HCQA Health Care Quality Assessment

Patient Safety Reporting System

2015 Summary Report

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Patient Safety Reporting System

2015 Summary Report

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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 2015:

- 979 events were reported to the Patient Safety Reporting System by all facility types;
- 724 events met the statutory definition of (or satisfied the criteria for) a serious preventable adverse event ("reportable");
- 255 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");
- 115 deaths were associated with the adverse events.

General Acute Care Hospitals:

- Submitted 491 reportable adverse events in 2015 compared to 451 events in 2014 and 542 events in 2013;
- The average number of reportable events per reporting hospital was 6.8 (does not take into account hospital sizes and bed capacity;
- There were 96 deaths associated with the adverse events; specific events with the highest percent of associated deaths were intraoperative or postoperative coma, death, or other serious preventable adverse events, surgery "other" events, care management "other" events[a] and fall events;
- 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 and supervision, 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 38 reportable events and 2 deaths associated with a fall and care management "other";
- The most frequently reported root causes were care planning process, communication among staff members and orientation and training of staff;
- Over one-half (55.3%) of the patients had minor surgery, loss of sensory function(s)

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

Executive Summary

or loss of organ(s). Others experienced a delay in care.

Psychiatric Hospitals:

- There were 18 reportable events and 4 deaths associated with care management "other" events;
- The most frequently reported root causes were care planning process, physical assessment process and communication among staff members;
- Over one-half or 55.6 percent of the patients received other additional diagnostic testing.

Special Hospitals:

- Twelve reportable events were submitted with no associated death;
- The most frequently reported root causes were physical assessment process and orientation;
- The most frequent impact of the events included additional patient monitoring in current location, other additional diagnostic testing, additional laboratory testing or diagnostic imaging, disability-physical or mental impairment and transfer to more intensive level of care.

Ambulatory Surgery Centers:

- Submitted 165 reportable events with 13 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, physical assessment process;
- The most reported impact of these adverse events were additional laboratory testing or diagnostic imaging, hospital admission and increased length of stay.

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 2015. While the report focuses primarily on events in 2015, please note that aggregate numbers are provided for 2013 and 2014 where applicable.

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 I.

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.

II. Overall Reporting Patterns by Facility Type

II. Overall Reporting Patterns by Facility Type

This annual report summarizes the 2015 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. It also provides an overview of all the years the PSRS has been in operation (2005-2015).

The number of reportable, not reportable and less serious events, and near misses submitted to the Patient Safety Reporting System for 2015 from all facilities totaled 979. Of this total, 724 were deemed reportable with 115 associated deaths. In 2013, the number of reportable events across all facility types was 800 with 96 associated deaths and in 2014, the number reported was 742 with 89 deaths.

Table 1 below shows the distribution of events reported to the New Jersey Department of Health, Patient Safety Reporting System by facility types for the year 2015.

Table 1: Reporting Pattern by Facility Type (2015)

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	72	491	8	67	96
Comprehensive Rehabilitation Hospitals	14	10	38	0	6	2
Psychiatric Hospitals	11	9	18	0	5	4
Special Hospitals	14	6	12	1	1	0
Ambulatory Surgery Centers	176	85	165	5	162	13
Total	287	182	724	14	241	115

III. General Acute Care Hospitals

A. Reporting Patterns (2005-2015)

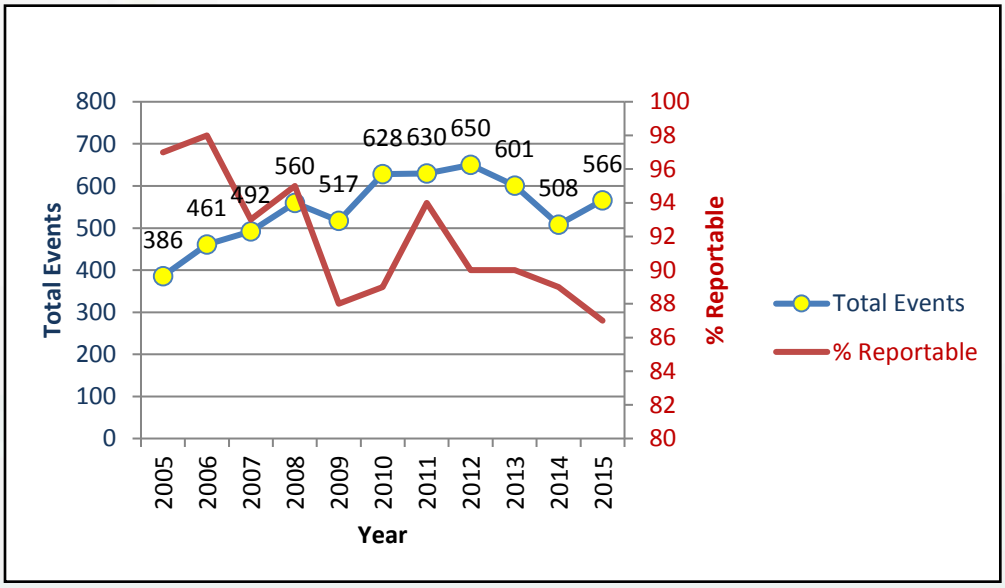
Figure 1 and Table 2 demonstrate the reporting patterns for general acute care hospitals over the past 11 years.

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 increased from 10 percent in 2013 to 11 percent in 2014 and 13 percent in 2015 respectively.

Figure 1: General Acute Care Hospitals: Trends in Reportable and Not Reportable Events 2005-2015



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

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

III. General Acute Care Hospitals

Since reporting began in February 2005, 5,504 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 2015. In 2015, the eleventh year of reporting, 491 reportable events from general acute care hospitals were submitted. The following describes the serious preventable adverse events that occurred in general acute care hospitals.

There was a 7.7 percent decrease in the number of reportable events in 2013 compared with 2012, followed by a 16.8 percent decrease from 2013 to 2014. However, there was a slight (8.9%) increase from 2014 to 2015. (Table 3). All of the 72 general acute care hospitals in New Jersey submitted reportable events. The average number of reports per reporting hospital was 6.8. This average does not take into account hospital size and bed capacity.

Table 3: General Acute Care Hospitals: Reporting Patterns (2005-2015)

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

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 491 adverse events reported by all New Jersey general acute care hospitals in 2015. There were 96 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--2015

Event Category	Total Events	Percent of Total Events	Total Death Events	Percent Deaths per Event Category
A: Care Management	132	26.9	33	34.4
B: Environmental	157	32.0	21	21.9
C: Product or Device	11	2.2	2	2.1
D: Surgery-Related	124	25.3	38	39.6
E: Patient Protection	67	13.6	2	2.1
Total	491	100.0	96	100.0

III. General Acute Care Hospitals

As Table 4 demonstrates, the surgery-related event category had the highest number of associated deaths (38 out of 96) or 39.6 percent of all deaths. The second highest category for reported deaths was care management (33) followed by environmental (21).

