

# Serious Reportable Events 2011-2013

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# Overview

- Background
- Serious Reportable Events
- Quality Improvement Initiative
- Outcomes
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# Background

- Adverse events that occur in the health care setting are a patient safety concern and public health issue.
  - It is estimated that 44,000 deaths in hospitals are annually attributed to potentially preventable errors (IOM, 1999).
- Section 51 H of the M.G.L. c. 111 authorizes DPH to collect adverse medical event data and disseminate the information publicly to encourage quality improvement.

# Background

- The National Quality Forum (NQF), a private quality organization that works closely with government, developed an adverse event identification and reporting framework used by DPH.
- NQF has operationalized a group of adverse events into measurable, evidence-based outcomes called serious reportable events (SRE).
- Other states use the SRE framework for mandatory reporting including Minnesota and Connecticut.

# SREs

- Statute:  
“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 (M.G.L. c. 111, §51H).
- Regulation:  
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 will issue a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 applies (105 CMR 130.332).
- Currently 29 SREs are grouped into seven categories.

## Reporting

- Hospitals and ambulatory surgical centers are required to report SREs to the patient/family, third party payer, and DPH's Bureau of Health Care Safety and Quality (BHCSQ) within seven days of the incident.
- An updated report to all three parties 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, DPH implemented regulations prohibiting health care facilities from charging for services provided as a result of preventable SREs.

# Quality Improvement Initiative

## •Evaluation

- Retrospective analysis of SREs started in 2012.
  - 1,490 incidents and complaints reviewed from the time period between January 2011 through June 2012.
  - Studied the internal decision-making process for trends
    - Consumer complaints, incidents and SREs can be investigated onsite at the facility, investigated further offsite, or reviewed and included in data reporting.
  - Noted variation between HCQ survey regions and among SRE types in how BHCSQ addressed/investigated incidents and identifies SREs.

## •Program development

- QI process started in 2013 and is ongoing to reduce variation through development of standardized policies and procedures

# Quality Improvement Initiative

Goal: To standardize SRE determination between facilities to improve reliability, facilitate transparency through public reporting, and support patient safety activities.

## Objectives:

- Reviewed all consumer and facility events reported for acute and non-acute care facilities from January 1, 2011 to December 31, 2013.
- Evaluated each event for inclusion or exclusion as a serious reportable event.
- Validate each facility's list of serious reportable events with a risk manager or member of the quality and safety department.
- Develop public reporting for SREs at non-acute facilities.
- Identify, if applicable, patterns in types of events reported and opportunities for improvement among the reporting facilities.

## Revisions to Reporting

- In 2012, DPH developed a secure electronic reporting system called Health Care Facility Reporting System (HCFRS) that facilities use to report adverse events.
  - Near universal adoption by acute care facilities by Fall 2013
  - Replaced previous process of faxing reports & manual data entry
- In 2011, NQF revised their definitions to lower the threshold for reporting an event.
  - In many definitions 'serious disability' changed to 'serious injury'
- Based upon the changes in the NQF definitions, DPH updated their list of SREs and implemented the new list in October 2012.
- Refinement of reporting process & definitions occurred through 2013.

## New Serious Reportable Events Introduced in October 2012

- Death or serious injury of a neonate associated with labor and delivery in a low-risk pregnancy.
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen.
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.
- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

