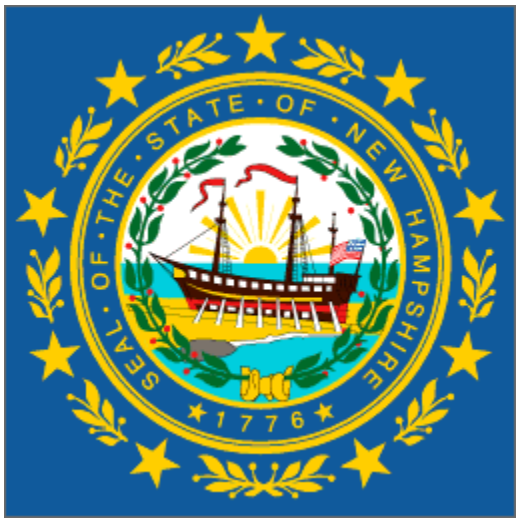


State of New Hampshire

ADVERSE EVENT REPORTING
2016 REPORT

Provided by
New Hampshire Department of Health and Human Services
Office of Operations Support
Bureau of Licensing & Certification

November 17, 2017

Adverse Event Report 2016 - Hospitals & Ambulatory Surgery Centers

In 2010, the state of New Hampshire enacted RSA 151-38 which adopted the National Quality Forum's (NQF) Serious Reportable Events and added a specific event related to the transmission of blood borne pathogens. The law requires hospitals and ambulatory surgery centers to report any of these events should they occur in their facility. There are twenty-nine (29) NQF Serious Reportable Events (SREs) structured around six categories: surgical, product or device, environmental, patient protection, care management, and potential criminal.

This report is submitted in accordance with New Hampshire law (NHRSA 151-39) which requires the Division of Licensing and Regulatory Services (the division) to annually report to the Legislature, health care facilities and the public on the aggregate number and type of adverse events for the prior calendar year; including rates of change, causative factors, and activities to strengthen patient safety in New Hampshire.

In 2016, the hospital's and ASC's have reported an 8.3% deceased in SRE's. The reportable/preventable pressure injuries had a significant reduction in the care management event area. The reportable events went from 22 in (2015) to 11 in (2016); this is due to the hospitals being proactively tailoring their services to the needs of the patients. We have seen improved overall care due to hospitals being proactive and optimizing available resources for patient safety.

National Quality Forum:

The National Quality Forum is a national, consensus-driven, private/public partnership aimed at developing common approaches to the identification of events that are serious in nature and have been determined to be largely preventable, (National Quality Forum, 2002). Sometimes referred to as "never events", the NQF list has increasingly become the basis for state mandatory reporting systems. The list of NQF SRE is intended to capture events that are clearly identifiable and measurable, largely preventable and of interest to the public and other stakeholders. More than half the states and the District of Columbia have enacted reporting systems using all or partial lists of the NQF.

Definition of Adverse Event:

Adverse events are outcomes determined to be unrelated to the natural course of the patient's illness or underlying condition, or the proper treatment of that illness or underlying condition.
An adverse event according to the NQF Serious Reportable Events is as follows:

SURGICAL OR INVASIVE PROCEDURE EVENTS

- Surgery or other invasive procedure performed on the wrong site
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient

PRODUCT OR DEVICE EVENTS

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

PATIENT PROTECTION EVENTS

- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person

- Patient death or serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

CARE MANAGEMENT EVENTS

- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a healthcare setting
- Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
- Artificial insemination with the wrong donor sperm or wrong egg (updated)
- 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

ENVIRONMENTAL EVENTS

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

RADIOLOGIC EVENTS

- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

POTENTIAL CRIMINAL EVENTS

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e battery) that occurs within or on the grounds of a healthcare setting

The state law also had the following addition to the RSA 151:38.

The exposure of a patient to a non-aerosolized blood borne pathogen by a health care worker's intentional, unsafe act. An act by hospital or ambulatory surgery center staff resulting in an infection or disease shall be considered to be purposefully unsafe if it meets all of the following criteria:

(1) There was an intentional act or reckless behavior;

(2) No reasonable person with similar qualifications, training, and experience would have acted the same way under similar circumstances; and

(3) There were no extenuating circumstances that could justify the act.

