

**Serious Reportable Events**

**Calendar Year 2019**

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Bureau of Health Care Safety and Quality Bureau of Health Care Safety and Quality

* 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 2019 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.
* 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.

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:

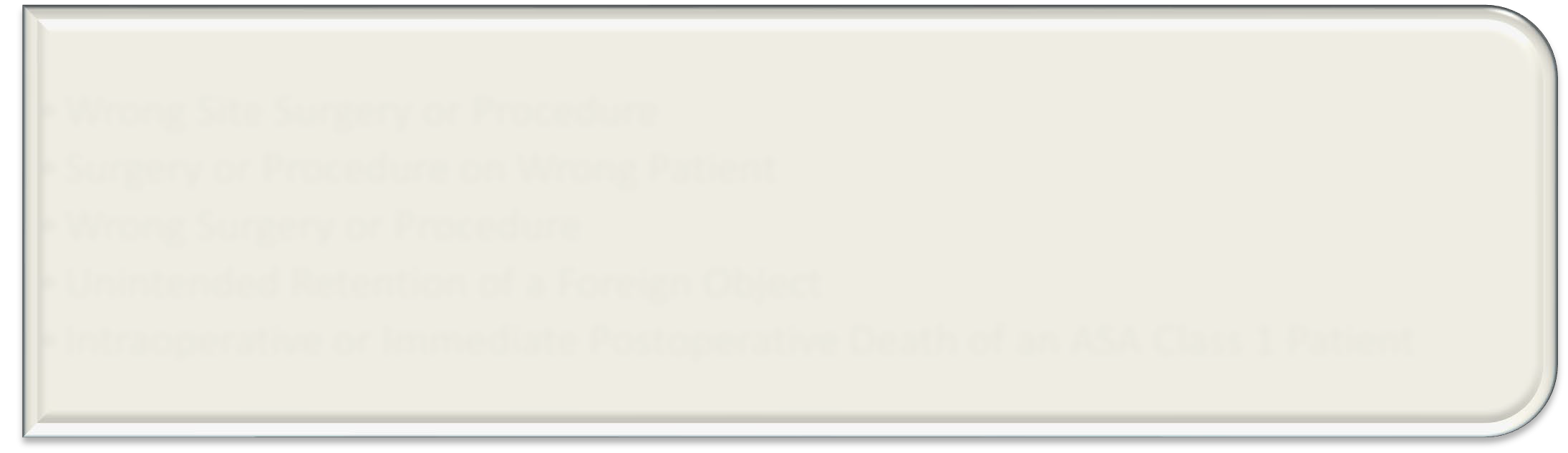
Serious Reportable Event (SRE) means an event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are usually or reasonably preventable, and of a nature such that 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 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



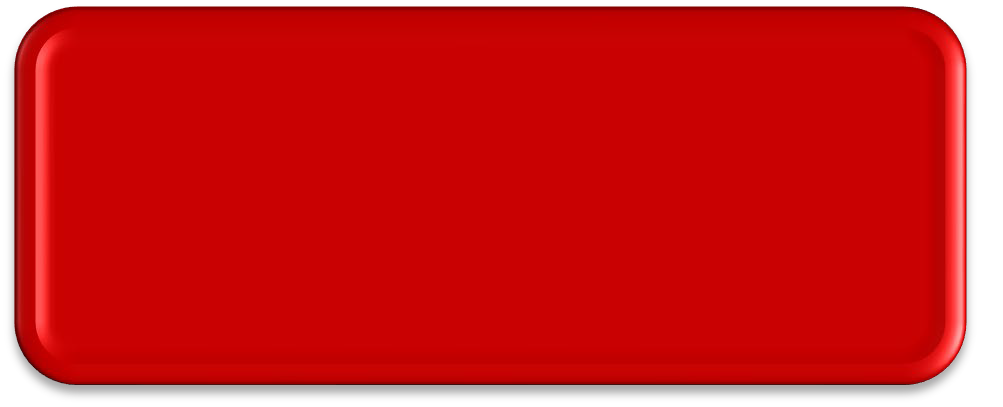
* Wrong Surgery or Procedure
* Unintended Retention of a Foreign Object
* Intraoperative or Immediate Postoperative Death of an ASA Class 1 Patient

