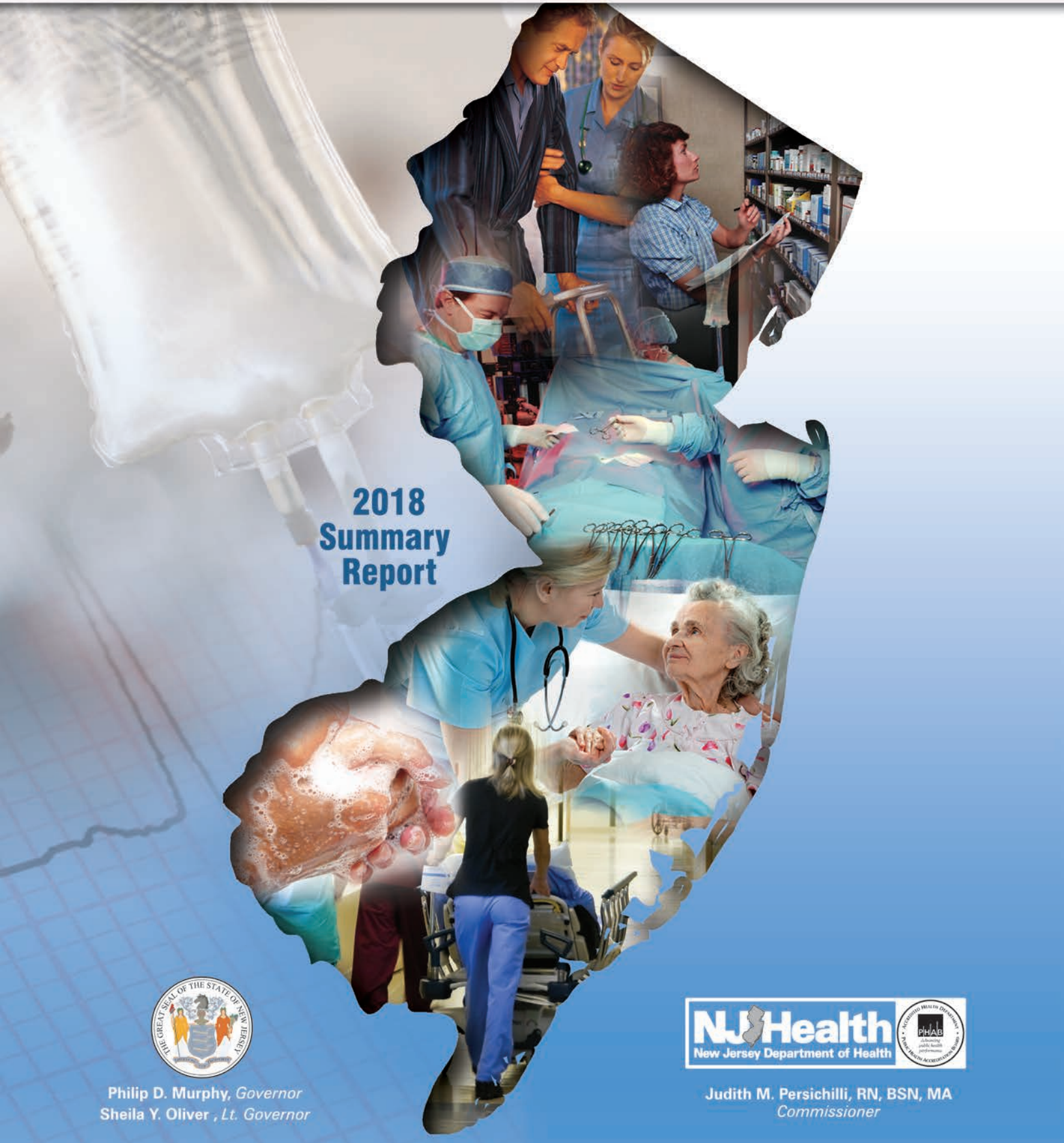
HCQA Health Care Quality Assessment

Patient Safety Reporting System



2018 Summary Report

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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."*

Patient Safety Reporting System

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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 2018:

- 799 events were reported to the Patient Safety Reporting System by all facility types;
- 631 events met the statutory definition of (or satisfied the criteria for) a serious preventable adverse event ("reportable");
- 168 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");
- 88 deaths were associated with the adverse events.

General Acute Care Hospitals:

- Submitted 403 reportable adverse events in 2018 compared to 405 events in 2017;
- The average number of reportable events per reporting hospital was 5.9 (does not take into account hospital sizes and bed capacity);
- There were 75 deaths associated with the adverse events; specific events with the highest percent of associated deaths were care management "other" events (35), a intraoperative or postoperative coma, death, or other serious preventable adverse events (18), surgery "other" events (10), and fall events (7);
- The most frequently reported events were falls, care management "other" events, pressure ulcers, retained foreign objects and suicide/ attempted suicide;
- Adverse events were most often caused by care planning process, communication among staff and/or with the patient/family, patient observation procedures, orientation and training of staff, and physical assessment process;

The most frequent consequences of the events were: additional patient monitoring, additional laboratory testing and increased length of stay.

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

Executive Summary

Comprehensive Rehabilitation Hospitals:

- There were 26 reportable events and one deaths associated with a restraint;
- The most frequently reported root causes were care planning process, and communication among staff members;
- Nearly 60 percent of experienced increased length of stay or hospital admission.

Psychiatric Hospitals:

- There were 25 reportable events with three deaths;
- The most frequently reported root causes were care planning process, patient observation process, and orientation and training of staff;
- Most of the 25 (60%) events resulted in a visit to the emergency department, transfer to more intensive level of care or increased length of stay.

Special Hospitals:

- Fourteen events were submitted by five reporting facilities and there were two associated deaths;
- The most frequently reported root causes were physical assessment process and orientation and training of staff;
- The most frequent impact of the events included additional patient monitoring increased length of stay and disability-physical or mental impairment.

Ambulatory Surgery Centers:

- Submitted 163 reportable events with seven deaths. Six of these deaths were 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, increased length of stay, visit to the emergency department as well as additional laboratory testing or diagnostic imaging.

Patient Safety Reporting System

I. 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 2018.

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 Behavioral Health Services (DBHS/Division) in section VI of this document.

II. Overall Reporting Patterns by Facility Type

This annual report summarizes the 2018 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 2018 from all facilities totaled 799.

Of this total, 631 were deemed reportable with 88 associated deaths. In 2017, the number of reportable events across all facility types was 596 with 87 associated deaths.

An in-depth analysis of the data shows that there were 35 more reportable events between 2017 and 2018. The highest increase in reportable events (19) was attributed to ambulatory surgery centers

The number of deaths in 2018 was 88 compared to 87 in 2017.

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 2018.

Table 1: Reporting Pattern by Facility Type (2018)

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	Percent Reportable Deaths
General Acute Care Hospitals	71	68	403	1	40	75	18.6
Comprehensive Rehabilitation Hospitals	14	11	26	0	1	1	3.8
Psychiatric Hospitals	11	7	25	0	2	3	12.0
Special Hospitals	14	5	14	0	0	2	14.3
Ambulatory Surgery Centers	218	89	163	10	114	7	4.3
Total	328	180	631	11	157	88	13.9

