HCQA Health Care Quality Assessment

Patient Safety Reporting System

2016 Summary Report

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Patient Safety Reporting System

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Patient Safety Reporting System

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* Most frequently reported events include falls, pressure ulcers, retained foreign objects and care management "other" events. Falls and care management "other" events have been reviewed in the section "Specific Events with the Highest Number of Associated Deaths."

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Patient Safety Reporting System

Executive Summary

The New Jersey Patient Safety Act (P.L.2004, c.9) requires all New Jersey licensed health care facilities to report every serious preventable adverse event to the Department of Health (DOH) for the purpose of enhancing patient safety. Facilities must perform a Root Cause Analysis (RCA) to identify the systems issues which led to the event and to implement strategies to prevent future events. The Act defines a serious preventable adverse event as "an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility."

The following types of facilities currently report to the New Jersey Department of Health's Patient Safety Reporting System:

- General acute care hospitals as of February 1, 2005;
- Comprehensive rehabilitation hospitals as of April 1, 2008;
- Psychiatric hospitals as of April 1, 2008;
- Special Hospitals as of April 1, 2008; and
- Licensed ambulatory surgery centers as of October 1, 2008.

Summary of reported adverse events for all facility types in 2016:

- 854 events were reported to the Patient Safety Reporting System by all facility types;
- 632 events met the statutory definition of (or satisfied the criteria for) a serious preventable adverse event ("reportable");
- 222 events did not meet the statutory definition and included less serious events, near misses and events that were not associated with the provision of health care ("not reportable");
- 79 deaths were associated with the adverse events.

General Acute Care Hospitals:

- Submitted 418 reportable adverse events in 2016 compared to 491 events in 2015;
- The average number of reportable events per reporting hospital was 6.1 (does not take into account hospital sizes and bed capacity);
- There were 72 deaths associated with the adverse events; specific events with the highest percent of associated deaths were care management "other" events (33),[a] intraoperative or postoperative coma, death, or other serious preventable adverse events (18), and surgery "other" events (9);
- The most frequently reported events were falls, care management "other" events, suicide/attempted suicide; pressure ulcers and retained foreign objects;
- Adverse events were most often caused by care planning process, communication among staff and/or with the patient/family, orientation and training of staff, physical assessment process and patient observation procedures;
- The most frequent consequences of the events were additional patient monitoring in current location, additional laboratory testing or diagnostic imaging, increased length of stay, disability- physical or mental impairment and major surgery.

Comprehensive Rehabilitation Hospitals:

- There were 36 reportable events and two deaths, each associated with care management "other" and suicide/attempted suicide;
- The most frequently reported root causes were communication among staff members, care planning process, and physical assessment process;
- Two-thirds (66.7%) of the patients experienced increased length of stay.

a: Refer to the Introduction section on page 3 for a description of "other" event types.

Executive Summary

Others had additional laboratory testing of diagnostic imaging or visit to the emergency department.

Psychiatric Hospitals:

- There were 18 reportable events with no deaths;
- The most frequently reported root causes were care planning, behavioral assessment process, and patient observation process;
- Thirteen out of the eighteen events resulted in a visit to the emergency department

Special Hospitals:

- Eight events were submitted but only six were deemed reportable and there was no associated death;
- The most frequently reported root causes were physical assessment process and communication among staff members;
- The most frequent impact of the events included additional patient monitoring in current location, disability- physical or mental impairment and increased length of stay.

Ambulatory Surgery Centers:

- Submitted 154 reportable events with four deaths which were all associated with intraoperative or postoperative coma, death or other serious preventable events;
- The most frequent root causes were care planning process and physical assessment process;
- The most reported impact of these adverse events were hospital admission and increased length of stay.

Patient Safety Reporting System

Introduction

This report presents the findings from serious preventable adverse events reported to the Department's Office of Health Care Quality Assessment (HCQA), Patient Safety Reporting System (PSRS). The findings of the report are based on data reviewed and analyzed from event and Root Cause Analysis (RCA) reports submitted in 2016.

Health care facilities are required to report serious preventable adverse events and perform a root cause analysis (RCA) for each reportable event. The Act defines a serious preventable adverse event as "an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility." Serious preventable adverse events ("reportable events") are divided into 5 categories: Care Management, Environmental, Product or Device-related, Surgery-related and Patient Protection-related.

Patient Safety Regulations also require facilities to report in the appropriate category events that are not specifically listed that meet the definition of a serious preventable adverse event. These types of events (such as lost surgical specimens and failure to follow up with results of diagnostic studies) are submitted as "Other" events in the appropriate category. The classification and definitions of serious preventable events can be found in Appendix 1.

The Act requires facilities to provide a description of the event; an analysis of why the event happened; the corrective actions taken for the patient; the method for identifying other patients that may be affected by a similar event; the systemic changes needed to reduce the likelihood of similar events; and how the corrective actions will be monitored (See Appendix 2 for additional details).

Each RCA is reviewed by PSRS professional clinical staff to ensure that the facility performed a thorough and credible review of the adverse event. PSRS staff work with facilities to improve their analysis and the corrective actions designed to minimize the recurrence of events.

Prior to the implementation of the web based reporting system, events were designated as reportable or not reportable. Since 2011, PSRS has the ability to capture less serious events and near misses pursuant to the Patient Safety Act. Less serious events, near misses and events that are not associated with the provision of health care ("not reportable events") do not require an RCA. However, healthcare facilities are encouraged to perform an RCA on less serious events and near misses which may be voluntarily submitted to the Patient Safety Reporting System.

This report is one component of the Department's commitment to supporting quality through collecting and analyzing information on health care and making this information available for consumers and health care providers.

The report also includes the findings of reportable events from the Division of Mental Health and Addiction Services (DMHAS) in section VI of this document.

II. Overall Reporting Patterns by Facility Type

II. Overall Reporting Patterns by Facility Type

This annual report summarizes the 2016 Patient Safety Reporting System (PSRS) reportable events and RCAs with a focus on events with a high percentage of associated deaths and the most frequently reported events. The report covers events and RCAs submitted by general acute care hospitals, specialty hospitals (comprehensive rehabilitation, psychiatric and special hospitals), and ambulatory surgery centers.

The number of reportable, not reportable and less serious events, and near misses submitted to the Patient Safety Reporting System for 2016 from all facilities totaled 854.

Of this total, 632 were deemed reportable with 79 associated deaths. In 2015, the number of reportable events across all facility types was 724 with 115 associated deaths.

An in-depth analysis of the data shows that there were 92 fewer reportable events between 2015 and 2016. The highest drop in reportable events (73) was attributed to general acute care hospitals. The second highest decrease (11) was from ambulatory surgery centers. A similar pattern is exhibited in relationship to reportable deaths.

There were 36 fewer deaths in 2016 compared to 2015. Of this decrease, acute care hospitals accounted for 24 and ambulatory surgery centers had nine fewer deaths.

Table 1 shows the distribution of events reported to the New Jersey Department of Health, Patient Safety Reporting System by facility types for the year 2016.

Table 1: Reporting Pattern by Facility Type (2016)

Facility Type	Number of Facilities	Number of Reporting Facilities	Number of Reportable Events	Number of Not Reportable Events	Number of Less Serious/Near Misses	Number of Deaths
General Acute Care Hospitals	72	68	418	4	49	72
Comprehensive Rehabilitation Hospitals	14	11	36	1	4	2
Psychiatric Hospitals	11	9	18	0	6	0
Special Hospitals	14	8	6	1	2	1
Ambulatory Surgery Centers	176	89	154	14	141	4
Total	287	185	632	20	202	79

III. General Acute Care Hospitals

A. Reporting Patterns (2005-2016)

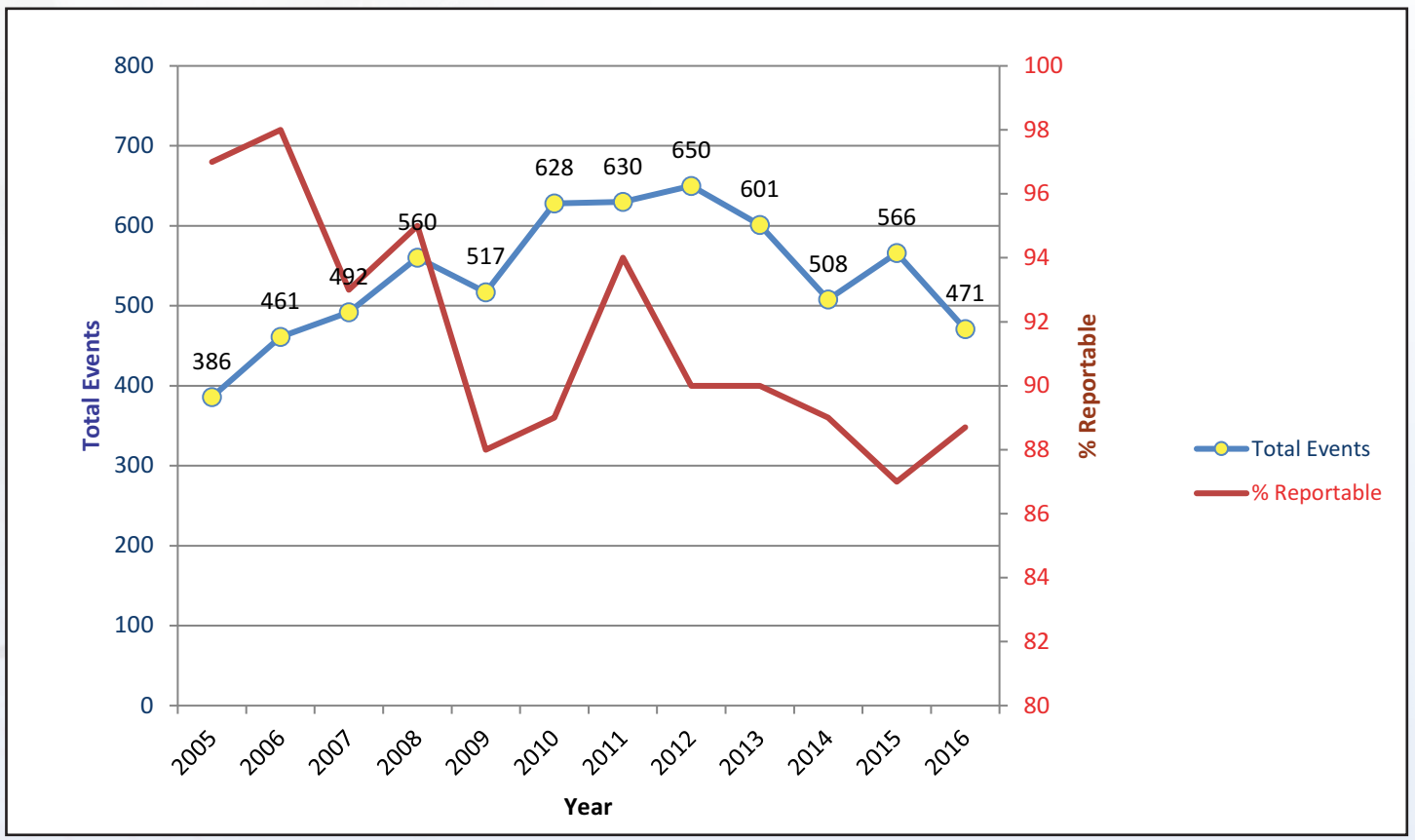
Figure 1 and Table 2 demonstrate the reporting patterns for general acute care hospitals over the past 12 years.