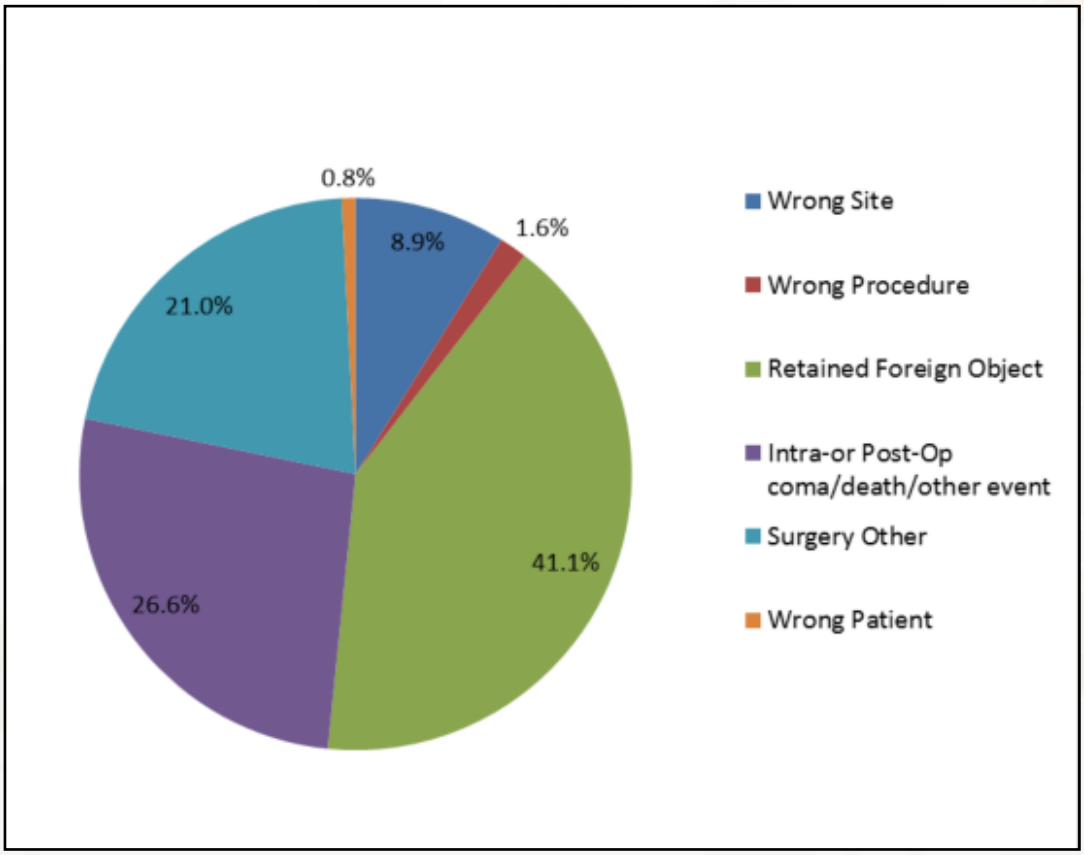
For individual surgery-related event types, there were 33 intraoperative or postoperative events with 23 associated deaths, or 60.5 percent of events in that category type. Of the 26 reported surgery "other" events, 15 resulted in death, or 39.5 percent. While the number of retained foreign objects reported increased from 29 in 2012 to 51 in 2015, there were no deaths reported for this event. 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
Intra-Op/Post-Op Coma/Death/Other Event	33	23	60.5
Retained Foreign Object	51	0	0.0
Surgery "Other"	26	15	39.5
Wrong Procedure	2	0	0.0
Wrong Patient	1	0	0.0
Wrong Site	11	0	0.0
Total	124	38	30.6

III. General Acute Care Hospitals

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 268 reportable events which represent 54.6 percent of all events reported. While the total number of deaths associated with all event types was 96, these four events resulted in 86 deaths and accounted for almost 90 percent (89.6%) of all deaths in 2015.

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
Intra-Op/Post-OP Coma, Death or Other Event	33	23	69.7
Surgery-Related "Other"	26	15	57.7
Care Management "Other"	65	28	43.1
Falls	144	20	13.9
All Other Event Types	223	10	4.5
Total	491	96	19.6

III. General Acute Care Hospitals

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

Reports of intraoperative or postoperative (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 patient varied over the years: 29 in 2013, 16 in 2014 and 33 in 2015. The number of deaths was higher in 2015 (23) compared to the previous two years (20 in 2013 and 9 in 2014).

The 33 intraoperative/postoperative events were submitted by 17 hospitals. Nine hospitals each submitted 1 event (27.3%), 6 hospitals submitted 2 events each (36.4%), 1 hospital reported 4 events (12.1%) and 1 reported 8 events (24.2%).

The events affected 13 outpatients (39.4%), 13 same day surgery patients (39.4%), 4 emergency department patients (12.1%) and 3 inpatients (9.1%).

At the time of the event, the majority of patients were designated as ASA Class II (11, 33.3%) or ASA Class III (11, 33.3%). Five patients were ASA Class I (15.2%) and 6 were ASA Class IV (18.2%).

Events reported for this event type in 2015 included death, cardiorespiratory arrest, hypotension (low blood pressure), blood vessel lacerations and organ perforation during or immediately (within 24 hours) following surgery.

2. 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 26 in 2015 compared to 52 in 2013 and 22 in 2014. The number of deaths decreased from 11 in 2013 to 9 in 2014 and increased 15 in 2015.

Thirteen hospitals submitted the 26 events: 7 submitted 1 event each (26.9%), 2 submitted 2 events (15.4%) and 3 hospitals submitted 3 events (34.6%). There were 6 events (23.1%) reported by one hospital.

At the time of the event, the majority of patients were designated as ASA Class III (17, 65.4%) or ASA Class IV (6, 23.1%).

Events reported for this event type in 2015 included death, vessel lacerations, organ perforations and surgical site infections.

3. Care Management "Other" Events

The third highest percentage of deaths was associated with care management "other" events 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 66 events in 2013, 62 in 2014 and 65 in 2015. The number of deaths, however, have been decreasing from 34 in 2013, 30 in 2014 and 28 in 2015.

The 65 care management 'other' events were submitted by 25 hospitals. Ten hospitals each submitted 1 event (15.4%), 8 hospitals submitted 2 events each (24.6%), 4 hospitals reported 3 events (18.5%) and 1 reported 4 events (6.2%). Eleven

events were submitted by 1 hospital (16.9%) and 12 events (18.5%) by another.

Care management "other" events include, but are not limited to, delays in medical care, such as failure to order appropriate diagnostic studies, failure to follow-up with the results of the studies, failure to communicate the results, failure to implement appropriate treatment or failure to do so in a timely manner.

Some of the events reported for this event type in 2015 were associated with newborn injury/death, failure to communicate changes to Doppler findings, IV extravasation leading to compartment syndrome, mislabeled patient specimens, failure to recognize abnormal fetal heart tracings, low volume cardiac/ventilator/ bipap disconnect alarms or alarms turned off, and failure to escalate concerns up the chain of command.

Care Management "Other" Event Specifics	Number	Percent
Event was due to a delay in care	24	36.9
Event was due to a failure to order appropriate test(s)	2	3.1
Event was due to a failure to obtain results from test(s)	2	3.1
Event was due to a failure to communicate panic value(s)	4	6.2
The event occurred to a newborn/neonate	14	21.5

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 2015 (144) was slightly lower than the number reported in 2014 (152) and 2013 (167). The number of deaths increased slightly over this time period (9 in 2013, 18 in 2014 and 20 in 2015).

Fifty-five hospitals submitted the 144 fall events. Thirteen hospitals reported 1 fall (9.0%), 20 hospitals reported 2 (27.8%), 9 submitted 3 events each (18.8) and 11 submitted 4 fall events (30.6%). Two hospitals each submitted 10 events (13.9%).

Thirteen (65.0%) of the patient deaths occurred in the Med/Surg Unit. Other units included the Emergency Department, Step Down and Telemetry. Twelve (60.0%) deaths occurred in the patient's room or bathroom and 4 (20.0%) occurred in a hallway/common area.

Prior to the fall, 94 patients (65.3%) were known to be at high risk, 28 (19.4%) were at medium risk, and 23 (16.0%) were considered to be at low risk for falls.

The majority of patients were engaged in the following activities prior to the fall: toileting-related activities (46, 31.9%), ambulating without assistance and/or assistive device (41, 28.5%), changing positions (23, 16.0%) and transferring to or from a chair, bed, etc. (10, 6.9%). Seven patients (4.9%) fell while ambulating with assistance and/or an assistive device and 2 patients (1.4%) fell while undergoing a diagnostic procedure.

In 135 events (93.8%), a fall risk screening tool was used to assess the patient's risk prior to the fall. Almost 90 percent of the screening tools used included the Morse Fall Risk Assessment (46, 34.1%), Hendrich/Hendrich II Fall Risk Assessment (31, 23.0%), John Hopkins Fall Risk Assessment Tool (28, 20.7%) and risk assessment tools developed by the individual facilities (15, 11.1%).

III. General Acute Care Hospitals

The majority of patients (88, 61.1%) were observed on patient rounds less than 30 minutes prior to the fall and less than 1 hour prior to the fall (40, 27.8%). In 3 (2.1%)events, the last patient rounds occurred more than 2 hours prior and the last time rounds occurred was unknown in another 3 events (2.1%).

