Massachusetts Department of Public Health

150 YEARS OF ADVANCING PUBLIC HEALTH

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.

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

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

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

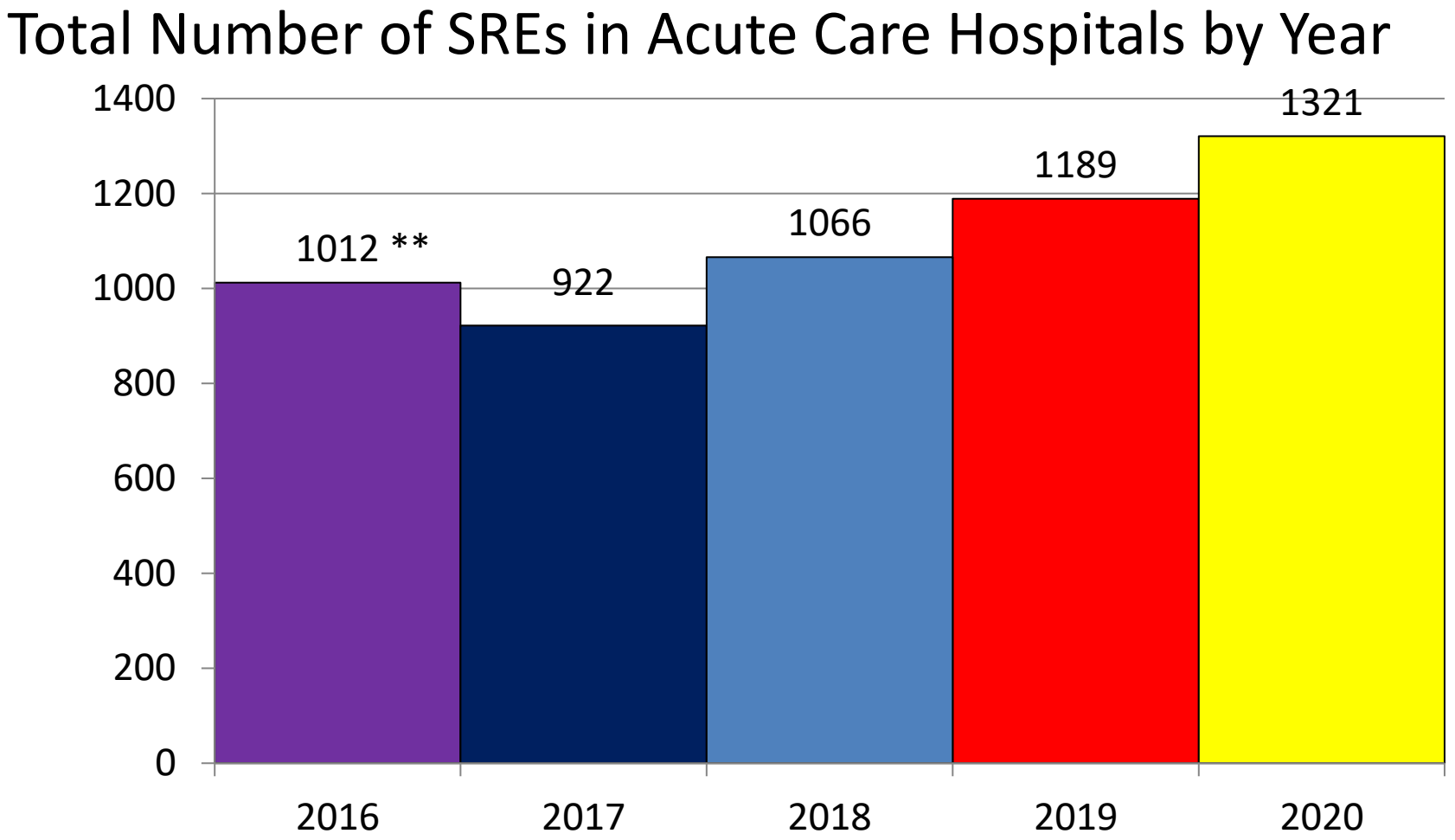
Radiologic Events

- 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

Acute Care Hospital Data



