Serious Reportable Events in 2014
Acute Care Hospitals, Non-Acute Care Hospitals and Ambulatory Surgical Centers

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Overview

• Purpose

• Background

• Serious Reportable Event Category Definitions

• Outcomes

• Positive Indicators

• Quality Improvement Activities
This presentation is given for the following purposes:

• To provide an update of the Serious Reportable Event program and related quality improvement activities at the Bureau of Health Care Safety and Quality; and

• To share the trends in the types and volume of Serious Reportable Events reported in 2014 and previous years.
• Adverse events that occur in the health care setting are a patient safety concern and public health issue.
  
  • It is estimated that 13.5% of Medicare patients nationally experience an adverse event during hospitalization (OIG, 2010).
  
  • Recent multiple hospital studies showed that nationally as many as 1/3 of patients were harmed during their hospitalization (Landrigan, et. al., 2010).

• Section 51H of chapter 111 of the Massachusetts General Laws authorizes the Department to collect adverse medical event data and disseminate the information publicly to encourage quality improvement.
• The National Quality Forum (NQF), a private quality organization that works closely with government, developed an adverse event identification and reporting framework used by the Department.

• NQF has operationalized a group of adverse events into measurable, evidence-based outcomes called Serious Reportable Events (SRE).

• MA adopted SREs as its adverse event reporting framework in 2008.

• 27 other states have state-based adverse event reporting programs and over half use the SRE framework including Connecticut, Minnesota and New Hampshire.
• Hospitals and ambulatory surgical centers (ASCs) are required to report SREs to the patient/family, third party payer, and the Bureau of Health Care Safety and Quality (BHCSQ) within seven days of the incident.

• An updated report to all three parties is required within 30 days of the incident, including documentation of the root cause analysis findings and determination of preventability as required by 105 CMR 130.332(c) & 105 CMR 140.308(c).

• In June 2009, the Department implemented regulations prohibiting health care facilities from charging for services provided as a result of preventable SREs.

• Reporting continues to improve likely because of internal efforts at facilities, the Department’s process improvement and joint engagement.
• **Section 51H of Chapter 111 of the General Laws:**
  “Serious reportable event”, an event that results in a serious adverse patient outcome that is clearly identifiable and measurable, reasonably preventable, and that meets any other criteria established by the department in regulations.

• **105 CMR 130.332:**
  Serious Reportable Event (SRE) means an event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are usually or reasonably preventable, and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the hospital. The Department will issue a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 applies.

• Currently, there are 29 SREs grouped into seven categories.
SRE Types

**Surgical or Invasive Procedure Events**
- Wrong Site Surgery or Procedure
- Surgery or Procedure on Wrong Patient
- Wrong Surgery or Procedure
- Unintended Retention of a Foreign Object
- Intraoperative or Immediate Postoperative Death of an ASA Class 1 Patient

**Product or Device Events**
- Death or Serious Injury Related to Contaminated Drugs, Biologics, or Devices^,
- Death or Serious Injury Related to Device Misuse or Malfunction^,
- Death or Serious Injury Due to Intravascular Air Embolism^,

**Patient Protection Events**
- Discharge of a Patient/Resident of Any Age to Other Than Authorized Person^,
- Death or Serious Injury Associated with Patient Elopement^,
- Patient Suicide, Attempted Suicide, or Self-Harm That Results in Serious Injury^,

^ Definition changed in October 2012
Care Management Events

- Death or Serious Injury Associated with a Medication Error^ 
- Death or Serious Injury Associated with Unsafe Blood Product Administration 
- Maternal Death or Serious Injury Associated with Low-Risk Pregnancy Labor or Delivery^ 
- Death or Serious Injury of a Neonate* 
- Death or Serious Injury Associated with a Fall^ 
- Stage 3, Stage 4 or Unstageable Pressure Ulcer^ 
- Artificial Insemination With Wrong Donor Sperm or Egg 
- Death or Serious Injury from Irretrievable Loss of a Specimen* 
- Death or Serious Injury from Failure to Follow Up on Test Result* 

^ Definition changed in October 2012    * New event in October 2012
SRE Types

Environmental Events
- Patient or Staff Death or Serious Injury Associated with an Electric Shock^ 
- Any Incident In Which No Gas, Wrong Gas or Contaminated Gas Delivered to Patient 
- Patient or Staff Death or Serious Injury Associated with a Burn^ 
- Death or Serious Injury Associated with Restraints or Bedrails^ 

Radiologic Events
- Death or Serious Injury of Patient or Staff Associated with Introduction of a Metallic Object Into MRI Area* 

^ Definition changed in October 2012
* New event in October 2012
SRE Types

Potential Criminal Events

- Any Instance of Care Provided by Someone Impersonating a Health Care Provider
- Resident/Patient Abduction
- Sexual Abuse/Assault on a Patient or Staff Member
- Death or Serious Injury of Patient or Staff Member as a Result of Physical Assault^  