III. General Acute Care Hospitals

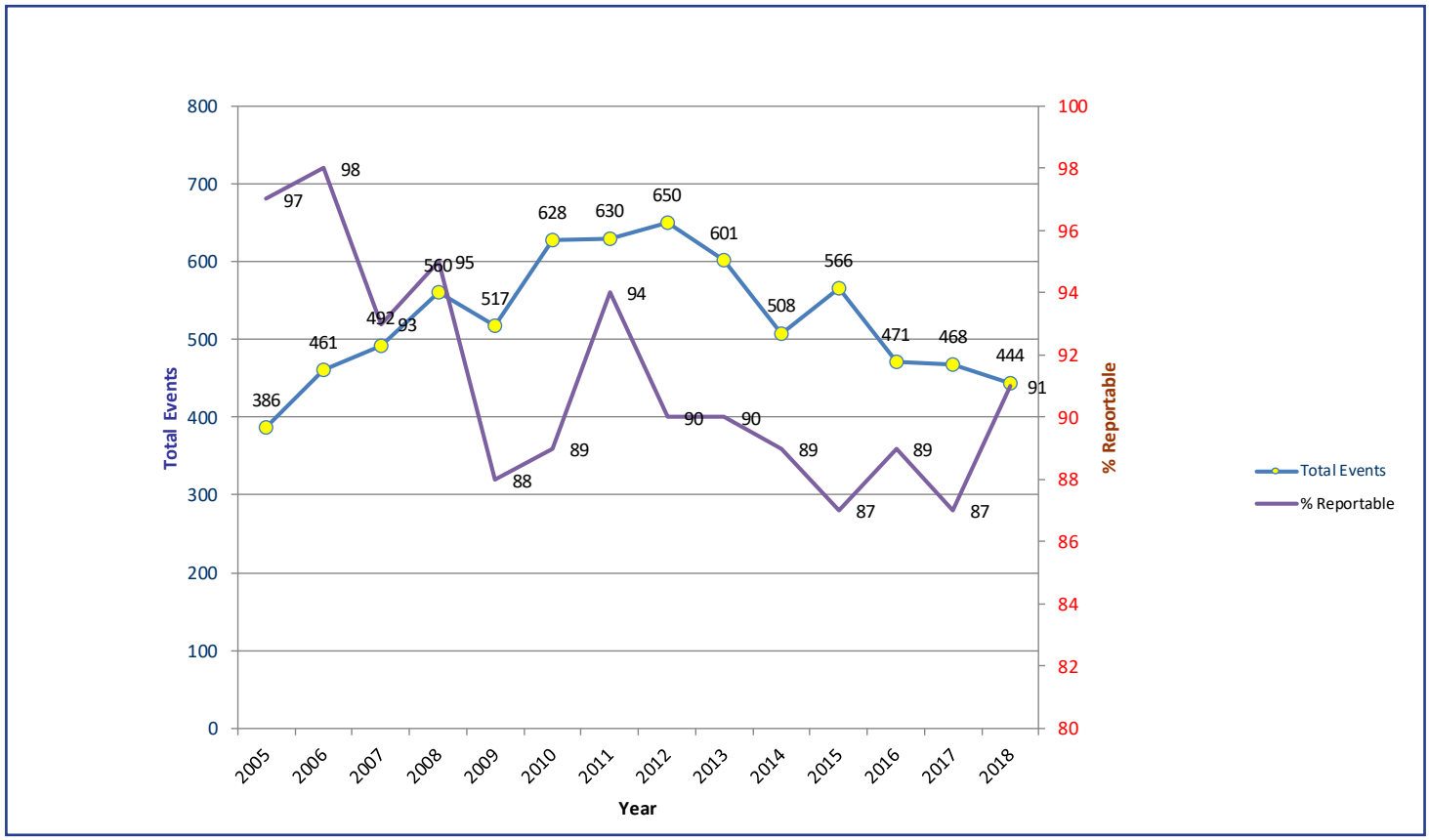
A. Reporting Patterns (2005-2018)

Figure 1 and Table 2 demonstrate the reporting patterns for general acute care hospitals over the past 14 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.

The percent of not reportable events by general acute care hospitals dropped from 13 percent in 2017 to 9.2 percent in 2018.

Figure 1: General Acute Care Hospitals: Trends in Reportable Events 2005-2018



III. General Acute Care Hospitals

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

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
2017	405	4	59	468	13	87
2018	403	1	40	444	9	91

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, 6730 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 2018.

In 2018, the fourteenth year of reporting, 403 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 2018, all 68 general acute care hospitals in New Jersey submitted reportable events. The average number of reports per reporting hospital was 5.9. This average does not take into account hospital size and bed capacity.

Please note that starting in 2016 the data includes the actual number of events which occurred in that year (2018). In prior years, the data was collected based on the year the event was reported and could have inflated the number for those years.

Table 3: General Acute Care Hospitals: Reporting Patterns (2005-2018)[a]

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
2017	405	72	72	100.0	5.6	75	18.5
2018	403	71	68	95.8	5.9	75	18.6

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 403 adverse events reported by New Jersey general acute care hospitals in 2018. Similar to last year, there were 75 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

Tables 4A and 4B provide 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 4A: General Acute Care Hospitals: Reportable Events and Associated Deaths by Event Category-2018

Event Category	Total Reportable Events	Percent of Total Events	Total Deaths per Events	Percent Deaths per Event Category
A: Care Management	95	23.6	37	49.3
B: Environmental	118	29.3	7	9.3
C: Product or Device	2	0.5	0	0
D: Surgery-Related	113	27.9	29	38.7
E: Patient Protection	75	18.7	2	2.7
Total	403	100.0	75	100.0

Table 4B: General Acute Care Hospitals: Reportable Events and Associated Deaths by Event Category-2018

Event Category	Total Reportable Events	Total Deaths per Event
A: Care Management	95	37
Care Management Other	49	35
Medication Error	8	2
B: Environmental	118	7
Fall	111	7
C: Product or Device	2	0
Product Contaminated	2	0
D: Surgery-Related	113	29
Intra/Post-Op, Coma/Death/Other Event	32	18
Surgical Other	19	10
Retained Foreign Object	47	1
E: Patient Protection	75	2
	71	
Elopement	1	1
Other	2	1
Total	337	75

As Tables 4A and 4B demonstrate, the care management event category had the highest number of associated deaths (35 out of 75) or 46.7 percent of all deaths. The second highest category for reported deaths was surgery-related (29), followed by environmental (7). Patient Protection accounted for two deaths and Product/ Device malfunction reported no death within that event category.

For individual surgery-related event types, retained foreign objects had the highest number of reported events (47); this was an increase of 18 or 62 percent increase from 2017.

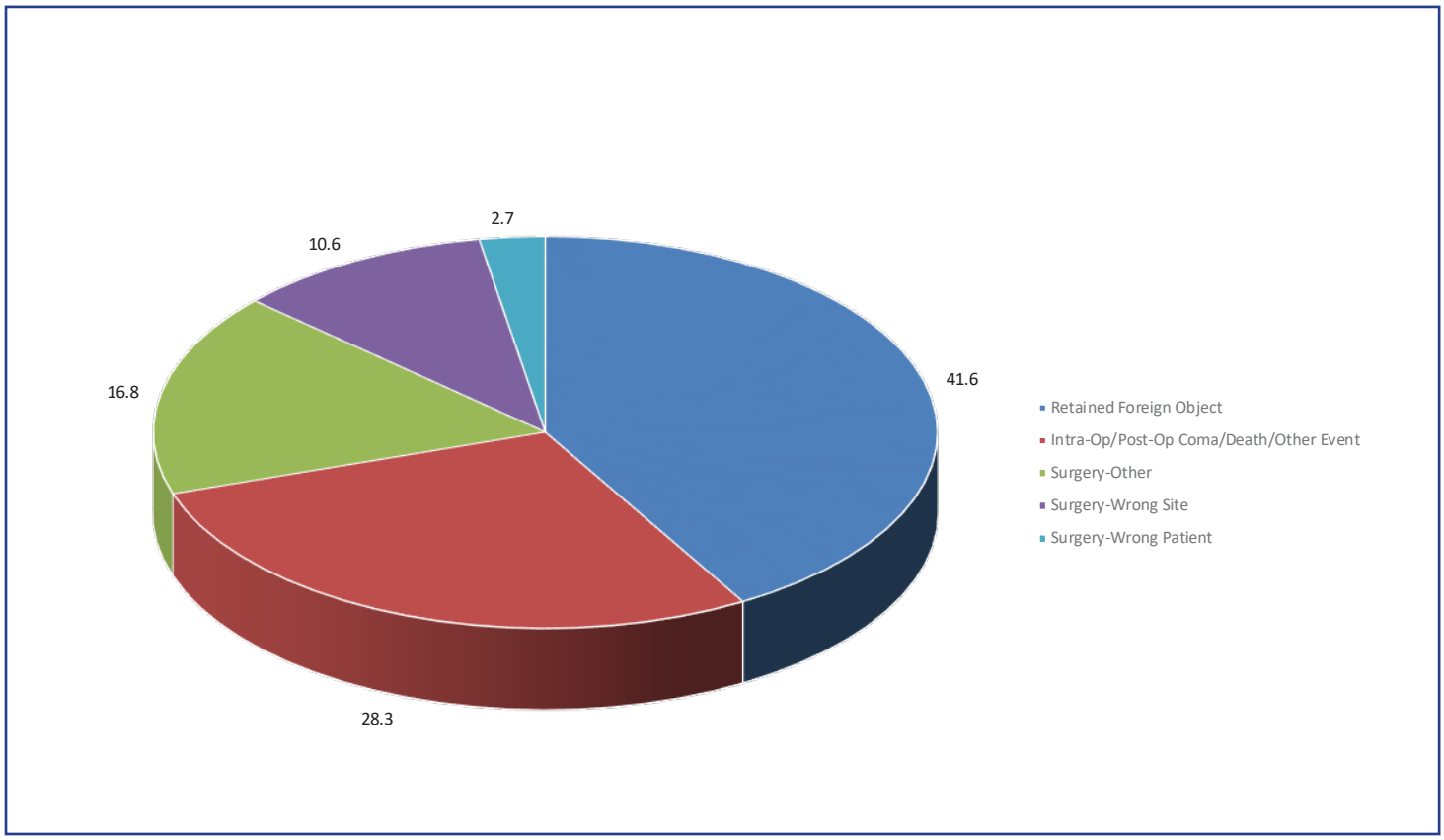
There was one death associated with this event. The second highest reported event was for intra-operative or post-operative events (32) with 18 associated deaths.

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	47	1	2.1
Intra-Op/Post-Op Coma/Death/Other Event	32	18	55.6 56.3
Surgery “Other”	19	10	52.3
Wrong Site	12	0	0.0
Wrong Patient	3	0	0.0
Total	113	29	25.7

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 211 reportable events which represent 52.4 percent of all events reported. However, the total number of deaths associated with these four events was 70 and accounted for more than 93 percent (93.3%) of all deaths in 2018.