**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

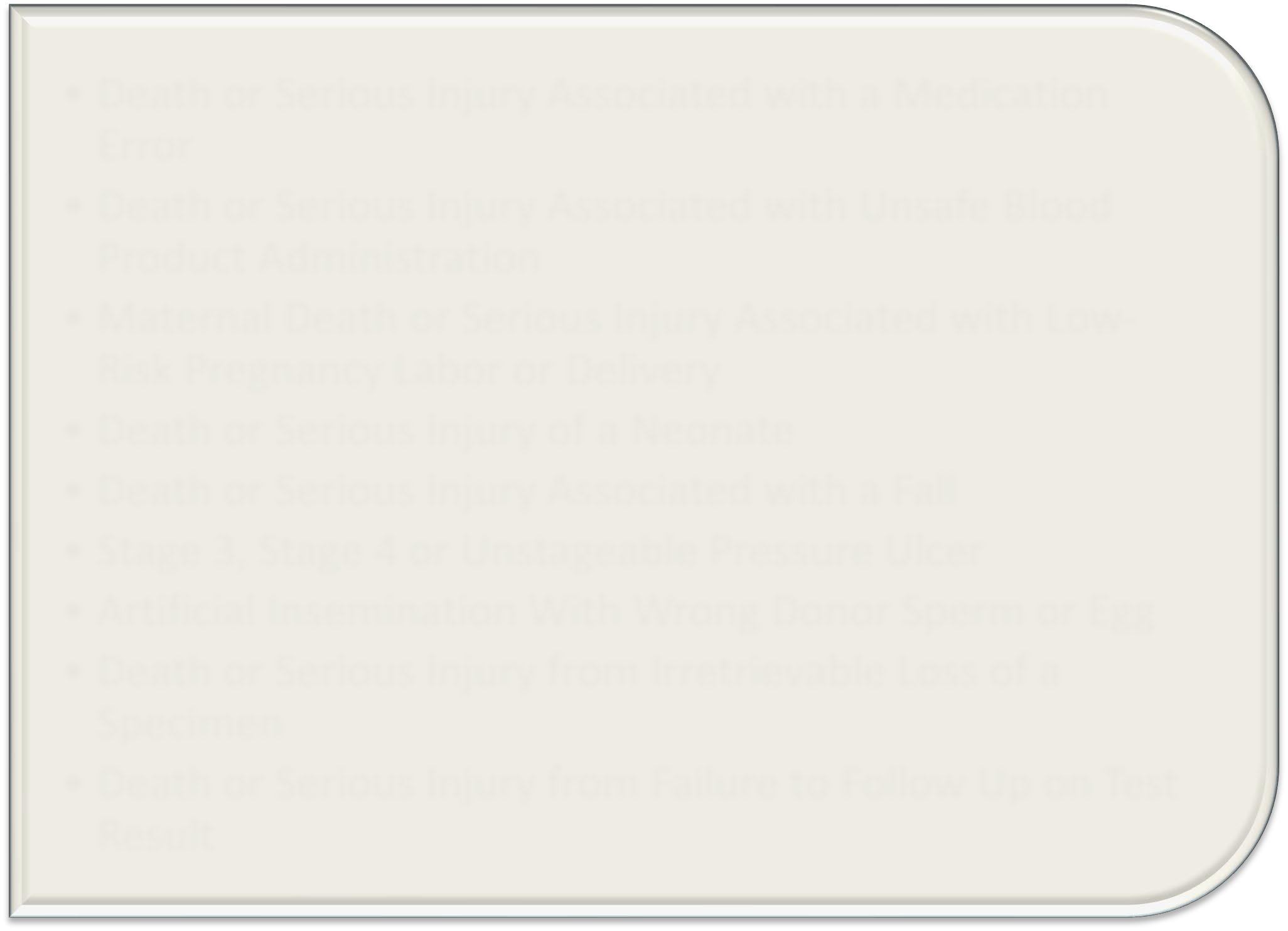
**Patient Protection Events**



* 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

Care Management Events

* + Death or Serious Injury Associated with a Medication Error
  + Death or Serious Injury Associated with Unsafe Blood Product Administration