In the early years of the reporting program, adverse events were designated as reportable if they met the statutory definition of a serious preventable adverse event or not reportable.

With the implementation of the web-based system in 2011, PSRS has the ability to capture less serious events and near misses pursuant to the Patient Safety Act.

The percent of not reportable events by general acute care hospitals decreased from 13 percent in 2015 to 11.3 percent in 2016.

Figure 1: General Acute Care Hospitals: Trends in Reportable Events 2005-2016



III. General Acute Care Hospitals

Table 2: General Acute Care Hospitals: Reportable, Less Serious Events/Near Misses and Not Reportable Events by Year

Year	Reportable	Not Reportable	Less Serious/Near Misses	Total Events	Percent Not Reportable	Percent Reportable
2005[a]	376	10	NA	386	3	97
2006	450	11	NA	461	2	98
2007	456	36	NA	492	7	93
2008	533	27	NA	560	5	95
2009	455	62	NA	517	12	88
2010	562	66	NA	628	11	89
2011	601	10	31	642	6	94
2012	587	22	41	650	10	90
2013	542	5	54	601	10	90
2014	451	2	55	508	11	89
2015	491	8	67	566	13	87
2016	418	4	49	471	11	89

a: Represents 11 months of data since the program started on February 1, 2005.

Patient Safety Reporting System

III. General Acute Care Hospitals

Since reporting began in February 2005, 5922 reportable adverse events have been submitted by New Jersey general acute care hospitals to the Patient Safety Reporting System (PSRS) through the end of year 2016.

In 2016, the twelfth year of reporting, 418 reportable events from general acute care hospitals were submitted. The following describes the serious preventable adverse events that occurred in general acute care hospitals.

In 2016, 68 general acute care hospitals in New Jersey submitted reportable events. The average number of reports per reporting hospital was 6.1. This average does not take into account hospital size and bed capacity.

When comparing 2016 data with prior years, please note that 2016 data includes the actual number of events which occurred. In prior years, the data was collected based on the year the event was reported. Since events are not always submitted in the year they occurred, the total number of events each year could potentially increase.

Table 3: General Acute Care Hospitals: Reporting Patterns (2005-2016)

Reporting Year	Number of Reportable events	Hospitals			Average number of reports per hospital	Reportable Deaths	Percent of Deaths
		Number	Number Reporting	Percent Reporting			
2005[a]	376	82	68	82.9	5.5	57	15.2
2006	450	81	71	87.7	6.3	47	10.4
2007	456	80	75	93.8	6.1	72	15.8
2008	533	72	72	100.0	7.4	75	14.1
2009	455	72	68	94.4	6.7	74	16.3
2010	562	72	71	98.6	7.9	85	15.1
2011	601	72	69	95.8	8.7	89	14.8
2012	587	72	72	100.0	8.1	84	14.3
2013	542	72	72	100.0	7.5	84	15.5
2014	451	72	72	100.0	6.3	75	16.6
2015	491	72	72	100.0	6.8	96	19.6
2016	418	72	68	94.4	6.1	72	17.2

a: Represents 11 months of data since the program started on February 1, 2005.

B. Reportable Events and Associated Deaths by Event Category

As indicated earlier in the report, there were 418 adverse events reported by 68 New Jersey general acute care hospitals in 2016. There were 72 deaths associated with these adverse events. The events reported are classified into five event categories as follows:

- Care Management
- Environmental
- Product or Device-Related
- Surgery-Related
- Patient Protection

Table 4 provides an overview of reportable events in the event categories with associated deaths. Please see Appendix 1 for the types of events associated with these categories.

Table 4: General Acute Care Hospitals:
Reportable Events and Associated Deaths by Event Category-2016

Event Category	Total Reportable Events	Percent of Total Events	Total Deaths per Events	Percent Deaths per Event Category
A: Care Management	110	26.3	36	50.0
B: Environmental	134	32.1	8	11.1
C: Product or Device	1	0.2	0	0
D: Surgery-Related	111	26.6	27	37.5
E: Patient Protection	62	14.8	1	1.4
Total	418	100.0	72	100.0

III. General Acute Care Hospitals

As Table 4 demonstrates, the care management event category had the highest number of associated deaths (36 out of 72) or 50 percent of all deaths. The second highest category for reported deaths was surgery-related (27) followed by environmental (8).

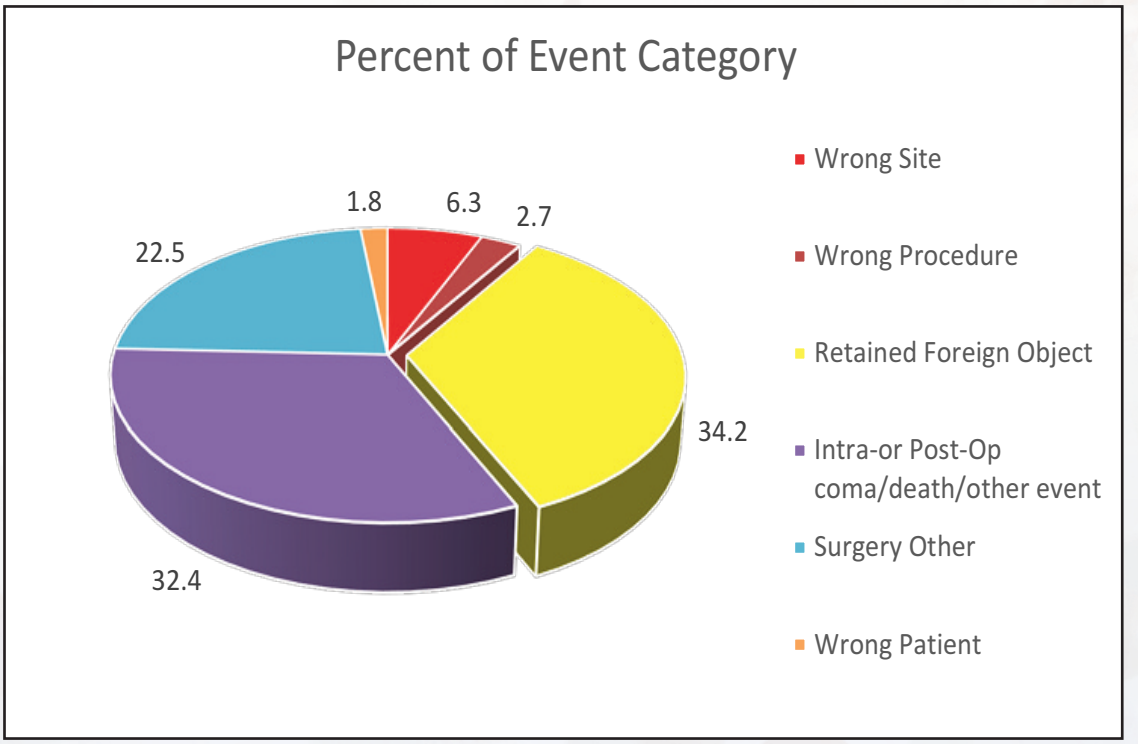
For individual surgery-related event types, retained foreign objects had the highest number of reported events (38); however, this was a decrease of 13 from 2015. Similar to 2015, there were no deaths associated with this event. The second highest reported event was for intra-operative or post-operative events (36). There were 18 deaths related to this event type.

Table 5 and Figure 2 show the results.

Table 5: Surgery-Related Event Types with Associated Deaths

Event Type	Reportable Events	Number of Deaths	Percent of Deaths by Event Type
Retained Foreign Object	38	0	0.0
Intra-Op/Post-Op Coma/Death/Other Event	36	18	66.7
Surgery "Other"	25	9	33.3
Wrong Site	7	0	0.0
Wrong Procedure	3	0	0.0
Wrong Patient	2	0	0.0
Total	111	27	37.5

Figure 2: General Acute Care Hospitals: Distribution of Surgery-Related Events



C. Events Types Associated with Highest Percent Deaths

Table 6 shows the event types with the highest percentage of deaths. In aggregate, the four event types identified below had a total of 247 reportable events which represent 59.1 percent of all events reported. The total number of deaths associated with all event types was 72 and these four events resulted in 68 deaths and accounted for more than 94 percent (94.4%) of all deaths in 2016.

Table 6: General Acute Care Hospitals: Event Types Associated with Highest Percent Deaths

Event Type	Number of Events	Number of Deaths	Percent Deaths to Events
Care Management "Other"	63	33	52.4
Intra-Op/Post-OP Coma, Death or Other Event	36	18	50.0
Surgery-Related "Other"	25	9	36.0
Fall	123	8	6.5
All Other Event Types	171	4	2.3
Total	418	72	17.2

III. General Acute Care Hospitals

1. Care Management "Other" Events

More than one-half (52.4%) of care management "other" events resulted in death as noted in Table 6. Care management "other" events include care management related events which do not meet the definition of the specific care management event types, such as medication errors and pressure ulcers. Events must meet the statutory definition of a serious preventable adverse event.

Care management "other" events have consistently been associated with one of the highest percentage of deaths and the number of deaths per year has remained relatively constant. There were 62 events in 2014, 65 in 2015 and 63 in 2016. Almost 24% of the events occurred to a newborn/neonate. The number of deaths changed slightly from 30 in 2014, to 28 in 2015 and increased to 33 in 2016. There were 3 infant/newborn/neonate deaths. The 63 events were submitted by 31 of the 72 general acute care hospitals.

Examples of events reported for this event type in 2016 include delays in responding to non-reassuring fetal heart rate tracings, delays in reporting or processing critical lab or EKG results, missing pathology specimen, incorrect placement of feeding tubes, IV extravasations/infiltrations, unexplained fractures, and failure to adequately monitor patients on cardiac monitors. Approximately 35% of all care management "other" events were related to a delay in care.

2. Intraoperative or Postoperative Coma, Death or Other Serious Event Preventable Adverse Event

There were 36 reports of intraoperative or postoperative (that is, within 24 hours) coma, death or other serious preventable adverse event in 2016. This was a slight increase from 2015 which reported 33 events. However, the number of deaths decreased from 23 in 2015 to 18 in 2016.

Based on the American Society of Anesthesiology (ASA) classification, the patients fell into the following classifications: ASA Class I, 30.6%, ASA Class II, 22.2%, ASA Class III, 25.0%, and ASA Class IV, 22.2%. See chart below.

Of the 36 reported events, eleven facilities submitted one event each, 3 reported 2 events each, 2 reported 3 events each, and two facilities reported 6 and 7 events respectively. The events affected 15 same day surgery patients (41.7%), 14 outpatients (38.9%), 4 inpatients (11.1%), and 3 emergency department patients (8.3%).