## 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\*

\* Definition changed in October 2012

## 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^

\* Definition changed in October 2012

^New event

## 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^

\* Definition changed in October 2012

^New event

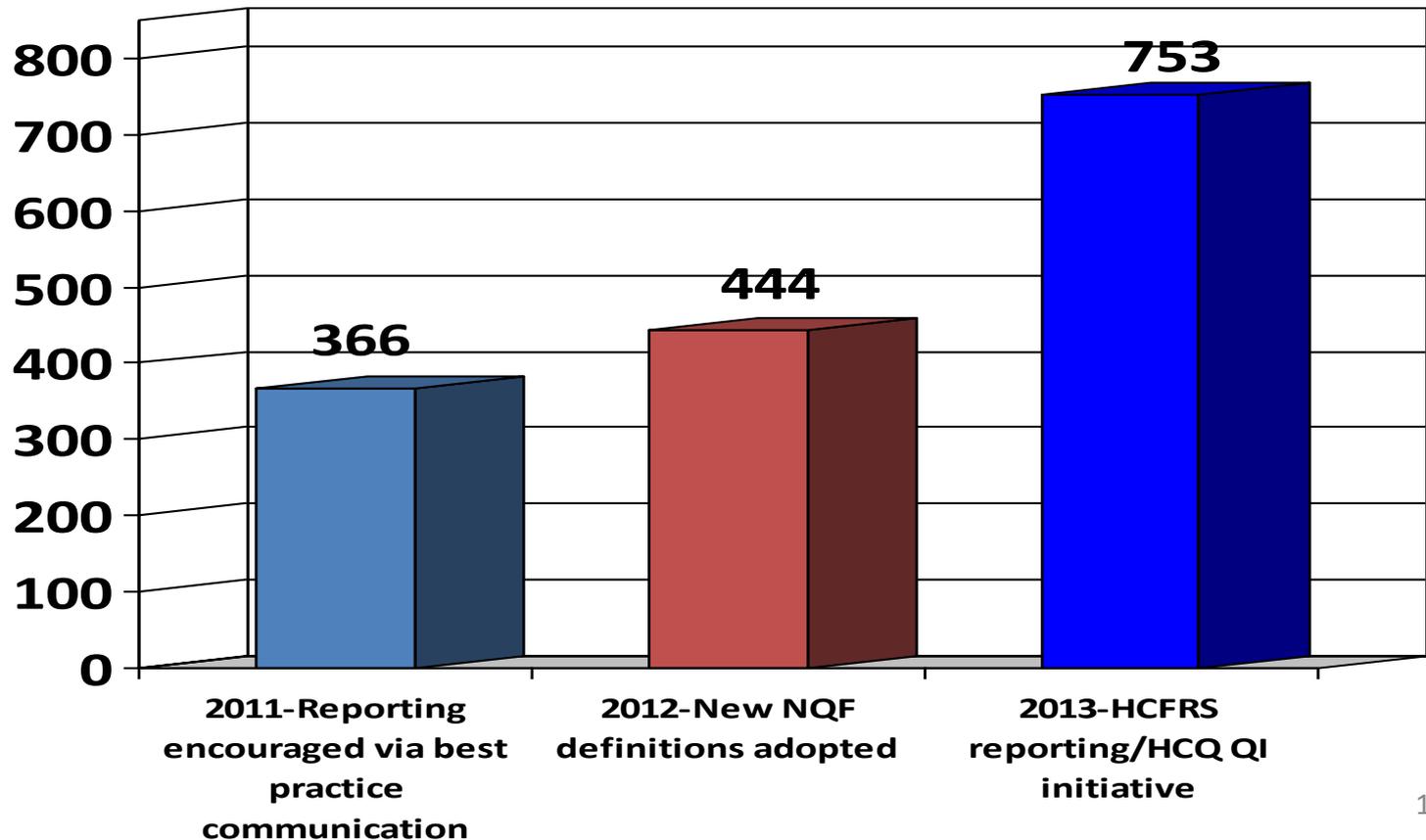
## Potential Criminal Events

- 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\*

\* Definition changed in October 2012

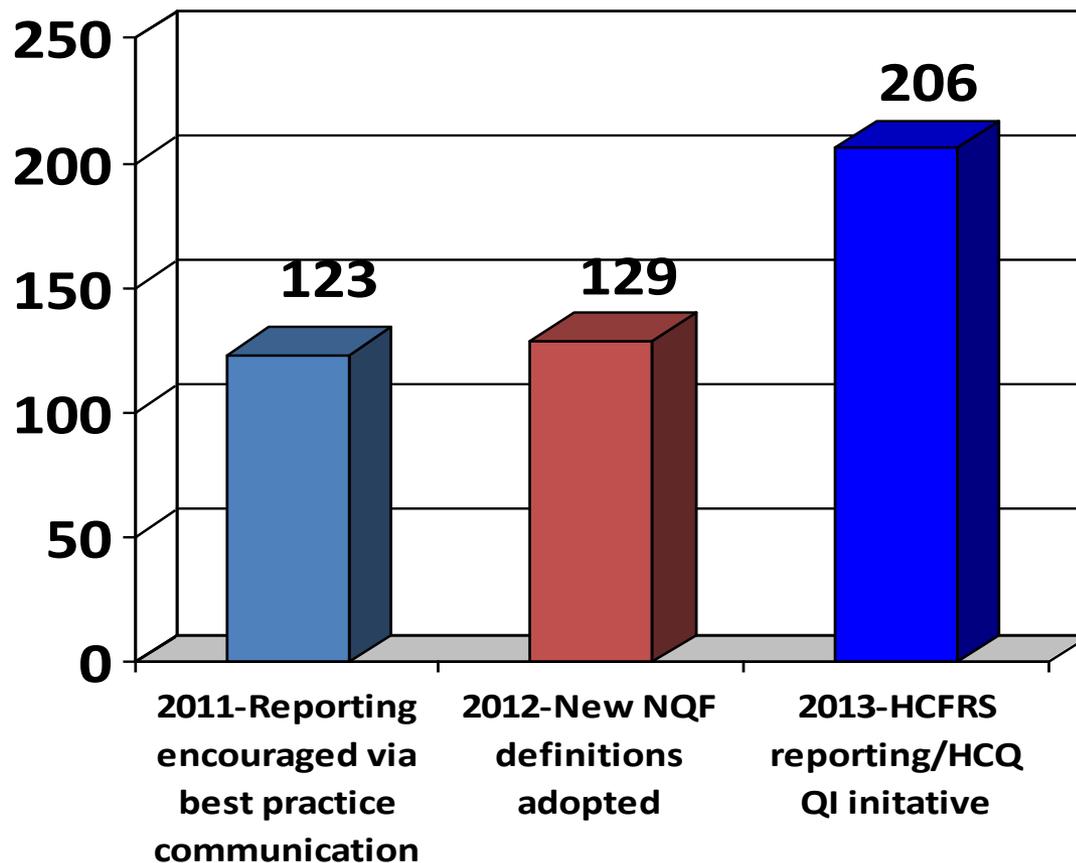
## Total Number of SREs in Acute Care Hospitals each Year

\* Significant increase in the # of SREs reported from 2012 to 2013 due to several factors:

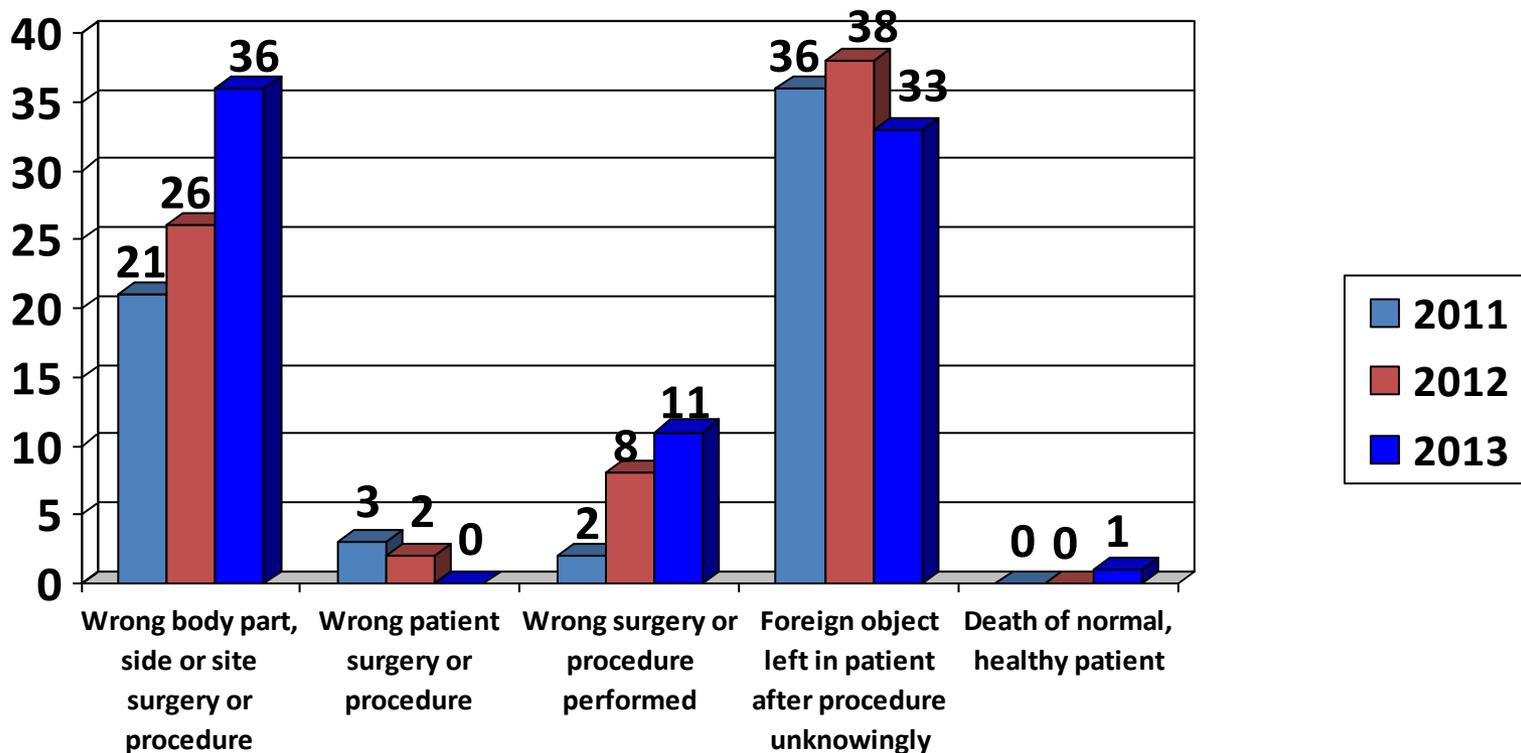


## Total Number of SREs in Non-Acute Care Hospitals each Year

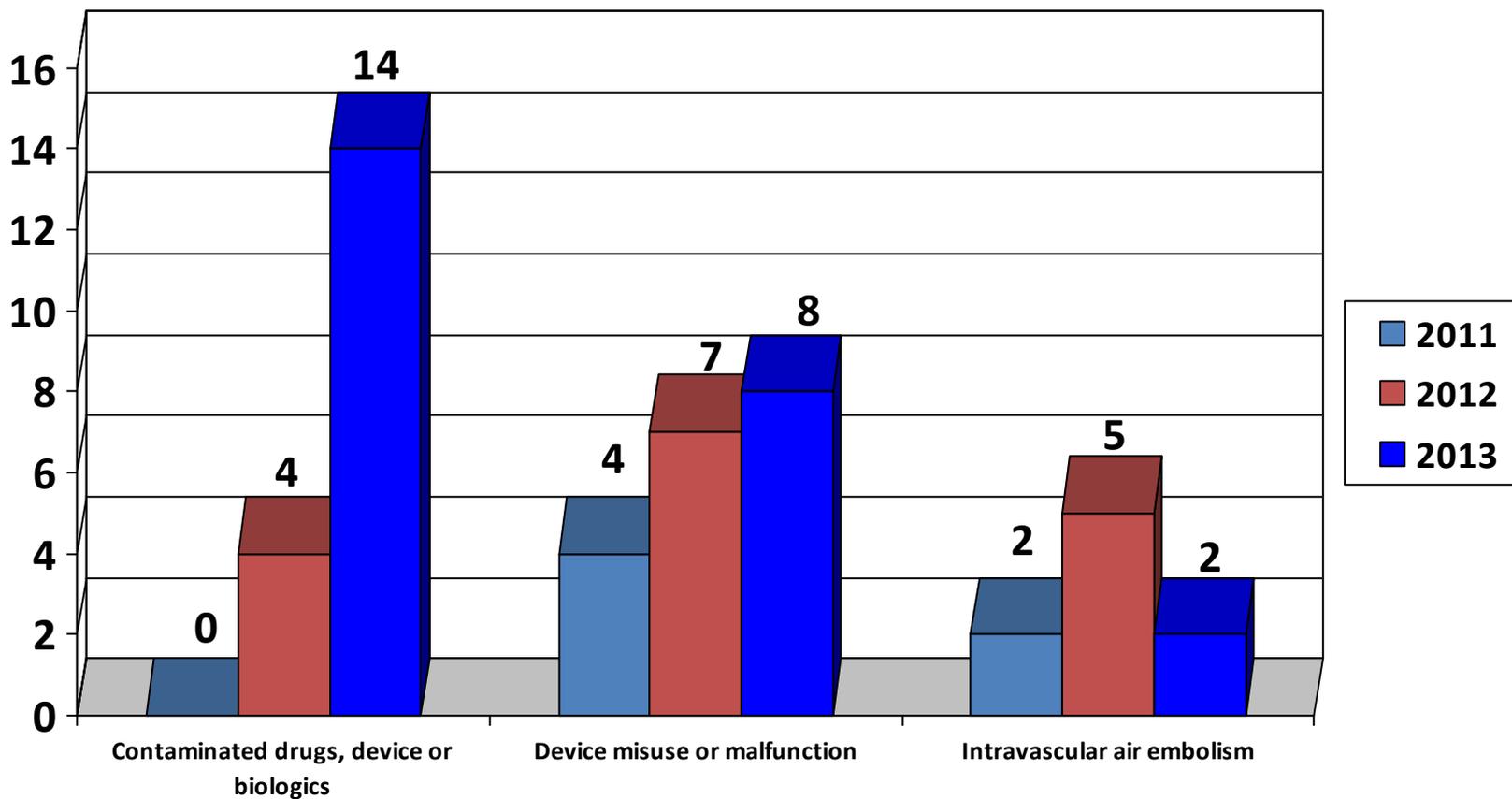
\* Significant increase in the # of SREs reported from 2012 to 2013 due to several factors:



## Surgical Event SREs 2011-2013 (Acute care hospitals)



## Product or Device SREs 2011-2013 (Acute care hospitals)



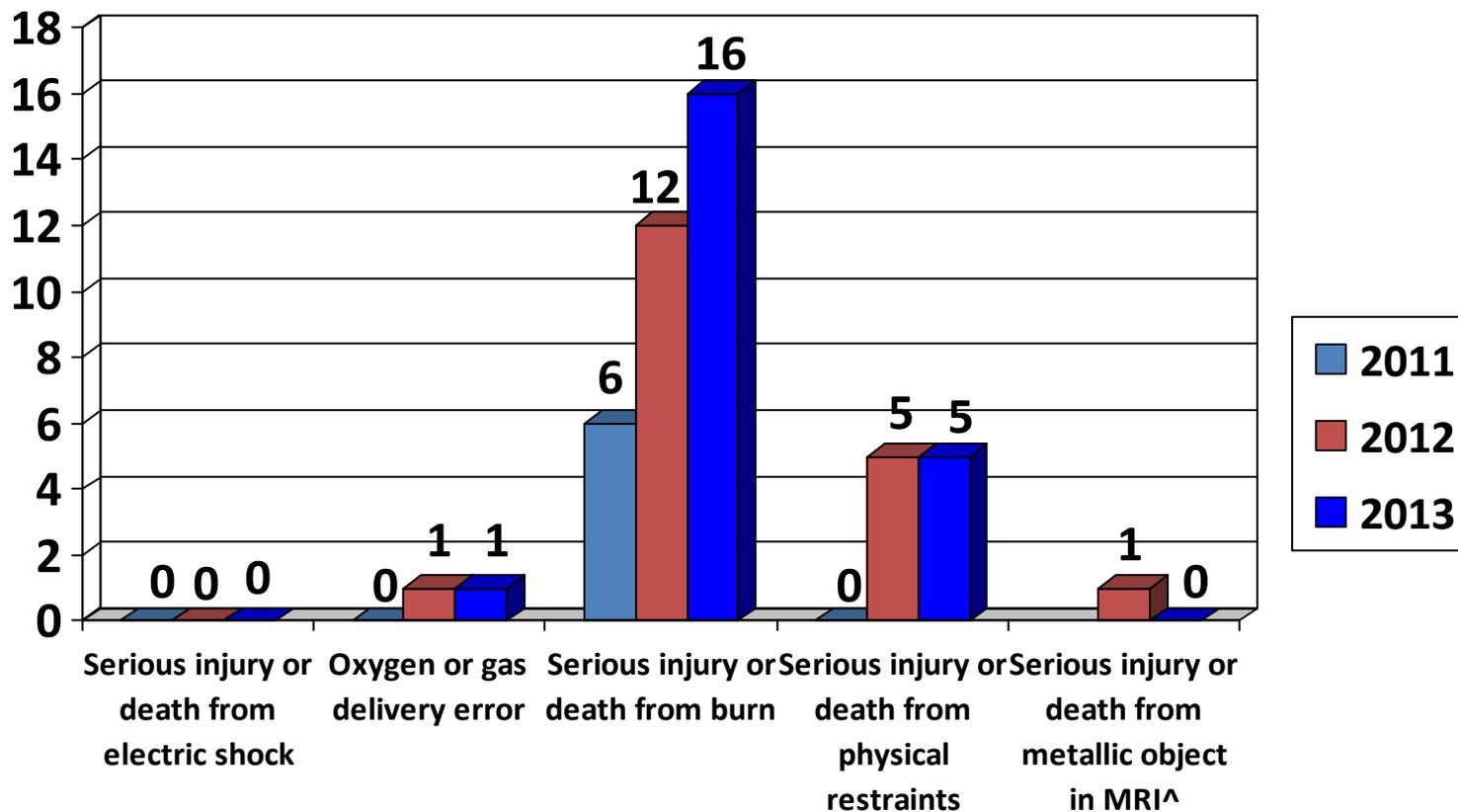
## Examples of device misuse or malfunction