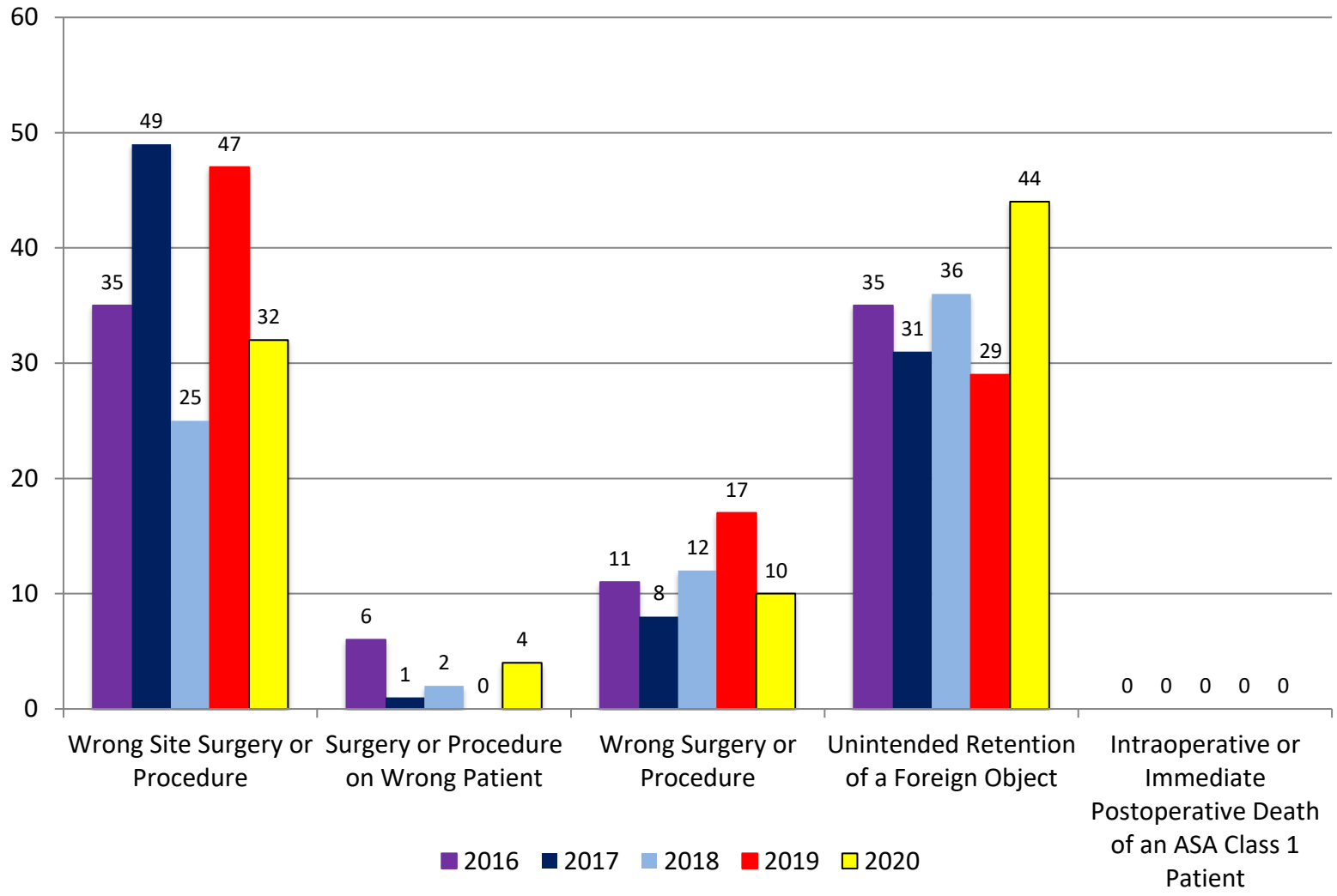
** An event in 2016 affected a large number of patients and is reflected in the increase in SREs reported.
Data abstracted on May 28, 2021 from the Health Care Facility Reporting System

Acute Care Hospital Surgical Event Data

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.



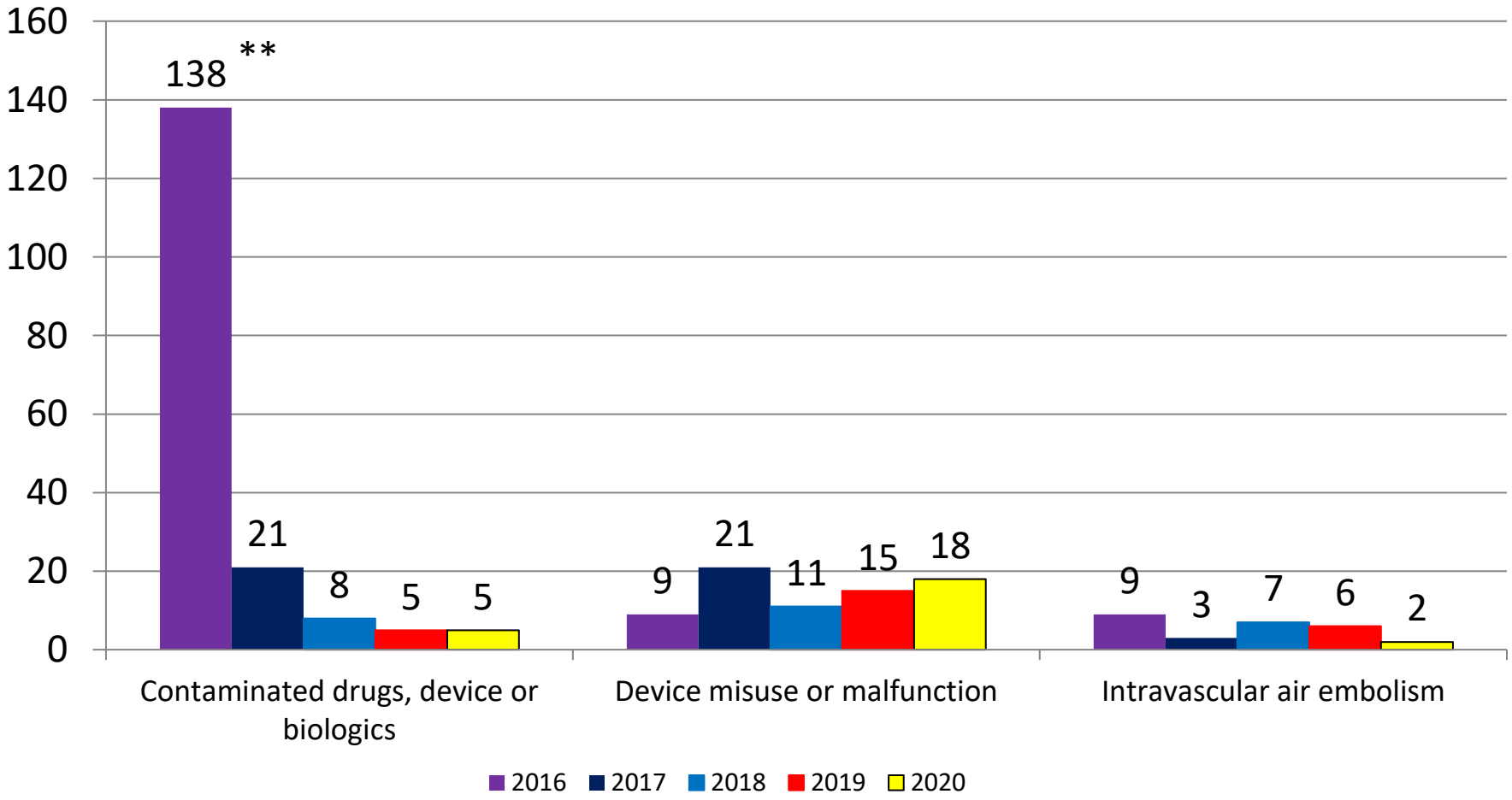
Data abstracted May 28, 2021 from the Health Care Facility Reporting System