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

Event Type	Number of Events	Number of Deaths	Percent Deaths to Events
Care Management "Other"	49	35	71.4
Intra-Op/Post-OP Coma, Death or Other Event	32	18	56.3
Surgery-Related "Other"	19	10	52.6
Fall	111	7	6.3
All Other Event Types	192	5	2.6
Total	403	75	18.6

1. Care Management "Other" Events

Of the 49 patients who received care in this event category in 2018, 35 (71.4 %) died. In 2017, 27 people died representing 55.1 percent of the total.

Table 6 shows the results.

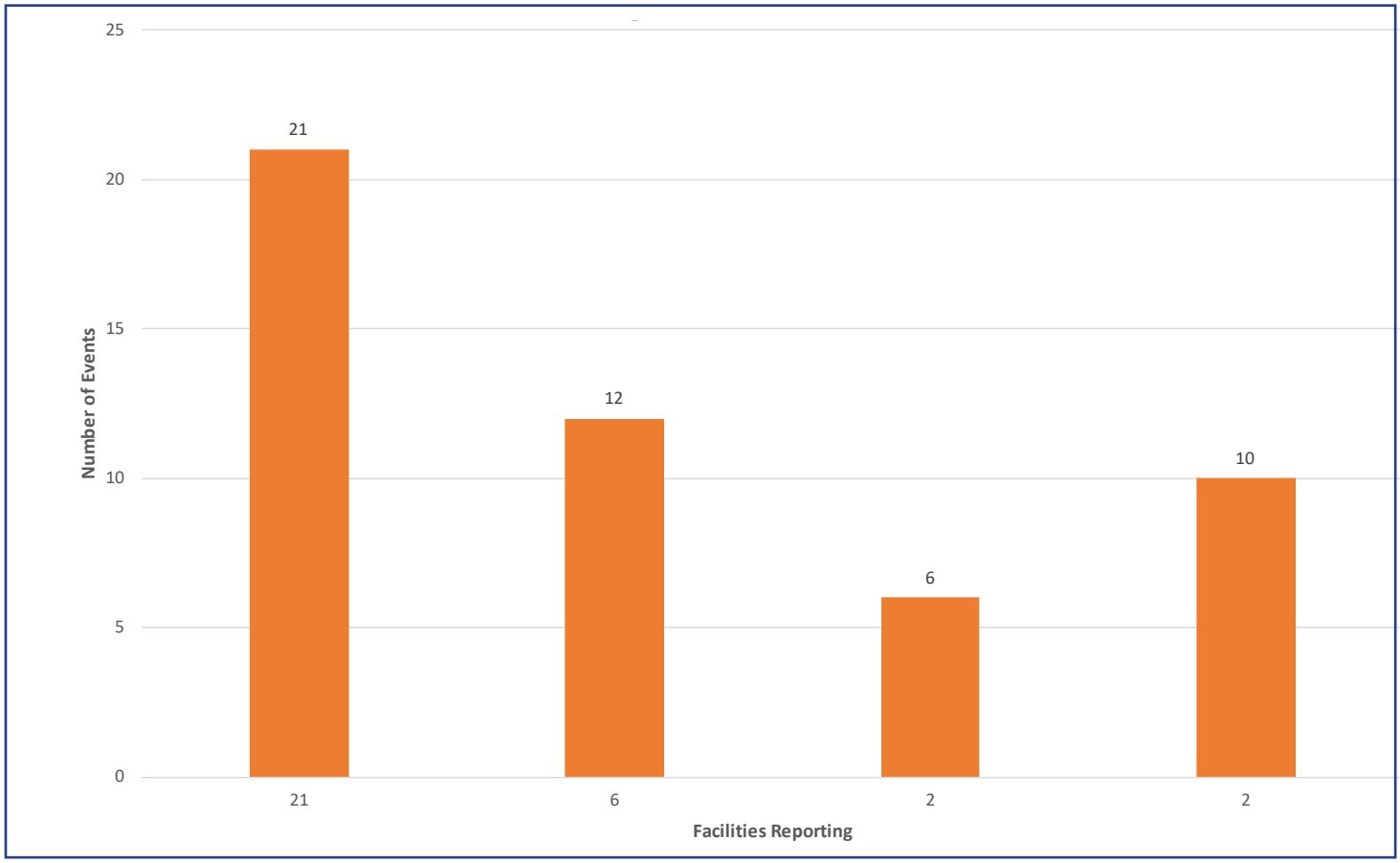
Care management "other" events include care management related events which do not meet the definition of the specific care management event types, such as medication errors and pressure ulcers. Events must meet the statutory definition of a serious preventable adverse event.

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.

Examples of events reported for this event type 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.

Figure 3 shows the number of facilities reporting this event type.

Figure 3: Care Management "Other" Events

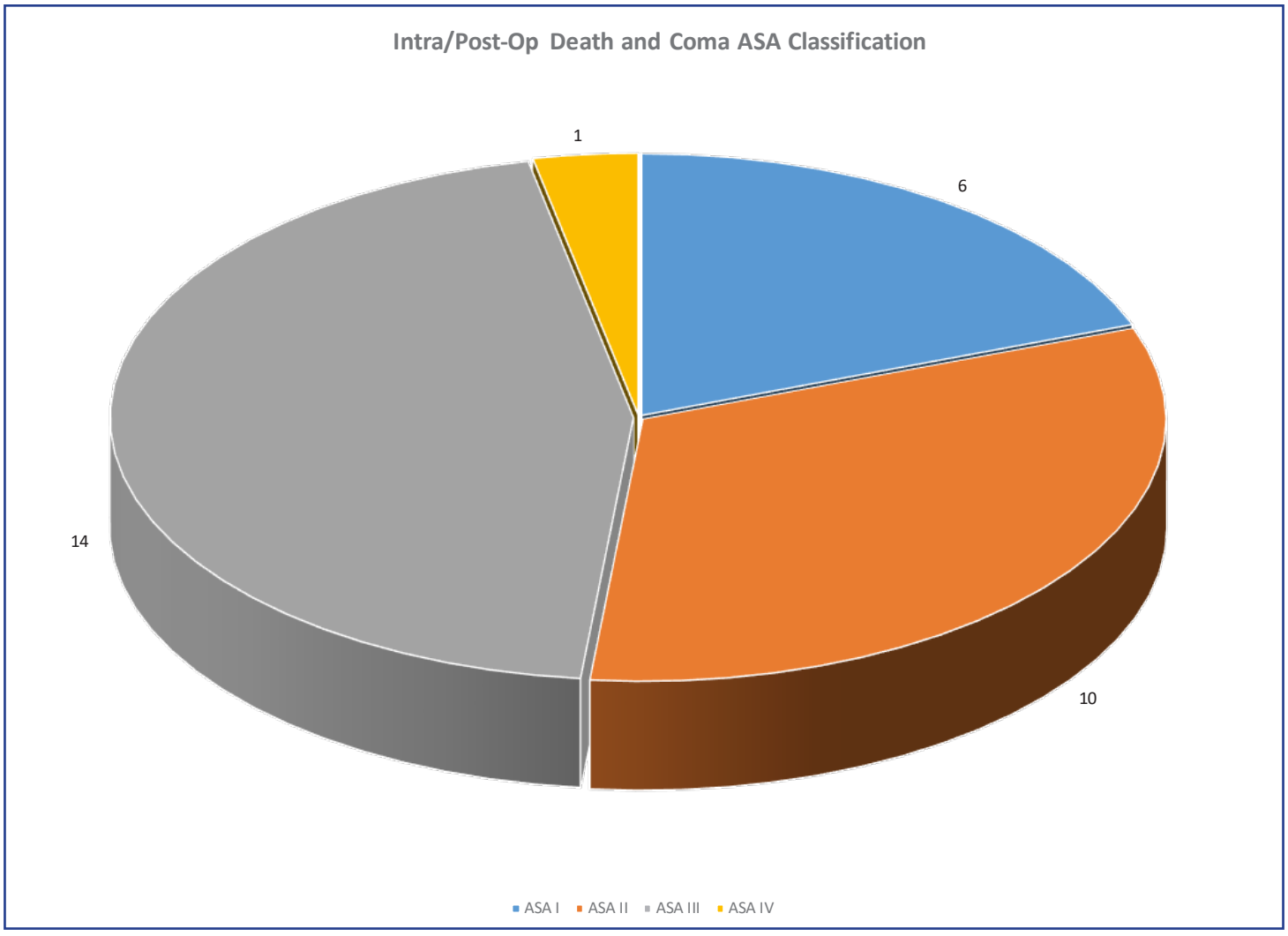


2. Intra-Operative or Post-Operative Coma, Death or Other Serious Event Preventable Adverse Event

There were 31 reports of intraoperative or postoperative (that is, within 24 hours) coma, death or other serious preventable adverse event in 2018 compared to 26 in 2017. The number of deaths increased from 15 in 2017 to 18 in 2018.