Requirements: Reporting

Any hospital or ambulatory surgical center facility must notify the Department of Health and Human Services (DHHS) within 15 working days after discovery of the event. The notification shall be filed in a format specified by the DHHS and shall not include any identifying information of the healthcare professionals, facility employees, or patients involved. The notification should include a brief description of the event. Within 60 (sixty) days the facility needs to submit a credible root cause analysis and corrective action plan.

What transpired in 2016?

Complaints and adverse events are handled by Health Facilities Administration-Certification (HFA-C) which has two distinct actions. Health Facilities Administration is responsible for the oversight and enforcement of basic standards to promote safe and appropriate care of persons receiving care and treatment in hospitals and other medical facilities. HFA-C carries out vital quality assurance, patient safety and regulatory support of the Department's goal. The Department received 54 adverse events for the calendar year (CY) with no corresponding consumer complaints.

RSA 151:40 establishes an "adverse event" fund, in which, if a facility fails to file a timely initial report, conduct a root cause and/or implement a corrective action plan the facility is subject to disciplinary action. During calendar year (CY) 2016 no actions were taken for late reporting.

Unpreventable / Unavoidable Harm

According to NQF, to qualify for the list of SREs an event must be "largely, if not entirely, preventable" in addition to other criteria. All hospitals and ASCs report Adverse Events as required by law. Upon completion of a detailed root cause analysis, they may occasionally find that, despite adoption of evidence based protocols and strict adherence to established standards of care, an optimal outcome is not achieved and harm still occurs. Individuals may have clinical conditions that can create a complex set of processes that lead to an event, despite providing the best prevention and/or treatment known. One of the goals of patient care is to do all that is possible and learn from all events, whether or not it was considered unavoidable.

Serious Reportable Events / Adverse Events

Since January 2010, NH hospitals and ASCs have been reporting adverse events to the Bureau of Health Facilities Certification as required by RSA 151: 38. The law was revised in 2013. It is important to note that changes and additions to the list of SREs, including changes in definitions, resulted in an increased number of reports in the following year. This is particularly evident in the category of pressure injuries, whose definition was expanded to include "unstageable", which resulted in a doubling of pressure ulcer reports between 2013 and 2014, from 11 to 22. The number of reported pressure ulcers stabilized in the year 2015. The facilities have learned about the weaknesses in their systems and have improved their processes. These improvements within their systems have prevented increased reportable pressure injuries.

It's crucial to remember that this data should not be used to compare the quality of care and safety of the facilities by the number or the type of SRE's reported. Consumers need to look at all factors such as: size of the facility, scope and complexities of the procedures as well as the number of procedures that are performed at the facility.

2016 Adverse Events per Organization and Event

CY2016		Surgical Event	Surgical Event	Surgical Event	Surgical Event	Patient Protection Event	Care Event	Care Event	Care Event	Care Event	Environmental Event	
Provider Name	# of staff Beds	Wrong Body Part	Wrong Patient	Wrong Procedure	Foreign Object	Suicide	Medication Error	Labor & Delivery	Stage 3 & 4& unstageable	Fall	Burn/shock	Total reported
Catholic Medical Center	240				1				2	1		4
Cheshire Medical Center	116							3		1		4
Concord Hospital	237	1								3		4
Elliot Hospital	266	1			2					4		7
Exeter Hospital	99	1								1		2
Frisbie Hospital	96										1/s	1
Hampstead Hospital	111					1						1
HealthSouth Rehabilitation Hospital	50								1	2		3
Lakes Region General Hospital	88						1			1		2
Mary Hitchcock Memorial Hospital	417		1	1			1		5	1		9
Northeast Rehabilitation Hospital Network	135								2	1		3
Portsmouth Regional Hospital	165					1	1			2	1/b	5
Southern NH Medical Center	163				1				1			2
Speare Hospital	25							1				1
St. Joseph Hospital	126			1					1			2
The New London Hospital	25									2		2
Weeks Medical Center	25				1							1
Nashua Ambulation Surgical Center		1										1
Total		4	1	2	5	2	3	4	12	19	2	54