For falls that occurred in the patient's room (136), the majority of patients (58, 42.6%) fell near or from the bed, 18 (13.2%) patients fell in the bathroom, 13 (9.6%) fell between the bed and the bathroom and 12 (8.8%) patients fell near or from a chair. Nine (6.6%) patients fell from a stretcher.

Fall Event Specifics

	Percent
The fall was witnessed	29.9
The fall occurred during change of shift	7.6
The fall occurred on a holiday/ weekend	27.8
A fall team regularly evaluates the falls program	99.3
A fall risk screening was documented at admission	95.8
A validated, reliable fall risk screening tool was used	93.8
The screening tool indicated that the patient was at risk for a fall if used	83.8
The patient had a history of a fall prior to admission	35.4
The patient was placed at risk due to clinical judgement	24.3
The facility's universal fall precautions were in place for this patient, if applicable	88.9
The patient was re-evaluated during each nursing shift, if applicable	97.0
The patient was re-evaluated upon transfer between units, if applicable	97.4
The patient was re-evaluated upon change in status, if applicable	96.9
The patient was re-evaluated post fall, if applicable	98.6
There was a visual indication alerting staff to patient's at-risk status	78.5
A fall prevention intervention plan was documented	86.8
The fall prevention plan focused on the patient's specific risk factors	78.5
The patient/family education was completed	82.6
Side rails were in proper position, if applicable	94.3
Restraints were used	0.0
The patient was wearing non-skid footwear	84.0
Footwear fit properly, if applicable	98.3
The patient was on culprit medication within 6 hours of the fall	47.9

D. Most Frequently Reported Event Types

As shown in Table 7 below, almost 90 percent of events submitted in 2015 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 89.8 percent of all events reported in 2015.

Figure 3 shows the reporting trends for these event types from 2012 to 2015.

Table 7: General Acute Care Hospitals: Most Frequently Reported Event Types-2015

Event Type	Number of Reportable Events	Percent of Events[a]
Fall	144	29.3
Care Management "Other"	65	13.2
Suicide/Attempted Suicide	64	13.0
Pressure Ulcer	58	11.8
Retained Foreign Object	51	10.4
Intra-Op/Post-Op Coma, Death or Other Serious Adverse Events	33	6.7
Surgery "Other"	26	5.3
All Other Events	50	10.2
Total	491	100.0

a: Data drawn from 491 RCAs submitted for 2015 events.

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 2012-2015

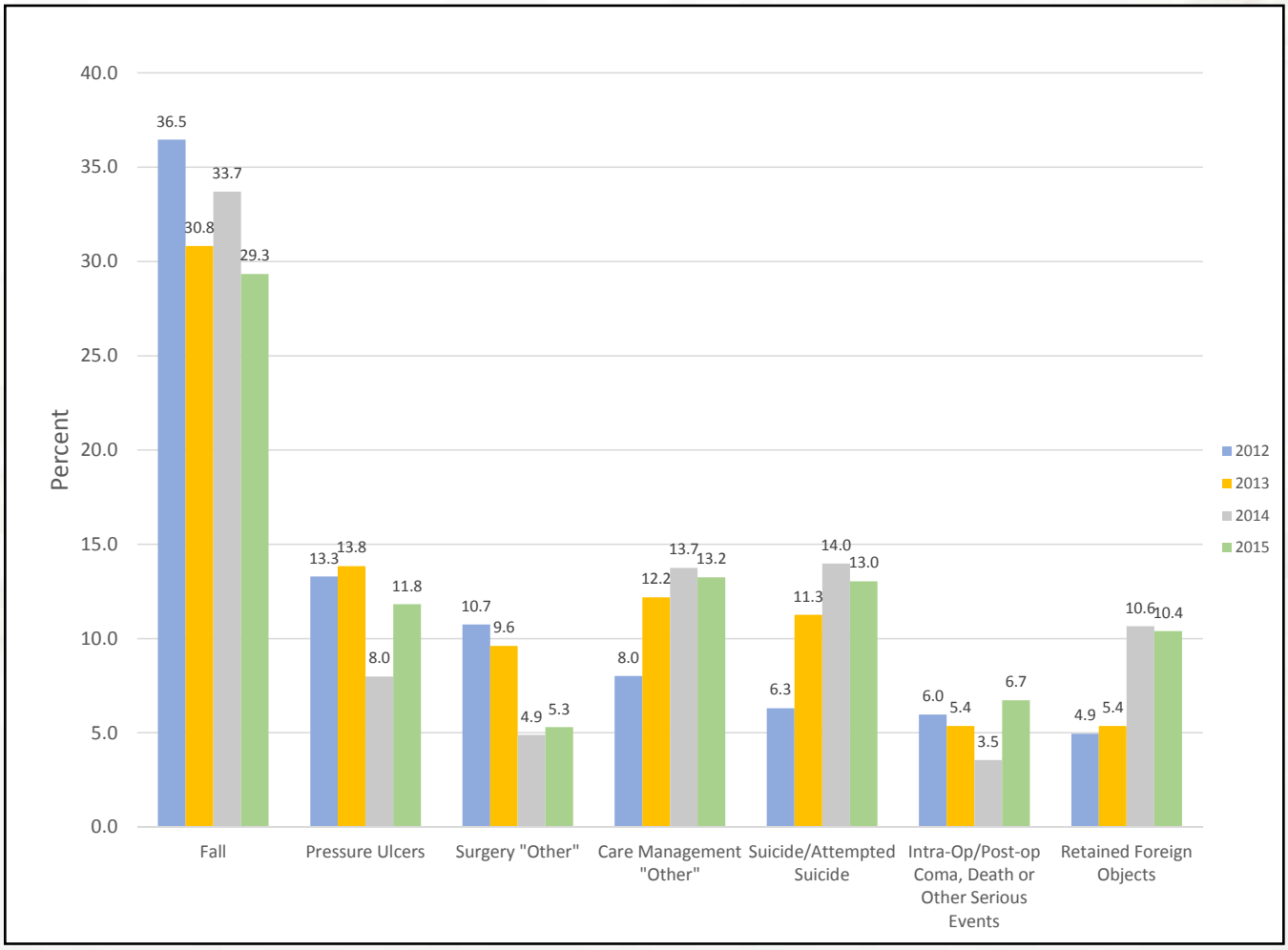


Figure 3 shows the four-year trend for the most frequently reported event types from 2012 to 2015.

- **Fall:** the percent of falls has declined from 36.5 (n=587) in 2012 to 29.3 (n=491) in 2015. The rates were 30.8 percent (n=542) in 2013 and 33.7 percent (n=451) in 2014.
- **Pressure Ulcer:** this event type accounted for 13.3 percent of all reportable events in 2012 (n=587). There was a slight increase to 13.8 percent in 2013 (n=542), a decrease to 8.0 percent (n=451) in 2014 and an increase to 11.8 percent in 2015 (n=491).
- **Surgery "Other":** in 2012, this event type represented 10.7 percent of all reportable events (n=587). In 2013 the percent reported decreased to 9.6 (n=542), and to 4.9 percent (n=451) in 2014. However, the rate increased slightly to 5.3 percent in 2015 (n=491).
- **Care Management "Other":** the percent of this event type increased from 8 (n=587) in 2012 to a high of 13.7 (n=451) in 2014. There was a slight drop in rate to 13.2 percent (n=491) in 2015.
- **Suicide/Attempted Suicide:** this event type accounted for 6.3 percent of reportable events (n=587) in 2012; 12.2 percent in 2013 (n=542); 13.7 percent in 2014 (n=451) and 13.2 percent in 2015 (n=491).
- **Intra-Op/Post-Op, Coma, Death of Other Serious Events:** the percent of events attributed to this event type was 6.0 in 2012 (n=587); 5.4 in 2013 (n=452); 3.5 in 2014 (n=451) and a high of 6.7 in 2015 (n=491).
- **Retained Foreign Object:** the percent reported for this event type ranged from a low of 4.9 in 2012 (n=587) to a high of 10.6 in 2014 (n=451 and 10.4 in 2015 (n=491).

