

Serious Reportable Events:

*Calendar Year 2022*

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

Bureau of Health Care Safety and Quality

**Katherine Saunders, M.S.**

Bureau of Health Care Safety and Quality

**Overview**

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

**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 2022 and previous years.

**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 27% of hospitalized Medicare beneficiaries (OIG, 2022).
* It is also estimated that 29% of Medicare patients nationally experience an adverse event during a rehabilitation hospital stay (OIG, 2022).

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.

**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.
* There is no federal adverse event reporting system, however this is the framework and definitions that the OIG uses in their publications. Additionally, twenty-seven other states have developed and implemented state-based adverse event reporting programs.

‒ Over half of those use the SRE framework including Connecticut, Minnesota and New Hampshire.

**SREs and the COVID-19 Public Health Emergency**

### In 2020, 2021 and 2022, nonessential and elective invasive procedures were temporarily reduced by:

* + Order Of The Commissioner Of Public Health Regarding Scheduling And Performance Of Elective Invasive Procedures *(May 18, 2020)*
  + COVID-19 Public Health Emergency Order No. 2021-14 *(November 23, 2021)*
  + COVID-19 Public Health Emergency Order No. 2022-10 (February 4, 2022)

### Very few SREs were reported by ambulatory surgical centers in calendar year 2021 and the number of SREs associated with surgical or invasive procedures was slightly diminished overall as compared to pre- pandemic levels.

**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 that are largely preventable and harmful, 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.

**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 BHCSQ, the patient/family, and the insurer 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.