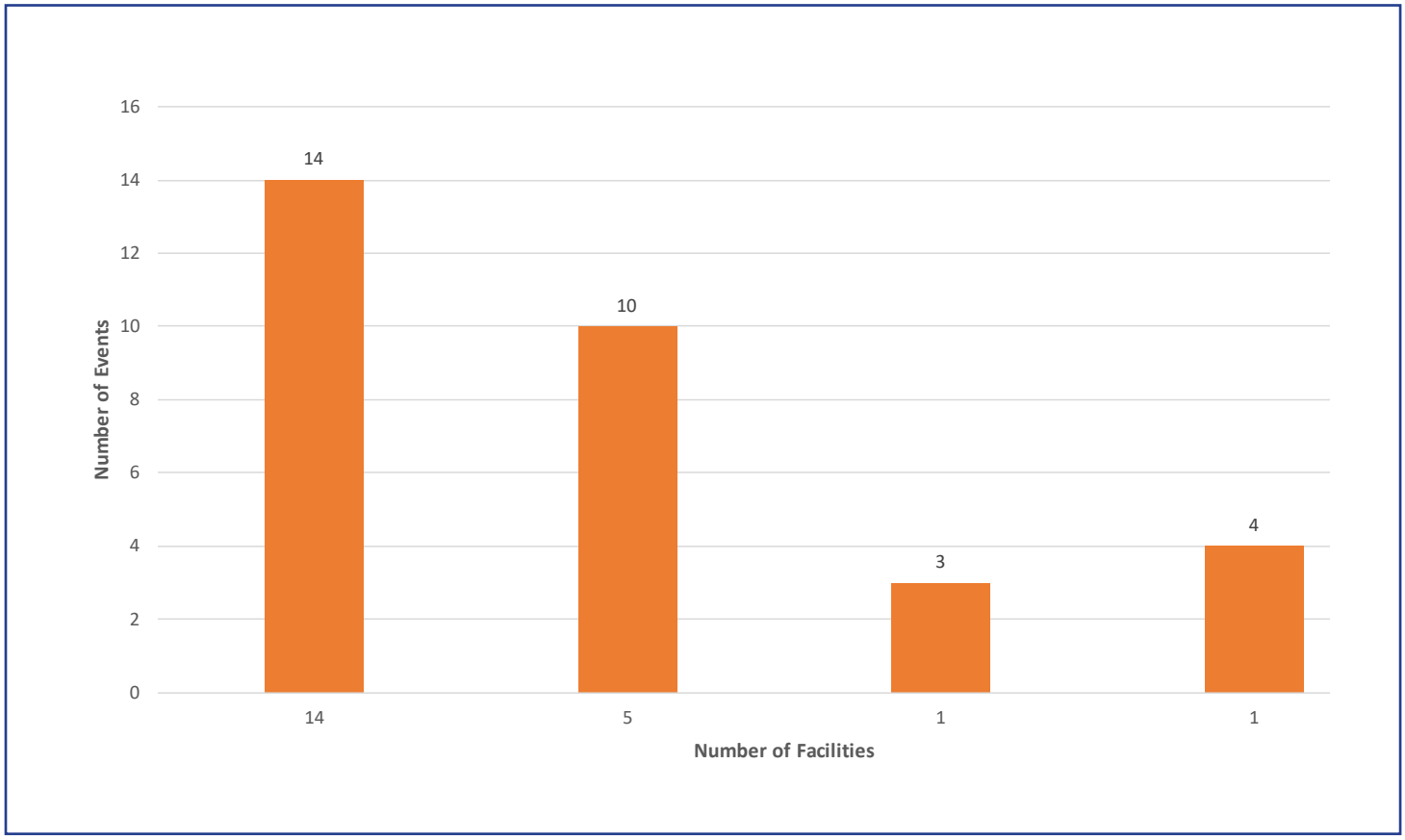
Based on the American Society of Anesthesiology (ASA) classification, the patients fell into the following classifications: ASA Class l: 6 (19.3%), ASA Class ll: 10 (32.3%), ASA Class lll: 14 (45.2%), and ASA Class lV: 1 (3.2%). See chart below.

Figure 4: ASA Classification



The 31 events were reported as follows by facilities:

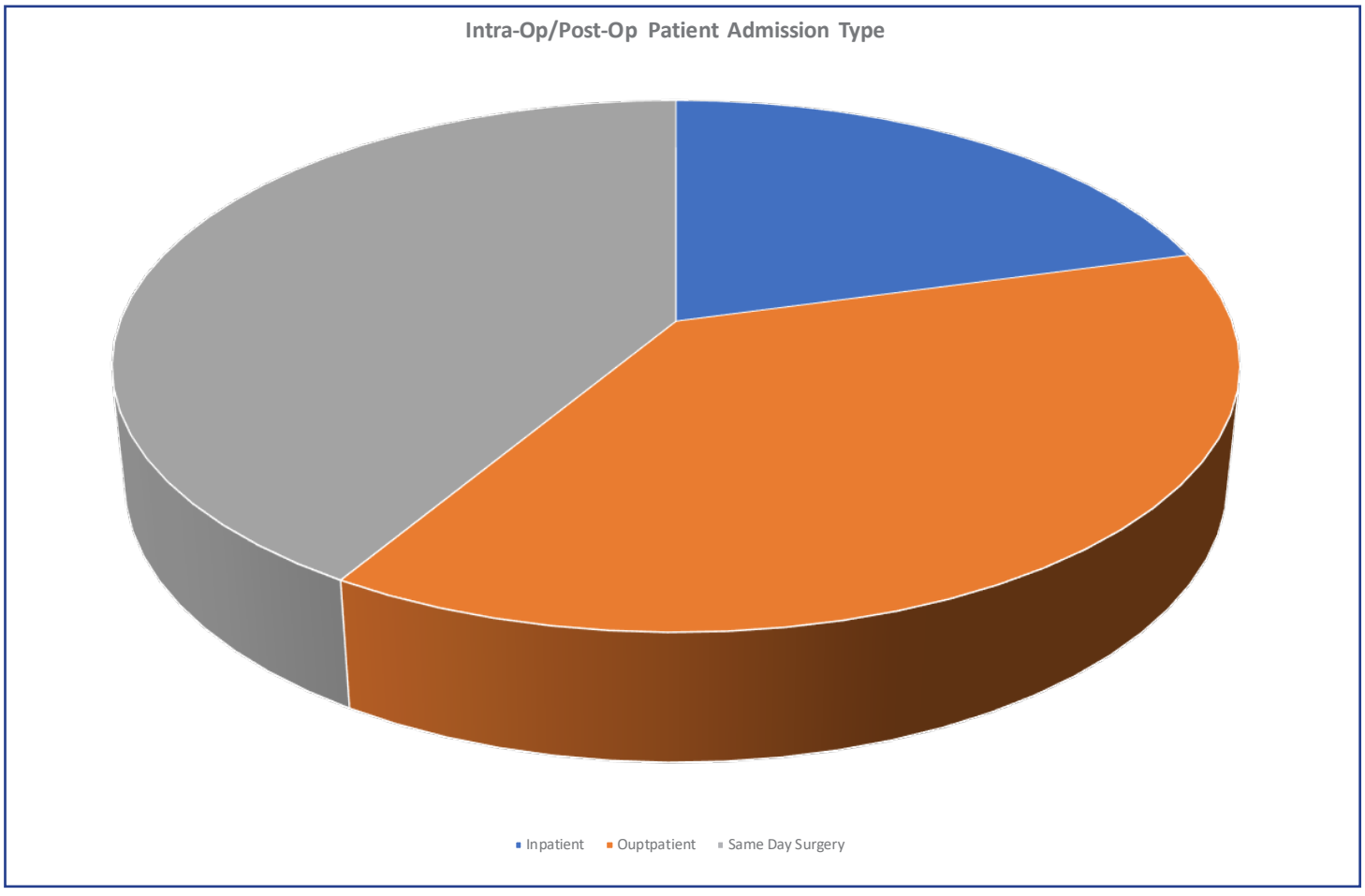
Figure 5: Number of Facilities Reporting Intra Op/Post-Op Events



Events reported for this event type 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.