III. General Acute Care Hospitals

1. Suicide/Attempted Suicide Events

There were 64 reportable adverse events for this event type in 2015, a minor increase from 2014 (63) and 2013 (61).

The 64 suicide attempts were submitted by 30 hospitals. Thirteen hospitals each submitted 1 event (20.3%), 9 hospitals each submitted 2 events (28.1%), 3 hospitals submitted 3 events each (14.1%) and 4 hospitals submitted 4 events (25.0%). One hospital submitted 8 suicide attempts (12.5%).

Prior to the suicide attempt, slightly more than half of the patients (35, 54.7%) were considered at risk and half (32, 50.0%) were seen by a psychiatrist. Forty-five patients (70.3%) had a prior suicide attempt. At the same time of the event, the following levels of observation were in place: 18 patients (28.1%) were on 1:1, 17 (26.6%) were on 15-minute checks, 9 (14.1%) were on close observation, 8 (12.5%) were on no observation, and 6 (9.4%) were on line of sight.

The majority of events occurred in the Behavioral Health Unit (23, 35.9%), the Emergency Department (19, 29.7%), the Emergency Crises Screening/Observation Unit (9, 14.1%) and Med/Surg units (7, 10.9%). Three events (4.7%) occurred in Telemetry and 1 event each in ICU/CCU/TCU, Labor/Delivery, and other location.

There were no suicides in 2015, compared to 4 in 2013 and 1 in 2014.

2. Pressure Ulcers

In 2015, there were 58 healthcare associated Stage III and IV pressure ulcers.

There was a fifty-two percent (52%) decrease in the number of pressure ulcers submitted in 2014 (36) compared to 2013 (75). However, there was a sixty-one percent (61.1%) increase in the number of pressure ulcers in 2015 compared to 2014.

The 58 pressure ulcer events were submitted by 26 hospitals. Fourteen hospitals each submitted 1 pressure ulcer (24.1%) and 6 submitted 2 each (20.7), which in aggregate represents 44.8% of the total. One hospital submitted 3 events and 2 submitted 4. Thirty-six percent (21, 36.2%) of the total number of pressure ulcers were submitted by 3 hospitals (5, 7, and 9 events).

Thirty-six (62.1%) of the pressure ulcers were located on the sacrum and 8 (13.8%) were on the buttocks. The remaining pressure ulcers were located on the ear, heels, neck and nose. There were 3 submitted events in which there were multiple locations of pressure ulcers.

The majority of reported pressure ulcers were Stage III (40, 69.0%).

Of the 58 pressure ulcers, 5 were possibly related to surgery or a procedure.

Five (8.6%) of the 58 pressure ulcers were device-related. The device included 2 nasal cannulas, 1 tracheostomy tube, 1 splint and 1 bipap machine.

Pressure Ulcers Patient Care Specifics	Percent Yes
Pressure ulcer risk assessment (Braden) was documented on admission and daily	89.7
Skin inspection was documented on admission and daily	91.4
Removal of devices such as stockings and splints was documented each shift, if applicable	100.0
Staff used documented care plan	91.4
Patients with impaired sensory perception, mobility and activity were repositioned every 2 hours	81.0
Patients with impaired sensory perception, mobility and activity had heels lifted off bed	86.2
Patients with impaired sensory perception, mobility and activity had appropriate support surfaces	89.7
Patients with friction/shear risk as defined by Braden scale had HOB 30 degrees or less	70.7
The patient refused repositioning	22.4
The patient had an unstable condition that prohibited repositioning	24.1
The patient had a long ambulance or other transport time	0.0
Pressure ulcer was possibly related to a surgery/procedure	8.6
Patients with nutritional deficits were followed by dietary services	91.4
Pain assessment and management adequately performed	91.4
Incontinence was addressed, if applicable	94.0
Patient/family skin safety education and patient response was documented	79.3

III. General Acute Care Hospitals

3. Retained Foreign Objects (RFOs)

There were 51 retained foreign object events submitted in 2015. This represents a slight increase from 2014 (48) and a large increase from 2013 (29). However, there was a change in the interpretation related to the classification of RFO and Device-Malfunction events in 2014. Previously, broken devices were classified as Device-Malfunction events even if a piece of the device was retained in the patient. In an effort to be more consistent with the National Quality Forum (NQF) (e.g. NQF Implementation Guidance for RFOs includes such items as catheter tips), the decision was made to classify these types of events as RFOs in 2014. In addition, hospitals often submitted these types of events as RFOs. During the same time period, there was a concomitant decrease in the number of Device-Malfunction events.

The 51 RFO events were submitted by 24 hospitals. Twelve hospitals submitted 1 RFO each (23.5%), four submitted 2 events each (15.7%) and five hospitals submitted 3 events each (29.4%). Three hospitals submitted the highest number of events each (4, 5, and 7); these represent 31.4% of all submitted events. Five events were discovered by a second facility.

Of the 51 RFOs, 12 were sponges/gauze (23.5%), 11 were guidewires/other wire (21.6%), 4 were needles (7.8%) and 3 were lap pads (5.9%). Examples of other RFOs included a surgical towel, bulb syringe, product label, blade, bandage, metal stent, IVC filter, plastic fragment, epidural catheter, metal pin and retractor.

Thirty-four patients (66.7%) required a second surgery to remove the object.

E. Major Root Causes for All Events

In 2015, the most frequent root causes of adverse events reported to PSRS were care planning process (52.3%), communication among staff (26.1%), orientation and training of staff (18.7%), patient observation procedures (15.7%), physical assessment process (13.6%) and equipment maintenance/management (12.2%).

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	257	52.3
Communication Among Staff Members	128	26.1
Orientation and Training of Staff	92	18.7
Patient Observation Procedures	77	15.7
Physical Assessment Process	67	13.6
Equipment Maintenance/Management	60	12.2
Other	53	10.8

a: Data drawn from 491 RCAs submitted for 2015 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]
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	350	71.3
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	325	66.2
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	257	52.3
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	201	40.9
Staff Factors *(May include training, experience and inadequate staffing levels.)*	153	31.2
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	130	26.5
Equipment *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	93	18.9
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	91	18.5

a: Data drawn from 491 RCAs submitted for 2015 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 96 deaths which represent 19.6% of the 491 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	278	56.6
Additional Lab Testing or Diagnostic Imaging	266	54.2
Increased Length of Stay	214	43.6
Disability-Physical or Mental impairment	184	37.5
Major Surgery	138	28.1
Transfer to more Intensive Level of Care	127	25.9
Death	96	19.6

a: Data drawn from 491 RCAs submitted for 2015 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 68 reportable events submitted from specialty hospitals in 2015.
Ten comprehensive rehabilitation hospitals submitted 38 reportable events, averaging almost four event reports per facility type.

Nine out of the eleven psychiatric hospitals submitted 18 reportable events, an average of 2.0 per facility while special hospitals submitted 12 reportable events averaging 2.0 reports per facility.

Special hospitals were the lowest reporters among the specialty hospitals, consistent with prior years. Variation in reporting may relate to the size and patient population of the facility.

