospital. It is indeed the case that higher volume institutions tend to report more SREs than lower volume institutions. The correlation between patient days and number of reported SREs is .686.

Figure 3
SREs Versus Patient Days



Serious Reportable Events and Rates. The calculation of rates of occurrence of SREs is controversial. Opponents of the practice argue that the reporting of rates legitimizes events that should in fact be occurring with a frequency of zero. Supporters of rate calculations argue that the rarest of events will in fact occur more frequently in hospitals with larger volumes, and that the calculation of rates allows comparison and analysis that would not be possible with raw numbers of SREs.

A compromise position might be the calculation of rates of falls, which, as we have seen, constitute 66% of all reported events, and which many argue are among the most difficult events to prevent. However, since the number of falls and the number of SREs are of necessity highly correlated ($r=.88$), we have included all SREs in the rate calculation in Table 2.

**Table 2
Serious Reportable Events by Hospital: Acute Care Hospitals, 2008.**

Acute Care Hospital	Total SREs	Patient Days	SREs per 10,000 Patient Days
Anna Jaques Hospital	1	39,007	0.26
Athol Memorial Hospital	0	3,117	0.00
Baystate Franklin Medical Center	0	19,876	0.00
Baystate Mary Lane Hospital	0	5,029	0.00
Baystate Medical Center	8	190,123	0.42
Berkshire Med Ctr Inc/Berkshire Cam	8	63,953	1.25
Berkshire Med Ctr Inc/Hillcrest Cam	0	8,347	0.00
Beth Israel Deaconess Hosp – Needham	1	8,327	1.20
Beth Israel Deaconess Med Ctr/Boston	17	195,824	0.87
Beverly Hosp/Addison Gilbert Campus	0	12,213	0.00
Beverly Hosp/Beverly Campus	2	83,204	0.24
Boston Medical Center Corp	6	147,494	0.41
Brigham & Women's Hospital	18	256,303	0.70
Cambridge Health Alliance/Cambridge	7	32,971	2.12
Cambridge Health Alliance/Somerville	1	27,727	0.36
Cambridge Health Alliance/Whidden Memorial	4	36,320	1.10
Cape Cod Hospital	10	69,859	1.43
Caritas Carney Hospital	5	40,528	1.23
Caritas Good Samaritan Med Ctr	7	58,191	1.20
Caritas Holy Family Hospital & Med Ctr	0	51,643	0.00
Caritas Norwood Hospital Inc	16	63,223	2.53
Caritas St Elizabeth's Medical Ctr	10	71,461	1.40
Children's Hospital Boston	5	102,575	0.49
Clinton Hospital	1	9,329	1.07
Cooley Dickinson Hospital, Inc.	1	38,703	0.26
Dana Farber Cancer Institute	1	8,197	1.22
Emerson Hospital	1	41,884	0.24
Fairview Hospital	3	4,843	6.19
Falmouth Hospital	3	24,817	1.21
Faulkner Hospital Corp.	5	37,487	1.33
Hallmark Health System Lawrence Memorial	2	31,392	0.64
Hallmark Health System Melrose- Wakefield	0	53,407	0.00
Harrington Memorial Hospital	0	14,323	0.00
HealthAlliance Hosp-Burbank Campus	0	7,503	0.00
HealthAlliance Hosp-Leominster Camp	0	27,045	0.00
Heywood Hospital	3	23,739	1.26
Holyoke Medical Center	2	40,212	0.50
Hubbard Regional Hospital	0	4,104	0.00
Jordan Hospital	4	44,434	0.90