The events occurred to the following types of patients as shown in the chart below:

Figure 6: Patient Admission Type



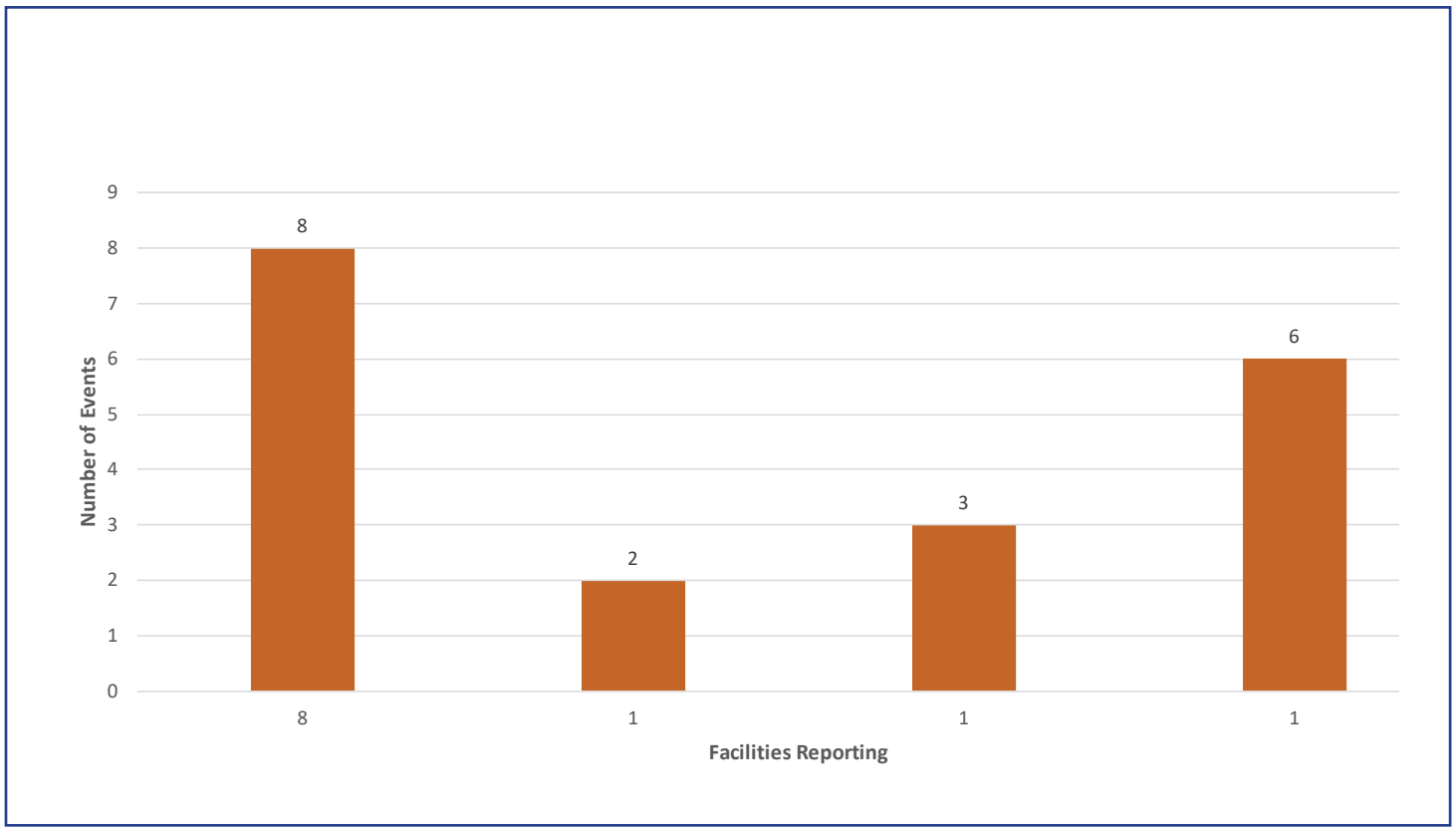
3. Surgery "Other" Events

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 19 in 2018 compared to 16 in 2017.

Eleven facilities reported 19 events as shown in the table below:

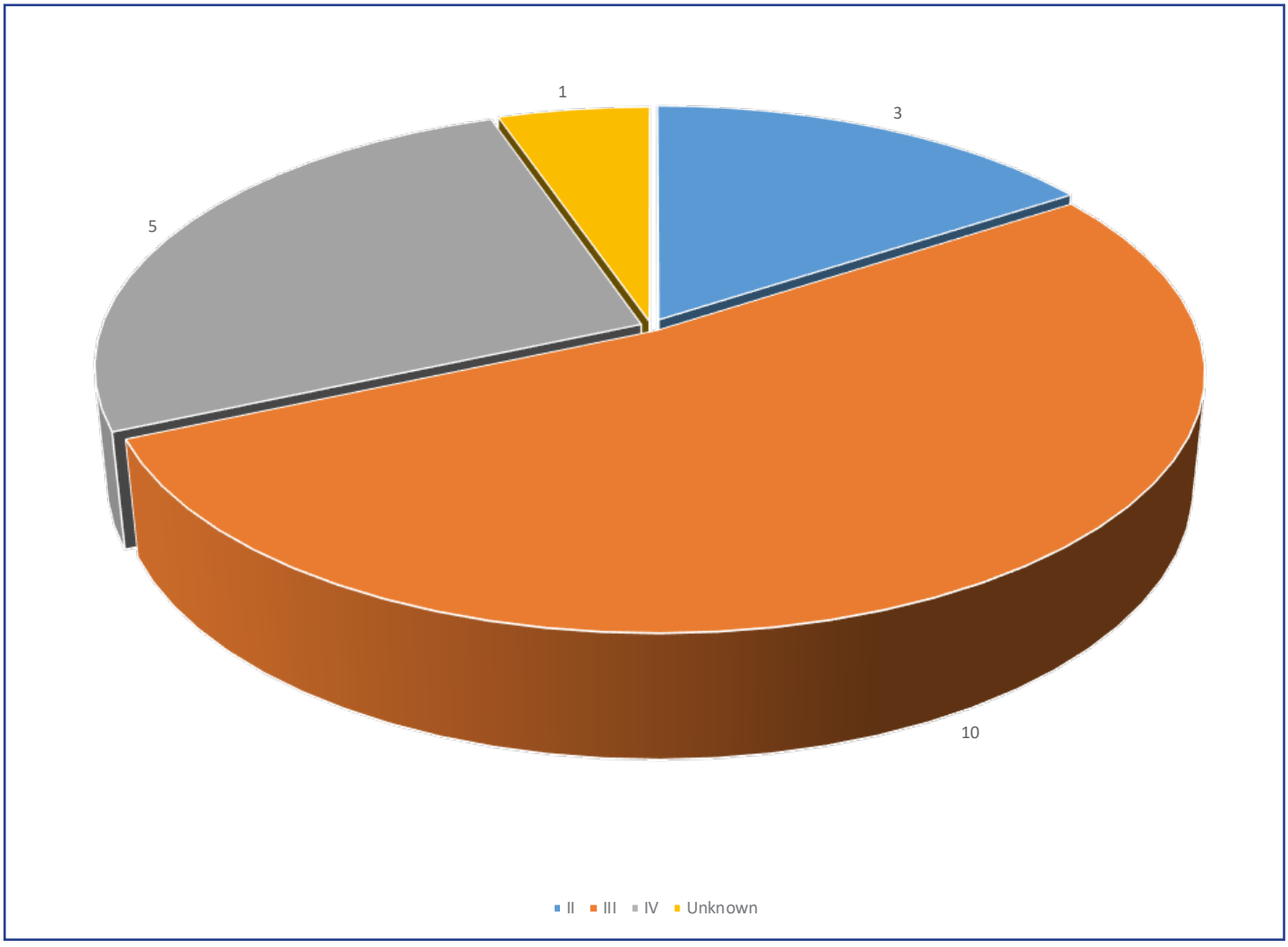
Figure 7: Surgery "Other" Facilities Reporting



Of the 19 events submitted, ten of the patients were designated as ASA Class lll (52.6%), five additional patients were designated as ASA Class IV (26.3%) and three as ASA Class II (15.8%). The remaining event was classified as unknown.