Table 11: Specialty Hospitals: Overall Reporting Pattern, 2015

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	10	38	3.8	2
Psychiatric Hospitals	11	9	18	2.0	4
Special Hospitals	14	6	12	2.0	0
Total	39	25	68	2.7	6

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

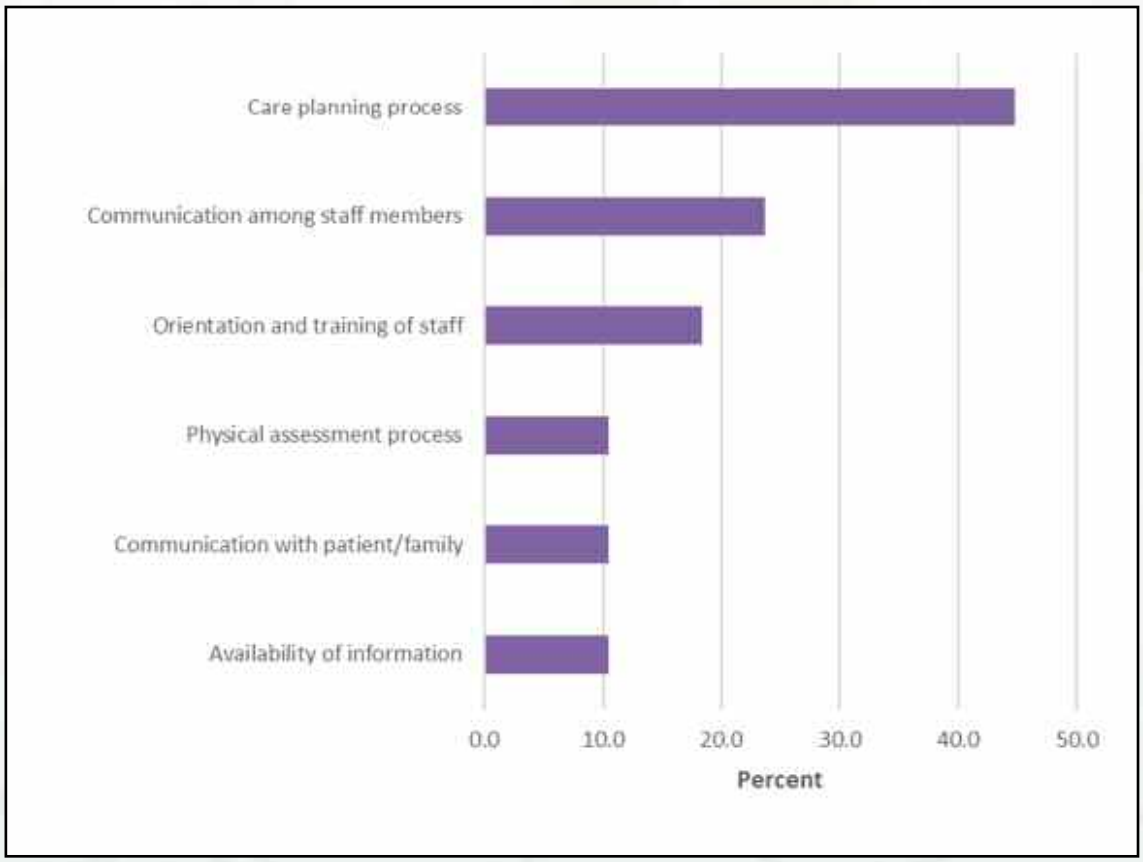
A. Comprehensive Rehabilitation Hospitals

Of the 14 comprehensive rehabilitation hospitals in the state, 10 (71.4%) reported at least one event in 2015. There were 38 reportable events and two deaths from these hospitals. These deaths were each related to a fall and care management "other" event. Most frequently reported event types are 18 falls, 13 pressure ulcers, 6 medication errors and one retained foreign object (RFO). These events are similar to previous years' reporting.

1. Root Causes for All Events

Figure 3 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 38 RCAs submitted for 2015 events.

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

2. Contributing Factors to All Events

In 2015, the most frequently reported contributing factors were patient characteristics (65.8%), task factors (52.6%), organization/management (39.5%), team factors (34%), staff factors and patient record documentation.

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.)*	25	65.8
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	20	52.6
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	15	39.5
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	13	34.2
Staff Factors *(May include training, experience and inadequate staffing levels.)*	9	23.7
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	5	13.2

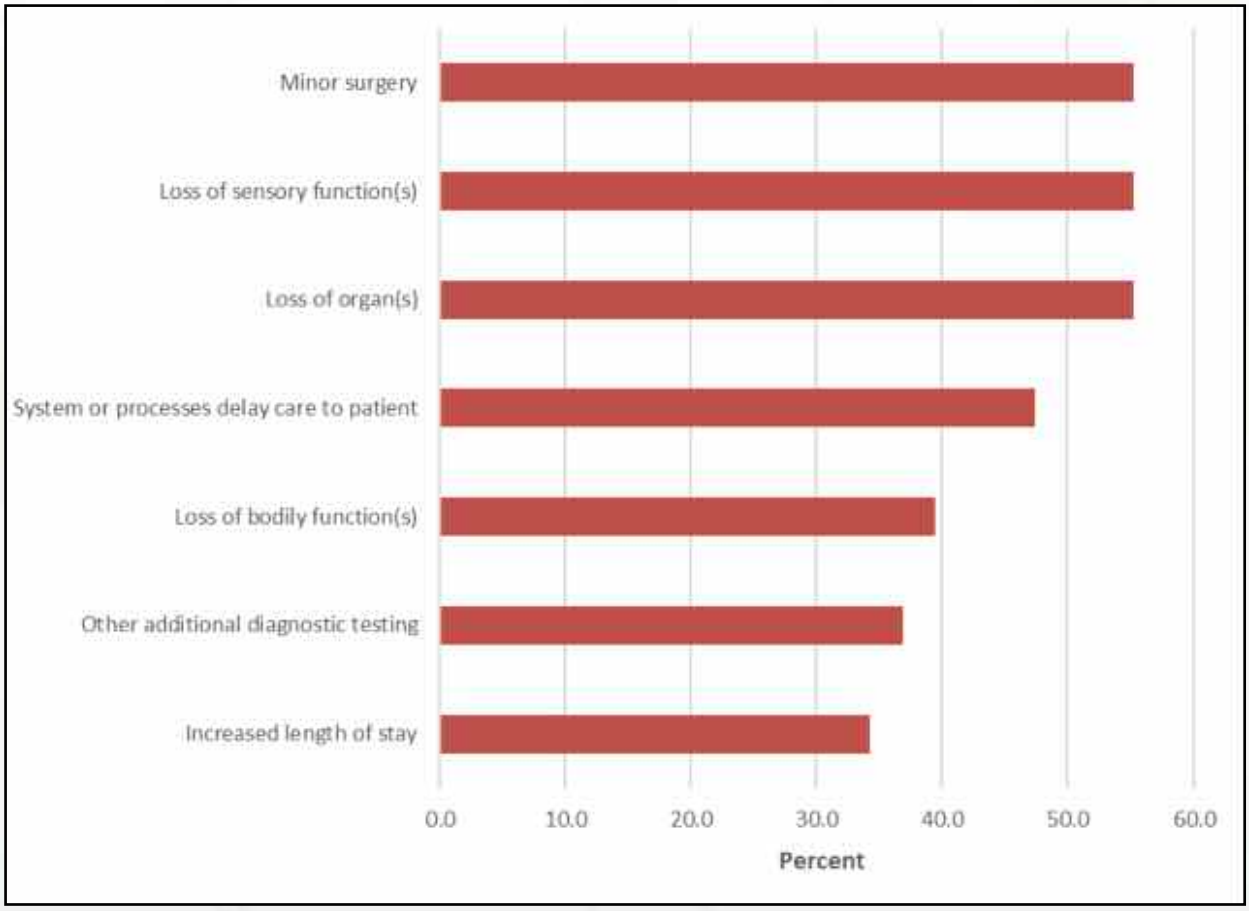
a: Data drawn from 38 RCAs submitted for 2015 events.

3. Impact of All Events

As a result of these adverse events, over one-half (55.3%) resulted in minor surgery, loss of sensory functions or loss of organ(s). Figure 5 shows other impacts associated with adverse events from comprehensive rehabilitation hospitals.

As stated earlier, there were two deaths reported from this facility type.

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



a: Data drawn from 38 RCAs submitted for 2015 events.