Acute Care Hospital: Product/Device Event Data

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.



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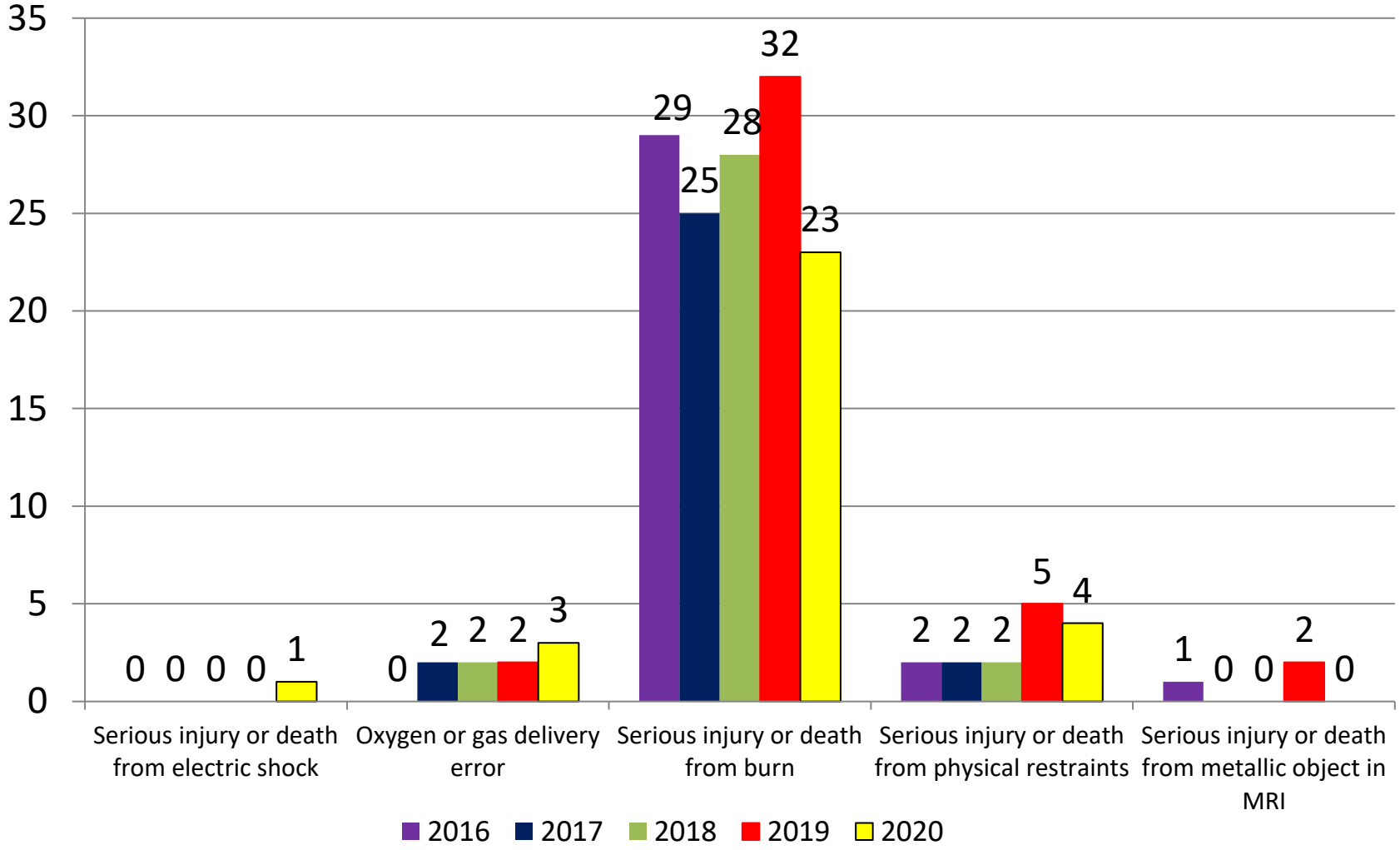
Acute Care Hospital: Environmental Event Data

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.