Comparison by Events - 2013 - 2016

SURGICAL OR INVASIVE PROCEDURE EVENTS	2013	2014	2015	2016
Wrong site	2	1	4	4
Wrong patient	0	1	0	1
Wrong procedure	2	2	1	2
Unintended retention of a foreign object	7	10	5	5
Intraoperative or immediately postoperative death of ASA Class 1 patient	0	0	0	0
PRODUCT OR DEVICE EVENTS				
Use of contaminated drugs, biologics or device	0	0	0	0
Misuse/malfunction of a device	0	0	1	0
Air embolism	0	0	0	0
PATIENT PROTECTION EVENTS				
Release of a patient of any age, who is unable to make decisions, to the wrong person	0	0	0	0
Patient elopement	0	0	0	0
Patient suicide, attempted suicide, or self-harm	0	3	0	2
CARE MANAGEMENT EVENTS				
Death or serious injury due to a medication error	0	0	2	3
Death or serious injury due to unsafe transfusion practices	0	0	0	0
Maternal death or serious injury In a low-risk pregnancy, labor or delivery	1	0	0	0
Death or serious injury of a neonate in a low risk pregnancy, labor or delivery	1	1	4	4
Death or serious injury associated with a fall	23	25	21	19
Stage 3 or 4 or unstageable pressure ulcers acquired after admission	11	22	22	12
Artificial insemination with the wrong donor sperm or donor egg	0	0	0	0
Death or serious injury from irretrievable loss of an irreplaceable biological specimen	0	0	0	0
Death or serious injury from failure to follow up or communicate laboratory, pathology, or radiology test results	0	3	2	0
ENVIRONMENTAL EVENTS				
Death or serious injury associated with an electric shock	0	0	0	1
Wrong gas, no gas or contamination in patient gas line	0	0	0	0
Patient or staff death or serious injury associated with a burn	1	2	1	1
Death or serious injury associated with the use of physical restraints or bedrails	0	0	0	0
RADIOLOGIC EVENTS				
Death or serious injury if a patient or staff with the introduction of a metallic object into the MRI	0	0	0	0
POTENTIAL CRIMINAL EVENTS				
Care ordered by or provided by someone impersonating an MD, RN, Pharmacist or other LIP	0	0	0	0
Abduction of a patient of any age	0	0	0	0
Sexual abuse/assault of a patient or staff member	1	1	0	0
Death or serious Injury of a patient or staff from physical assault (battery)	2	2	1	0
TOTAL	**51**	**73**	**64**	**54**

What are NH hospitals doing about Serious Reportable Events?

In analyzing the events reported in CY 2016 it should be noted that there were three major areas responsible for 79% of the events reported. These areas were as follows:

Falls	**35%**
Pressure Ulcers	**22%**
Surgical Events	**22%**

Given the fact that these represent 79**%** of the events, it is important that we focus on these and address what the NH hospitals are doing in these areas and improve.