B. Psychiatric Hospitals

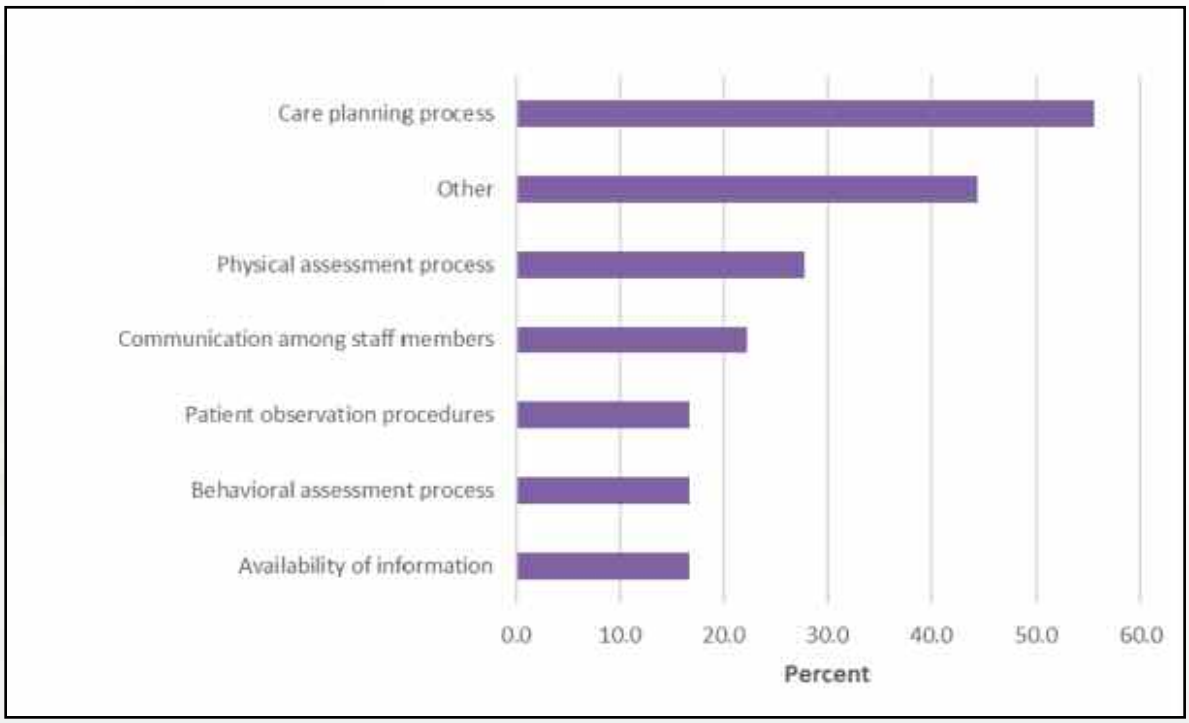
Nine out of 11 psychiatric hospitals reported at least one event during 2015, an increase in reporting from 5 facilities in 2012. A total of 18 reportable events were submitted to the Patient Safety Reporting System. Of the 18 events, seven (38.9%) were falls, six were care management "other" events (33.3%). Pressure ulcers and suicide/attempted suicide had two reported events each. The average submission by this facility type was 2.

A total of four deaths were reported and attributed to care management "other" events.

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 2015 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.)*	9	50.0
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	8	44.4
Staff Factors *(May include training, experience and inadequate staffing levels.)*	7	38.9
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	7	38.9

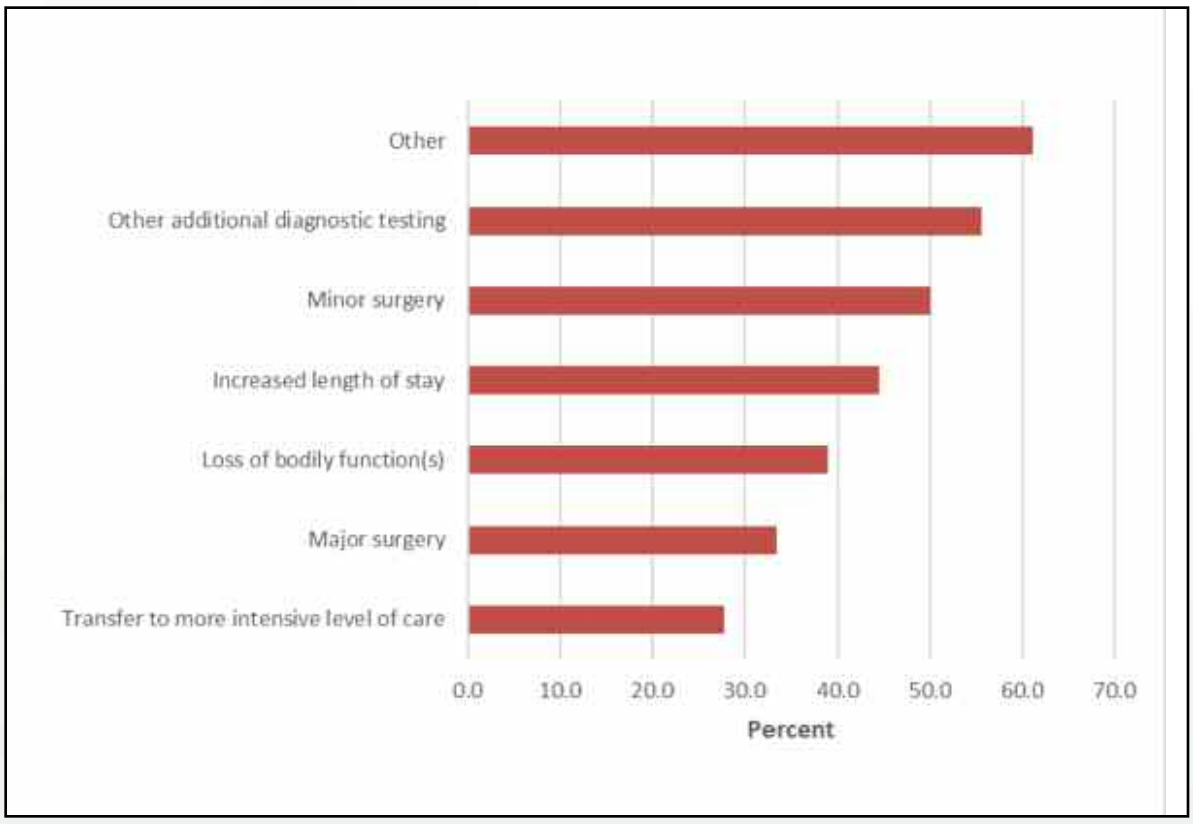
a: Data drawn from 18 RCAs submitted for 2015 events.

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. As noted earlier, there were four deaths reported and all were associated with care management "other" events.

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



a: Data drawn from 18 RCAs submitted for 2015 events.

C. Special Hospitals

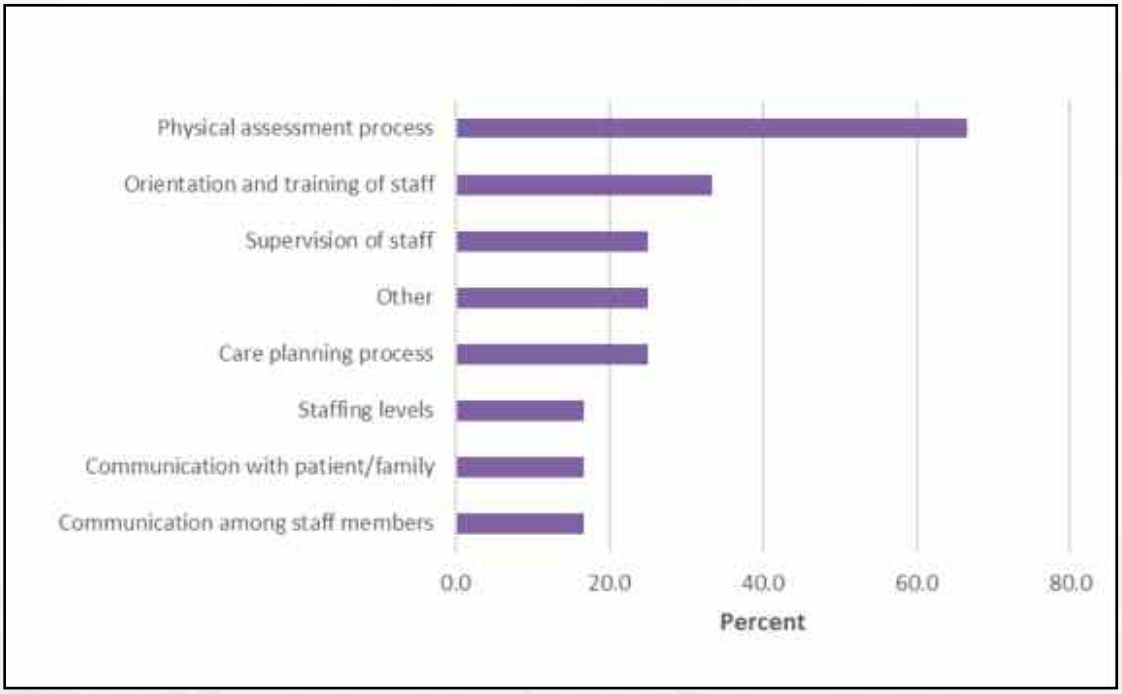
There were 14 special hospitals in 2015 but only six reported at least one event during the year. This low reporting is consistent with prior years. A total of 12 reportable events were submitted compared to seven in 2014 and eight in 2013. Nine of the events were from the care management category: pressure ulcers (4), care management "other" events (4) and one medication error. The remaining three events were falls. Except for 2013 with one death, no deaths were reported for this facility type in 2014 and 2015.