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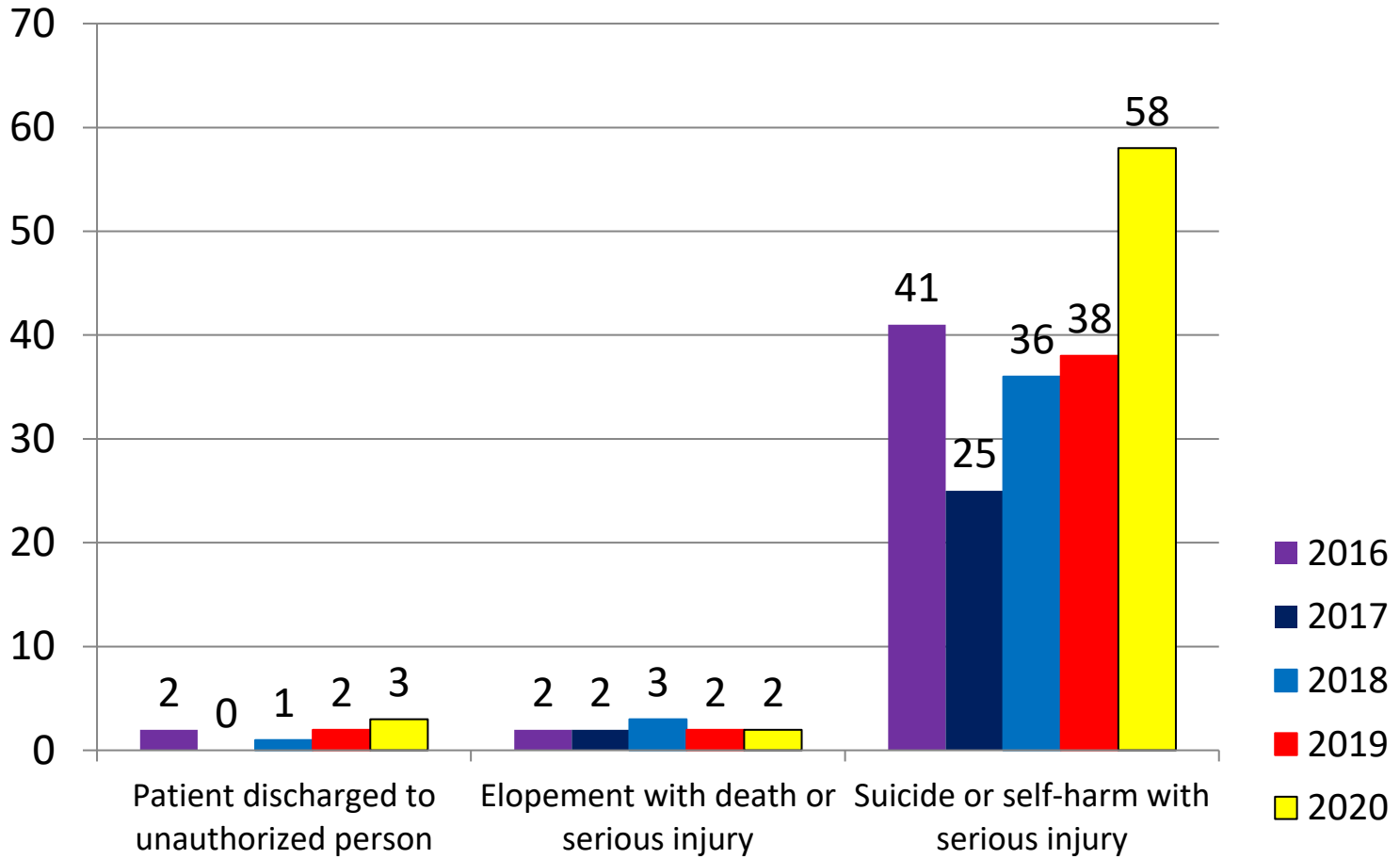
Acute Care Hospital: Patient Protection Event Data

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.