- Not meant to capture events where there is user error.
  - Piece of operating room equipment breaks off inside patient during procedure & requires additional procedure to remove it.
  - Telemetry monitor fails to alarm for lethal rhythm.

## Example of Contaminated Biologics

- Surgical equipment not sterilized to specified standards in between patient use resulting in potential exposure to blood borne pathogens.

## Environmental Event SREs 2011-2013 (Acute care hospitals)



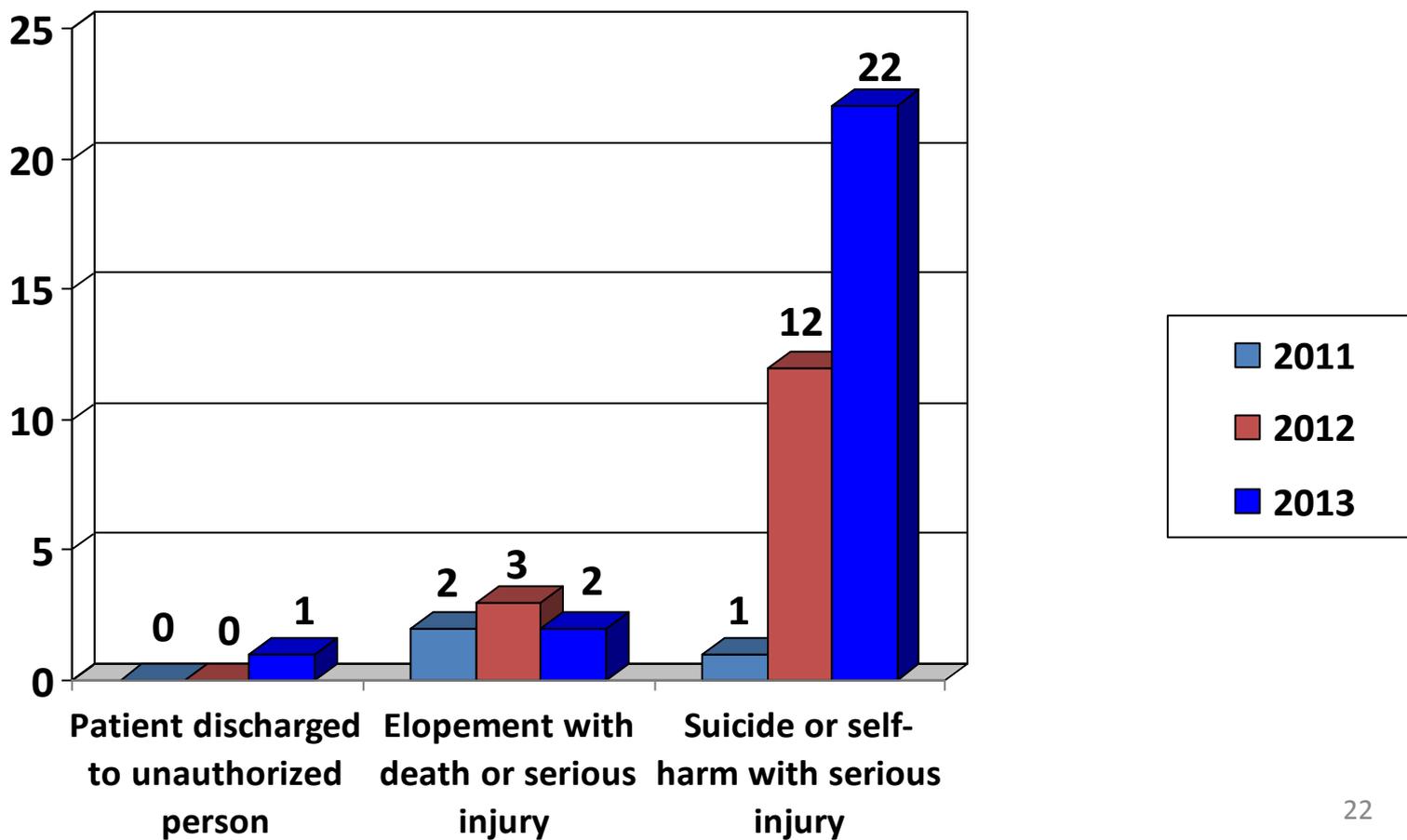
<sup>^</sup>New event in October 2012

## Examples of reported serious injuries from burns

Includes any second degree (or greater) burn:

- Operating room fires caused by equipment use
- Hot coffee, tea or other beverage spills
- Heating packs applied without protective cover, for too long a period of time, or not meeting safe standards (e.g. improvised heating pads)

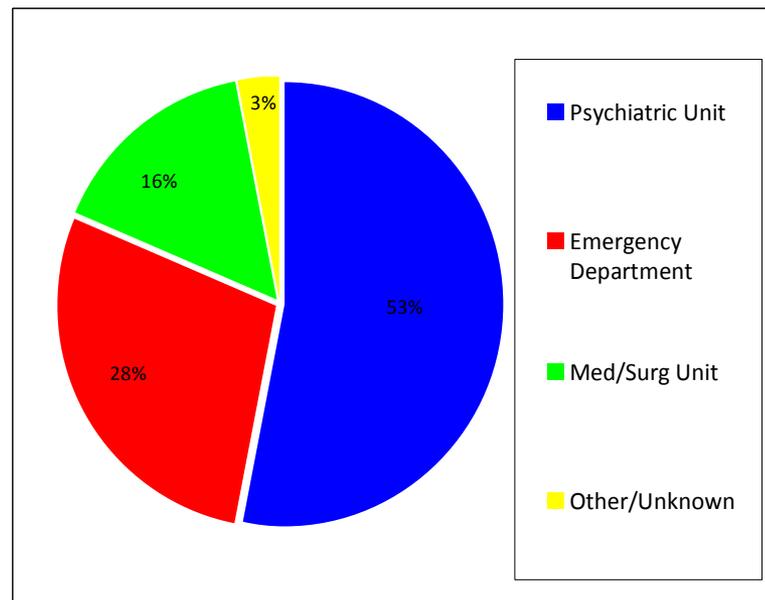
## Patient Protection SREs 2011-2013 (Acute care hospitals)