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

Figure 8: Surgery "Other" ASA Classifications



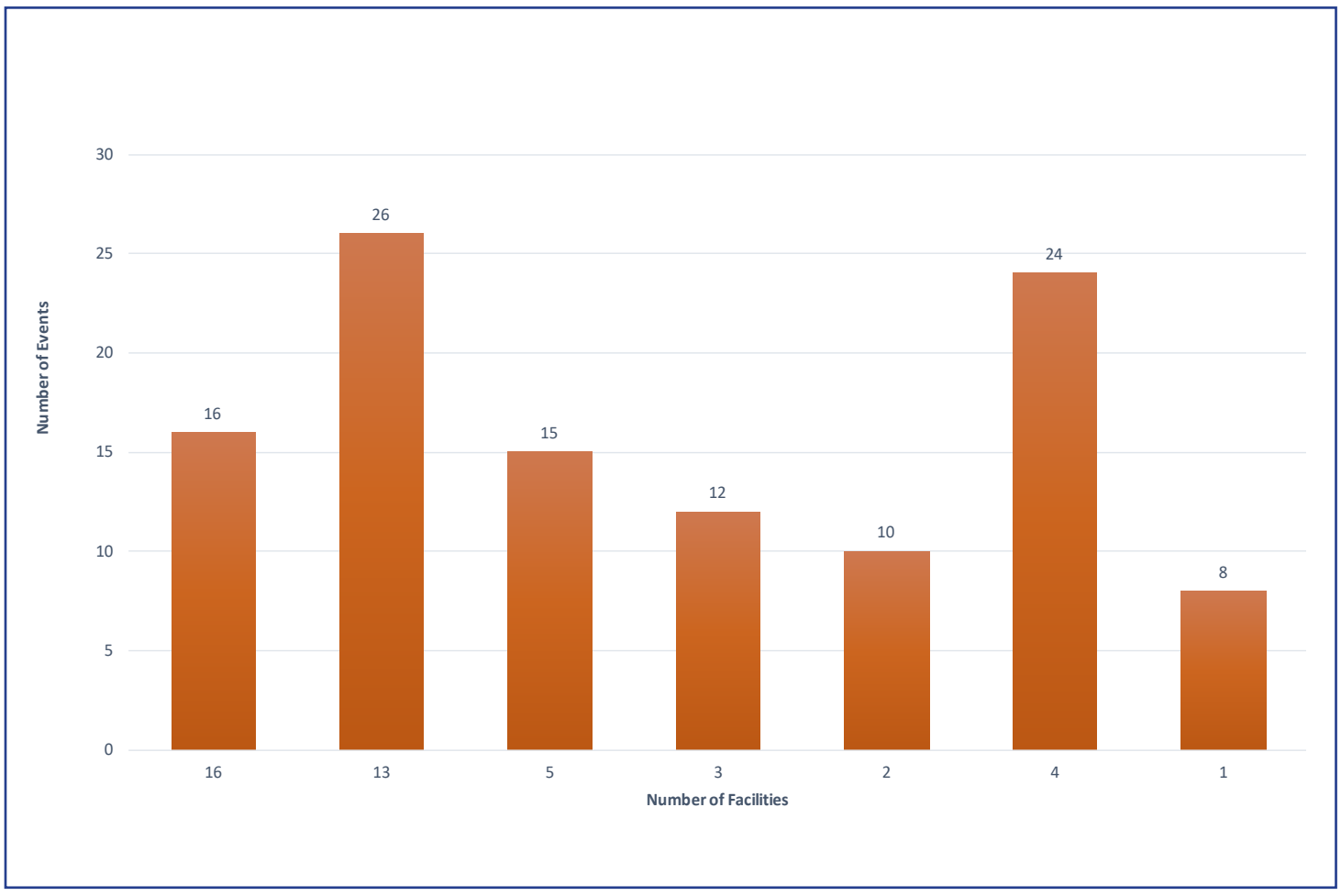
4. Fall Events

Falls continue to be the most frequently reported event submitted to the Patient Safety Reporting System. The number of reported falls in 2018 was 111 compared to 138 in 2017.

There were seven reported deaths from these events, compared to 10 in 2017.

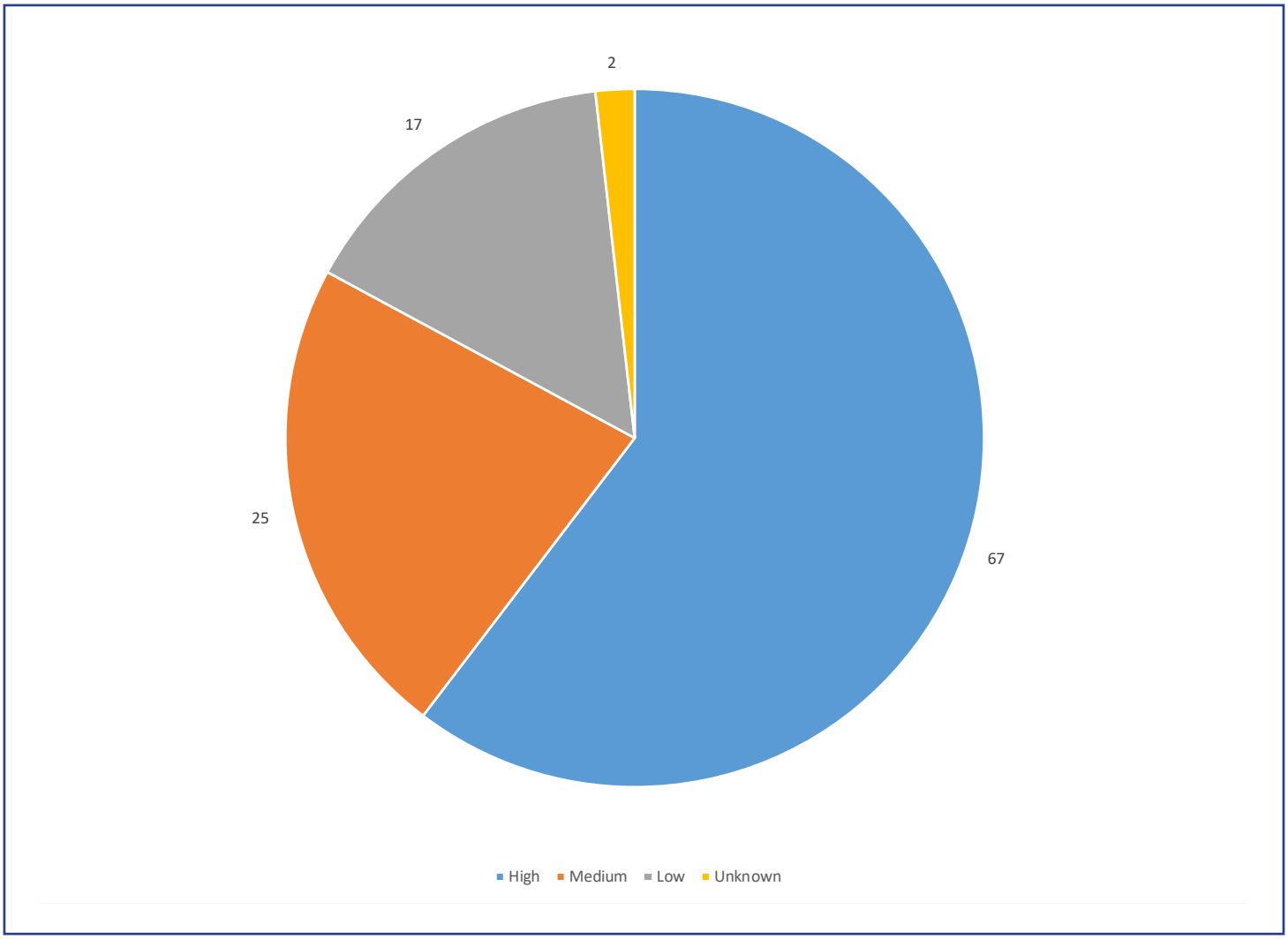
A total of 44 hospitals submitted 111 fall events as follows:

Figure 9: Number of Facilities Reporting Fall Events



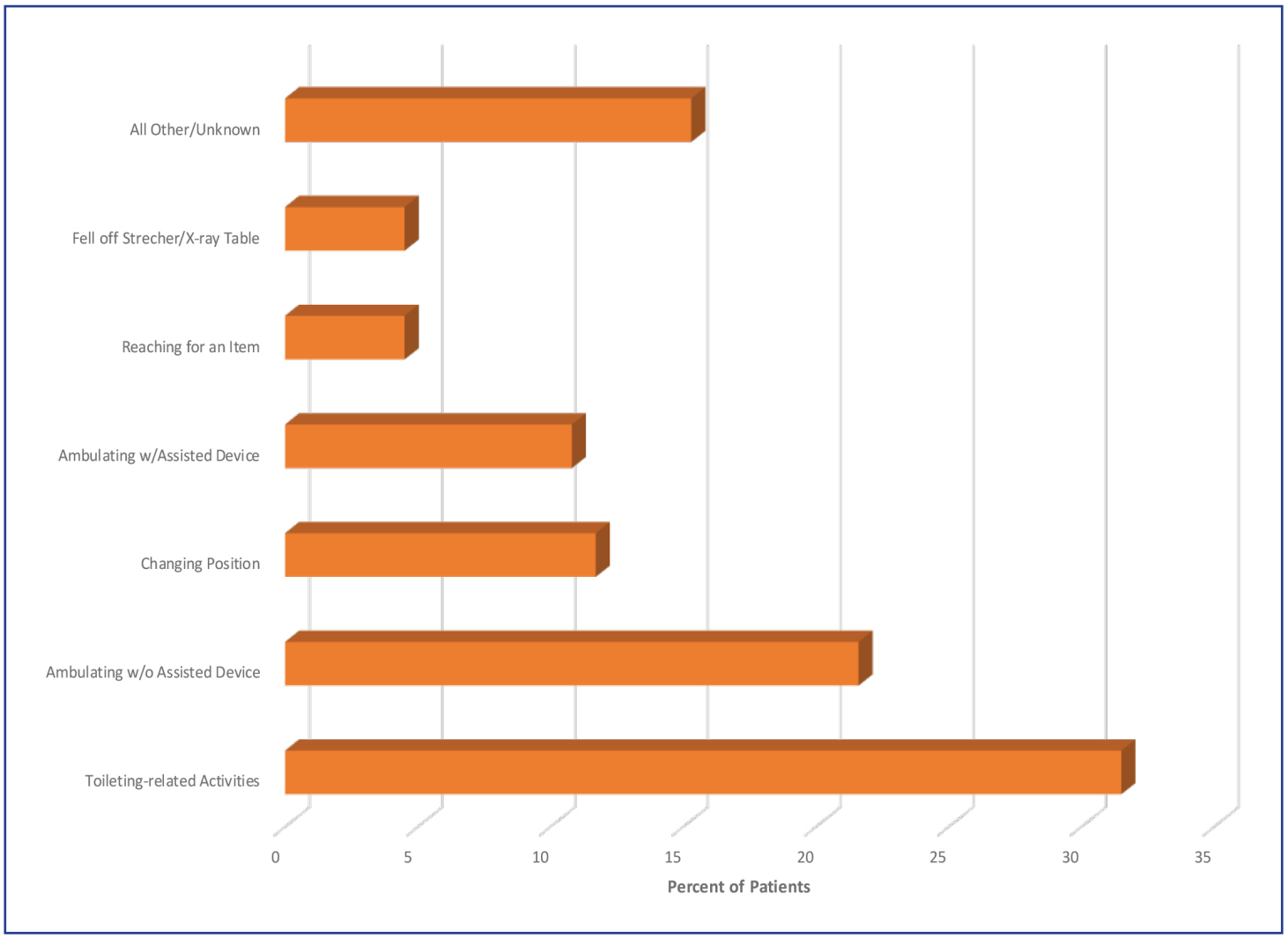
Prior to the fall, 67 patients (60.3 %) were known to be at high risk; 25 (22.5 %) were at medium risk; and 17 or (15.3 %) were considered to be at low risk for falls.