Events reported for this event type in 2016 were similar to past years and included death, cardiorespiratory arrest, ischemic leg following cardiac catheterization, infarct of brainstem and cerebellum following cervical fusion, hypotension (low blood pressure), blood vessel lacerations, perforations during or immediately (within 24 hours) following surgery.

3. Surgery "Other" Events

Surgery "other" events include surgery-related events which do not meet the definition of the specific surgery event types, such as retained foreign objects, intraoperative or postoperative events and wrong site surgery events.

The number of reported events for this event type was 25 in 2016 compared to 26 in 2015. The number of deaths decreased from 15 in 2015 to 9 in 2016.

Of the 25 events reported, 6 facilities had one event each (24.0%), 4 facilities had 2 events each (32.0%), one facility had 4 events (16.0%), and another facility reported 7 events (28.0%).

At the time of the event, nine of the patients were designated as ASA Class lll (36.0%), an additional eight patients were designated as ASA Class ll (32.0%) and seven as ASA Class lV (28.0%).

Similar to prior years, events reported for this event type in 2016 included death, spinal cord compression, compartment syndrome, major vessel lacerations, organ perforations, surgical site infections and sepsis.

4. Fall Events

Falls continue to be the most frequently reported event submitted to the Patient Safety Reporting System. The number of reported falls in 2016 (123) was lower than the number reported in 2015 (144). Similarly, the number of deaths decreased from 20 in 2015 to eight in 2016.

Fifty-one hospitals submitted the 123 fall events as follows: 22 hospitals reported 1 fall each (17.9%), 13 hospitals reported 2 each (21.1%), 3 submitted 3 events each (7.3%), 6 reported 4 fall events each (19.5%), 3 submitted 6 events each (14.6%) and 2 submitted 7 events each (11.4%).

As reported earlier, there were eight deaths associated with falls. A majority (75.0%) of the patient deaths occurred in the Med/Surg Unit. One death occurred in the Telemetry unit and the other at the Emergency Department Crisis Screening/Observation unit.

Prior to the fall, 73 patients (59.8%) were known to be at high risk, 23 (18.9%) were at medium risk, and 26 (21.3%) were considered to be at low risk for falls.

Similar to 2015, the majority of the patients were engaged in the following activities prior to the fall: toileting-related activities (44, 36.1%), ambulating without assistance and/or assistive device (28, 23%), changing positions (22, 18.0%) and reaching for an item (7, 5.7%). Two patients fell while ambulating with assistance and/or an assistive device and another two patients fell while transferring to/or from bed, chair, etc.

III. General Acute Care Hospitals

A fall risk screening tool was used to assess the patient's risk prior to the fall. The most prevalent screening tool used was the Morse Fall Risk Assessment (46, 37.4%). The next mostly used tool was the John Hopkins Fall Risk Assessment Tool (26, 21.1%) and the Hendrich/Hendrich II Fall Risk Assessment (19, 15.4%). Over one-fourth of the patients were assessed by using Facility developed or "Other" risk assessment tools (32, 26.0%).

Almost two-thirds of the patients (79, 64.7%) were observed on patient rounds less than 30 minutes prior to the fall and less than 1 hour prior to the fall (28, 22.9%). For five of the events (5, 4.1%), the last patient rounds occurred more than 2 hours prior and the last time rounds occurred was unknown in another eight events (8, 6.6%).

A majority of the falls occurred near or from the patient's bed (50, 41.3%). Fifteen of the patients fell between the bed and the bathroom (15, 12.4%) while almost a similar number fell specifically in the bathroom (14, 11.6%). Other falls occurred near or from a chair (11, 9.1%), and from a stretcher (65.0%).

The table below shows the fall patient care specifics.

Fall Patient Care Specifics	Percent Yes
A fall team regularly evaluates the falls program	97.5
A fall risk screening was documented at admission	97.5
A validated, reliable fall risk screening tool was used	94.3
The screening tool indicated that the patient was at risk for a fall if used	78.0
The patient had a history of a fall prior to admission	42.6
The patient was placed at risk due to clinical judgement, if applicable	43.3
The facility's universal fall precautions were in place for this patient, if applicable	93.9
The patient was re-evaluated during each nursing shift, if applicable	95.2
The patient was re-evaluated upon transfer between units, if applicable	98.5
The patient was re-evaluated upon change in status, if applicable	97.4
The patient was re-evaluated post fall, if applicable	97.4
There was a visual indication alerting staff to patient's at-risk status	80.3
A fall prevention intervention plan was documented	83.6
The fall prevention plan focused on the patient's specific risk factors	78.7
The patient/family education was completed	85.2
Side rails were in proper position, if applicable	85.2
Restraints were used	3.3
The patient was wearing non-skid footwear	84.4
Footwear fit properly, if applicable	100.0
The patient was on culprit medication within 6 hours of the fall	47.5

D. Most Frequently Reported Event Types

As shown in Table 7 below, over 91 percent of events submitted in 2016 were for the following specific events: fall, care management "other", suicide/attempted suicide, pressure ulcer, retained foreign object, intra-op/post-op coma/death or other serious events and surgery-related "other". Cumulatively, these seven events were the most frequently reported and accounted for 91.4 percent of all events reported in 2016.

Figure 3 shows the reporting trends for these event types from 2013 to 2016.

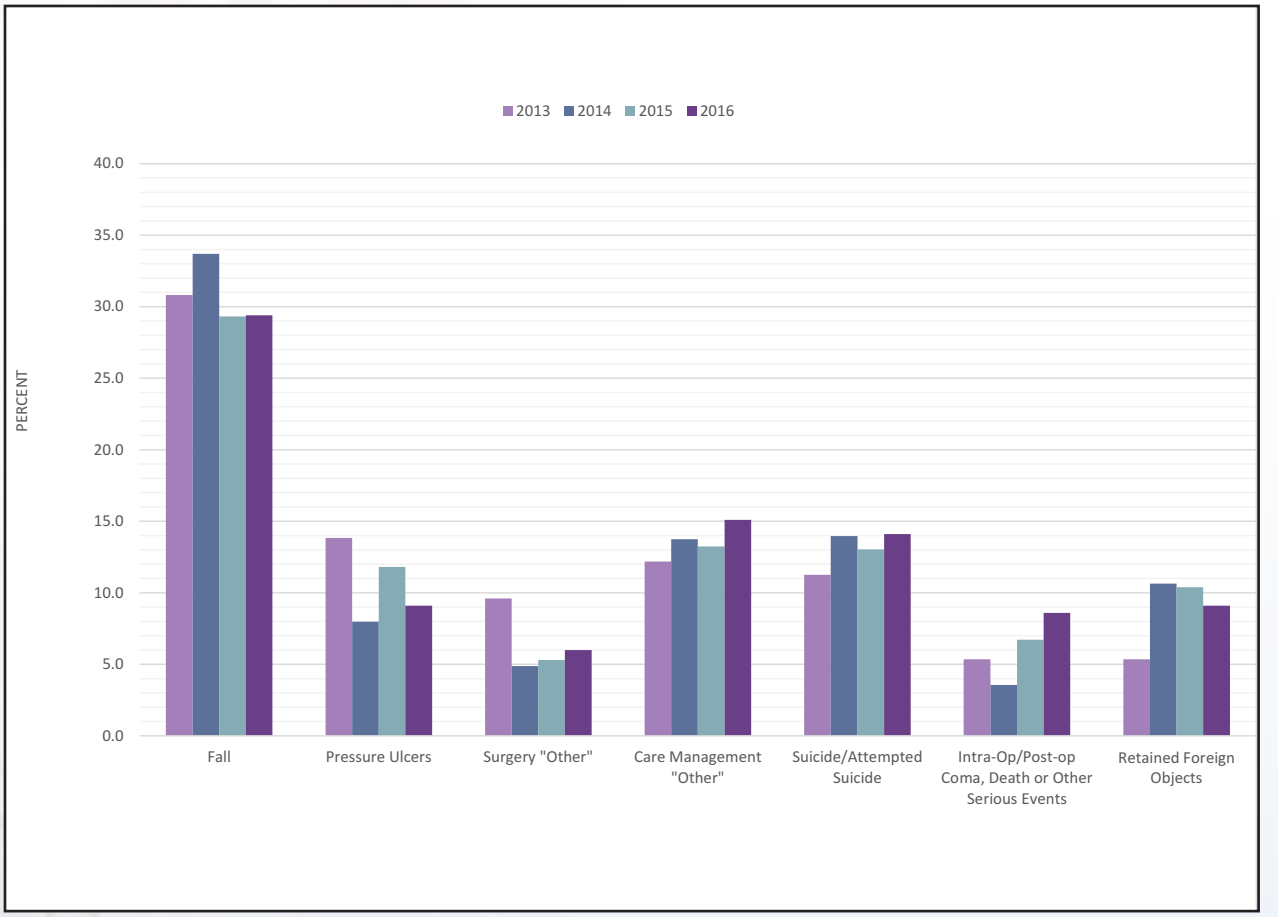
Table 7: General Acute Care Hospitals: Most Frequently Reported Event Types-2016

Event Type	Number of Reportable Events	Percent of Events[a]
Fall	123	29.4
Care Management "Other"	63	15.1
Suicide/Attempted Suicide	59	14.1
Pressure Ulcer	38	9.1
Retained Foreign Object	38	9.1
Intra-Op/Post-Op Coma, Death or Other Serious Adverse Events	36	8.6
Surgery "Other"	25	6.0
All Other Events	36	8.6
Total	418	100.0

Note: Falls, care management "other" events, intra-op/post-op coma, death or other serious adverse events and surgery-related "other" events have been described in the prior section titled "Event Types Associated with the Highest Percent Deaths."

III. General Acute Care Hospitals

Figure 3: Most Frequently Reported Event Types 2013-2016



III. General Acute Care Hospitals

1. Suicide/Attempted Suicide Events

There were 59 reportable adverse events for this event type in 2016, a slight decrease from 2015 (64).

Similar to 2015, the 59 suicide attempts were submitted by 30 hospitals. Twelve hospitals each submitted 1 event (20.3%), 10 hospitals each submitted 2 events (33.9%), 5 hospitals submitted 3 events each (25.4%) and 3 hospitals submitted 4 events (20.3%).

Prior to the suicide attempt, more than half of the patients (36, 62.1%) were considered at risk and 31 (53.4%) were seen by a psychiatrist. Thirty-five patients (59.3%) had a prior suicide attempt. Fifty-four (91.5%) of the patients saw a psychiatrist after the attempted suicide event. At the time of the event, the following levels of observation were in place: 17 patients (28.9%) were on 1:1, 17 (28.9%) were on 15-minute checks, 4 were on close observation, 4 on hourly visits, 4 on arm's length and 2 on line of sight. Eleven were on "other" or no observation.

The events reported mostly occurred in the Behavioral Health Unit (23), the Emergency Department (21), the Emergency Crises Screening/Observation Unit (8), and Med/Surg (5) units.

There was one suicide-related death in 2016 and this occurred in the patient's room in the Behavioral Health Unit.

2. Pressure Ulcers

In 2016, there were 38 healthcare associated Stage III and IV pressure ulcers compared to 58 in 2015.