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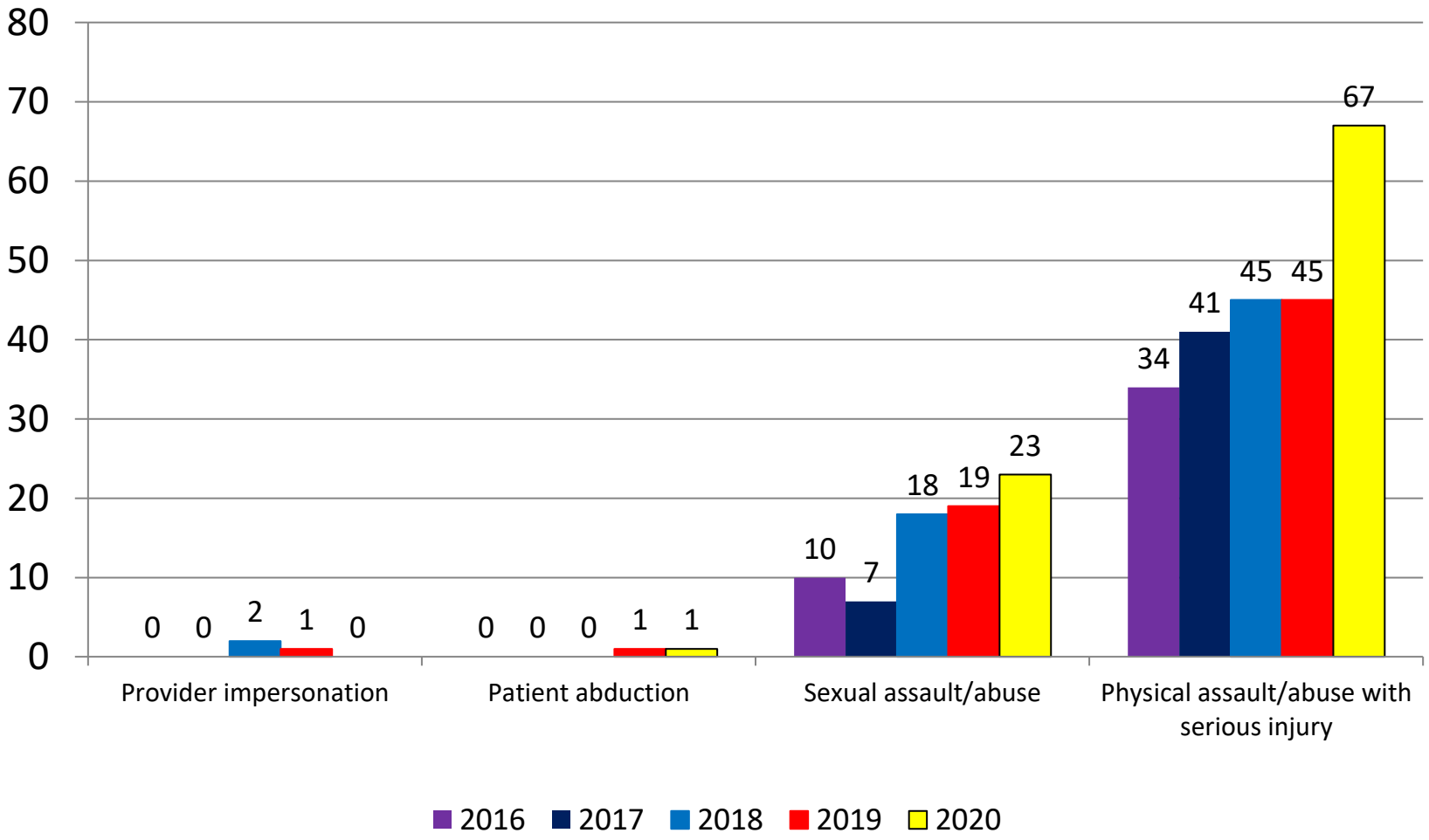
Acute Care Hospital: Potential Criminal Event Data

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.



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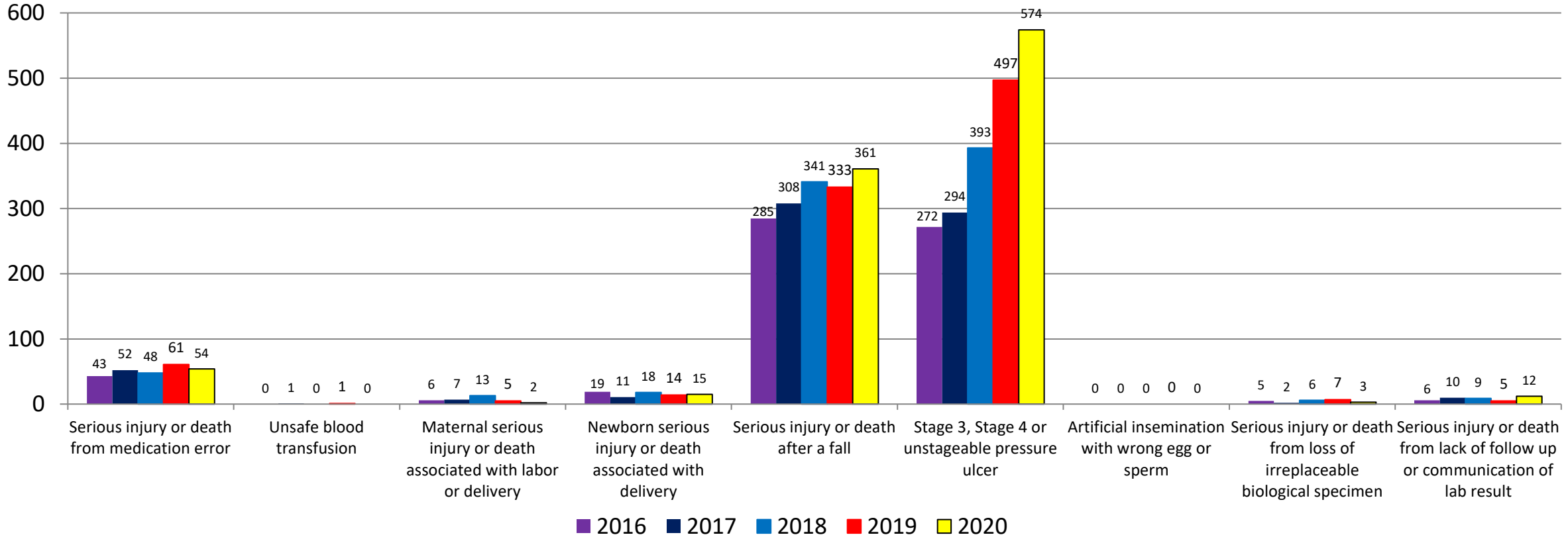
Acute Care Hospital: Care Management Event Data