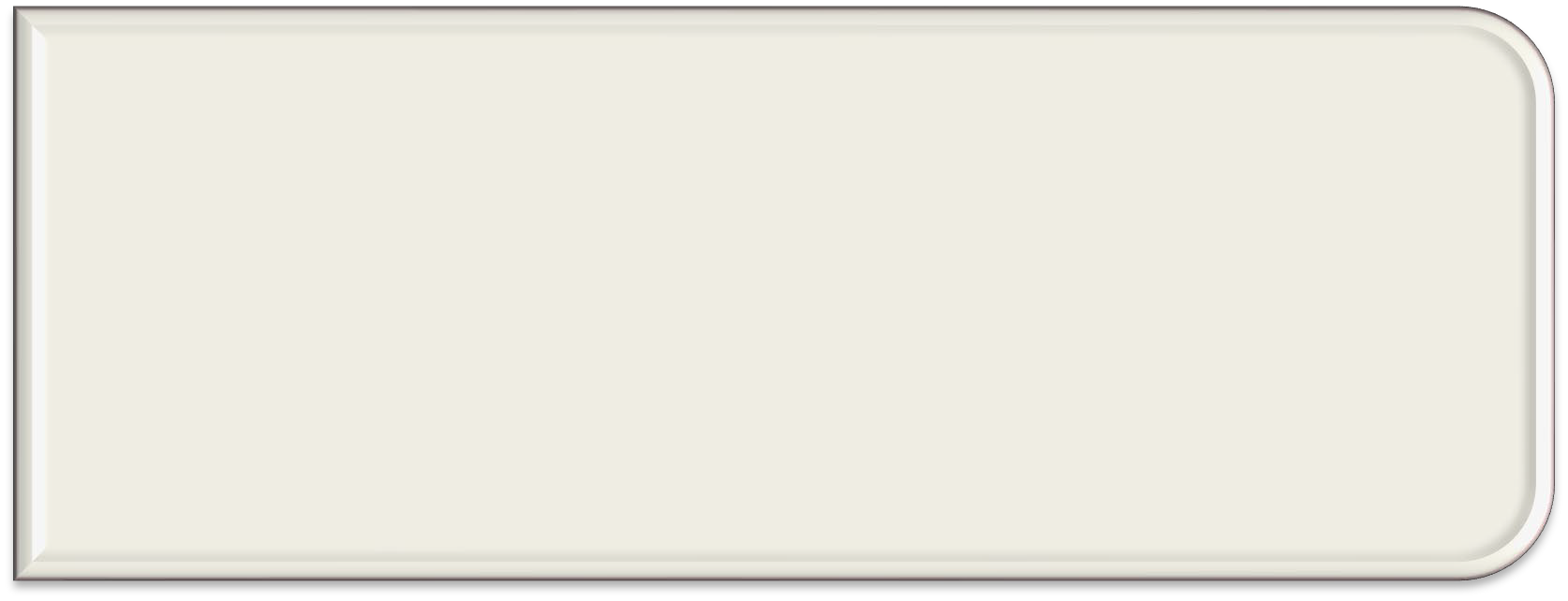
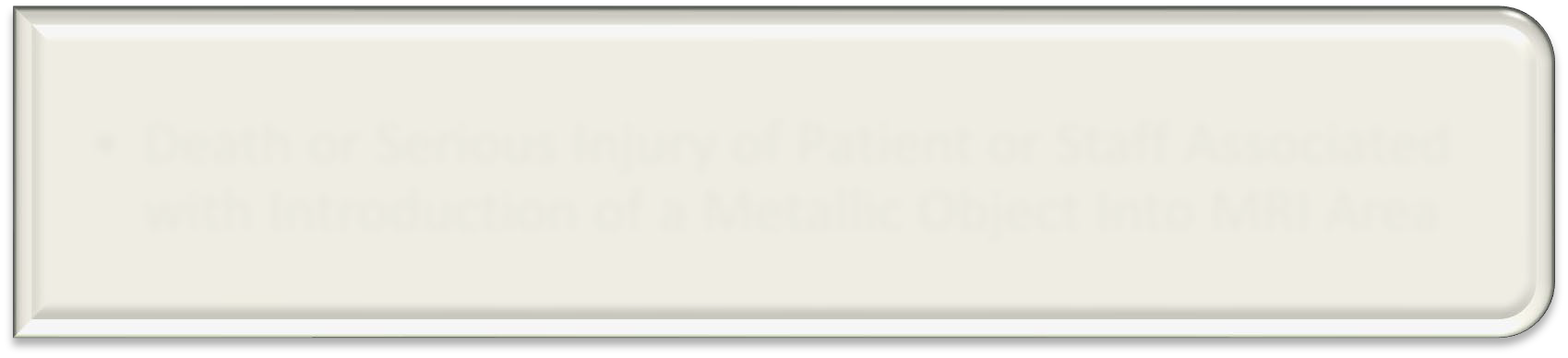