There was a 34 percent decrease in the number of pressure ulcers submitted in 2016 compared to 2015 (58).

The 38 pressure ulcer events were submitted by 23 hospitals. Thirteen hospitals each submitted one pressure ulcer event which accounted for more than a third of the events reported (13, 34.2%). Six hospitals submitted 2 each (12, 31.6%) and three submitted three each (9, 23.7%) of the total. One hospital reported four events (10.5%).

Over one half (55.3%) of the ulcers reported were located in the sacrum while three were on the buttocks and nine classified as "other".

Of the 38 events, 25 or 65.8 percent were Stage III and the rest Stage IV.

3. Retained Foreign Objects (RFOs)

There were 38 retained foreign object events submitted in 2016. This represents a significant decrease (25.5%) from 2015 (51).

The 38 RFO events were submitted by 21 hospitals. Half of the RFO events (19) were submitted by 5 hospitals: One submitted 6 events, one submitted four, and three hospitals submitted 3 events each. Three events were discovered by a second facility.

Of the 38 RFOs, 7 were sponges/gauze (18.4%), 5 were guidewires (13.2%), 4 were needles (10.5%) and 4 were lap pads (10.5%).

Examples of other RFOs included a surgical towel, vaginal prep stick, umbilical tape, hemovac drain, gauze inside of a glove, piece of a cardiac stent, and piece of a drain.

Nineteen patients (50.0%) required a second surgery to remove the object.

Pressure Ulcers Patient Care Specifics

	Percent Yes
Pressure ulcer risk assessment (Braden) was documented on admission and daily	97.4
Skin inspection was documented on admission and daily	92.1
Removal of devices such as stockings and splints was documented each shift, if applicable	75.0
Staff used documented care plan	86.8
Patients with impaired sensory perception, mobility and activity were repositioned every 2 hours	84.2
Patients with impaired sensory perception, mobility and activity had heels lifted off bed	89.5
Patients with impaired sensory perception, mobility and activity had appropriate support surfaces	89.5
Patients with friction/shear risk as defined by Braden scale had HOB 30 degrees or less	81.6
The patient refused repositioning	23.7
The patient had an unstable condition that prohibited repositioning	15.8
The patient had a long ambulance or other transport time	0.0
Pressure ulcer was possibly related to a surgery/procedure	11.4
Patients with nutritional deficits were followed by dietary services	94.4
Pain assessment and management adequately performed	94.7
Incontinence was addressed, if applicable	96.6
Patient/family skin safety education and patient response was documented	93.9

E. Major Root Causes for All Events

In 2016, the most frequent root causes of adverse events reported to PSRS were care planning process (49.5%), communication among staff (28.5%), "other" (13.6%), orientation and training of staff (13.4%), physical assessment process (12.0%) patient observation procedures (10.5%), and behavioral assessment (8.1%).

The root cause of "other" signifies that the hospital did not initially identify a system root cause for the event.

General acute care hospitals averaged almost two root causes per reportable event.

Table 8 shows the major types of root causes reported and the percent of all adverse events caused by each.

Table 8: General Acute Care Hospitals: Major Root Causes for All Events[a]

Root Cause	Number of Events	Percent of Events[a]
Care Planning Process	207	49.5
Communication Among Staff Members	119	28.5
Other	57	13.6
Orientation and Training of Staff	56	13.4
Physical Assessment Process	50	12.0
Patient Observation Procedures	44	10.5
Behavioral Assessment Process	34	8.1

a: Data drawn from 418 RCAs submitted for 2016 events.

F. Contributing Factors to All Events

Table 9 shows the most frequently identified factors that contributed to the adverse events reported to the Patient Safety Reporting System.

Table 9: General Acute Care Hospitals: Contributing Factors to All Events[a]

Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	288	68.9
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	216	51.7
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	203	48.6
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	144	34.4
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	93	22.2
Staff Factors *(May include training, experience and inadequate staffing levels.)*	83	19.9
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	74	17.7
Equipment *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	64	15.3

a: Data drawn from 418 RCAs submitted for 2016 events.

G. Impact of All Events on Patients

Table 10 shows the impact of the events reported by the acute care general hospitals. In addition to the other impacts identified below, there were 72 deaths which represent 17.2% of the 418 reportable events submitted.

Table 10: General Acute Care Hospitals: Impact of All Events on Patients[a]

Impact/Outcome	Number of Events	Percent of Events
Additional Patient Monitoring in Current Location	226	54.1
Additional Lab Testing or Diagnostic Imaging	206	49.3
Increased Length of Stay	175	41.9
Disability-Physical or Mental impairment	135	32.3
Transfer to more Intensive Level of Care	117	28.0
Major Surgery	108	25.8
Death	72	17.2

a: Data drawn from 418 RCAs submitted for 2016 events.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

Mandatory adverse event reporting for the comprehensive rehabilitation, psychiatric and special hospitals began on April 1, 2008.

There were 60 reportable events submitted from specialty hospitals in 2016 compared to 68 in 2015.

Eleven comprehensive rehabilitation hospitals submitted 36 reportable events, a decrease of 2 from 2015. The average event reports per this facility type was slightly over 3 (3.3).

There were two deaths associated with this facility type.

Similar to 2015, nine out of the eleven psychiatric hospitals submitted 18 reportable events in 2016; an average of 2.0 per facility with no deaths. Special hospitals submitted 6 reportable events averaging approximately 1.0 reports per facility.

Consistent with prior years, special hospitals have been the lowest reporters among the specialty hospitals. Variation in reporting may relate to the size and patient population of the facility.

Table 11: Specialty Hospitals: Overall Reporting Pattern, 2016

Facility Type	Number of Facilities	Number of Facilities Reporting	Number of Reportable Events	Average Number of Reports per Facility	Number of Deaths
Comprehensive Rehabilitation	14	11	36	3.3	2
Psychiatric Hospitals	11	9	18	2.0	0
Special Hospitals	14	8	6	1.0	1
Total	39	28	60	2.1	3

a: Only psychiatric hospitals licensed by DOH are included in this section.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

A. Comprehensive Rehabilitation Hospitals

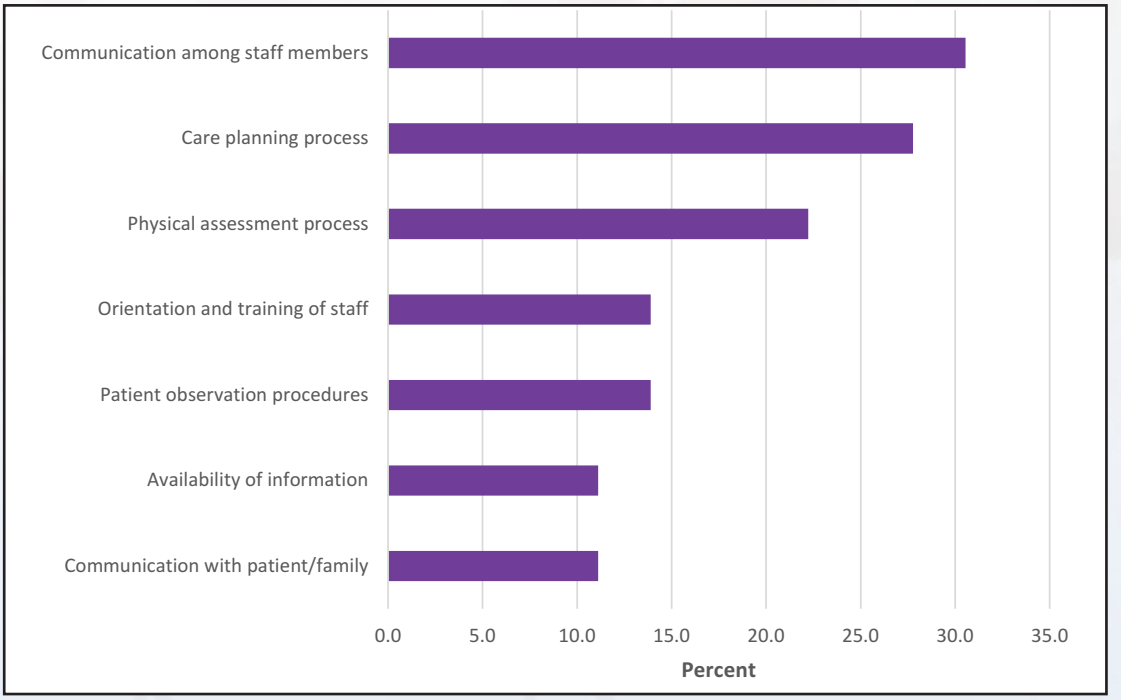
Of the 14 comprehensive rehabilitation hospitals in the state, 11 (78.6%) reported at least one event in 2016. There were 36 reportable events and two deaths from these facilities. These deaths were each related to a fall and care management "other" event.

Most frequently reported event types were 22 falls, 10 pressure ulcers, and three care management "other" events. These events are similar to previous years' reporting.

1. Root Causes for All Events

Figure 4 shows the major causes for the events reported by this facility type.

Figure 4: Comprehensive Rehabilitation Hospitals: Root Causes for All Events[a]



a: Data drawn from 36 RCAs submitted for 2016 events.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

2. Contributing Factors to All Events

In 2016, the three most frequently reported contributing factors were patient characteristics (63.9%), task factors (58.3%) and team factors (41.7%).

Table 12 shows the results.

Table 12: Comprehensive Rehabilitation Hospitals: Contributing Factors to All Events[a]

Contributing Factors	Number of Events	Percent of Events
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	23	63.9
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	21	58.3
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	15	41.7
Staff Factors *(May include training, experience and inadequate staffing levels.)*	14	38.9
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	11	30.6
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	8	22.2

a: Data drawn from 36 RCAs submitted for 2016 events.