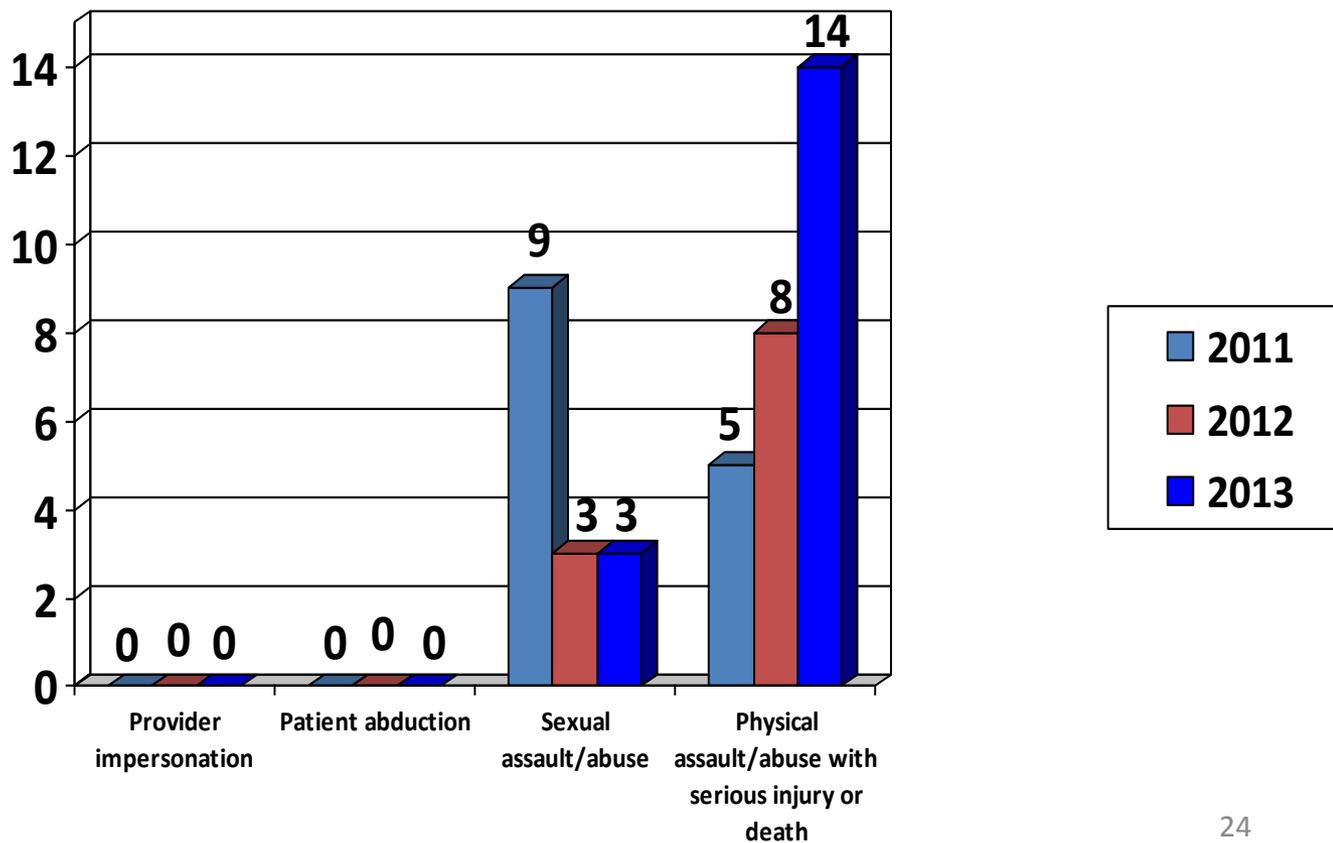
## Suicide, attempted suicide & self-harm with serious injury SREs 2011-2013 (Acute care hospitals)

- Age ranges from 13-88 years; average age is 40.1 years
- Most common injury: laceration requiring sutures or staples

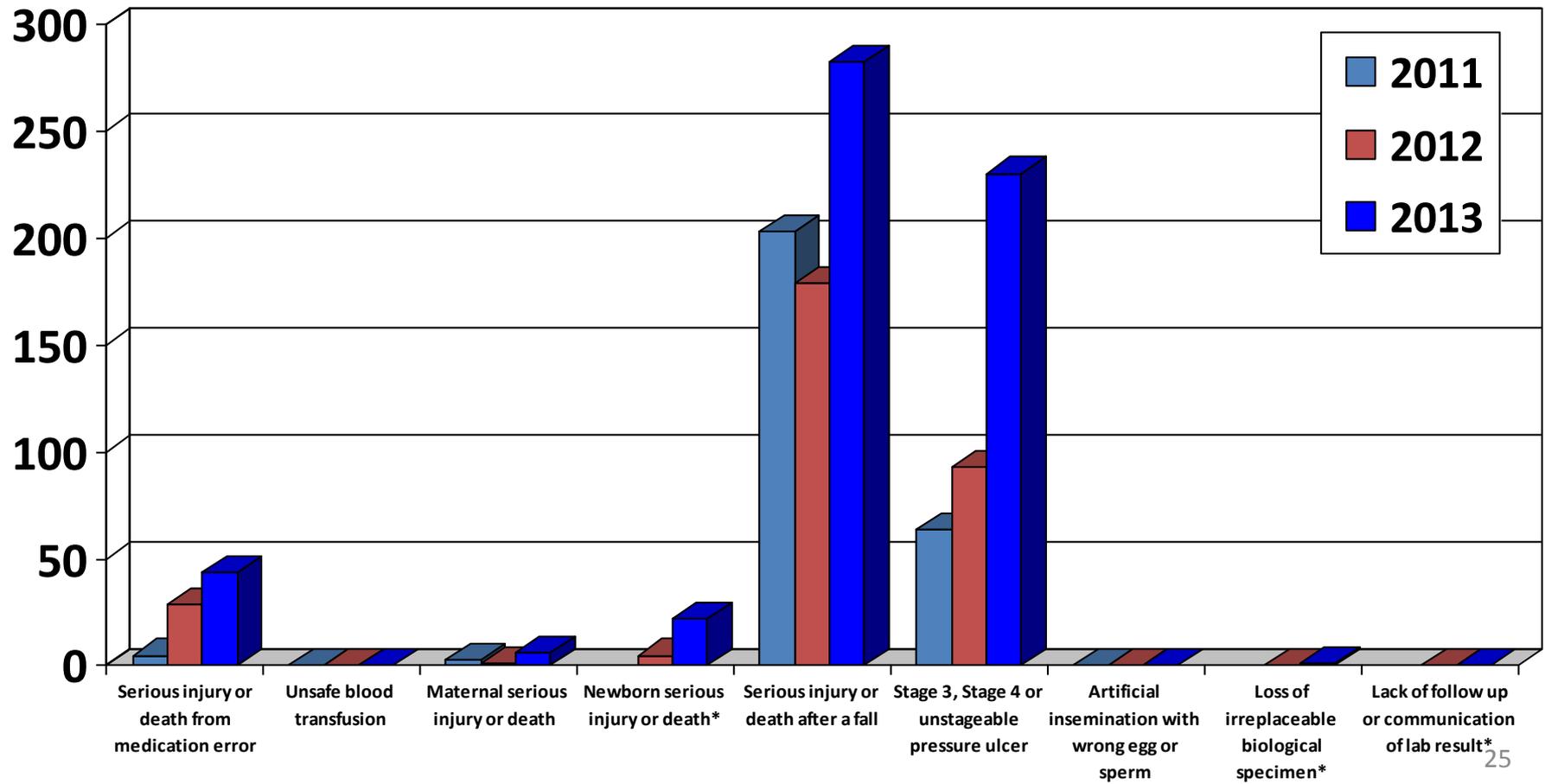
Harm Method	Number of Individuals (Percent)
Ingesting/Poisoning	14 (40%)
Cutting	9 (25.7%)
Hanging/Strangling	6 (17.1%)
Throwing self on the floor/at wall	3 (8.6%)
Missing	3 (8.6%)



