Serious Reportable Events in 2016
Acute Care Hospitals, Non-Acute Care Hospitals
and Ambulatory Surgical Centers

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Overview

• Purpose
• Background
• Serious Reportable Event Category Definitions
• Outcomes
• 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 2016 and previous years.
• Adverse events that occur in the health care setting are a patient safety concern and public health issue.

  • The Office of the Inspector General found that adverse events occur in 13.5% of hospital admissions of Medicare beneficiaries (2010).

  • It is also projected that 10% of Medicare patients nationally experience an adverse event during a rehabilitation hospital stay (OIG, 2016).

• 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) 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.
SREs Defined

- **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 and 105 CMR 140.308:**
  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 issued a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 and 105 CMR 140.308 apply in guidance.
• Hospitals and ambulatory surgical centers (ASCs) are required to report SREs to the patient/family 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.

• Amendments adopted as part of the hospital regulatory review completed earlier this year streamlined the reporting process without removing transparency.
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
SRE Types

- 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
• 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

- **2012**: 599
- **2013**: 891 *
- **2014**: 821
- **2015**: 1313 **
- **2016**: 1012 **

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
** Two events in 2015 and 2016 affected a large number of patients and is reflected in the increase in SREs reported
Key Findings

- Increasingly these events occur outside of the operating room in radiology, labor and delivery and ambulatory units.

- The most frequently reported outcome is that patients require an additional surgery or procedure.
Key Findings

- In the contaminated drugs, device or biologics event, one incident, that affected a significant number of patients in 2016, represents most of the category.

- The hospital engaged in corrective action plan to address the root causes of these incidents.

**Two events in 2015 and 2016 affected a large number of patients and is reflected in the increase in SREs reported.**
Key Findings

- The burns event represents second degree or more severe burns.
- They result from cautery devices, chemotherapy and hot beverage spills, and instant hot packs.

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Key Findings

- There was 1 completed suicide and 40 self-harm or attempted suicide events in 2016.
- Inpatient psychiatric units followed by emergency departments are the locations with the highest incidence of suicide and self-harm events.

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Key Findings

- Over half of the physical assaults or abuse events that resulted in serious injury were patient on staff member encounters.

- Since the beginning of SRE reporting there has never been any provider impersonation or patient abduction reported.

- Inpatient psychiatric units are the most frequently reported location within the hospital for these events.

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Key Findings

- Falls and pressure ulcers are the two most common events.
- Fractures are the most common serious injury.

*Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions*
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
Key Findings

- Three types of hospitals: public health, rehabilitation or psychiatric.
- Like acute care hospitals, falls and pressure ulcers continue to be the most common events.

* Significant increase in the # of SREs reported from 2012 to 2013 due to adoption of new NQF definitions
Key Findings

- There are 59 ASCs in Massachusetts.
- 2014 was the first year ASC SRE data was publicly reported.
- Outreach and education regarding reporting and trends in order to encourage submissions is ongoing.
Quality Improvement Activities

• Continued collaboration with DPH’s Suicide Prevention Program to share event data and promote use of online curriculum detailing best practices for reducing suicide and self-harm in the facility setting.

• Sharing de-identified pressure ulcer events with wound ostomy and continence nurse stakeholder groups.

• Actively participating in MA Coalition for the Prevention of Medical Errors.

• Partnering with Betsy Lehman Center to address the following:
  • Utilize their monthly newsletter to share patient safety trends; and
  • Maintaining an Interagency Service Agreement to allow for more seamless data sharing, as intended by the 2012 cost containment act.

• 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.

• Utilizing DPH list serves for widespread education and to share appropriate guidance.
Thank you for the opportunity to present this information today.

Please direct any questions to:
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