Acute Care Hospital	Total SREs	Patient Days	SREs per 10,000 Patient Days
Lahey Clinic Hospital	5	96,598	0.52
Lawrence General Hospital	4	52,162	0.77
Lowell General Hospital	5	44,766	1.12
Marlborough Hospital	1	16,600	0.60
Martha's Vineyard Hospital	2	5,531	3.62
Mass Eye & Ear Infirmary	4	4,124	9.70
Mass General Hospital	15	284,719	0.53
Mercy Medical Center Campus	9	57,095	1.58
Merrimack Valley Hospital	3	20,730	1.45
MetroWest Med Ctr / Framingham Union Campus	2	41,504	0.48
MetroWest Med Ctr / Leonard Morse Campus	3	25,979	1.15
Milford Regional Medical Center	5	36,815	1.36
Milton Hospital Inc	4	21,349	1.87
Morton Hospital & Medical Ctr Inc	6	36,679	1.64
Mount Auburn Hospital	9	60,742	1.48
Nantucket Cottage Hospital	0	2,500	0.00
Nashoba Valley Medical Center	2	7,870	2.54
New England Baptist Hospital	3	29,723	1.01
Newton-Wellesley Hospital	5	70,974	0.70
Noble Hospital Inc	2	21,537	0.93
North Adams Regional Hospital	0	14,493	0.00
North Shore Med Ctr/Salem Hospital	7	78,588	0.89
North Shore Med Ctr/Union Hospital	3	31,799	0.94
Providence Behavior Health Hosp Campus	1	41,557	0.24
Quincy Medical Center	5	40,363	1.24
Saints Memorial Medical Center	4	32,081	1.25
Signature Healthcare Brockton Hospital	3	63,102	0.48
South Shore Hospital	7	90,204	0.78
Southcoast Hosps Grp Inc/Charlton	5	95,224	0.53
Southcoast Hosps Grp Inc/St Luke's	4	96,598	0.41
Southcoast Hosps Grp Inc/Tobey	2	16,521	1.21
St Anne's Hospital	3	33,250	0.90
St Vincent Hospital	25	78,496	3.18
Sturdy Memorial Hospital	3	28,924	1.04
Tufts Medical Center	6	95,385	0.63
UMass Memorial Med Ctr/ Mem Campus	6	103,702	0.58
UMass Memorial Med Ctr/ Univ Campus	6	108,830	0.55
Winchester Hospital	5	53,353	0.94
Wing Memorial Hospital & Med Ctrs	2	11,641	1.72

Rates range from 0-9.7 per 10,000 discharges. The three highest rates are from facilities with relatively few patient days.

Race and Ethnicity

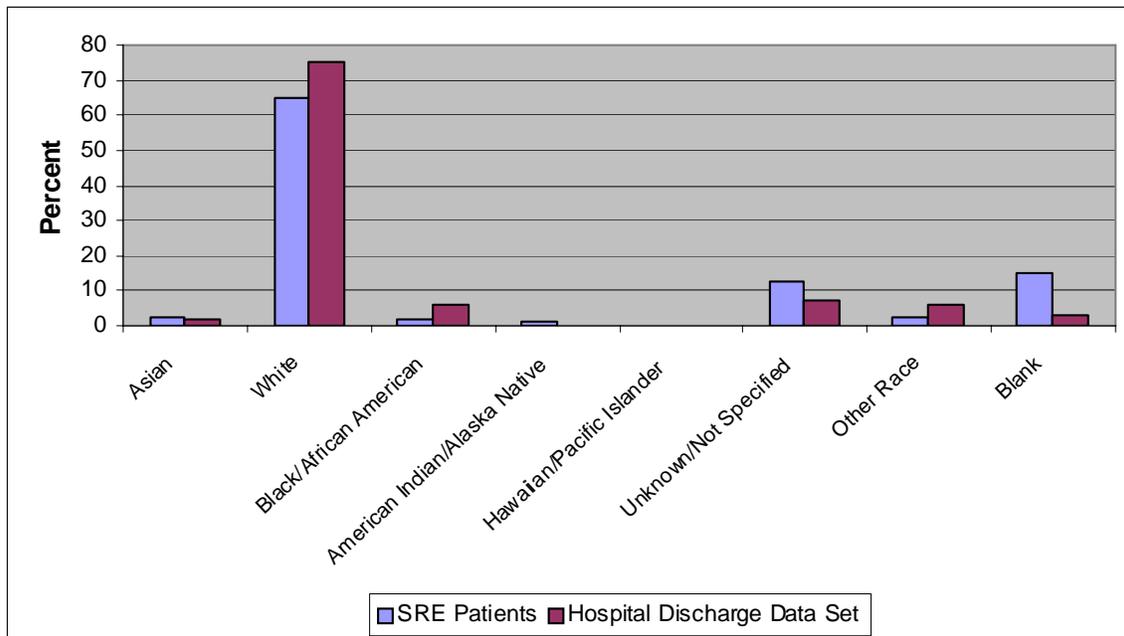
Beginning in mid-2008, hospitals began to include race and ethnicity data as part of the SRE reporting process. While hospitals had been collecting race data for many years, the ethnicity measure is a new one. Since the ethnicity measure is so new and the reporting so limited to date, the focus in this section will be on the race data. Below is a chart showing the distribution of race for patients involved in SREs.