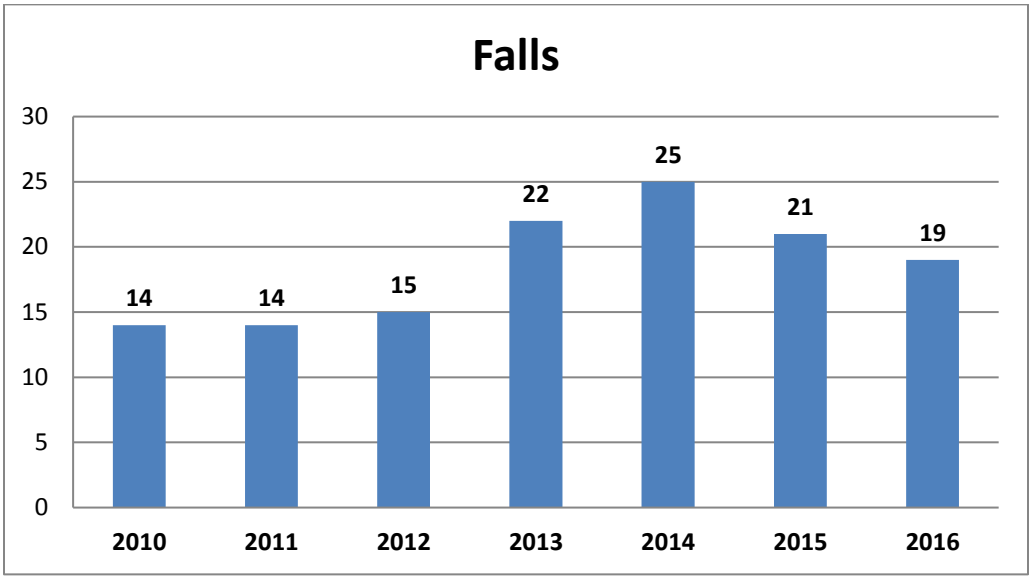
Falls with Injury

Problem Summary:

A fall is defined a "sudden, unintentional change in position causing an individual to land at a lower level , on an object, the floor, on the ground, other than as a consequence of a sudden onset of paralysis epileptic seizures, or overwhelming external forces." Falls are the second leading cause of unintentionally injury death. Although many fall-prevention programs focus on the elderly, age isn't the only determining factor. Other factors to consider are confusion and weakness caused by illness, medications and even diagnostics tests. Fall-related injuries can be non-fatal or fatal injuries, though most are non-fatal. Falls are common. "The Center for Disease Control and Prevention (CDC) "estimates that one in three U.S adults age 65 and older fall each year. (CDC "Important Facts About Falls"). According to the "Sentinel Event Alert" by the Joint Commission, hundreds of thousands of patients fall every year in hospitals with 30% to 50 % of them resulting in injuries. The Joint Commission states that falls involving serious injuries consistently rank among the top 10 sentinel events reported to the agency. Falls in a hospital can, and often do, complicate the hospital stay and delay the patient returning to the community. According to the report that Health Research & Education Trust, published October 2016: "*Preventing Patient Falls: A Systemic Approach from the Joint Commission Center for Transforming Healthcare Project"* 10 contributing factors for falls are within 6 categories. These categories are:

1. Falls risk assessment issues
2. Hand off communication issues
3. Toileting issues
4. Call light issues
5. Educational issues and organizational issues
6. Medication issues

For those who suffer from injuries it can require additional testing and a prolonged duration of stay in the hospital. The majority of patients who suffer a serious injury may also suffer from several chronic diseases and conditions that impact balance, strength, and mobility either due to the medications they are taking or because of their medical condition.



Contributing Factors:

Many factors over the years have been identified by NH hospitals. These include but may not be limited to the following:

- Physical challenges with mobility and oxygenation impairments
- History of falls in the past several months prior to admission
- Adults who fall may not call the nurse because:
    - They don't remember to call the nurse
    - They are adults who have independently toileted themselves up until recently
- Patients admitted to hospitals have complicated care issues and critically ill
- Medical conditions may impact mobility such as impaired blood flow to lower legs
- Medications may interfere with mobility and judgment, such as post-operative pain medications
- Communication with changes in condition to providers
- Hand off discussion when patient is moved from unit to unit

Strategies in place in NH hospitals include but are not limited to:

- Focus on patient rounding to see and determine the safety and comfort of patients at least every hour
- Use of a standardized Fall Risk Assessment upon admission, updated every eight hours and re-evaluated after every fall
- Staff debriefing (huddles) immediately after every fall to determine contributing factors and how events occurred in an attempt to learn how to better provide patient care to prevent further falls
- Dedicated resources to a "sitter" program to provide human companionship and help alert nurses in a timely manner when a patient is trying to get up creating a fall risk
- Regular training and technology to improve the uses of motion sensors - pads and alarms activated by patient movement that alert staff to movement
- Fall Prevention Teams – interdisciplinary team to review and discuss ways to prevent falls and reduce injury that would include the following: Physicians, nurses, pharmacists, and physical and occupational therapists.
- Gait Belts – used to help maintain balance and give staff more control if patient demonstrates weakness while walking – to help lower them to the floor instead of falling to the floor.