The average submission by this facility type was 2.

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 12 RCAs submitted for 2015 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 the table shows, the most frequently reported contributing factor was patient characteristics (91.7%), followed by procedures (58.3%). Team factors, task factors and organization/management each accounted for 50.0% of the adverse events.

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

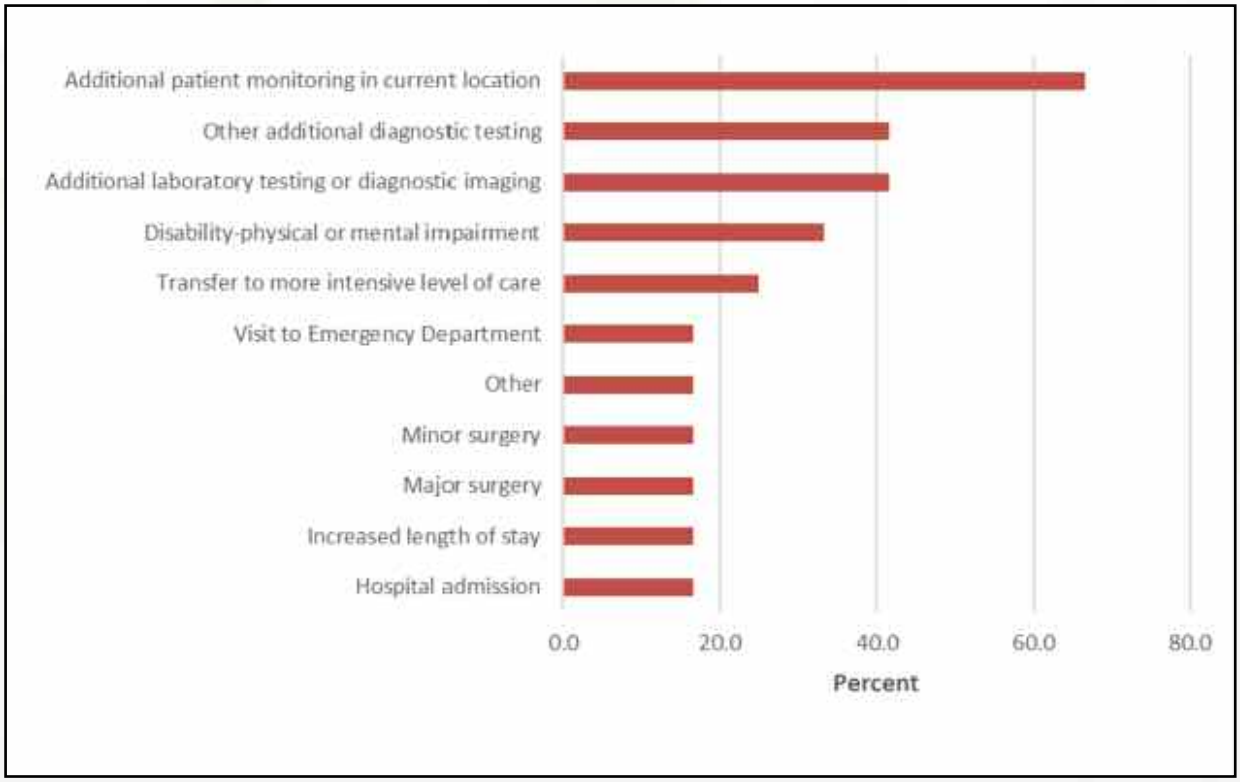
Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	11	91.7
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	7	58.3
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	6	50.0
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	6	50.0
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	6	50.0
Staff Factors *(May include training, experience and inadequate staffing levels.)*	5	41.7
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	5	41.7
Medications *(May include inappropriate administration, dose and prescribed medications not administered.)*	4	33.3

a: Data drawn from 12 RCAs submitted for 2015 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 12 RCAs submitted for 2015 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, less than one-half (85, 48.3%) submitted events in 2015. A total of 332 events were submitted of which 165 were reportable (49.7%), and 167 (50.3%) were not reportable. There were 13 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 2015.

Table 15 and Figure 10 show the reporting patterns for the period 2008 to 2015.

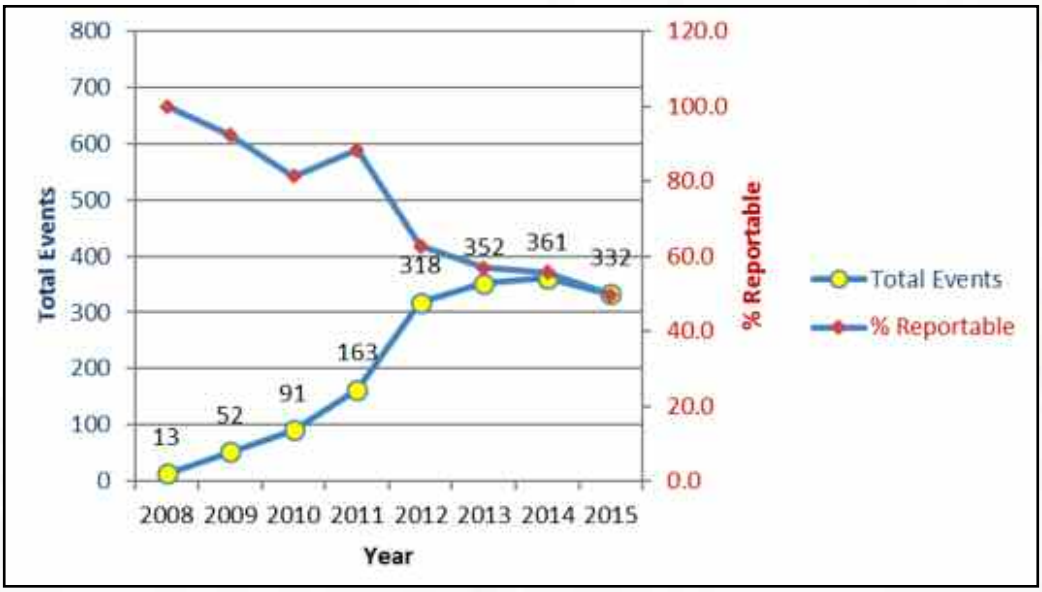
Table 15: Ambulatory Surgery Centers: Reporting Patterns (2008-2015)

Year	Reportable	Not Reportable	Less Serious/Near Misses	Total Events	Percent Not Reportable	Percent Reportable
2008[a]	13	0	NA	13	0	100.
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

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 2008-2015



V. Ambulatory Surgery Centers

Similar to previous years and as shown in Table 16 below, a majority of the cases were intraoperative or postoperative coma, death or other serious preventable adverse events. These events in aggregate accounted for over two-thirds (67.3%) of all events reported by ambulatory surgery centers. The next highest event type was surgery-related "other" events with 45 cases or 27.3 percent of the total events reported from ambulatory surgery centers.

These two event types accounted for 156 cases or 94.5 percent of the total events reported (n = 165).

There were 13 deaths reported and all were associated with intraoperative or postoperative coma, death or other serious preventable adverse events type. The dealth rate for this event type was 11.7 percent (13/111).