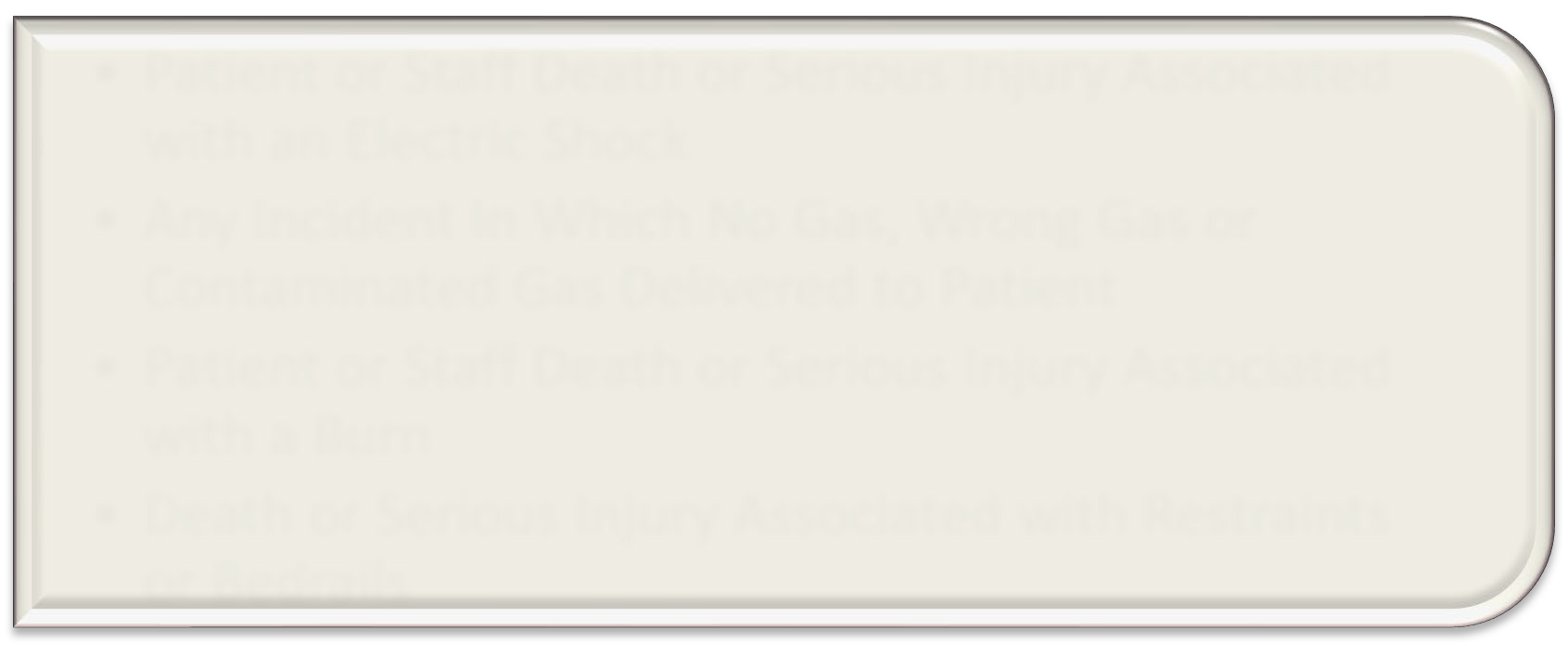