Plan Moving Forward:

- Link specific interventions to prevent falls to the fall risk assessment score
- Staff education orientation/refresher on fall prevention including the content of assessment and making changes in interventions as needed to address the changing fall risk of the patient
- Expand the act of purposeful rounding to include toileting at least hourly. Current standard is to "ask" the patient but in high risk cases, the facility may need to trial a new standard of actually taking patients to the bathroom
- Revitalize fall prevention teams, rotating new staff and clinicians into committees for a fresh approach in reviewing the events
- Re-evaluate and improve use of sitter programs and incorporate patient family engagement in the process
- Expand risk assessments upon hospital admission to include a history of falls at home as well as assessing for evidence of falls such as bruising
- Nurse to nurse reports which would include patient care unit to unit reports.

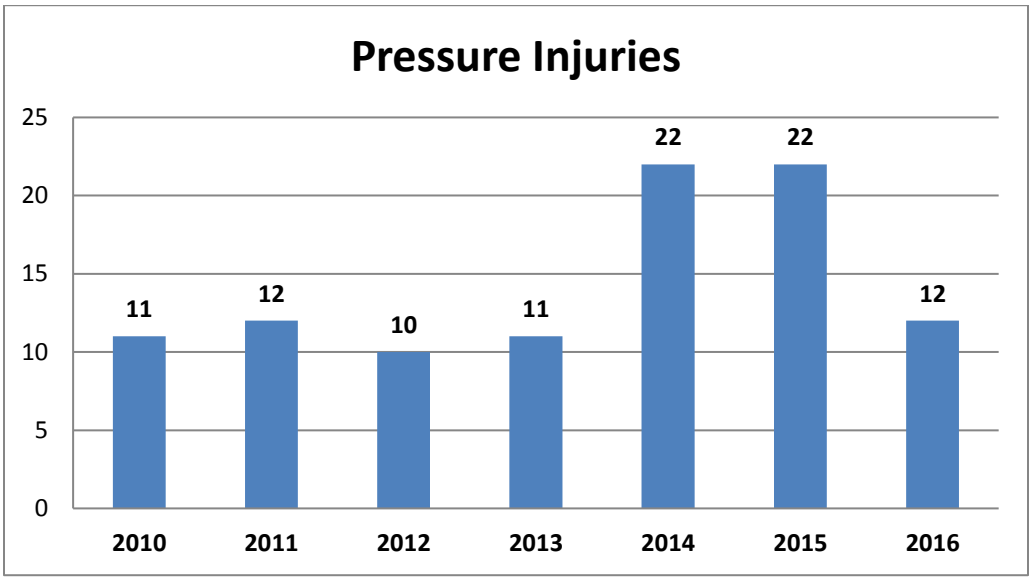
Conclusion:

Over the next 10 years the population of NH Seniors (age 65+) is expected to double to 325,000 people. Many may have multiple medical conditions and changing mentation. The typical patient will be on no fewer than 8-10 routine medications, many that may interfere with mobility. Hospitals in New Hampshire will continue to assist patients and their families during the hospital stay. Educate the patient to have a safe admission and identify all high risk areas for the patient. By educating the patient, the hospital can help facilitate patients to have a safe discharge back into the community.

Hospital Acquired Pressure Injuries Adverse Events

Problem Summary:

Pressure injuries, also more commonly referred to as "bedsores", "decubitus ulcers" or "pressure sores" are skin lesions which can be caused by friction, humidity, temperature, incontinence, medication, shearing force, age and unrelieved pressure. In April 2016, the National Pressure Ulcer Advisory Panel (NPUAP) replaced the term "pressure ulcer" with "pressure injury" in the NPUAP Injury Staging System to describe both intact and ulcerated skin. In addition, NPUAP has adopted new verbiage for staging. The term "suspected" has been removed and new definitions have been included such as Medical Device Related Pressure Injury and Mucosal Pressure Injury. More than 2.5 million people in the United States develop pressure ulcers every year. Patients prone to pressure injuries are those who sit or lie down in one position for more than 2 hours at a time. Poor nutrition, dehydration, and medical conditions that cause poor blood circulation to extremities, such as diabetes can increase the risk of pressure injuries. Pressure injuries can bring increased pain, risk for serious infections and need for additional health care staff while in the hospital. Inadequate performance of proper skin inspections, infrequent repositioning, and inability to maintain clean dry skin, can contribute to the development of a hospital acquired pressure injury. However, not all pressure injuries are preventable. The skin is an organ just like the heart and lungs. Sometimes overwhelming illness contributes to the failure of the underlying skin tissue and despite excellent care; the tissue breakdown will progress to a pressure injury. The most common areas for pressure ulcers include hips, back, ankles, and buttocks.