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.



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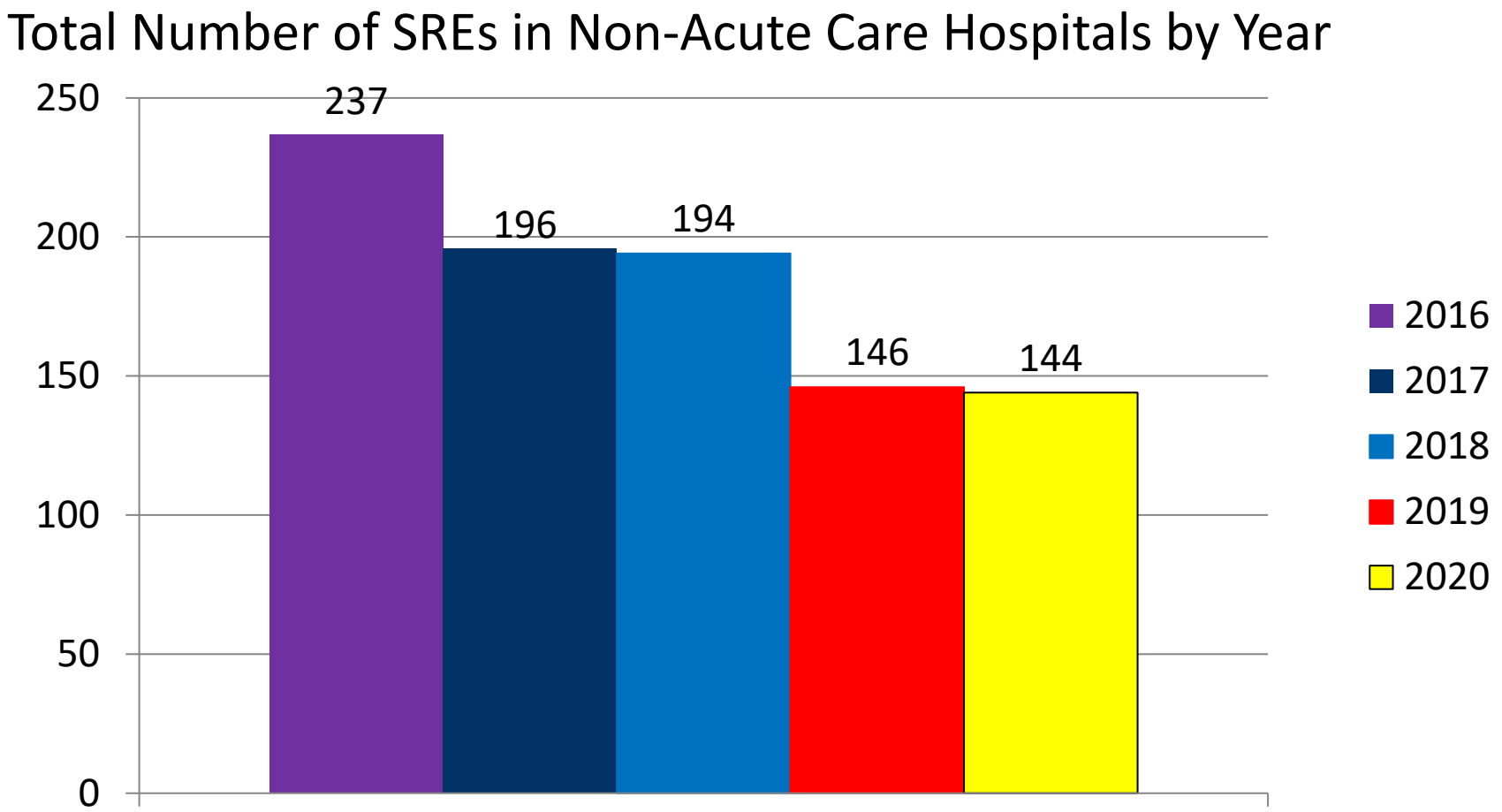
Non-Acute Care Hospital Data