## Potential Criminal Event SREs 2011-2013 (Acute care hospitals)



## Care Management SREs 2011-2013 (Acute Hospitals)

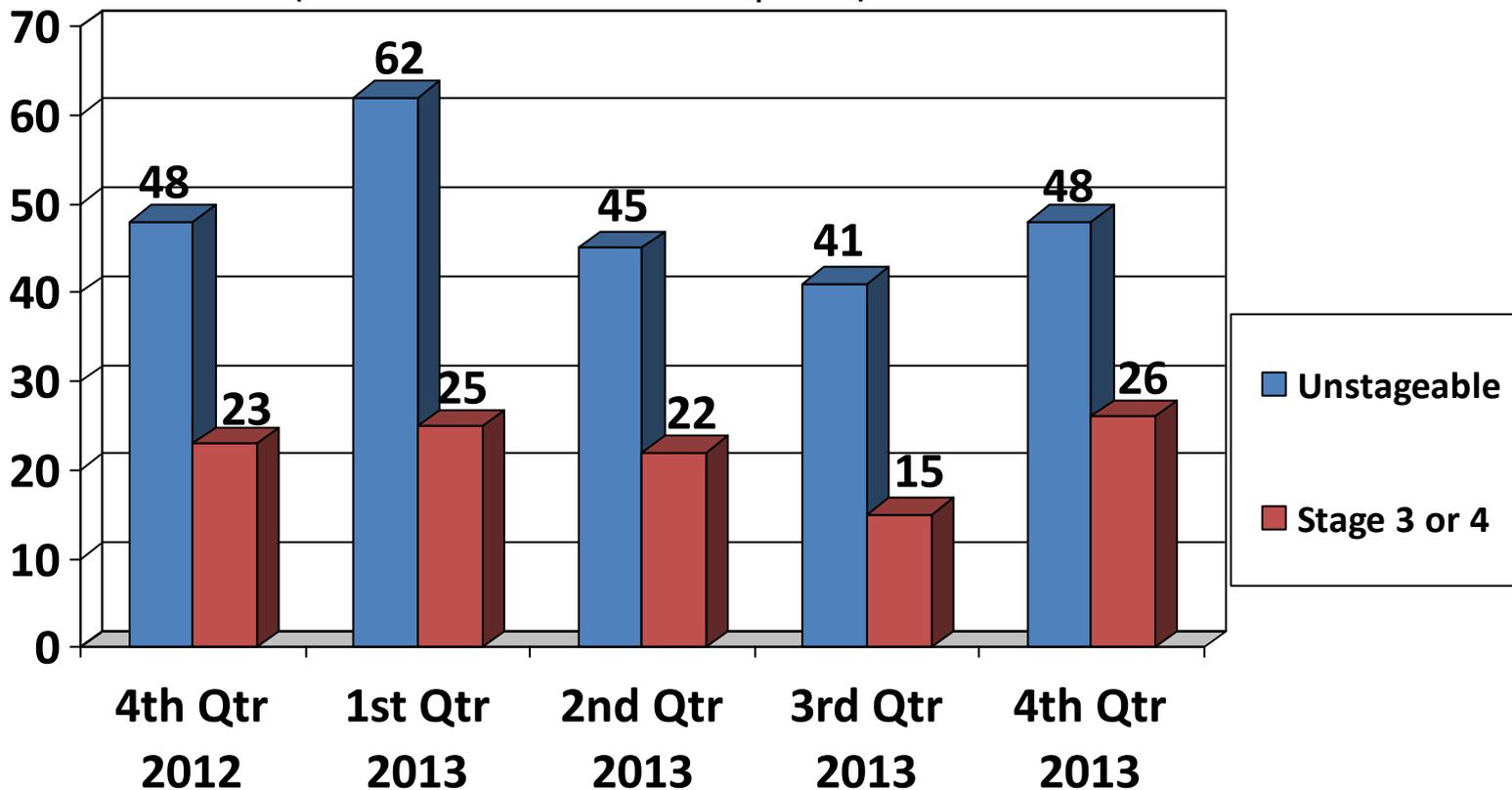


## DPH Activity to Address Pressure Ulcer Reporting

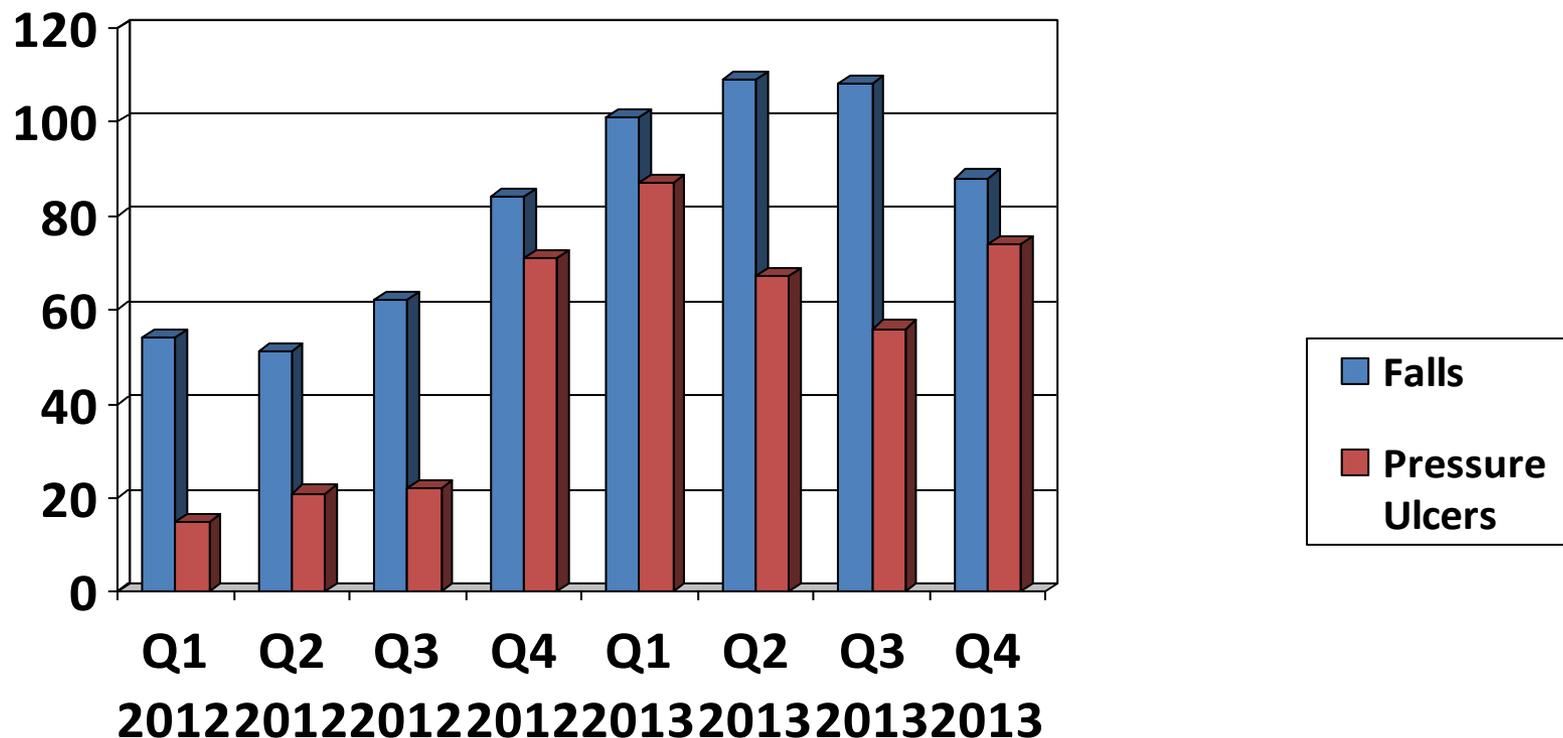
- Adoption of new guidelines added unstageable pressure ulcers that were acquired after hospitalization and made several changes in pressure ulcer staging during hospitalization reportable.
  - Ex. Unstageable pressure ulcer upon admission becomes Stage IV pressure ulcer.
