**Serious Reportable Events**

**Calendar Year 2020**

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Public Health Council

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**Overview**

* Purpose
* Background
* Serious Reportable Event Category Definitions
* Outcomes
* 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 2020 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 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.

**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. Twenty-seven other states developed and implemented state-based adverse event reporting programs.
	+ Over half use the SRE framework including Connecticut, Minnesota and New Hampshire.

**SREs and COVID-19**

* As part of the COVID-19 response, all nonessential and elective invasive procedures were suspended beginning March 15, 2020 and were able to resume on June 24, 2020 under a set of limited circumstances. There was a similar restriction on these procedures again in December of 2020.
* No SREs were reported by ambulatory surgical centers in calendar year 2020 and the number SREs associated with surgical or invasive procedures was significantly diminished overall.

**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

Radiologic 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

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

**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

**Acute Care Hospital Data**

Total Number of SREs in Acute Care Hospitals by Year

1400

1321

1189

1012 \*\*

1066

922

1200

1000

800

600

400

200

0

2016 2017 2018 2019 2020

\*\* An event in 2016 affected a large number of patients and is reflected in the increase in SREs reported.

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System

60

49

47

44

35

35

36

32

31

29

25

17

11

12

10

8

6

4

1

2

0

0 0 0 0 0

**Key Findings**

For 2020, there was an

increase in the number of events where there was an unintended retention of a foreign object.

The most frequently

reported outcome is that patients require an additional surgery or procedure to remove the foreign object that was unintentionally retained.

50

40

30

20

10

0

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

2016 2017 2018 2019 2020

**Acute Care Hospital Surgical Event Data**

Data abstracted May 28, 2021 from the Health Care Facility Reporting System

of an ASA Class 1 Patient

160

**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 a robust corrective action plan to address the root causes of these incidents.

Since 2016, the number of

product/device events has decreased although there was a slight increase in device misuse or malfunction for 2020.

140

120

100

80

60

40

20

0

Contaminated drugs, device or biologics

138 \*\*

21

21

8

5

5

9

11

15

18

9

3

7

6

2

Device misuse or malfunction Intravascular air embolism

2016 2017

2018

2019

2020

**Acute Care Hospital: Product/Device Event Data**

\*\*An event in 2016 affected a large number of patients and is reflected in the increase in SREs reported.

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

35

32

29

25

28

23

5

4

0 0 0 0 1

2 2 2

0

3

2 2 2

1 0 0 2 0

**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.

30

25

20

15

10

5

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 MRI

2016

2017

2018

2019

2020

**Acute Care Hospital: Environmental Event Data**

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

70

58

41

36 38

2

0

1

2

3

2

2

3

2

2

25

**Key Findings**

There was 1 completed

suicide event and 57 self- harm or attempted suicide events in 2020.

Cutting and ingesting

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

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

2016

2017

2018

2019

2020

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

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

80

67

45 45

41

34

23

18 19

10

7

0

0

2

1

0

0 0

0

1 1

**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.

Emergency departments

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

70

60

50

40

30

20

10

0

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

serious injury

2016

2017

2018

2019

2020

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

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

**Acute Care Hospital: Care Management Event Data**

**Key Findings**

Pressure injuries and falls that result in serious injury are the two most commonly reported events.

Pressure ulcers are the most common serious injury, about 56% of those reported occurred on the back, spine or buttocks and 41% occurred

in patients under the age of 65 years.

600

574

497

393

361

341 333

308

294

285

272

43

52 48 61 54

0 0 0

1 1

6 7 5

13

2

19 11 18 14 15

0 0 0 0 0

5 6

2

7

3

6

10 9

5

12

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

2016

2017

2018

2019

2020

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

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

250

237

196

194

146

144

200

150

100

50

2016

2017

2018

2019

2020

**Non-Acute Care Hospital Data**

0

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

Reported SREs 2016-2020 (Non-acute care hospitals)

140

119

108

95

91

73

71

60

43 43

16 11 13

17

11 13

14

12

15

4

7

8

6 6

5

0

2

1 1

2

4

0 0 0

1

**Key Findings**

There are three types of hospitals: public health, rehabilitation or psychiatric.

Like acute care hospitals,

falls and pressure ulcers continue to be the most common events.

120

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

Serious injury or

death after a fall

2016

2017

2018

2019

2020

**Non-Acute Care Hospital: Category Data**

Data abstracted on May 28, 2021 from the Health Care Facility Reporting System.

**SRE Types by Race**

900

849

**Key Findings**

Although most SREs reported in CY 2020 are in white patients (71%

N=1046), a significant proportion of events are reported with unknown race (10% N=144), other race (4% N=56), or missing race (5% N=66).

Most events with unknown race, other race or missing race were in the care management and potential criminal event domains.

80

105

2 3

28

19 8

3

1

29

43

44

42

62

2

3 5

6 12 2

9

2

6

2

1 19

3 2

5 1

5 16 1 1

45

800

700

600

500

400

300

200

100

0

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

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

**SRE Types by Ethnicity**

1000

868

**Key Findings**

Although most SREs are reported in Non-Hispanic patients

(N=1084), about 6% (N=84) are reported for Hispanic patients, about 16% (N=238) are reported for patients with Unknown ethnicity and another 4% (N=59) are reported for patients with missing ethnicity.

 183

71

66

17

1

27

48

7

5

16

37

37

2

2

7

18

6

2

5

19

1

900

800

700

600

500

400

300

200

100

0

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

Hispanic Non-Hispanic Unknown Missing

**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.

* Collaborating with EHS agencies to ensure patient safety maintained during COVID-19 pandemic.
* 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 servs for widespread education and to share appropriate guidance.
* Exploring opportunities to collaborate with stakeholders to decrease incidence of pressure injuries.

**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

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