# 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

**SRE Types**

* 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

**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

## 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

**SRE Types**

* 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

### Total Number of SREs in Acute Care Hospitals by Year

1,800

**Acute Care Hospital: Total SREs**

1,600

1,400

1,200

1,000

800

600

400

200

0

Serious Reportable Events

2018

2019

1,632

1,430

1,321

1,189

1,066

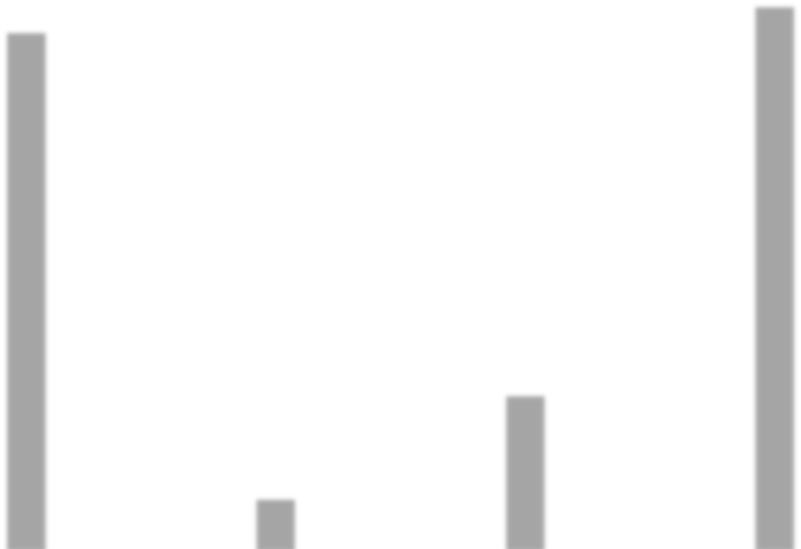
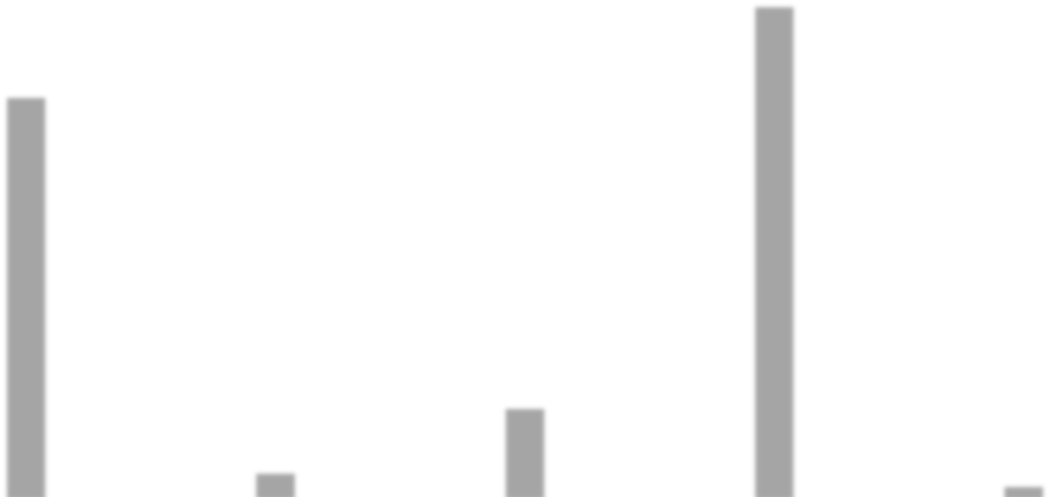
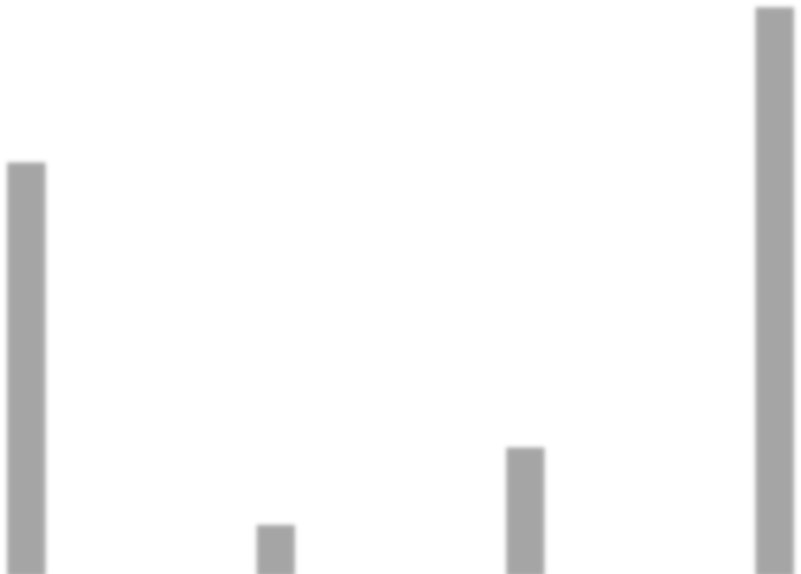
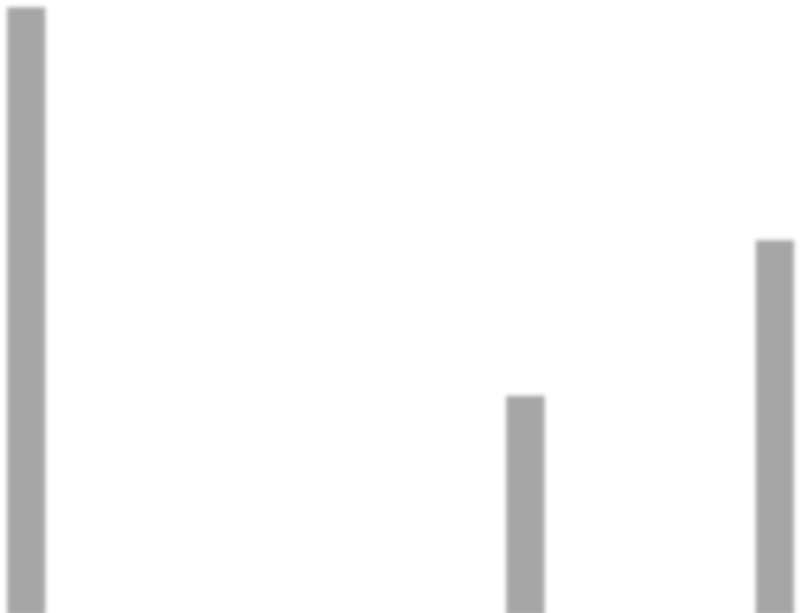
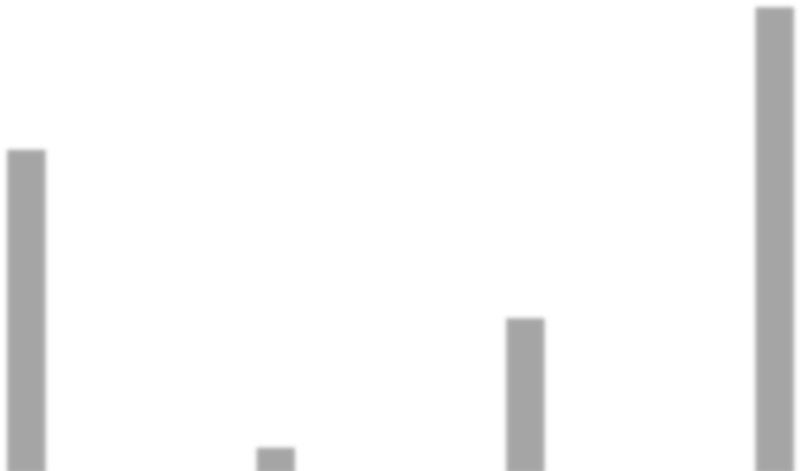
2020