Contributing Factors:

Many factors over the years have been identified by NH hospitals. These include but may not be limited to the following:

- Lack of thorough skin inspection/assessment
- Inaccurate staging of pressure injuries
- Poor communications between staff and providers
- Not repositioning every 2 hours to relieve pressure
- Attention to addressing and improving hydration and nutritional status
- Education of the wound care equipment (dressings and specialty beds)
- High risk medical conditions and history including: Diabetes, Smoking, Chronic Obstructive Pulmonary Disease, Vascular Disease, bed or chair bound patients, bladder and/or bowel incontinence, and poor hygiene
- Operative procedures which necessitate the patient's position be maintained in a single place for extended periods of time

Strategies in place in NH hospitals include but are not limited to:

- Skin Assessment upon admission to identify pressure injuries at the time of admission so that prompt care can be initiated and reassessed every 8 hours to detect early development of pressure injuries to prevent progression
- Use of Braden Scale and similar tool for predicting pressure injury risk to determine other risk factors such as poor nutrition, dehydration, and hygiene issues so that high risk patients can be promptly identified and preventative interventions can be implemented before a pressure injury occurs
- Use of smooth soft surfaces and special pads for surgical patients undergoing lengthy procedures
- Development of protocols for cleaning and treating wounds
- Enhanced protocols for wound debridement (removal of dead tissue to allow for healing)
- Education/training on wound care at orientation of clinical staff with refresher classes offered at least every 2 years

- The use of a valid tool to measure nutritional status

Plan Moving Forward:

- Training and education on skin inspection/assessment and documentation of any sign of pressure injury development
- Provider engagement in early detection and planning for risk of skin breakdown during hospitalization
- Adoption of new evidence based practices including new wound care treatments for faster healing
- Engagement of local provider practices and home care agencies in inspections, assessments, and preventative treatment and patient/family education
- Education on wound dressing application and specialty beds
- Standardize the hand off/huddle reports

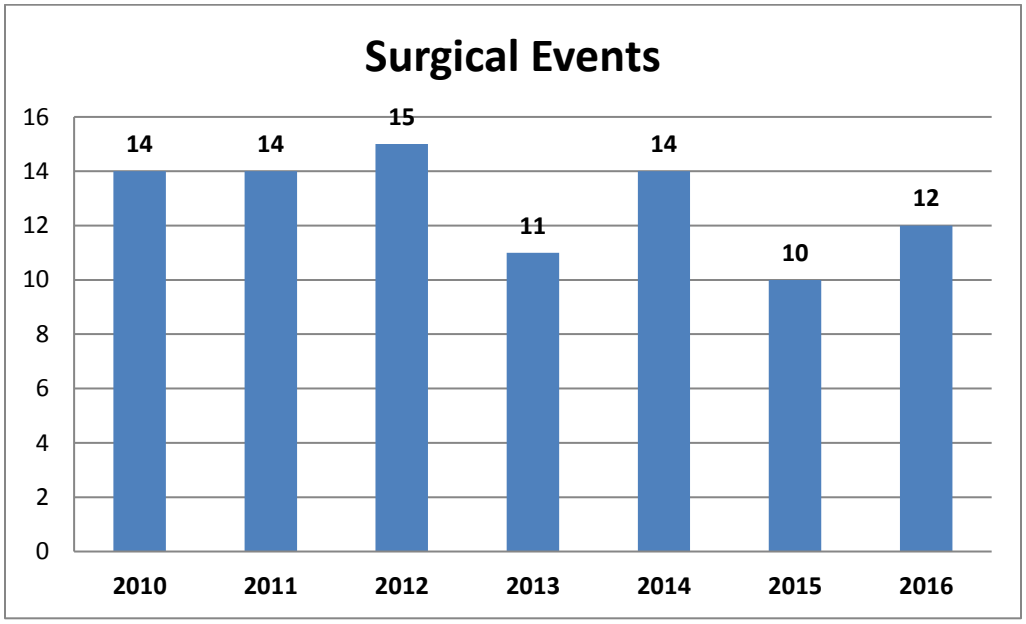
Conclusion:

All NH hospitals are chasing zero – meaning they are striving for NO hospital acquired pressure injuries. The majority of wounds start when patients are in the community. Reaching out to services that can influence prevention before and in addition to after hospitalization is being considered as part of efforts to reduce pressure injury harm in NH communities.