Figure 10: Fall Risk Categories



The chart below shows the various activities the patients were engaged in prior to the fall:

Figure 11: Activities Prior to Fall

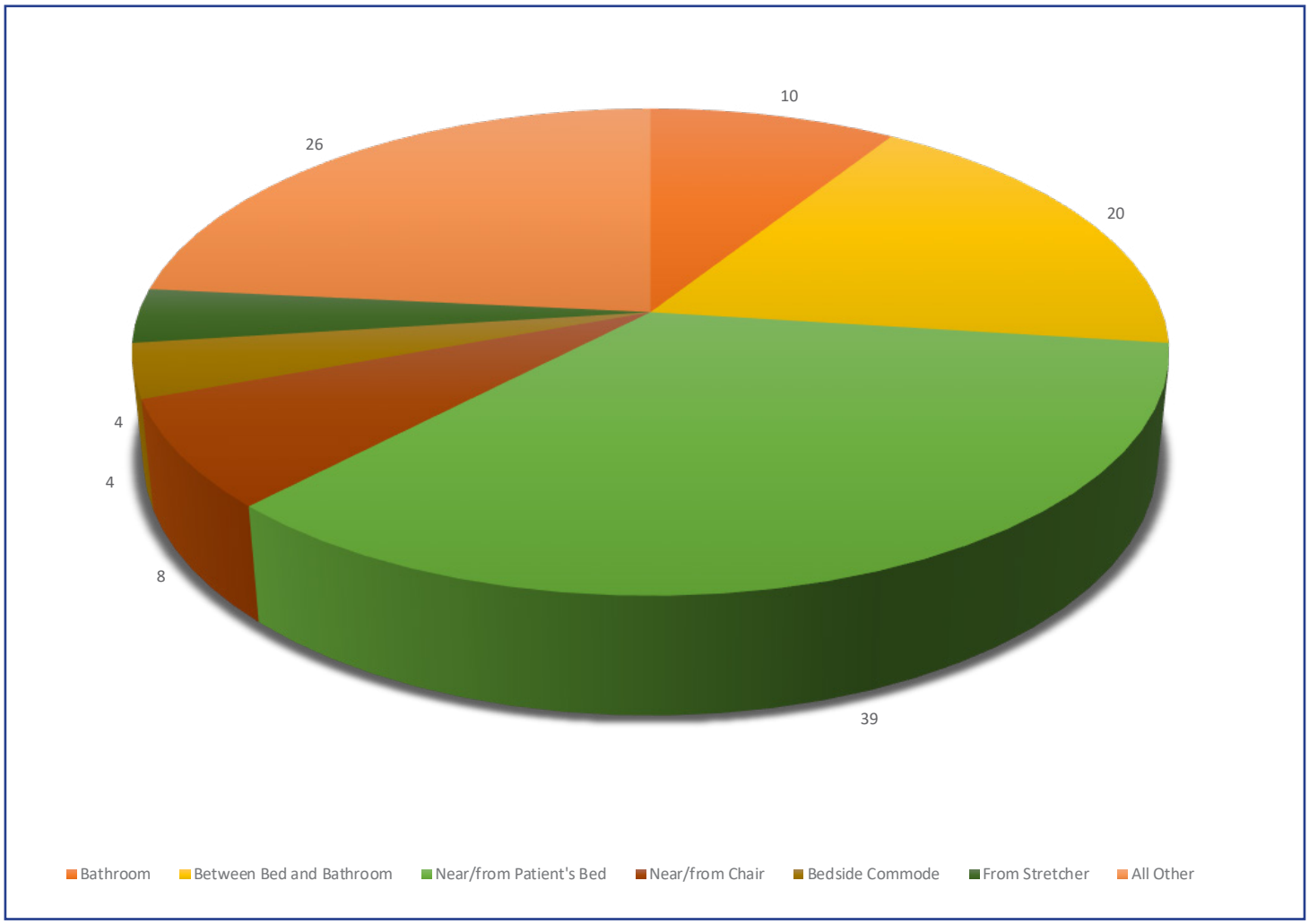


In the past, a fall risk screening tool was used to assess the patient's risk prior to the fall. The most prevalent screening tool used was the Morse Fall Risk Assessment (53, 47.7 %). The next mostly used tool was the Johns Hopkins Fall Risk Assessment Tool (34, 30.6 %), followed by the Hendrich/ Hendrich II Fall Risk Assessment (9, 8.1 %). Fifteen patients were assessed by using "Other" risk assessment tools (15, 13.5 %).

More than one-half of the patients (64, 57.6 %) were observed on patient rounds less than 30 minutes prior to the fall and another 32 (28.8%) were seen less than 1 hour prior to the fall. For eight of the events (7.2 %), the last patient rounds occurred less than 2 hours prior. There were four events for which the last time rounds was "unknown".

Similar to 2017, a majority of the falls occurred in the locations shown in the chart below.

Figure 12: Percent of Patient Fall Locations



D. Most Frequently Reported Event Types

As shown in Table 7 below, the highest total number of events submitted in 2018 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 events were the most frequently reported and accounted for 91.1 percent of all events reported in 2018.

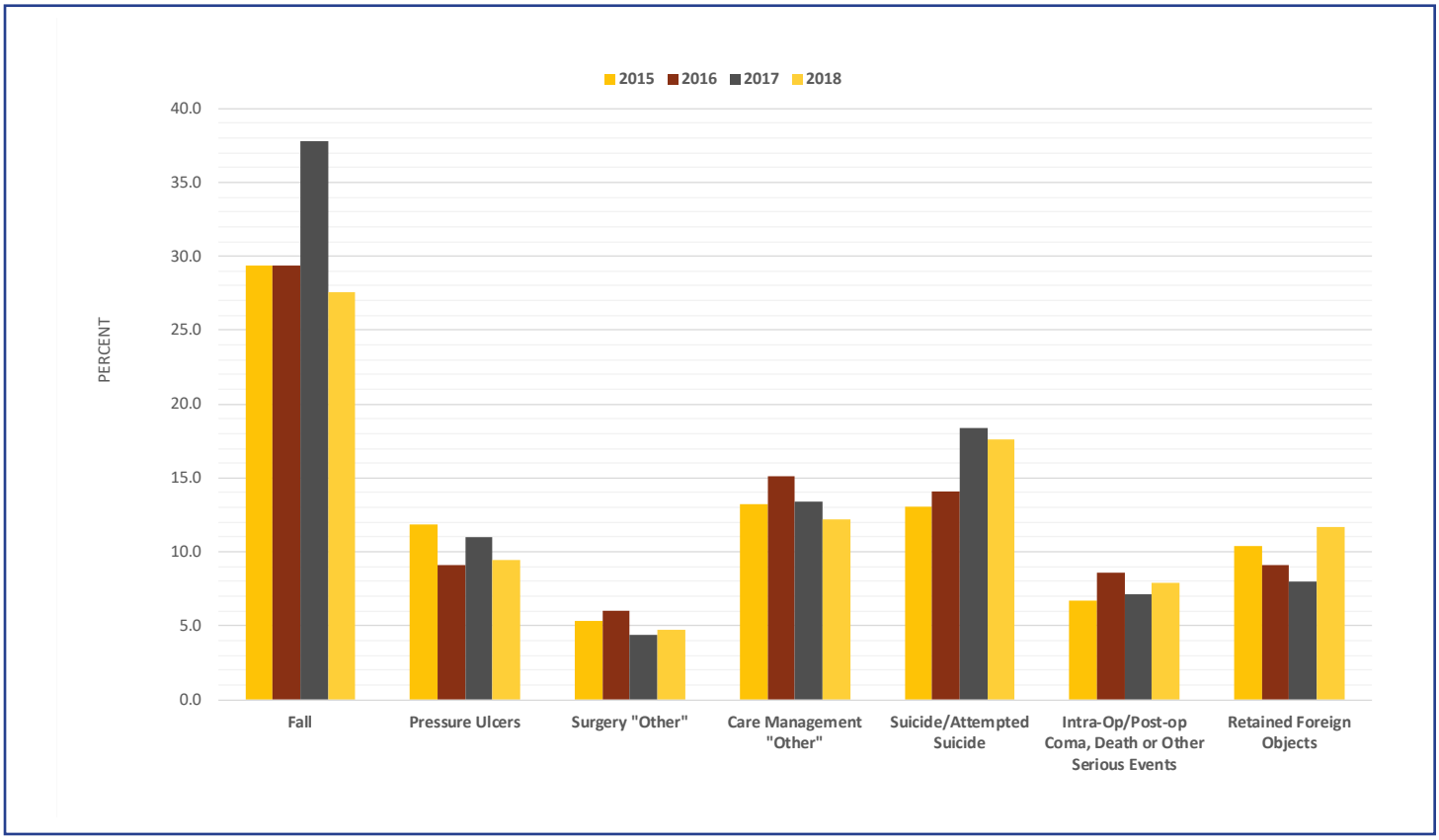
Figure 13 shows the reporting trends for these event types from 2015 to 2018.