2021

2022

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

50



47

44

42

40

38

36

32

31

29

25

17

12

12

10

7

4

4

2

2

0

0 0

0

1

0

45

**Key Findings**

For 2022, surgical

events increased, approaching levels seen prior to 2020.

The most frequently

reported outcome is that patients require an additional surgery or monitoring.

40

35

30

25

20

15

10

5

**Acute Care Hospital: Surgical Event SREs**

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

0

Wrong Site Surgery or Procedure

Surgery or Procedure on Wrong Surgery or Unintended Retention Wrong Patient Procedure of a Foreign Object

2018 2019 2020 2021 2022

Intraoperative or Immediate Postoperative Death of an ASA Class 1 Patient

60

50

32

28

2321

0 0 1 0 0

2 2

6 6

3

9

5 4 5

2

0 2 0 0 0

**Key Findings**

Burn events, the most

common in this category, represent second degree or more severe burns.

Burn events result from

equipment including radiology machines and cautery devices, hot packs and hot beverage spills. Most resolve during the course of the hospital stay without complications.

50

40

30

20

10

0

Serious injury or death

from electric shock

Oxygen or gas delivery error

Serious injury or death from burn

Serious injury or death from physical restraints

Serious injury or death from metallic object in

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

**Acute Care Hospital: Environmental Event SREs**

2018 2019 2020 2021 2022

MRI

80

**Key Findings**

Suicide and self-harm with

serious injury are the most common SRE in this category. Cutting or injury with an object and ingesting objects were the most common events, followed by medication overdose and hanging/strangulation/ intentional hypoxia. Most of these events occurred in adults aged 26-65 but one third were among adolescents aged 12-19.

68

58

36 38

40

6

1

2

3

5

3

7

2

2

1

70

60

50

40

30

20

10

0

Patient discharged to unauthorized person

Elopement with death or serious injury

Suicide or self-harm with serious injury

2018

2019

2020

2021

2022

**Acute Care Hospital: Patient Protection Event SREs**

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

90

**Key Findings**

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

Emergency departments

followed by inpatient medical/surgical and psychiatric units are the most frequently reported location within the hospital for these events to occur.

80

74

67

43

45 45

28

23

18

19

2

1

0

1

1

0

1

1

0

0

80

70

60

50

40

30

20

10

0

Provider impersonation Patient abduction Sexual assault/abuse Physical assault/abuse with

serious injury

**Acute Care Hospital: Potential Criminal Event SREs**

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

2018

2019

2020

2021

2022

## Acute Care Hospital: Care Management SREs

##### Key Findings

Pressure ulcers and falls that result in serious injury are the two most reported events. Pressure ulcers are most frequently reported as occurring on the back or spine (40%) followed by ones reported on the head or neck (20%).