- Feedback from individual hospitals and MHA after implementation was that several of the new reporting requirements actually reflected the standard of care as opposed to adverse events.
- DPH met with hospital risk managers, MHA, and wound care experts in July 2013.
- Changes made to reduce reporting requirements for facilities were implemented in August 2013 (to limit unintended consequences).

## Pressure Ulcer SREs by Quarter and Type from Change in Definition

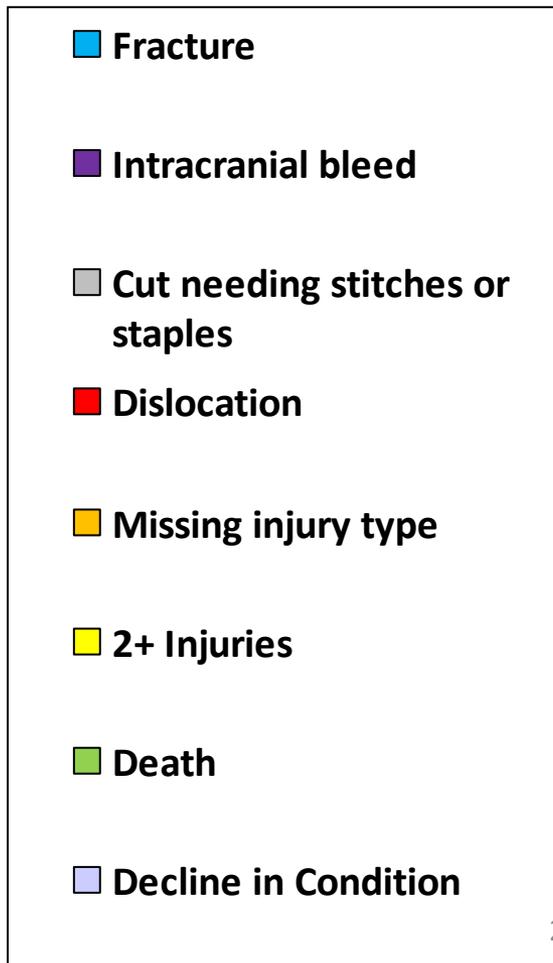
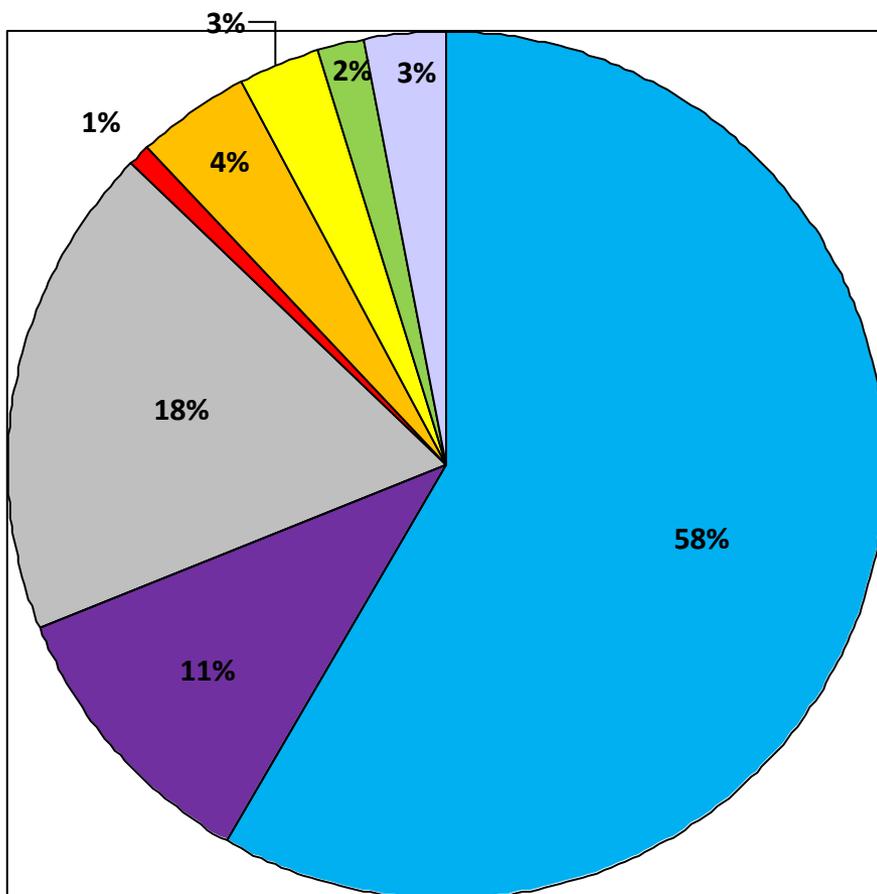
(Acute & Non-acute Hospitals)