* + Maternal Death or Serious Injury Associated with Low- Risk Pregnancy Labor or Delivery
  + Death or Serious Injury of a Neonate
  + Death or Serious Injury Associated with a Fall
  + Stage 3, Stage 4 or Unstageable Pressure Ulcer
  + Artificial Insemination With Wrong Donor Sperm or Egg
  + Death 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



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

Total Number of SREs in Acute Care Hospitals by Year

1400

1313 \*\*

1189

1012\*\*

1066

922

1200

1000

800

600

400

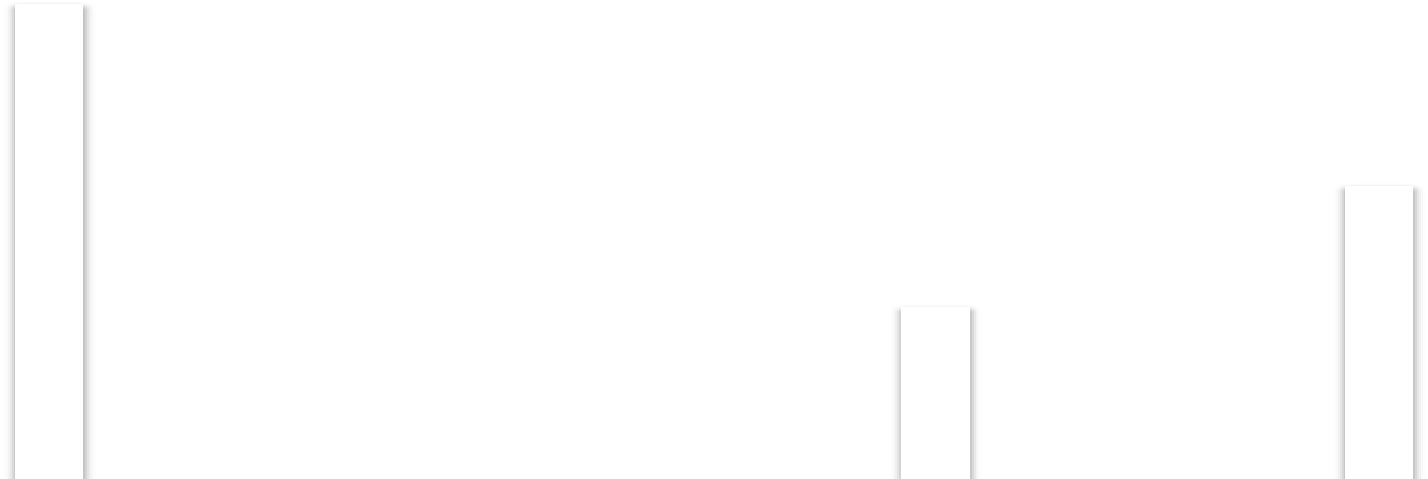
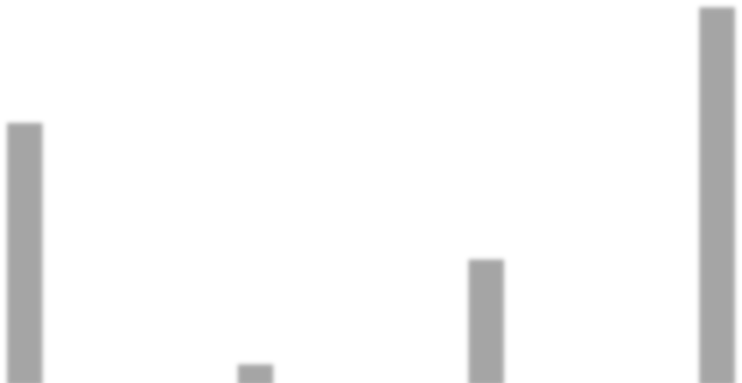
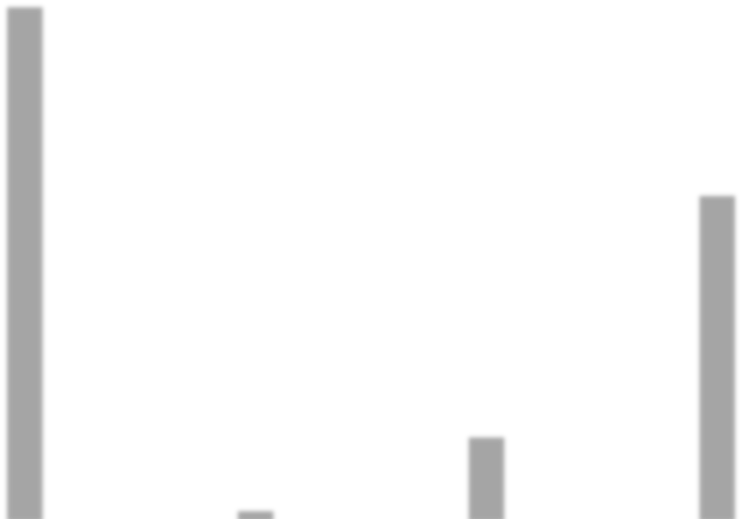
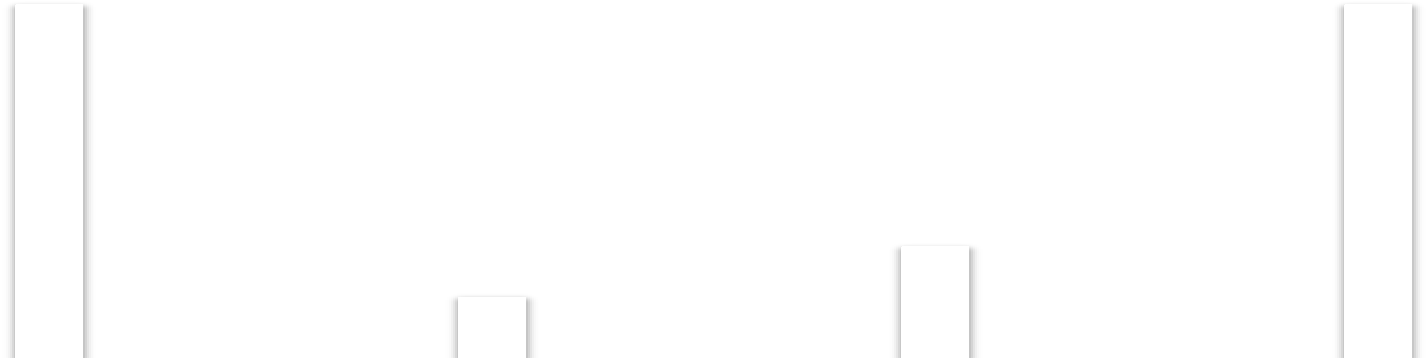
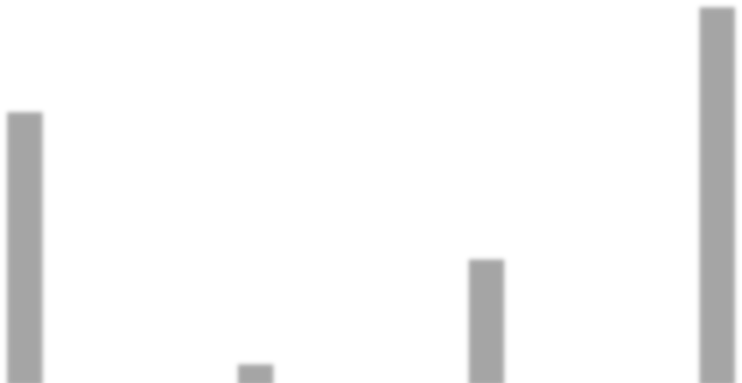
200