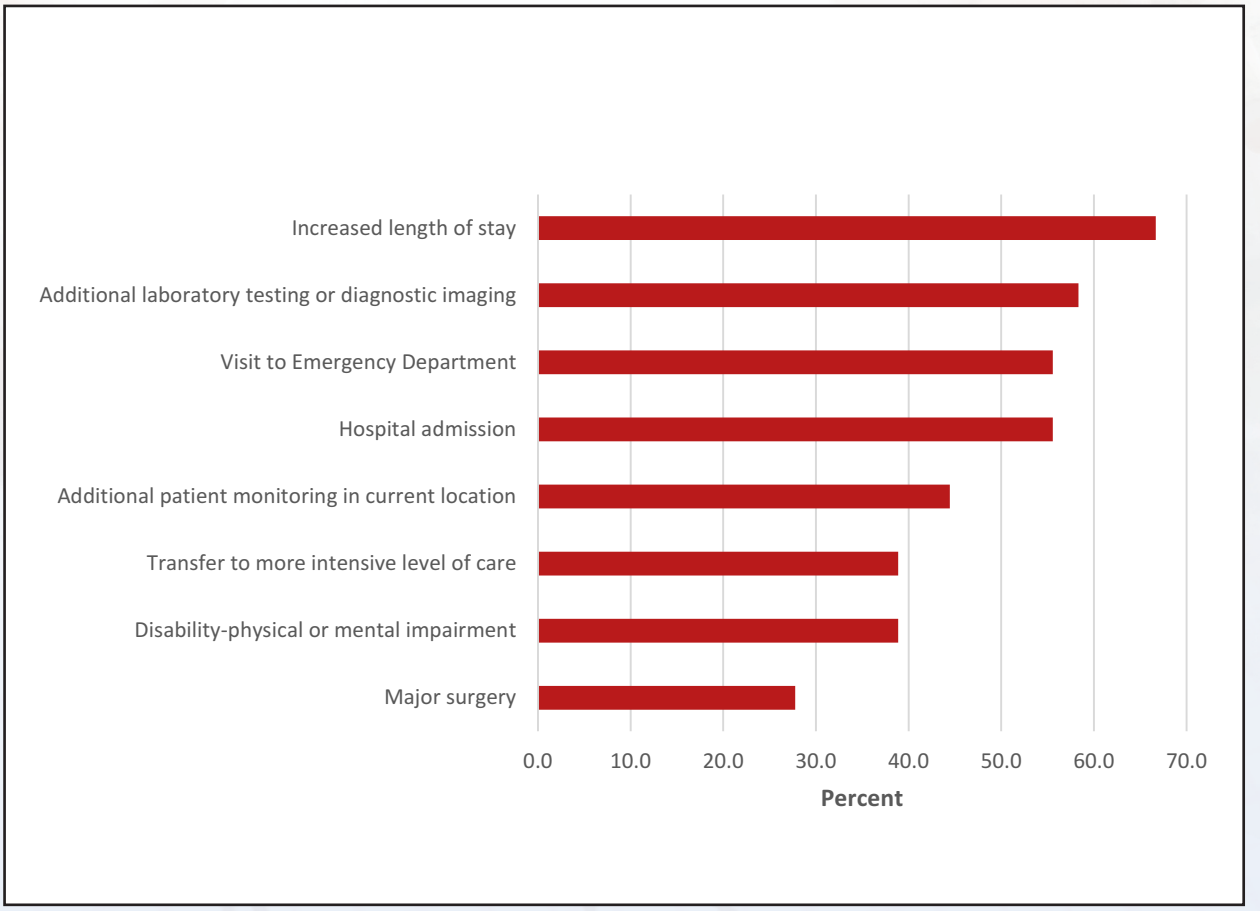
3. Impact of All Events

As a result of these adverse events, about two-thirds (66.7%) resulted in increased length of stay, additional laboratory testing or diagnostic imaging (58.3%) and visit to the emergency department and hospital admission (55.6%) each.

Figure 5 shows other impacts associated with adverse events from comprehensive rehabilitation hospitals.

There were two deaths reported from this facility type; one each for fall and care management "other".

Figure 5: Comprehensive Rehabilitation Hospitals: Impact of All Events[a]



a: Data drawn from 36 RCAs submitted for 2016 events.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

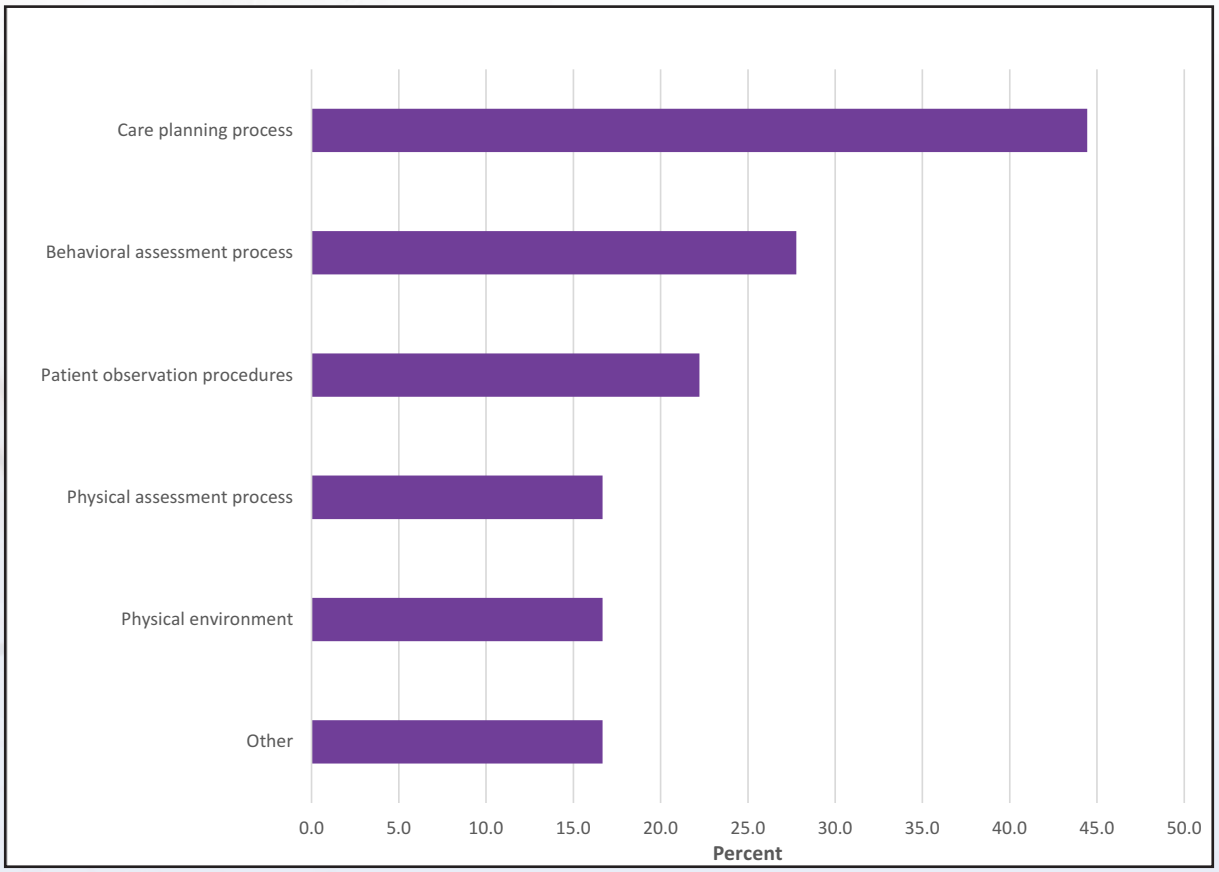
B. Psychiatric Hospitals

Nine out of 11 psychiatric hospitals reported at least one event during 2016. A total of 18 reportable events were submitted to the Patient Safety Reporting System. Like 2015, 18 events were reported as follows: thirteen (72.2%) were falls, three suicide/attempted suicide (16.7%) and two were care management "other" events (11.1%). The average submission by this facility type was 2. There were no reported deaths for this facility type.

1. Root Causes for All Events

Figure 6 shows the most reported causes for the events that occurred in Psychiatric hospitals

Figure 6: Psychiatric Hospitals: Root Causes for All Events[a]



a: Data drawn from 18 RCAs submitted for 2016 events.

2. Contributing Factors to All Events

Table 13 shows the most frequently reported contributing factors for the events.

Table 13: Psychiatric Hospitals: Contributing Factors to All Events[a]

Contributing Factors	Number of Events	Percent of Events
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	17	94.4
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	11	61.1
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	10	55.6
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	10	55.6
Medications *(May include inappropriate administration, dose and prescribed medications not administered.)*	6	33.3

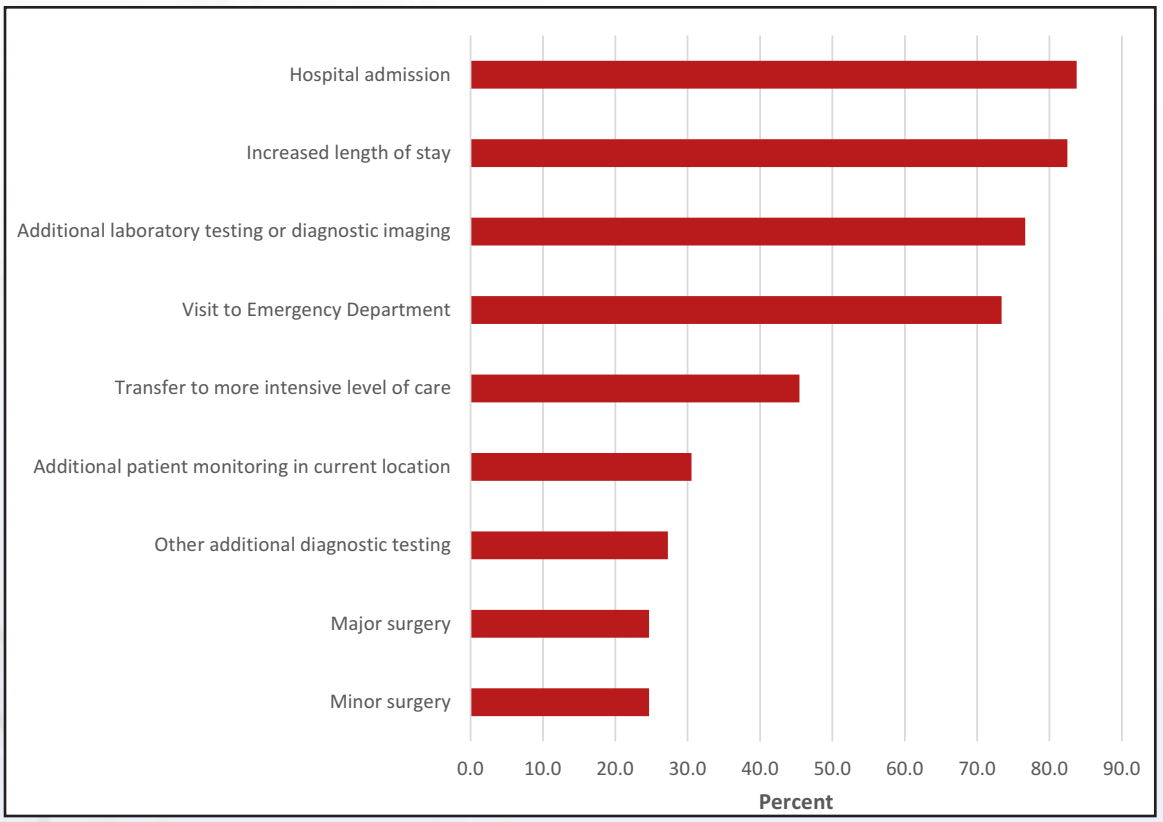
a: Data drawn from 18 RCAs submitted for 2016 events.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

3. Impact of All Events

Figure 7 shows the most frequently reported impact of the events. There were no deaths reported from the 18 reportable events.

Figure 7: Psychiatric Hospitals: Impact of All Events[a]



a: Data drawn from 18 RCAs submitted for 2016 events.