Table 16: Ambulatory Surgery Centers: Events Reported (2015)

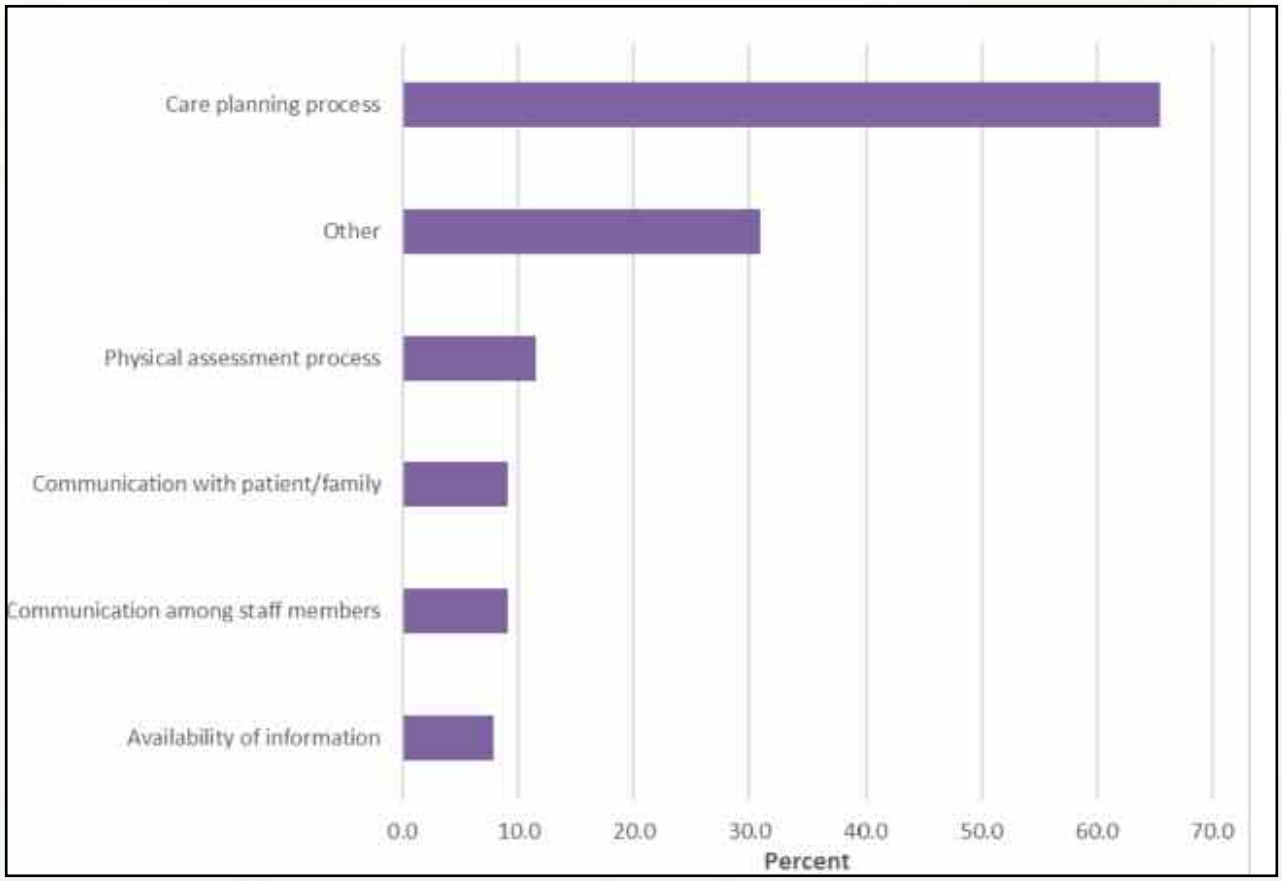
Event Type	Number of Events	Percent of Total Events	Number of Deaths
Intra-or Post-Operative Coma, Death or Other serious preventable adverse event	111	67.3	13
Surgery-Related "Other" Event	45	27.3	0
Wrong Site	3	1.8	0
Wrong Procedure	3	1.8	0
Fall	2	1.2	0
Retained Foreign Object	1	0.6	0
Total	165	100.0	13

V. Ambulatory Surgery Centers

A. Root Causes for All Events

Figure 11 shows the most frequently identified root causes of the events reported by ambulatory surgery centers in 2015.

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



a: Data drawn from 165 RCAs submitted for 2015 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]

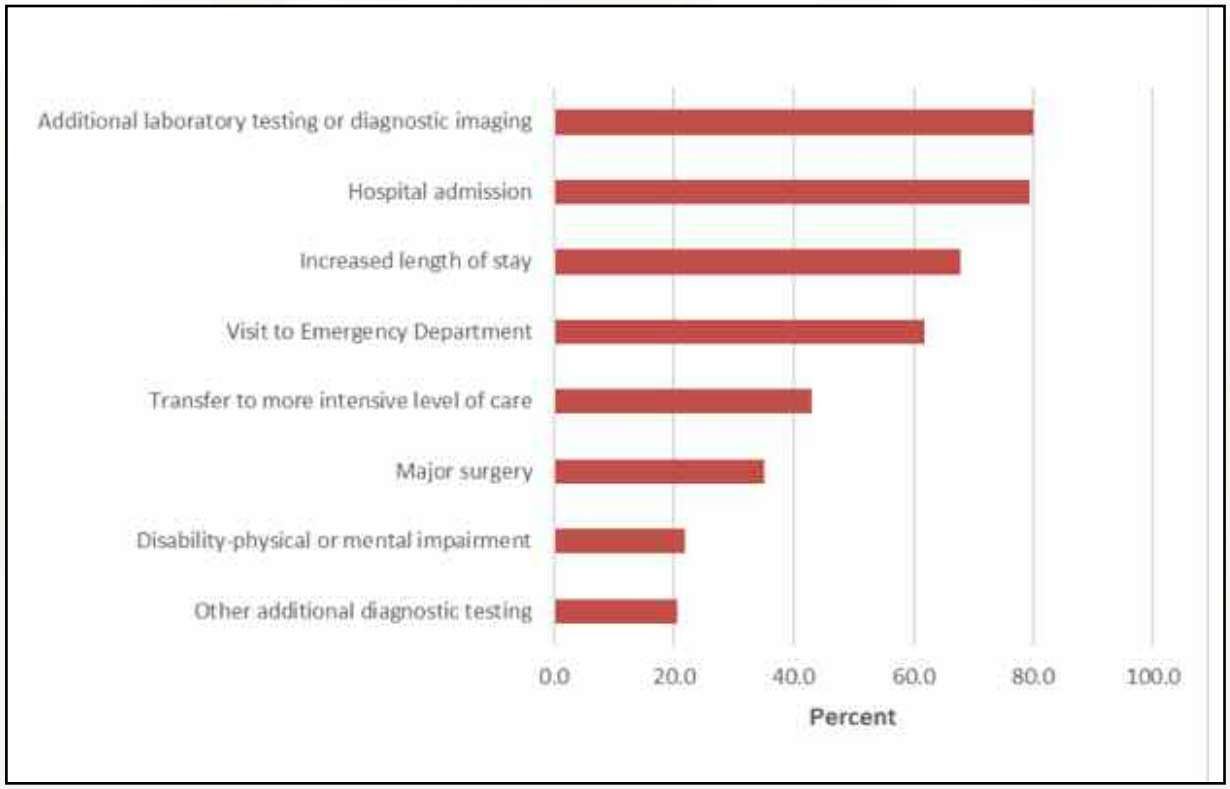
Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the Patient's choice to refuse care.)*	107	64.8
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	95	57.6
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	60	36.4
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	57	34.5
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	52	31.5
Other Factors *(Includes factors not identified in the other categories.)*	36	21.8
Staff Factors *(May include training, experience and inadequate staffing levels.)*	32	19.4

a: Data drawn from 165 RCAs submitted for 2015 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 165 RCAs submitted for 2015 events.

Appendix I: 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 kernicterus[a] associated with failure to identify and treat hyperbilirubinemia[b] 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 I: 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 II: 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.

Contact Information

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2015 Summary Report

Patient Safety Reporting System
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