0

2015 2016 2017 2018 2019

\*\* Two events in 2015 and 2016 affected a large number of patients and is reflected in the increase in SREs reported. Data abstracted on October 27, 2020 from the Health Care Facility Reporting System

60



49

47

35

36 35

36

31

29

26

17

12 11

12

6

2

1

2

0

0 0 0 0 0

8

25

**Key Findings**

Increasingly SREs occur

outside of the operating room in radiology, intensive care, and outpatient procedure units.

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

2015 2016 2017 2018 2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System

of an ASA Class 1 Patient

### 500

450

400

350

300

250

200

150

100

50

0

Contaminated drugs, device or biologics

446 \*\*

138 \*\*

21

8

5

12

9

21

11

15

2

9

3

7

6

Device misuse or malfunction Intravascular air embolism

**Key Findings**

In the contaminated drugs,

device or biologics event, one incident, that affected a significant number of patients in 2015, represents most of the category.

The hospital engaged in a

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

2015 2016 2017 2018 2019

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

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

35

32

30

29

25

28

5

1 2 2 2

2 1 0 0 2

2 2 2

0 0

0 0 0 0 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

2015

2016

2017

2018

2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

### 45

41

38

36

31

25

2

2

3

0

1

2

0

2

2

2

**Key Findings**

There were 3 completed

suicide events and 35 self-harm or attempted suicide events in 2019.

Cutting and ingesting

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

40

35

30

25

20

15

10

5

0

Patient discharged to unauthorized person

Elopement with death or serious injury

Suicide or self-harm with serious injury

2015

2016

2017

2018

2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

### 50

45 45

41

34

18 19

20

9

10

7

0 0

0

2

1

0 0 0

0

1

45

40

35

30

25

20

15

10

5

0

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

with serious injury

2015 2016 2017

2018

2019

**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. This has changed from last year when inpatient psychiatric units were the most frequent location.

