SERIOUS REPORTABLE EVENTS IN MASSACHUSETTS HOSPITALS

JANUARY 2010 – JUNE 2011

PUBLIC HEALTH COUNCIL

Madeleine Biondolillo, MD, Director
Iyah Romm, Special Assistant to the Director

BUREAU OF HEALTH CARE SAFETY AND QUALITY
DECEMBER 14, 2011
BACKGROUND

• Chapter 305 of the Acts of 2008, Section 9 requires the Department of Public Health (“Department”) to collect hospital-specific data on adverse medical events and medical errors

• Two previous reports were issued on acute care hospital SRE data for 2008 and 2009

• In June 2009, DPH promulgated regulations to prohibit health care facilities from charging for services provided as the result of an SRE
REPORTING PROCESSES

After identification of an SRE

• An initial 7-day report is provided to the Department
• Report updated within 30 days of filing, and sent to patient by hospital
• Reports provided to payers

• The patient or patient’s representative must be notified verbally and in writing about:
  • occurrence of an event including unanticipated outcomes of care
  • policies, procedures, and the documented review process for making a determination of preventability

An extensive data validation process is conducted in close cooperation with hospitals prior to public release of SRE reports. Each individual reported SRE is reviewed by the Department and by the respective hospital’s risk management personnel.
REPORTING PHILOSOPHY

- To gain a greater understanding of how adverse events happen and how they can be prevented in the future
- To catalyze hospital-specific and statewide initiatives to address the most prevalent adverse events through identification and dissemination of best practices
- To ensure that the rate of preventable adverse health events continues to decrease
- To further inform consumers, policy-makers, and providers on the frequency and setting of adverse events
- The reporting of SREs is *not* intended to be punitive, but to inform
NATIONAL QUALITY FORUM SRE DEFINITIONS

• Since 2007, the Department has utilized a reporting framework based in National Quality Forum (NQF) measures.
  • Developed in collaboration with the Board of Registration in Medicine, the Massachusetts Hospital Association and other stakeholders

• 28 discrete adverse medical events that must be reported are grouped into six major categories:
  1. Surgical events
  2. Product or device events
  3. Patient protection events
  4. Care management events
  5. Environmental events
  6. Criminal events

• Changes to NQF SRE list released in 2011, DPH will assess potential shifts in current reporting framework.
**NQF SRE LIST**

**Surgical Events**
- Wrong body part
- Wrong patient
- Wrong procedure
- Retained foreign object
- Intraoperative or immediate postoperative death in an ASA Class I patient

**Care Management**
- Medication error
- Wrong blood product
- Maternal death or disability
- Hypoglycemia
- Hyperbilirubinemia
- Pressure ulcers (stage III/IV)
- Spinal manipulative therapy
- Wrong sperm or egg during AI

**Product or Device Related Events**
- Death or disability related to contaminated drugs, biologics, or devices
- Death or disability related to device function/use
- Death or disability related to intravascular air embolism

**Patient Protection Events**
- Infant discharged to wrong person
- Patient elopement
- Patient suicide or attempted suicide

**Environmental Events**
- Death or disability related to electric shock
- Wrong or contaminated gas
- Death or disability associated with burns
- Fall resulting in death or disability
- Death or disability related to restraints or bedrails

**Criminal Events**
- Impersonation of a health care provider
- Abduction of a patient
- Sexual assault on a patient
- Death or disability of a patient or staff member resulting from physical assault on premises of a health care facility
Massachusetts acute care hospitals reported 369 SREs in 2010
  - 53% (n=197) of these events were Environmental
  - 97% (n=192) of the Environmental Events were falls
  - Acute care hospitals reported SREs in all six NQF categories
ACUTE CARE HOSPITALS, 2011
(JANUARY 1-JUNE 30)

- Massachusetts acute care hospitals reported 159 SREs from January 1 to June 30, 2011
  - 57% (n=91) of these events were Environmental
  - 98% (n=89) of the Environmental Events were falls
- No patient protection or product/device SREs were reported by acute care hospitals

![Pie chart showing SREs in acute care hospitals by category, 2011: Environmental 57%, Care Management 21%, Surgical 20%, Criminal 2%]
Massachusetts non-acute care hospitals reported 143 SREs in 2010:

- 55% (n=79) of these events were Environmental
- 99% (n=78) of the Environmental Events were falls
- Zero surgical or product/device SREs were reported
Non-Acute Care Hospital SREs by Category, 2011