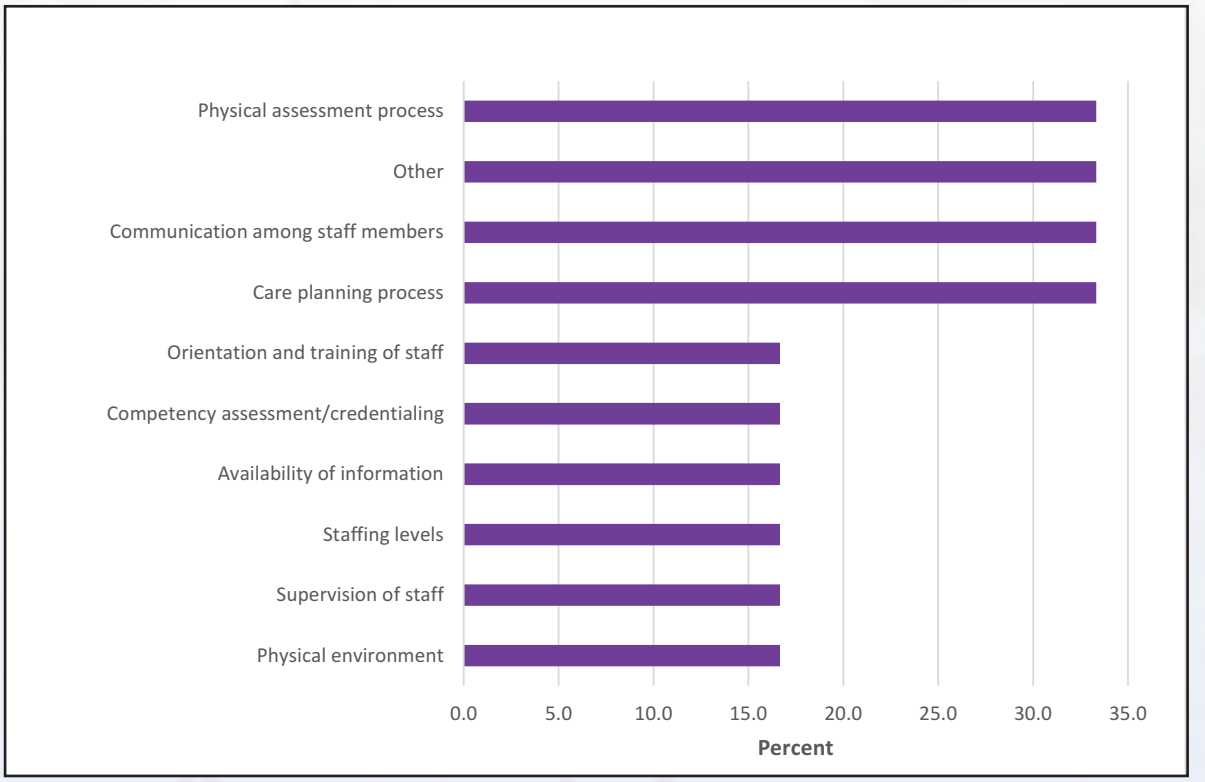
C. Special Hospitals

There were 14 special hospitals in 2016 and eight submitted reports but only six were deemed to be reportable events. This low reporting is consistent with prior years. There were no deaths reported for this facility type in 2016, similar to 2014 and 2015.

1. Root Causes for All Events

Figure 8 shows the most frequent root causes of events in this facility type.

Figure 8: Special Hospitals: Root Causes for All Events[a]



a: Data drawn from 6 RCAs submitted for 2016 events.

IV. Overall Reporting Patterns for Specialty Hospitals: Comprehensive Rehabilitation, Psychiatric and Special Hospitals

2. Contributing Factors to All Events

Table 14 shows the most frequent contributing factors to the events reported by special hospitals. As in 2015, the most frequently reported contributing factor was patient characteristics (83.3%), followed by task factors, staff factors and organization/management, each accounting for 50.0% of the adverse events.

Table 14: Special Hospitals: Contributing Factors to All Events[a]

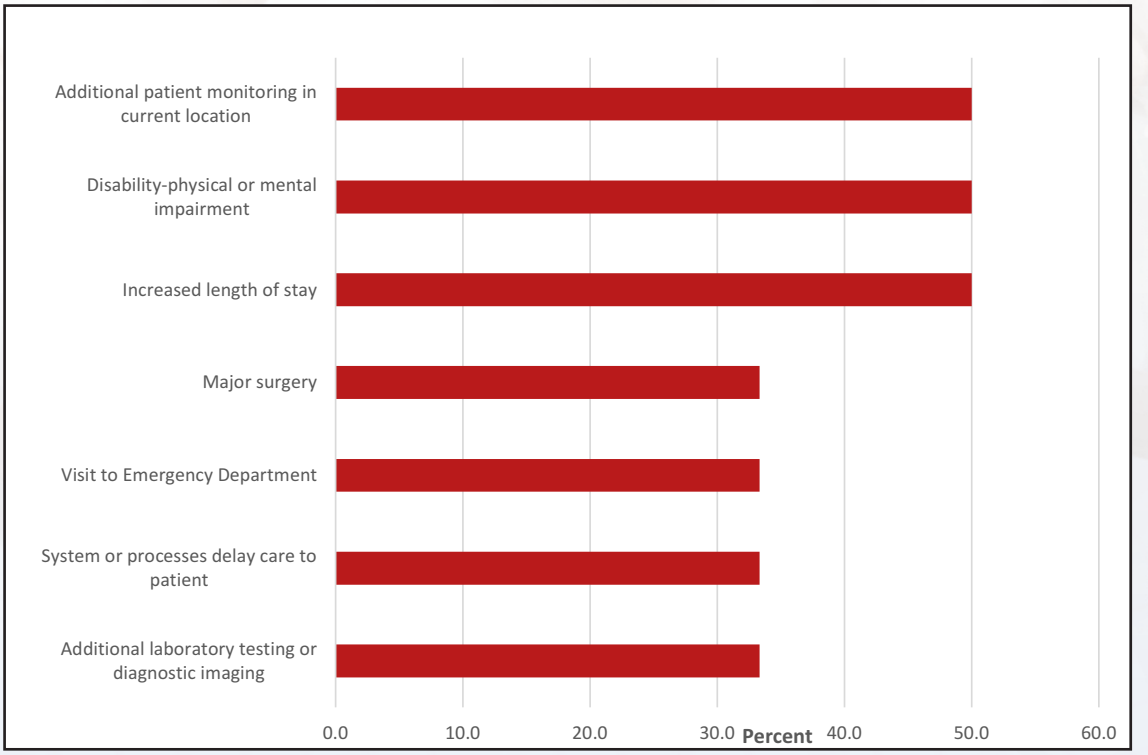
Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	5	83.3
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	3	50.0
Staff Factors *(May include training, experience and inadequate staffing levels.)*	3	50.0
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	3	50.0
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	2	33.3
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	2	33.3
Equipment *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	2	33.3

a: Data drawn from 6 RCAs submitted for 2016 events.

3. Impact of All Events

Figure 9 exhibits the most frequently identified impact from the reportable adverse events submitted by special hospitals.

Figure 9: Special Hospitals: Impact of All Events[a]



a Data drawn from 6 RCAs submitted for 2016 events

V. Ambulatory Surgery Centers

New Jersey licensed ambulatory surgery centers (ASCs) began reporting serious preventable adverse events to PSRS as of October 1, 2008. Of the 176 ambulatory surgery centers in New Jersey, 89 facilities (about one-half) submitted events in 2016. A total of 309 events were submitted of which 154 were deemed reportable (49.8%). There were 4 deaths associated with these events and all were related to intraop or postop coma, death or other serious preventable adverse events. The average number of events submission by this facility type was 2 in 2016.

Table 15 and Figure 10 show the reporting patterns for the period 2008 to 2016.

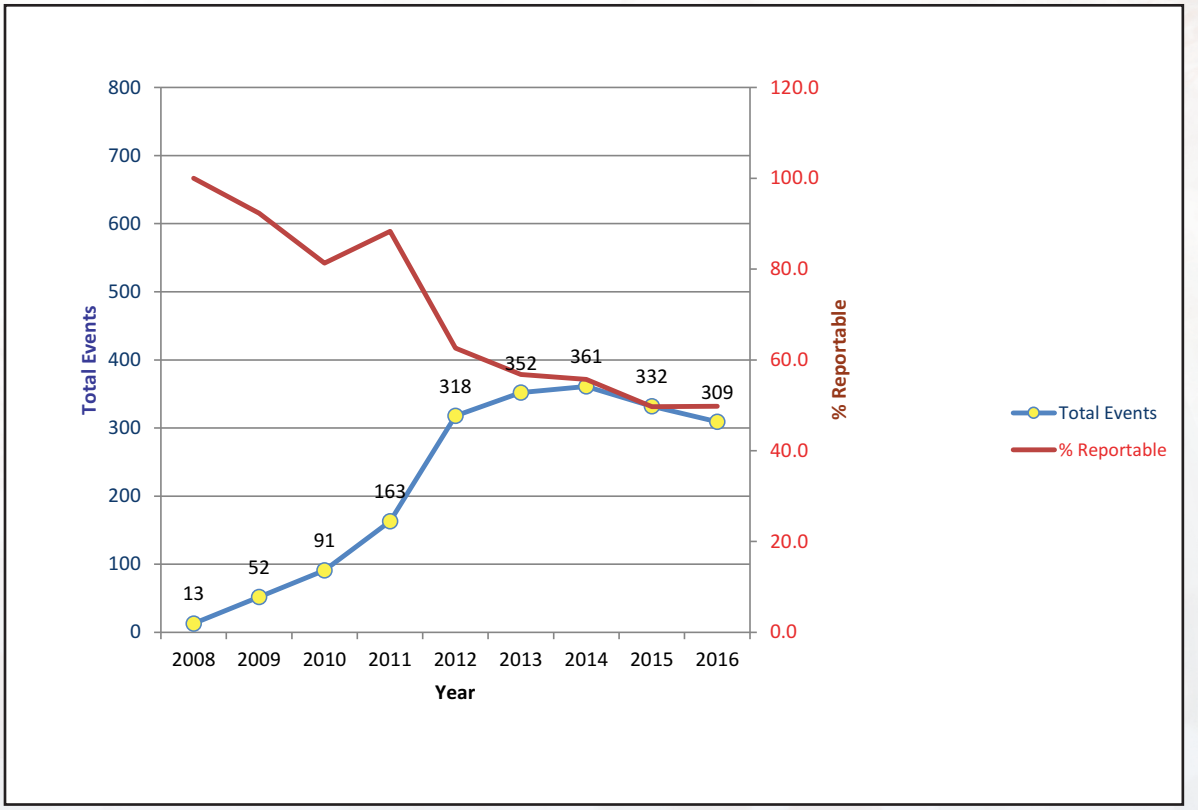
Table 15: Ambulatory Surgery Centers: Reporting Patterns (2008-2016)

Year	Reportable	Not Reportable	Less Serious/Near Misses	Total Events	Percent Not Reportable	Percent Reportable
2008[a]	13	0	NA	13	0	100.0
2009	48	4	NA	52	7.7	92.3
2010	74	17	NA	91	18.7	81.3
2011	144	10	9	163	11.7	88.3
2012	199	31	88	318	37.4	62.6
2013	200	17	135	352	43.2	58.6
2014	201	6	154	361	44.3	55.7
2015	165	5	162	332	50.3	49.7
2016	154	14	141	309	50.2	49.8

a: Represents 3 months of data since reporting started on October 1, 2008.