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

# Acute Care Hospital: Care Management Data

**Key Findings**

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

Pressure ulcers are the most common serious injury, about 64% of those reported occurred on the back, spine or buttocks and 40% occurred in patients under the age of 65 years.

500

450

400

350

300

250

200

150

100

50

0

Serious injury or death

Unsafe blood

Maternal serious

Newborn serious

Serious injury or death

497

Stage 3, Stage 4 or

317 308

294

285

272

226

51

43

52 48 61

0 0 1 0

1

10

6

7

13

5

15 19 11 18 14

0 0 0 0 0

1

5 6

2

7

1 6

10 9 5

341 333

393

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

2015

2016

2017

2018

2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

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

### 250

237

237

196

194

146

200

150

100

50

2015

2016

2017

2018

2019

0

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

Reported SREs 2015-2019 (Non-acute care hospitals)

140

128

119

108

95

91

71

58

60

43

16 16 11

17

13

12 11 13

14

12

15

5

4

6 6 6

5

0

2

1

2

0 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

2015

2016

2017

2018

2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

### 10

4

4 4

2 2

1

1

0

0 0 0

0 0 0 0

0

0 0

0

1

1

2

2

2

3

**Key Findings**

There are 54 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.

9

8

7

6

5

4

3

2

1

0

Wrong patient procedure or surgery

Wrong site/side procedure or surgery

Wrong procedure or surgery

Serious injury or death after fall

Device Misuse

2015

2016

2017

2018

2019

Data abstracted on October 27, 2020 from the Health Care Facility Reporting System.

900

803

**Key Findings**

Although most SREs are reported in white patients (75%), a

significant proportion of events are reported with unknown race (9%), other race (4%), or missing race (3%). Most events with unknown race, other race or missing race are from acute care hospitals.

73

84

71

2 23

8

4

2

27

40

48

3 3 1

4

4 3 4

3 2

3 10

22

1 1 14 2 7 1

2

2 6

3 15 1

37

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

1000

875

**Key Findings**

Although most SREs are reported in Non-Hispanic patients

(N=1104), about 7% (N=78) are reported for Hispanic patients, about 10% (N=121) are reported for patients with Unknown ethnicity and another 3% (N=36) are reported for patients with missing ethnicity.

59

88

54

82

8

5

30

43

4

1

2

6 4

5

8

21

2

18

5 1

0 2 0 0

5

10

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

**SRE Types Among Veterans**

30

25

**Key Findings**

Similar to the total population, the

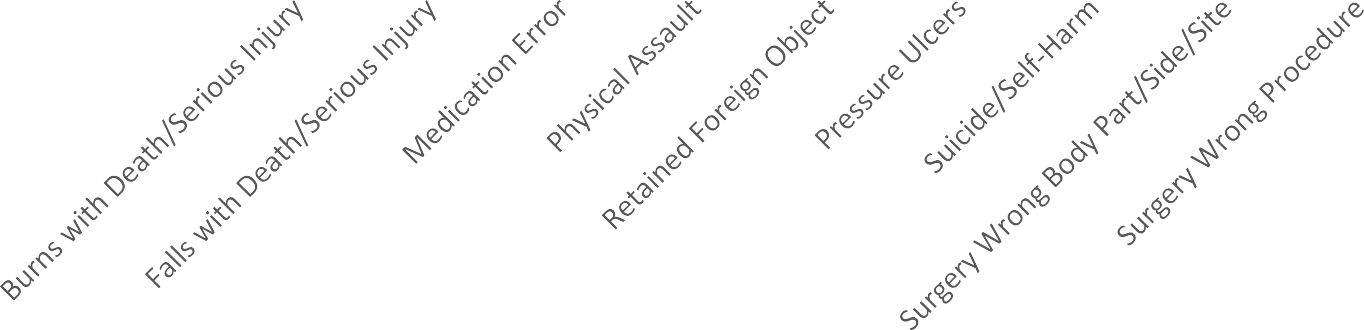
most common SRE reported for Veterans (N=49) across all reporting settings was pressure ulcers (N=26) and falls (N=16).

20

15

10

5

0

Veterans

* 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.
* 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 servs for widespread education and to share appropriate guidance.

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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