^ Definition changed in October 2012
Total Number of SREs in Acute Care Hospitals by Year

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Surgical Event SREs 2011-2014 (Acute care hospitals)

- Wrong Site Surgery or Procedure: 21, 26, 36, 24
- Surgery or Procedure on Wrong Patient: 3, 2, 0, 0
- Wrong Surgery or Procedure: 2, 8, 11, 10
- Unintended Retention of a Foreign Object: 36, 38, 33, 41
- Intraoperative or Immediate Postoperative Death of an ASA Class 1 Patient: 0, 0, 1, 0

- Blue: 2011
- Red: 2012
- Green: 2013
- Purple: 2014
Product or Device SREs 2011-2014 (Acute care hospitals)

- Contaminated drugs, device or biologics
  - 2011: 0
  - 2012: 4
  - 2013: 14
  - 2014: 37

- Device misuse or malfunction
  - 2011: 4
  - 2012: 7
  - 2013: 8
  - 2014: 14

- Intravascular air embolism
  - 2011: 2
  - 2012: 5
  - 2013: 2
  - 2014: 6
Environmental Event SREs 2011-2014 (Acute care hospitals)

- Serious injury or death from electric shock:
  - 2011: 0
  - 2012: 1
  - 2013: 1
  - 2014: 0

- Oxygen or gas delivery error:
  - 2011: 0
  - 2012: 1
  - 2013: 0

- Serious injury or death from burn:
  - 2011: 6
  - 2012: 12
  - 2013: 16
  - 2014: 30

- Serious injury or death from physical restraints:
  - 2011: 0
  - 2012: 5
  - 2013: 5
  - 2014: 4

- Serious injury or death from metallic object in MRI:
  - 2011: 0
  - 2012: 1
  - 2013: 0
  - 2014: 1
Patient Protection SREs 2011-2014 (Acute care hospitals)


Legend:
- Blue: 2011
- Red: 2012
- Green: 2013
- Purple: 2014
Potential Criminal Event SREs 2011-2014 (Acute care hospitals)

- Provider impersonation: 9
- Patient abduction: 3
- Sexual assault/abuse: 3
- Physical assault/abuse with serious injury or death: 14

2011
2012
2013
2014
Care Management SREs 2011-2014 (Acute care hospitals)

- Serious injury or death from medication error
- Unsafe blood transfusion
- Maternal serious injury or death associated with labor or delivery
- Newborn serious injury or death associated with delivery
- Serious injury or death after a fall
- Stage 3, Stage 4 or unstageable pressure ulcer
- Artificial insemination with wrong egg or sperm
- Serious injury or death from loss of irreplaceable biological specimen
- Serious injury or death from lack of follow up or communication of lab result

Graph showing the number of incidents per year from 2011 to 2014.
Total Number of SREs in Non-Acute Care Hospitals by Year

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Reported SREs 2011-2014 (Non-acute care hospitals)
There are 59 ASCs in Massachusetts.

2014 is the first year ASC SRE data is being publicly reported.

Outreach and education is ongoing through the Massachusetts Association of Ambulatory Surgical Center regarding reporting and trends.

Despite this outreach, the low volume of reports compared with acute and non-acute care hospitals may be observed.
Positive Indicators

As noted, there has been a continued increase in the number of SREs in 2014. These increased numbers may be based on the following:

- Adoption of the NQF’s updated SRE list and definitions led to a marked rise in reporting in several existing categories, including falls and pressure ulcers.

- Process improvement including internal quality improvement and near universal utilization of the Health Care Facility Reporting System (HCFRS), an online reporting system that has reduced barriers and streamlined the facility reporting process.

- Department outreach to facilities and emphasis on reporting as an important quality improvement priority likely increased reporting.
Quality Improvement Activities

• Partnering with Betsy Lehman Center to address the following:
  • Wrong site and wrong procedure cataract surgeries; and
  • Drafting an Interagency Service Agreement to allow for more seamless data sharing, as intended by the 2012 cost containment act.

• Working with the Department of Mental Health and DPH’s Suicide Prevention Program to develop and disseminate best practices for reducing suicide and self-harm in the inpatient setting;

• Collaborating with the Board of Registration in Medicine on an obstetric emergency advisory.
Quality Improvement Activities

• Working with individual facilities after a SRE occurs to develop corrective action plans and prevent an event of a similar type from happening in the future;

• Cohosting workgroups with Massachusetts Coalition for the Prevention of Medical Errors to accomplish the following:
  • Evaluate patient and family SRE communication process and effectiveness of 7-day and 30-day reports; and
  • Analyze pressure ulcer reports in an effort to streamline reporting.
• Thank you for the opportunity to present this information today.

Please direct any questions to:
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