- Environmental: 67%
- Care Management: 29%
- Criminal: 4%

Massachusetts non-acute care hospitals reported 58 SREs from January 1 to June 30, 2011

- 67% (n=39) of these events were Environmental, all of which were falls
- Zero surgical, product/device, or patient protection SREs were reported
higher volume institutions tend to report more SREs than lower volume institutions. The correlation between patient days and number of reported SREs in acute care hospitals in 2010 is 0.71.
PATIENT VOLUME & SRES, 2011

Higher volume institutions tend to report more SREs than lower volume institutions. The correlation between patient days and number of reported SREs in acute care hospitals from January 1-June 30, 2011 is 0.46.
When compared to the patients in the hospital discharge data set (DHCFP), there is no evidence that minority populations are disproportionately represented among SRE patients.
TOTAL MA SRES, 2009-2011 (PROJ.)

SREs in Massachusetts Hospitals 2009 - 2011 (Projected)
ACUTE CARE HOSPITAL FALLS & PRESSURE ULCERS

Fall and Pressure Ulcer SREs Acute Care Hospitals 2009 - 2011 (Projected)

Number of SREs

250

200

199

192

178

150

100

65

81

64

50

2009 2010 2011 (projected)

Year

Fall With Death/Disability
Stage III/IV Pressures Ulcers
FALLS AS A PERCENT OF TOTAL SRES

Acute Care Hospitals

Non-Acute Care Hospitals
UNDERSTANDING FALLS & PRESSURE ULCERS

- Falls and pressure ulcers initially required significant definitional clarification
  - MDPH worked closely with partners to ensure clarity of “disability” with regard to falls.
  - Pressure ulcer definitions were conservative with regard to “stageability” given lack of clarity among the reporting community.

<table>
<thead>
<tr>
<th>Ulcer upon Admission:</th>
<th>Ulcer Becomes:</th>
<th>Adjudication: SRE/Not an SRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>Stage 3 or 4</td>
<td>SRE</td>
</tr>
<tr>
<td>Stage 2</td>
<td>Stage 4 (skips Stage 3)</td>
<td>SRE</td>
</tr>
<tr>
<td>Stage 2</td>
<td>Stage 3</td>
<td>Not an SRE (per NQF)</td>
</tr>
<tr>
<td>Unstageable</td>
<td>Stage 3 or 4</td>
<td>Not an SRE (per DPH)</td>
</tr>
<tr>
<td>None/Stage 1 or 2</td>
<td>Unstageable</td>
<td>Not an SRE (per DPH)</td>
</tr>
</tbody>
</table>
FALL & PRESSURE ULCER PREVENTION INITIATIVES

- QI (feedback) for Acute- and Non-Acute Care Hospital Staff During Routine Surveys and Incident Investigation
- MDPH worked in close collaboration with Massachusetts Falls Prevention Coalition on fall-reduction initiatives.
- PatientCareLink, developed by the Massachusetts Hospital Association and the Massachusetts Organization of Nursing Executives: highlights a series of initiatives to reduce falls and pressure ulcers.
- Current Hospital-based Initiatives Include:
  - Berkshire Medical Center: wound care specialist “champions” on all units act as a resource for patients, family and staff. Champions attend pressure ulcer-related trainings and disseminate skills and knowledge.
  - Beth Israel Deaconess Medical Center: Nurses report all stage 2-4 pressure ulcers, deep tissue injuries, and unstageable ulcers through widely-accessed electronic patient safety reporting system
  - Boston Medical Center: nurse-staffed “skin team” rotates and consults upon identification of any pressure ulcer to provide support and longitudinal tracking.
  - Brigham & Women’s Hospital: Re-education of entire nursing staff as well as incorporation of information sharing technology, pressure redistribution mattresses, and Dolphin pads are components of a hospital-wide initiative to eliminate pressure ulcers.
  - Cooley-Dickinson Hospital: zero pressure ulcers in three of the last eight quarters through a combination of ulcer tracking and quarterly unit-based survey.
  - Jordan Hospital: creation of an 8-bed special unit (“pod”) for patients at high risk of falls.
  - Mercy Medical Center: Pressure Ulcer Prevention Team reduced med/surg pressure ulcers by 88% over 17 months through a comprehensive approach including education, a signal device, and pressure reduction tools.
  - Southcoast Health System: reducing falls through co-location of high-risk patients, utilization of ‘low to ground’ beds for at-risk patients, innovative alarms, activities aprons, and more.
IMPACTS OF COMPELLED RELEASE

• Some critics of SRE reporting note that compelled release, which may be required for civil judicial proceedings, criminal judicial proceedings, or administrative proceedings, limits comfort with reporting.