700

664

623

574

497

454

421

393

361

341 333

48 61 54 49 69

0 0

1 0 0

13

5 3

2

6

18 14 15 24 23

0 0

0

0 0

6 7 3

9 11

9

5

12

9 14

600

500

400

300

200

100

0

Serious injury or death

Unsafe blood

Maternal serious

Newborn serious

Serious injury or death

Stage 3, Stage 4 or

Artificial insemination Serious injury or death Serious injury or death

from medication error

transfusion

injury or death associated with labor or delivery

injury or death associated with delivery

after a fall

unstageable pressure ulcer

with wrong egg or sperm

from loss of irreplaceable biological specimen

from lack of follow up or communication of lab result

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

2018

2019

2020

2021

2022

250

200

194

196

225

150

100

146 144

2018

2019

2020

2021

2022

**Non-Acute Care Hospital: Total SREs**

50

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

0

## Non-Acute Care Hospital: SREs by Category

##### Key Findings

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

120

108

10099

91

73

62

52

43 43

29

17

18

13

14

19

15

7 7

8

12

8

2

1 1

2 2

6

2

4

1

3

0

1

0

2

0 0

0 0

1 1

15

100

80

60

40

20

0

Serious injury or

death from medication error

Suicide or self harm

Serious injury or death after physical assault

Serious injury or death after burn

Serious injury or death from physical restraints

Stage 3, 4 or unstageable pressure ulcer

Sexual Assault on a patient/staff

Serious injury or death after a fall

Elopement with death/serious injury

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

2018 2019 2020 2021 2022

**Ambulatory Surgical Centers: Total SREs**

16

15

9

1

0

0

14

12

10 2018

2019

8 2020

2021

6 2022

4

2

*Data abstracted April 1,*

*2023 from the Health Care*

*Facility Reporting System* 0

1400

1200

1000

1144

##### Key Findings

Most SREs reported in CY 2022 are in white patients (78% N=1463). Most events for people of color (all non-white categories) were in Care Management SREs (N=157), similar to the overall population.

800

600

400

200

132 94

54 69 97

3 21

0

0 1 3 0 3

0 9 0

13 0 2

0 4 0

19 0 8

0 19 2

0 0 1

20 0 1 0

0 0 0

0 0 0 0

8 0 4

7 1 7 0

Care Management Environmental Patient Protection Potential Criminal Product or Device Radiologic Surgical or Invasive

**SRE Types by Race**

|  |  |  |
| --- | --- | --- |
| African American | American Indian/Alaska Native | Asian |
| Native Hawaiian/Pacific Islander | White | Other |
| Unknown | More than 1 |  |

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

1400

1215

**Key Findings**

Although most SREs in CY 2022 were reported in Non-Hispanic patients (N=1549), about 7% (N=137) are reported for Hispanic patients, about 9% (N=172) are reported for patients with unknown or missing ethnicity.

96

93

113

5

54

6

15

66

83

17

14

40

0

18

0

0 0 1

7

9

1200

1000

800

600

400

200

0

Care Management Environmental Patient Protection Potential Criminal Product or Device Radiologic Surgical or Invasive

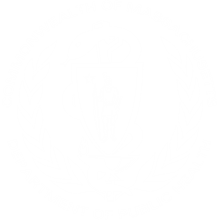
Hispanic Non-Hispanic Unknown

**SRE Types by Ethnicity**

*Data abstracted March 1, 2023 from the Health Care Facility Reporting System*

**Quality Improvement Activities**

* Working with individual facilities after an SRE occurs to develop corrective action plans and prevent an event of a similar type from happening in the future.
* 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.
* Partnering with Betsy Lehman Center to address SRE trends and maintain an Interagency Service Agreement to allow for more seamless data sharing, as intended by the 2012 cost containment act.
* Exploring opportunities to collaborate with stakeholders to decrease incidence of pressure injuries and falls including:
  + Scheduled presentation to ASC sector organization in June.
  + Planning presentations to New England Region Wound, Ostomy, and Continence Nurses Society, and the Massachusetts Society for Health Care Risk Management



**Thank you for the opportunity to present this information today. Please direct any questions to:**

**Katherine Saunders, M.S.**

Manager, Data Analysis and Integrity Bureau of Health Care Safety and Quality [katherine.saunders@mass.gov](mailto:katherine.saunders@mass.gov)