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

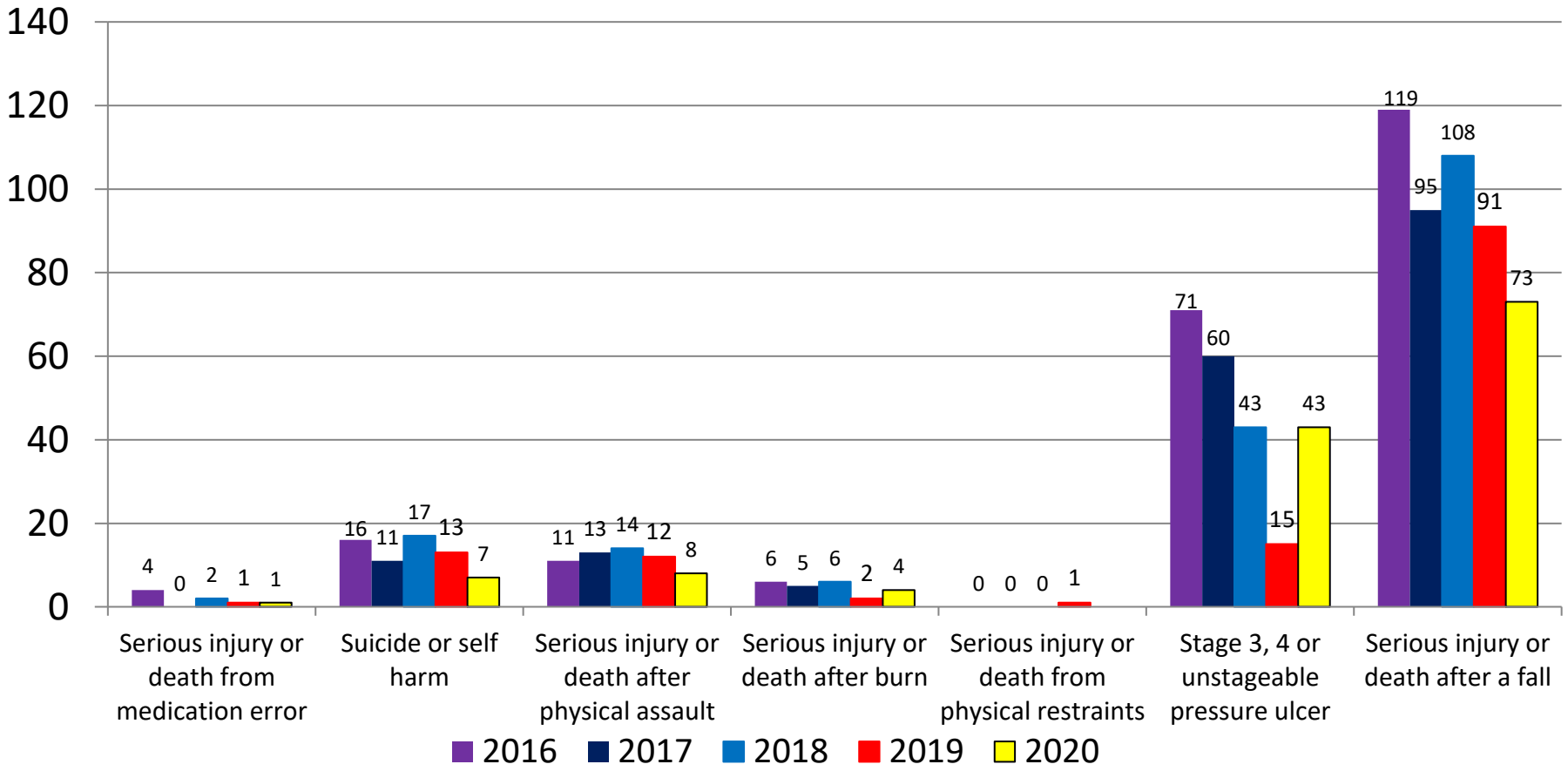
Non-Acute Care Hospital: Category Data

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.