Surgical or Invasive Procedure Adverse Events

Problem Summary:

Surgical interventions in modern medicine take many different forms. Some are minor procedures performed in an office or bedside setting, taking a single clinician no more than a few minutes to complete. Others are highly complex invasive procedures requiring a team of 10 or more experts in a traditional operating room where a single surgery may take anywhere from 1-30 hours and requires hundreds of instruments and a variety of technical equipment. It is estimated that 1 wrong site event per 100, 000 surgeries occur; while in an estimated 1 in 10,000 surgeries a retained foreign object is left inside a patient in the United States each year. More procedures are being done in a of variety settings designed for minimally invasive procedures such as interventional radiology, cardiology, endoscopy suites and ambulatory surgery centers. Highly complex procedures can now be safely performed in these settings due to advances in the use of robotics, scopes, and procedural imaging. NH hospitals and ASCs are working to prevent surgical errors in all these settings through the use of checklists, team time outs, and briefings. Despite these efforts, surgical and procedural errors do occasionally happen. These errors include surgical instruments or objects such as sponges unintentionally left behind in the patient.



Contributing Factors:

Many factors over the years have been identified by NH hospitals and ASCs. These include but may not be limited to the following:

- Lack of frequent hand-offs of information during the continuum of care from the time of the original diagnosis of the issue requiring surgery to the actual team preforming the procedure; vital information is sometimes misrepresented or lost completely as it is handed off along the way
- Lack of policies to address un-reconciled supply counts, little consistency in time-outs, or consents being filled out correctly.

Strategies in place in NH hospitals and ASCs include but are not limited to:

- Full investigations of near miss events to understand failures and improve reliability of systems before an error causing harm occurs
- Engagement of Medical Staff by incorporation of time out/checklist performance into the provider evaluation process. Patient engagement in the development of patient safety steps regarding surgical preparations and communication about the process, include the patient in the safety checks, together with the goals of the procedure from the patient's perspective, helps to get all team members unified on the plan of care

Plan Moving Forward:

- Continue to educate staff in the use of the checklist and time out process including the understanding of the limitations of these tools to prevent all surgical errors
- Continue to foster a safe culture that encourages staff to speak up and stop the process if they suspect a problem, by training the surgeon in leadership methods that invite team communication and collaboration
- Enhance high reliability performance of the surgical team by including the patient's goals of care in the safety checks or briefings
- Explore and consider the implementation of pauses during the procedure prior to critical steps to assure all team members understand the plan and their role in executing it

- Track and trend near miss events to improve systems and processes before actual error occurs
- When a surgical error causing harm occurs, continue to develop methods for supporting the affected patient and family as well as the team members involved in the error
- NH hospitals and ASCs continue to work collaboratively to establish best in class surgical safety practices

Conclusion:

Surgical events are overwhelming to patients, families and the healthcare team involved with the error. Strong leadership during the surgical time out reinforces the important role of each team member in ensuring patient safety. Each team member must verbally state their name and purpose of the surgery and discuss any concerns before the surgery. With collaboration among team members, each member has a vested interest in the patient's outcome.

Summary
The ongoing goal for the NH hospitals and ASCs is to continue to look at their identified root cause analyses and make the Corrective Action Plans (CAPs) that can enhance patient safety. The Hospitals and the ASCs remain committed to educate their personnel and professional staff about patient safety to promote the best outcomes for their patients.
The DHHS and the representatives from the NH Healthcare Quality Assurance Commission will participate in a pilot program to meet quarterly to review the Adverse Events in the upcoming year.

Acknowledgements:

The DHHS's Adverse Event Reporting Staff would also like to thank the many staff at New Hampshire's hospitals and ASCs for their prompt reporting of events and reporting of root cause analysis and corrective action plans.

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