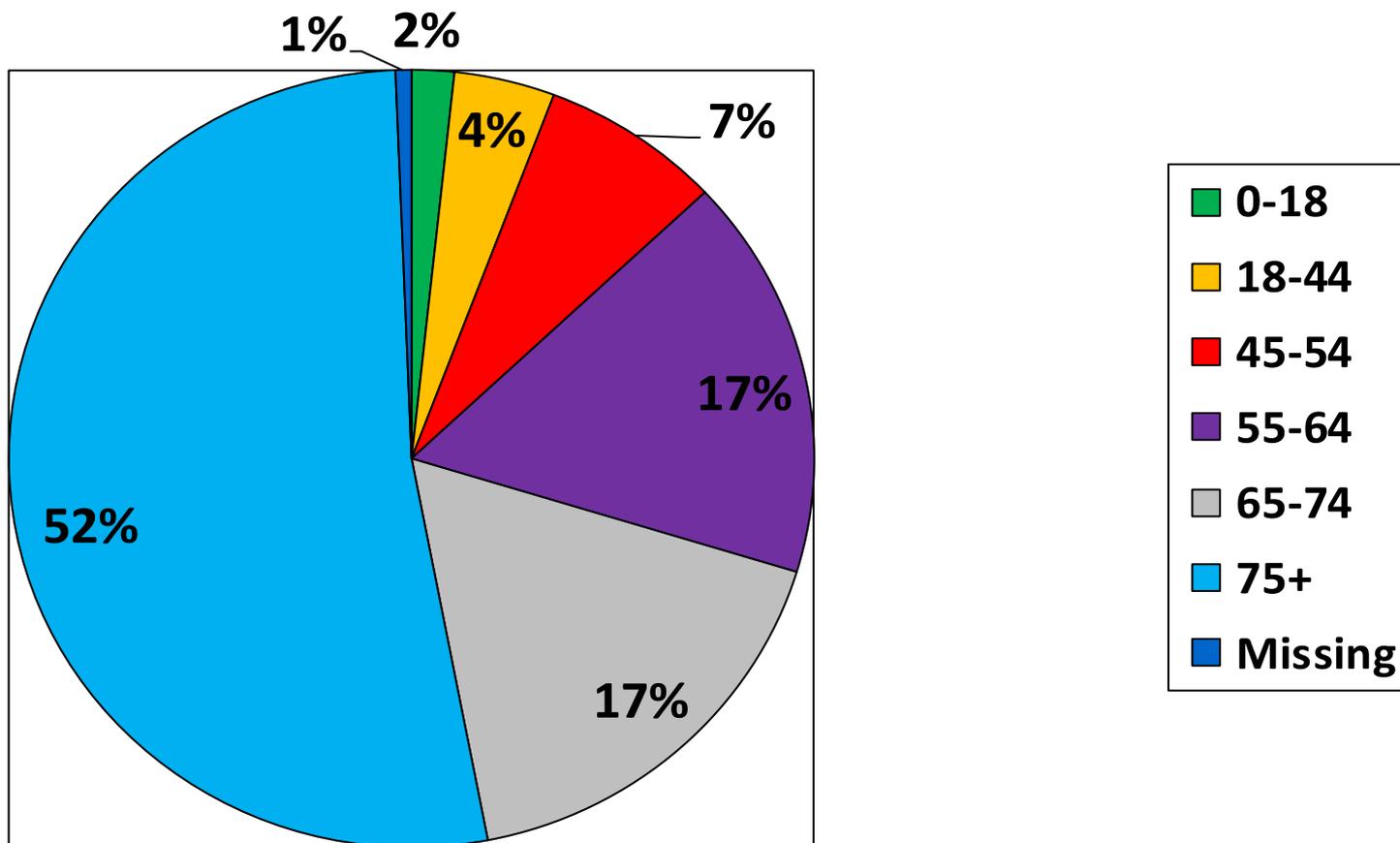
## Fall and Pressure Ulcer SREs by Quarter 2012 & 2013 (Acute & Non-acute Hospitals)



## 2013 Falls SRE by Type of Injury Sustained (Acute & Non-acute Hospitals)



## 2011-2013 Falls SRE by Age (Acute & Non-acute Hospitals)



## Effect of Public Reporting

A comparison with Board of Registration in Medicine acute & non-acute hospital SRE data suggests that compelled release has not negatively impacted reporting.

Year	BORIM SREs	BHCSQ SREs
2011	393	489
2012	315	573
2013	406	959

The annual reports released by BORIM for 2012 & 2013 do not break down the number of SREs by category.

# Positive Indicators

- Increase in the number of SREs 2011-2013:
  - Adoption of the NQF's updated SRE list and definitions led to a marked rise in reporting in several existing categories: falls and pressure ulcers.
  - Process improvement including internal quality improvement and near universal utilization of online reporting system (HCFRS) reduced barriers and streamlined facility reporting process.
  - DPH outreach to facilities and emphasis on reporting as an important quality improvement priority likely increased reporting.
- Reporting also likely increased due to collaborative initiatives that raise awareness and encourage institutional reporting of adverse events.
  - Currently six hospitals participating in MA Alliance for Communication & Resolution after Injury (MACRMI) pilot, CARE, that emphasizes institutional reporting of adverse events.
  - Several hospitals addressing workplace safety for staff in response to physical assaults on employees.
- Anticipate continued upward trend in number of reported events in 2014 as facilities become increasingly efficient in evaluation & reporting.

## Current Activities

- Partnering with MA Coalition for Prevention of Medical Errors & Betsy Lehman Center to host workgroups that:
  - Identify opportunities for improved medication error reporting
  - Share best practices for reducing suicide and self-harm in the inpatient setting
  - Evaluate patient and family SRE communication process and effectiveness of 7 and 30 day reports
  - Analyze pressure ulcer reports since 10/2012 in an effort to streamline reporting
- DPH continues to refine SRE investigation process to maximize available resources and outcomes.
- DPH planning root cause analysis and preventability analysis training.
- Increasing ambulatory surgical center reporting and publicly reporting SREs for ASCs for CY 2014.
  - DPH staff presented at ASC quarterly meeting in May 2014 to educate on reporting requirements and online enrollment

Thank you, Questions?

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