• A comparison with Board of Registration in Medicine SRE data (of which release is prohibited) suggests that compelled release has not hindering reporting.

1Massachusetts Board of Registration in Medicine Annual Report, 2010
# Adverse Event Reporting Across the Country

- Highly Variable

## Table: Adverse Event Reporting Across the Country

<table>
<thead>
<tr>
<th>State</th>
<th>Hospital</th>
<th>Type of Event</th>
<th>Location or Service Where Event Occurred</th>
<th>Date of Event</th>
<th>Date of Discovery</th>
<th>State or City of Event Description</th>
<th>Event Description</th>
<th>Impact of Event on Patient</th>
<th>Patient Age or Sex</th>
<th>Patient Diagnosis</th>
<th>Patient Medical Record Number</th>
<th>Report Date</th>
<th>Report Time</th>
<th>Root Cause Analysis</th>
<th>Corrective Action Plan and Risk Reduction Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorado</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connecticut</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florida</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indiana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kansas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minnesota</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Jersey</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ohio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oregon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Carolina</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Dakota</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tennessee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utah</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vermont</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washington</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wyoming</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total States**  
- 26
- 26
- 20
- 24
- 10
- 11
- 18
- 12
- 19
- 16
- 5
- 2
- 7
- 12
- 16
- 20
- 10
- 11
- 10
- 4
- 9

CONCERNS WITH DATA VALIDITY AND/OR MEANINGFULNESS: WHAT’S HAPPENING IN MA HOSPITALS?

Total Medication Errors Acute Hospitals 2008 – 2011 (projected)

Year

Number of Medication Errors

- 2008: 12
- 2009: 7
- 2010: 9
- 2011 Projected: 0
LOOKING TO THE FUTURE: SRE REPORTING IN MASSACHUSETTS

- Adverse events, including SREs, are a core measure of hospital quality and safety

- As no national (or even robust state) baselines exist, it is misleading to draw strong conclusions about the overall quality of care at an individual hospital based on a raw number or types of SREs reported. Indeed a higher number of SREs may indicate a strong reporting culture, rather than a quality concern

- While it is widely accepted that not all SREs are preventable, our goal remains elimination of all preventable adverse events. 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

- SRE reporting in the Commonwealth to date lacks breadth and depth to have sufficient impact on reduction of adverse events

- “Near misses” are not centrally reported in the Commonwealth yet are critical to understanding hospital safety and quality

- BHCSQ is sufficiently sensitive to detect trends in quality and safety
IDENTIFICATION & DISSEMINATION OF BEST PRACTICES

- Best practices and lessons learned from root cause analyses are insufficiently disseminated.

- Barriers to reporting may include the sensitivity of SRE definitions, reporting culture (both with regard to public accountability and physician responsibility), fear of litigation/disclosure, or indeed a combination of these or other factors.

- Root Cause Analyses and Preventability Determinations conducted by hospitals after the occurrence of an SRE are reported to the DPH.

- In the next six months, the DPH will conduct an analysis of root causes/contributing factors for the eight most commonly reported SREs. Root causes and identified best practices will be disseminated in the following areas of focus:
  - Rules, Policies, and Procedures, including Utilization of Near-Miss Tracking
  - Communication
  - Environment/Equipment
  - Training
  - Physical Barriers
  - Fatigue/Scheduling
IMPACT OF NON-PAYMENT

• In the next six months, the Department will conduct an assessment of cases in which payment was not sought by healthcare providers in response to the occurrence on an SRE. Focus areas will include:

  • Hospital response to causative factors of event.
  • Assessment of pertinent “near-misses” to assist in furtherance of Departmental pattern-recognition.
FOCUS AREAS

• Understanding aggregate root causes and preventability, including examining trends in cases of non-payment

• Disseminating best practices

• Further refining pressure ulcer definitions

• Understanding the incidence of medication errors and near misses in Massachusetts hospitals
POTENTIAL PARTNERS

• Board of Registration in Medicine/Board of Registration in Nursing
• Health Care for All
• Massachusetts Association of Health Plans
• Massachusetts Coalition for the Prevention of Medical Errors
• Massachusetts Health Quality Partners
• Massachusetts Hospital Association
• Massachusetts Organization of Nursing Executives
• Mass Senior Care
• Minnesota Department of Health
• Society of Physician Quality Officers