Table 4
Race Distribution – Patients Involved in SREs

Race	Number	Percent
Asian	3	2.80
White	69	64.49
Black/African American	2	1.87
American Indian/Alaska Native	1	0.93
Hawaiian/Pacific Islander	0	0.00
Unknown/Not Specified	15	14.02
Other Race	2	1.87
Blank	16	14.95
Total	108	100.00

When compared to the patients in the overall hospital discharge data set, there is no evidence that minority populations are disproportionately represented among SRE patients.

Race Distribution Comparison – Patients Involved in SREs
Versus Total Hospital Discharge Data Set Patients



It is important to keep in mind that the SRE patient race data was collected for only 5 months of the reporting year, and the ethnicity measure is new. In future years, more robust analyses of any potential racial or ethnic disparities found in SRE patients will be conducted, along with trend analyses.

Comparison to Minnesota

Going forward, it may be useful to compare Massachusetts' experience to that of other states. Due to definition changes and the availability of current data, Minnesota is the state with which the most standardized comparison can be made. Minnesota has released its report of 2008 data, which includes non-fatal falls in its calculations, an issue that had made the prior year's data less comparable to Massachusetts.

At this stage, any comparison is purely for illustrative purposes. There is not sufficient comparable data to draw any conclusions. Should reporting definitions become more comparable as national standards are developed, the cross-state comparisons could be useful.

Massachusetts' total calculated SRE rate is slightly lower than Minnesota's. Two categories of SREs show marked differences between the two states: Care Management and Environmental. The care management variance can be identified in the pressure ulcer reporting. Minnesota had 122 events, with 86 of them unstageable, while Massachusetts acute care hospitals reported only 12 events. Early 2009 reporting data indicates that pressure ulcers may have been underreported in Massachusetts in 2008. The environmental category difference is found in the number of falls. At 5.53 falls per 100,000 patient days, the Massachusetts fall rate was 67% higher than the Minnesota fall rate of 3.32 per 100,000 patient days

**Table 5
Comparison of SRE Rates – Massachusetts and Minnesota**

SRE	MA		MN ¹¹	
	#	Rate*	#	Rate*
Surgical Events	62	1.53	77	2.69
Product or Device	5	0.12	3	0.10
Patient Protection	3	0.07	3	0.10
Care Management	26	0.64	130	4.54
Environmental	231	5.70	98	3.42
Criminal	11	0.27	1	0.03
Total	338	8.34	312	10.90

*Rate is SRE count per 100,000 patient days

What conclusions might be drawn from these comparisons? At very the least, it is reassuring that these two states have rates that are so similar. We may hope that this similarity means that we are using definitions similarly and are counting events in the same way. As these data become more reliable in the future, such comparisons may help draw attention to actual or potential disparities between states, and offer guidance as to where attention may be needed.

¹¹ <http://www.health.state.mn.us/patientsafety/ae/09ahereport.pdf>

E. Current Status

As previously noted, the first year (especially the first half of the year) involved a learning curve for all participants. The data collection process is now working well, and the data have become cleaner and more appropriate for detailed analysis. The communication between the Department and reporting institutions continues to be strong. Hospital responses to the SREs demonstrate a commitment to reducing these events in the future and the compilation of their lessons learned will be a valuable resource in the development of best practices in event prevention.

Several clear areas of interest have emerged (falls, reporting of pressure ulcers). It is anticipated that the ability to conduct more sophisticated analyses of the data in the next several years will help us to better understand the specific factors influencing the patient care environment.

The cooperative process undertaken by hospitals, the Department, and many other stakeholders has enabled the first year of SRE data collection to be a strong baseline for future analysis and has helped to create processes that ensure accurate collections and reporting, leading to the identification of trends, best practices, and eventually better outcomes.