V. Ambulatory Surgery Centers

Figure 10: ASC Trends in Reportable and Not Reportable Events 2008-2016



V. Ambulatory Surgery Centers

As shown in Table 16 below, more than two-thirds of the reportable cases were intraoperative or postoperative coma, death or other serious preventable adverse events. The second highest event type was surgery-related "other" events with 36 cases or 23.4 percent of the total events reported from ambulatory surgery centers.

These two event types accounted for 140 cases or 90.9 percent of the total events reported (n = 154).

There were four deaths reported and all were associated with intraoperative or postoperative coma, death or other serious preventable adverse events type.

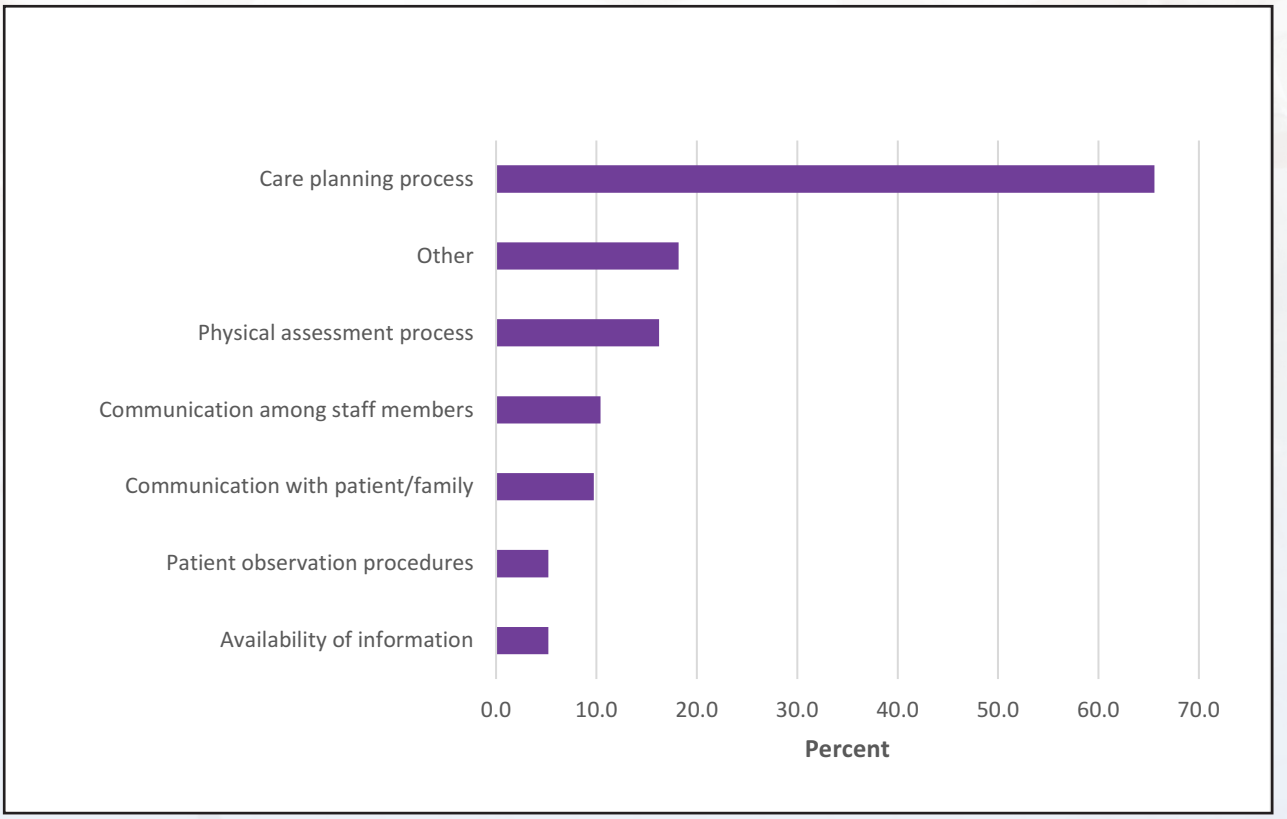
Table 16: Ambulatory Surgery Centers: Events Reported in 2016

Event Type	Number of Events	Percent of Total Events	Number of Deaths
Intra-or Post-Operative Coma, Death or Other serious preventable adverse event	104	67.5	4
Surgery-Related "Other" Event	36	23.4	0
Wrong Procedure	4	2.6	0
Wrong Site	3	1.9	0
Wrong Patient	2	1.3	
Medication Error	2	1.3	0
Wrong Blood Product	1	0.6	0
Fall	1	0.6	0
Device Malfunction	1	0.6	0
Total	154	100.0	4

A. Root Causes for All Events

Figure 11 shows the most frequently identified root causes of the events reported by ambulatory surgery centers in 2016.

Figure 11: Ambulatory Surgery Centers: Root Causes for All Events[a]



a: Data drawn from 154 RCAs submitted for 2016 events.

B. Contributing Factors to All Events

Table 17 shows the most frequently reported contributing factors at ambulatory surgery centers.

Table 17: Ambulatory Surgery Centers: Contributing Factors to All Events[a]

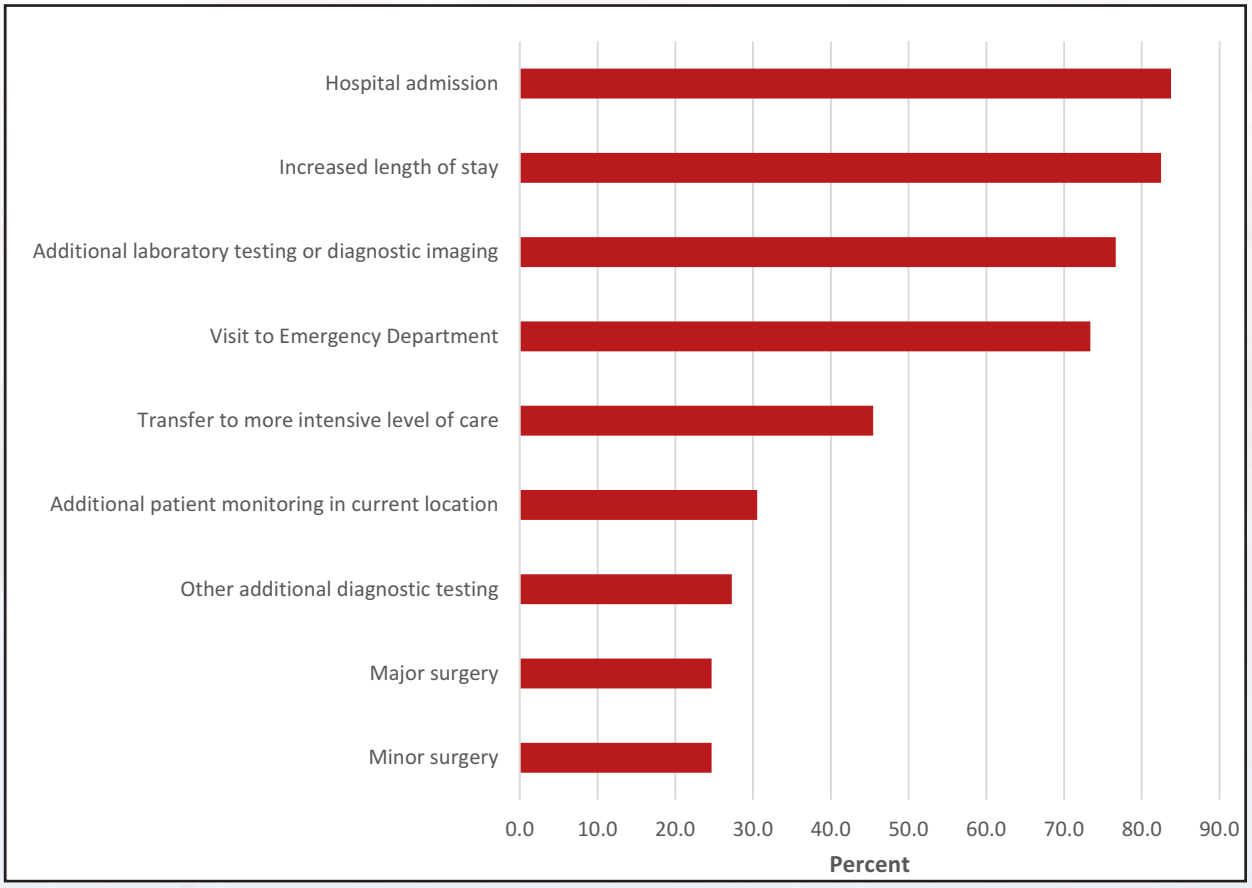
Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the Patient's choice to refuse care.)*	95	61.7
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	82	53.2
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	63	40.9
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	41	26.6
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	38	24.7
Staff Factors *(May include training, experience and inadequate staffing levels.)*	26	16.9
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	22	14.3
Medications *(May include inappropriate administration, dose and prescribed medications not administered.)*	21	13.6
Other Factors *(May Includes factors not identified in the other categories.)*	21	13.6

a: Data drawn from 154 RCAs submitted for 2016 events

C. Impact of All Events

Figure 12 displays the most frequently reported impact of adverse events at ambulatory surgery centers.

Figure 12: Ambulatory Surgery Centers: Impact of All Events[a]



a: Data drawn from 154 RCAs submitted for 2016 events.

VI. Division of Mental Health and Addiction Services 2016 Report

Division of Mental Health and Addiction Services
Department of Health
Annual Patient Safety Act Report
January 1, 2016 through December 31, 2016

Implementation

The Division of Mental Health and Addiction Services' (DMHAS) Patient Safety Act oversight committee continues to receive and review the root cause analyses (RCA) submitted under the Patient Safety Act (PSA) by the three NJ state psychiatric hospitals and one forensic psychiatric center. A log of PSA related events is maintained to ensure the timely submission and review of submitted RCA's.

This committee assesses the root cause analyses for thoroughness and credibility. Questions or concerns are shared with the RCA team/facilitator and the respective Director of Quality Assurance and a conference call is held to review these questions/concerns. If necessary, a revision to the RCA is requested.

An ongoing issue was noted with the analysis process at one of the hospitals, even after a training conducted by members of the Division of Mental Health and Addiction Services oversight committee in 2015. A second issue was noted regarding the timeliness of completion and submission of the RCA report. Finally, an issue with the composition of the Patient Safety Committee was noted at this facility. The issues were brought to the CEO, and a plan made for a second training to occur, due to the large turnover of leadership. This training was offered to the entire Executive Staff and members of the QI Department in the spring of 2017. The training focused on the definitions of reportable events, reporting responsibilities, and how to conduct a thorough analysis to produce a credible report with viable risk reduction strategies with the goal of preventing future events. Recruitment of a Chief Operating Officer and Human Resources Director took place in 2016 and recruitment efforts continued for a Medical Director, Deputy CEO, Quality Improvement Director, Chief of Psychiatry and a Chief Nursing Officer.

