Slide 1

**Serious Reportable Events 2018**

Public Health Council

June 12, 2019

Katherine T. Fillo, Ph.D, RN-BC

Bureau of Health Care Safety and Quality

Katherine Saunders, MS  
Bureau of Health Care Safety and Quality

Slide 2  
**Overview**

* Purpose
* Background
* Serious Reportable Event Category Definitions
* Outcomes
* Quality Improvement Activities

Slide 3  
**Purpose**

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 2018 and previous years.

Slide 4  
**Background**

* 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 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.

Slide 5  
**Background**

* 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.

Slide 6  
**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 14.308 apply in guidance.

Slide 7  
**Reporting Requirements**

* 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 the patient/family, BHCSQ and third party payer 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 in 2017 streamlined the reporting process without removing transparency.

Slide 8  
**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

Slide 9  
**SRE Types**

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

Slide 10  
**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

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

Slide 11  
**Acute Care Hospital Data**  
  
2014: 821  
2015: 1313\*\*  
2016: 1012\*\*  
2017: 922  
2018: 1066

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

Data abstracted on May 22, 2019 from the Health Care Facility Reporting System

Slide 12  
**Acute Care Surgical Data**  
  
Chart of Surgical or Invasive Procedure Events, 2014-2018

Key Findings

Increasingly SREs occur outside of the operating room in radiology, labor and delivery, and outpatient procedure units.

The most frequently reported outcome is that patients require an additional surgery or procedure to remove the object.

Slide 13  
**Acute Care Hospital Product/Device Data**

Chart of Product or Device Events, 2014-2018

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.

Slide 14  
**Acute Care Hospital Environmental Data**

Chart of Environmental Events, 2014-2018

Key Findings

Burn events represent second degree or more severe burns.

Burn events result from equipment including radiology machines and cautery devices, chemotherapy and hot beverage spills.

Slide 15  
**Acute Care Hospital Patient Protection Data**

Chart of Patient Protection Events, 2014-2018

Key Findings

There were 2 completed suicide and 34 self-harm or attempted suicide events in 2018.

Cutting and ingesting objects are the methods reported as having the highest incidence in the suicide and self-harm events.

Slide 16  
**Acute Care Hospital Potential Criminal Event Data**

Chart of Potential Criminal Events, 2014-2018

Key Findings

Over half of the physical assaults or abuse events that resulted in serious injury were patient on staff member encounters, often resulting in lost work days.

Inpatient psychiatric units followed by emergency departments and medical-surgical units are the most frequently reported location within the hospital for these events.

Slide 17  
**Acute Care Hospital Care Management Data**

Chart of Care Management Events, 2014-2018

Key Findings

Falls that result in serious injury and pressure ulcers are the two most commonly reported events.

Pressure injuries are most common serious injury, about 60% of those reported occurred on the back, spine or buttocks.

Slide 18  
**Non-Acute Care Hospital Data**

Total Number of SREs in Non-Acute Care Hospitals by Year

2014: 236  
2015: 237  
2016: 237  
2017: 196  
2018: 194

Data abstracted on June 15, 2018 from the Health Care Facility Reporting System

Slide 19  
**Non-Acute Care Hospital Category Data**  
  
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.

Slide 20  
**Ambulatory Surgical Centers 2014-2017 SRE Totals**

Key Findings

There are 59 ASCs in Massachusetts.

All SREs were related to cataract procedures.

DPH continues to outreach and provide education regarding reporting and trends in order to encourage submissions.

Slide 21  
**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.
* Sharing de-identified pressure ulcer events with wound ostomy and continence nurse stakeholder groups.
* 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.
* Actively participating in MA Coalition for the Prevention of Medical Errors.
  + Sharing electronic health system related events and opportunities to address causal factors.
* 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.
* Utilizing DPH list serves for widespread education and to share appropriate guidance.

Slide 22  
**Contact Information**

Thank you for the opportunity to present this information today.

Please direct any questions to:

Katherine T. Fillo Ph.D, MPH, RN-BC

Director, Clinical Quality Improvement

Bureau of Health Care Safety and Quality

[katherine.fillo@state.ma.us](mailto:katherine.fillo@state.ma.us)