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



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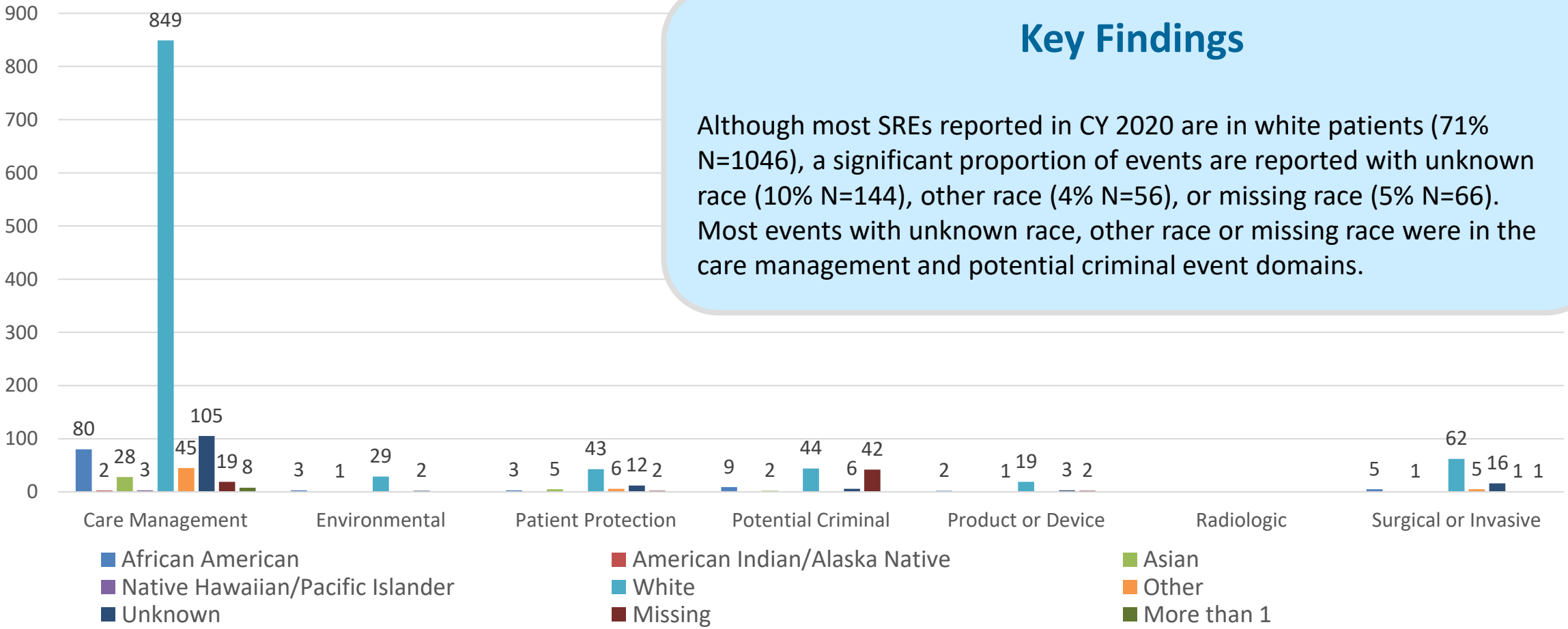
SRE Types by Race

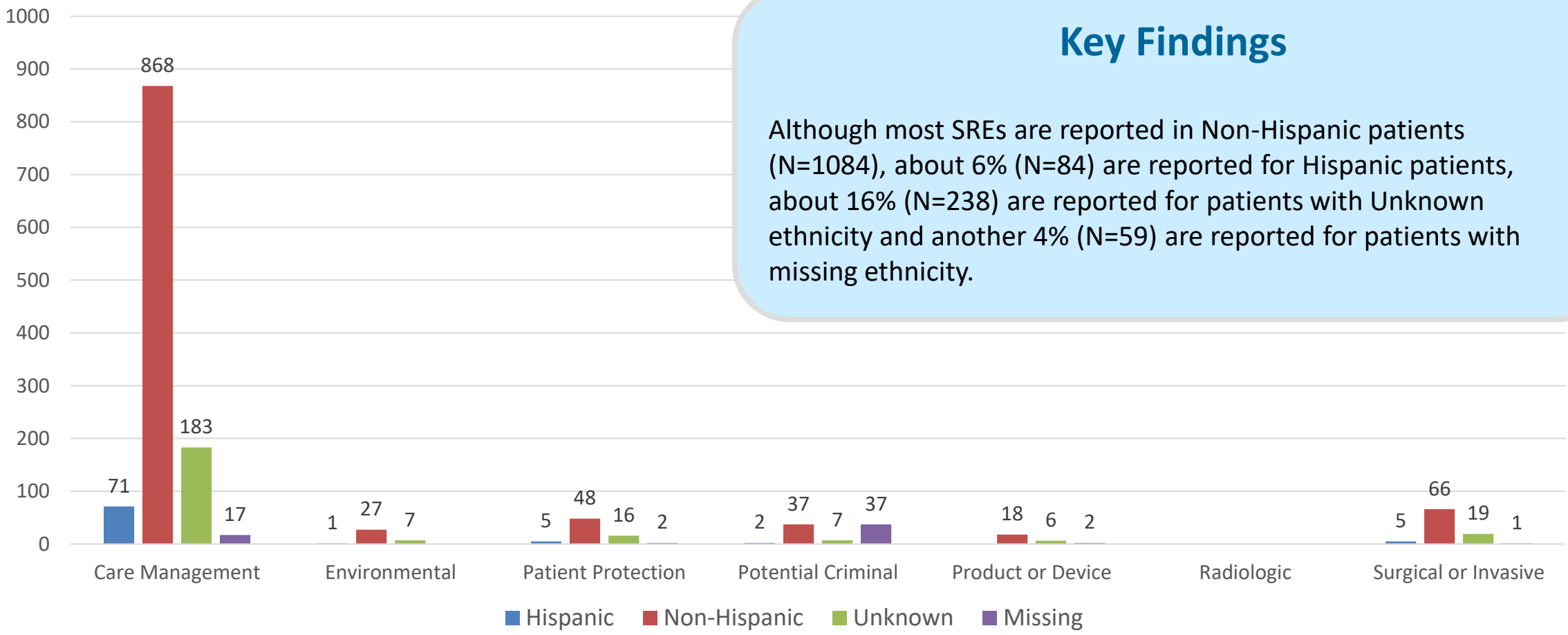


Key Findings

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.

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

SRE Types by Ethnicity



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.

Data abstracted on May 28, 2021 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.
- 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:
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