The Division implemented a Trauma Informed Care initiative which has been operationalized at one hospital, with a plan to implement at all the NJ State Psychiatric facilities. A team of ten direct care staff train and model appropriate response to the patient escalation and conduct psychiatric emergency drills and debriefings. The team also assists with contraband searches. Training includes the use of Therapeutic Options, Therapeutic Communication, Open Questions, Affirmation, Reflective Listening and Summary Reflections (OARS); and 3 Steps to Safety (psychiatric emergency response).

The Division developed a new Administrative Bulletin to address the identification of suicide risk using evidence based tools. Every patient will be screened at admission with follow-up assessment as indicated. Training was organized for the administration of these instruments.

Overall Reporting Patterns

From January 1, 2016, through December 31, 2016, a total of ten (10) events were reported and reviewed. Nine of these ten events occurred at one facility. Four of the ten events were suicide attempts, three were unexpected deaths of patients, two were patient to patient assaults resulting in major injuries, and one was a patient fall which resulted in a fractured femur.

Focus on Specific Events

a.Falls

In 2016, an 85 year old man stated that he had tripped and fallen in his bedroom, which resulted in a fractured femur. The patient's most recent fall assessment had placed him at moderate risk according to the Morse Fall Scale and he was on fall precautions. Precipitating factors for the fall included limited space in the bedroom due to a third occupant and multiple physical conditions.

Root Cause:

- Failure to address and implement fall precaution interventions on patient's comprehensive individualized treatment plan.

Prevention Strategies:

- Revised protocol for implementation of fall precautions
- Provided training for team and nursing staff on fall protocols
- Monitored implementation of revised protocols
- Provided in-service on linking fall precaution interventions to the individualized treatment plan and monitor plans for proper implementation.
- Enhancement of the Physical Therapy Department to include a shoe clinic, better equipment, and training especially in the geriatric units to prevent falls.

b.Attempted Suicides

There were a total of four suicide attempts in 2016. Two of the four were made by the same patient. All three patients were males; one 54 year old, one 18 year old and one 22 year old. All four events occurred in the same facility.

One of the events occurred while the patient was on an approved home visit, two events occurred in the Study Room of the unit, and one event occurred when the patient ran from the building and climbed to the roof. The incidents involved the following; an alleged overdose of insulin while on a home visit, a bed sheet placed on a hinge of a door, the use of a glass light bulb removed from the light fixture in the ceiling, and an attempt to jump from the roof of one building to another.

Root causes

- Architectural design for hanging points of doors and removable ceiling tiles in patient areas, as well as environmental factors around main entrance and
- Inadequate area monitoring.
- Unfamiliarity with de-escalation techniques and removing surrounding patients from patients in psychiatric emergencies.
- Inadequate documentation/communication of immediate clinical issues.
- Inadequate documentation of action taken or not taken of recommendation from specialist.
- Failure to follow patient transfer policy.
- Failure to complete suicide risk assessment prior to brief visit.

Prevention strategies

- Re-education of charge nurses on assigning staff to specific areas.
- Changes to environment to address possible ligature points.
- Ensured treatment plan reflects change of patient status.
- Evaluation and remediation of potentially unsafe environmental issues in patient areas.
- Strengthened communication protocols for transferring patients during off shifts.
- Strengthened de-escalation techniques and removing surrounding patients from patients in psychiatric emergencies.
- Reviewed criteria for determining emotionally deregulated behavior versus para-suicidal behaviors and gestures, and management of suicidal ideation and self-injurious behavior of patients by psychiatry department.

c.Assaults

During this reporting period there were two incidents of patient-to-patient assaults resulting in major injuries. The events occurred at two different hospitals. The patients injured were male patients; one was 44 years old and one was 80. One patient sustained a subarachnoid hemorrhage and the other sustained a fractured hip as a result of the assault.

Root causes

- Failure to incorporate identified problem areas such as violence risk/aggression from assessments into the active treatment plan.
- Incomplete assessments.
- Inadequate hand off communication between staff.
- Failure to follow patient movement policy.

Prevention strategies

- Strengthened importance of including admission history information on the individualized treatment plan.
- Reinforced immediate need for clinical issues to be included in the treatment plan and communicated to clinical staff.
- Tracked incomplete information in the integrated assessments and audit results.
- Situation, background, assessment, recommendation (SBAR) training was conducted for all nursing staff to facilitate prompt and accurate communication.
- Provided access to 24 hour nursing report for treatment team members.

d.Unexpected Deaths

There were three unexpected deaths which occurred during 2016. All three occurred at the same facility. Two patients were males and the other was female; the female was 27 years old, one male was 25 years old and one male was 74. It was later determined that their deaths were due to the following causes; intoxication due to prescribed medications, accidental blunt trauma to the head, and acute intoxication of prescribed medications and illegal drugs.

Root causes:

- Failure to follow policies regarding completion of contraband checks, implementation of visitation policy and face check procedures due to competing events, rushing to complete tasks, and staff fatigue.
- Inadequate clinical pathway track for patients in various stages of co-occurring recovery.
- Failure to follow proper emergency reporting procedures (Dial 6).
- Delay of treatment caused by inability to access locked patient area.

Prevention strategies:

- Training conducted for staff regarding nursing procedures with weekly audits of and supervisory observation of implementation of procedures.
- Revision of the visitors' policy as well as the search policy, with a central location for visitors of most patients. Strengthen implementation of the visitation policy, which includes direct supervisory observation.
- Clinical review of patients who are known substance abusers to determine additional safety procedures.
- Development of clinical pathway track for patients in various stages of co-occurring recovery.
- Improved accessibility of staff keys.
- Implementation of frequent Mock Code drills for Dial 6 and accessing locked patient areas.
- Expanded use of drug sniffing dogs to all areas.

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Appendix 1: Classification of Serious Preventable Adverse Events

Pursuant to the Patient Safety Regulations (N.J.A.C. 8:43E-10.6), the types of serious preventable adverse events include, but are not limited to, the categories listed below. A facility shall report in the appropriate category events that are not specifically listed that meet the definition of a serious preventable adverse event.

A. Patient or resident care management-related events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a medication error (such as errors involving the wrong drug, wrong dose, wrong patient or resident, wrong time, wrong rate, wrong preparation, or wrong route of administration);
2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
3. Maternal death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge associated with labor or delivery in a low-risk pregnancy while in a health care facility;
4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge associated with hypoglycemia, the onset of which occurs while the patient or resident is being cared for in the health care facility;
5. Death or kernicterusa associated with failure to identify and treat hyperbilirubinemiab in a neonate while the neonate is a patient in a health care facility;
6. Stage III or IV pressure ulcers acquired after admission of the patient or resident to a health care facility. Progression from stage II to stage III is excluded, provided that stage II was recognized and documented upon admission; and
7. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with spinal manipulative therapy provided in a health care facility.

a: "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.
b: "Hyperbilirubinemia" means elevated bilirubin levels. Bilirubin is a breakdown product of red blood cells.

B. Environmental events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with an electric shock while being cared for in a health care facility. Events involving planned treatments, such as electric countershock (heart stimulation) or elective cardioversion, are excluded;
2. Incidents in which a line designated for oxygen or other gas to be delivered to a patient or resident contains the wrong gas or is contaminated by toxic substances and results in patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge;
3. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a burn incurred from any source while in a health care facility;
4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a fall while in a health care facility; and
5. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days, or in the case of a non-residential health care facility, still present at discharge, associated with the use of restraints or bedrails while in a health care facility.

C. Product or medical device-related events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with use of generally detectable contaminated drugs, medical devices, or biologics provided by the health care facility, regardless of the source of contamination or product. "Generally detectable" means capable of being observed with the naked eye or with the use of detection devices in general use;
2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days, or in the case of a non-residential health care facility, still present at discharge, associated with the use or function of a medical device in patient or resident care in which the device is used or functions other than as intended, including, but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators;
3. Intravascular air embolism that occurs while the patient or resident is in the facility. This does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism; and
4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with the use of a new or reprocessed single-use device in patient or resident care in which the device is used or functions other than as intended.

Appendix 1: Classification of Serious Preventable Adverse Events

D. Surgery-related events include, but are not limited to:

1. Surgery initiated (whether or not completed) on a patient that is not consistent with the patient's documented informed consent, including, but not limited to, a surgical procedure intended for a patient "A" that is initiated on the wrong body part of patient "A," and a surgical procedure intended for another patient of the facility, but initiated on patient "A". Surgery-related events exclude emergent situations that occur in the course of surgery and as to which exigency precludes obtaining informed consent;
2. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention, objects present prior to surgery that were intentionally retained, and retained broken microneedles; and
3. Intraoperative or post-operative (that is, within 24 hours) coma, death, or other serious preventable adverse event in any patient of an ambulatory surgery facility, in any hospital same-day surgery patient, or in any American Society of Anesthesiologists (ASA) Class I hospital inpatient. This includes all patient deaths, coma or other serious preventable adverse events in situations where anesthesia was administered, regardless of whether the planned surgical procedure was carried out.

E. Patient or resident protection-related events include, but are not limited to:

1. Discharge of an infant to the wrong person, excluding patient or resident abductions covered under N.J.A.C. 8:34E-10.11(b);
2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days associated with patient or resident elopement; and
3. Patient or resident suicide or attempted suicide while in a health care facility. This does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility.

Appendix 2: Required Components of a Root Cause Analysis

N.J.A.C. 8:43E-10.6(l)

The root cause analysis performed by a facility in response to a report of an occurrence of a serious preventable adverse event may vary in substance and complexity, depending on the nature of the facility and the event involved, but shall include the following general components:

1. A description of the event, including when, where and how the event occurred and the adverse outcome for the patient or resident;

2. An analysis of why the event happened that includes an analysis not only of the direct cause(s) of the event, but also potential underlying causes related to the design or operation of facility systems;

3. The corrective action(s) taken for those patients or residents affected by the event;

4. The method for identifying other patients or residents or settings having the potential to be affected by the same event and the corrective action(s) to be taken;

5. The measures to be put into place or systematic changes needed to reduce the likelihood of similar events in the future; and

6. How the corrective action(s) will be monitored to assess their impact.

New Jersey Department of Health Review of Root Cause Analyses

N.J.A.C. 8:43E-10.6(m)

The Department shall:

1. Review an RCA to determine whether it satisfies the criteria in (l) above; and

2. Return an RCA that does not meet the criteria in (l) above to the facility for revision and shall not consider the RCA complete until the Department determines that the RCA meets the criteria in (l) above.

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Limited copies of this report are available by writing to the New Jersey Department of Health, Office of Health Care Quality Assessment, P.O. Box 360, Trenton, NJ 08625, by calling (800) 418-1397, by e-mailing hcqa@doh.nj.gov or by fax at (609) 984-7735. The report is also posted on the New Jersey Department of Health' website at www.nj.gov/health/ps.