Table 7: General Acute Care Hospitals: Most Frequently Reported Event Types (2018)

Event Type	Number of Reportable Events	Percent of Events[a]
Fall	111	27.5
Suicide/Attempted Suicide	71	17.6
Care Management "Other"	49	12.2
Retained Foreign Object	47	11.7
Pressure Ulcer	38	9.4
Intra-Op/Post-Op Coma, Death or Other Serious Adverse Events	32	7.9
Surgery "Other"	19	4.7
All Other Events	36	8.9
Total	403	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."

Figure 13: Most Frequently Reported Event Types 2015-2018

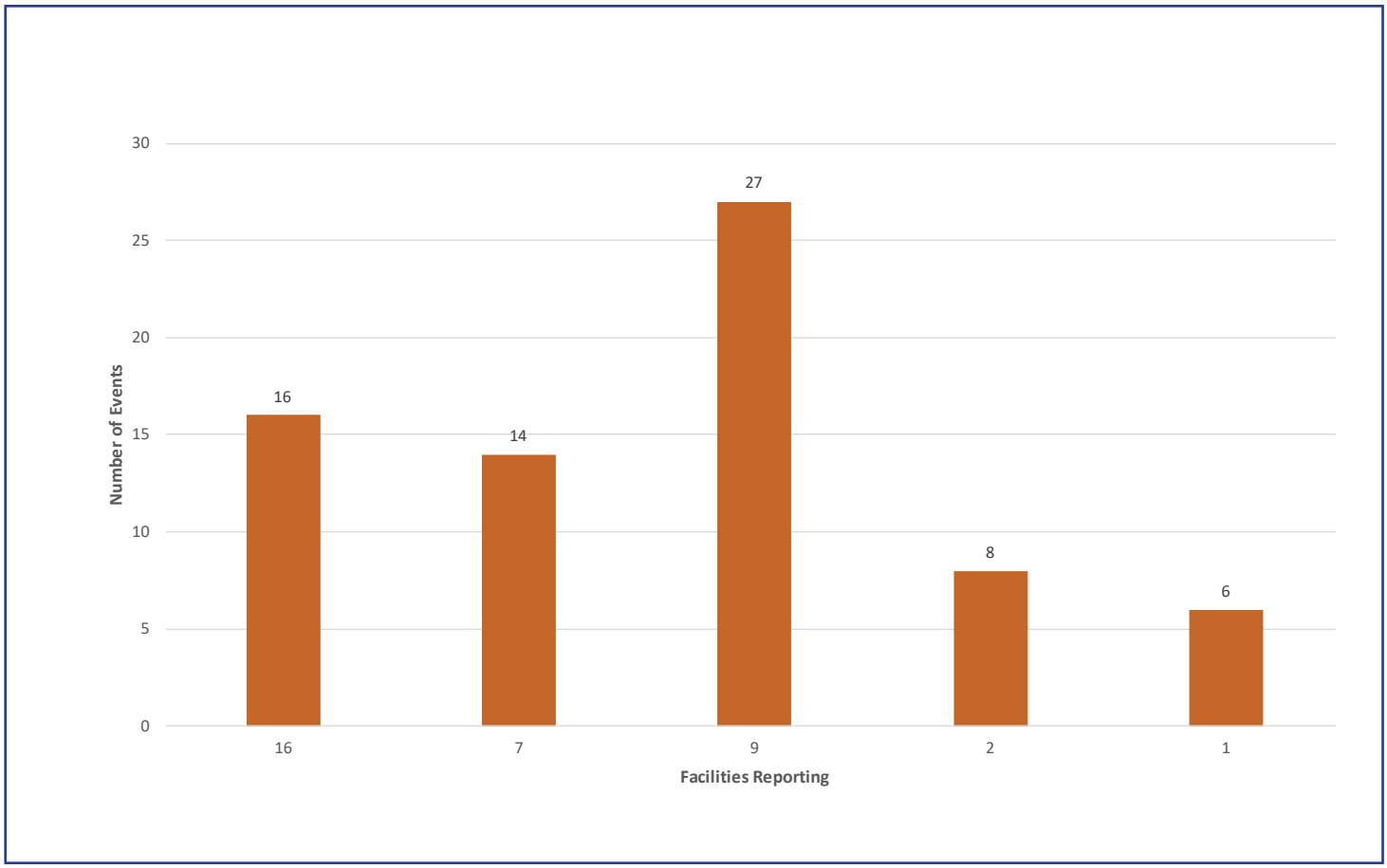


1. Suicide/Attempted Suicide Events

There were 71 reportable adverse events for this event type in 2018, an increase of four from 2017 (67).

The 71 suicides and attempted suicides were submitted by 35 hospitals as shown in the chart below.

Figure 14: Suicide/Attempted Suicide Events



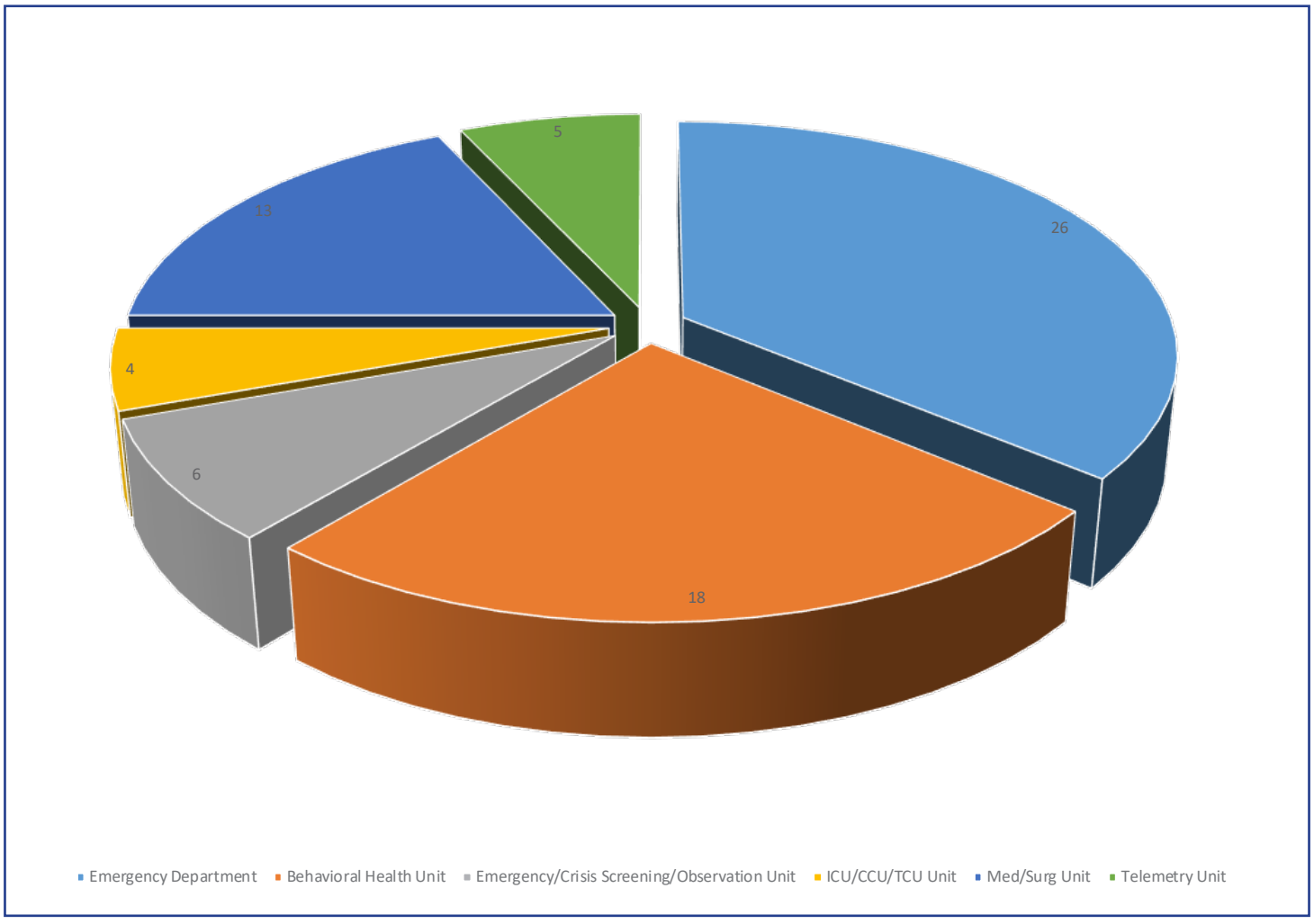
Of the 71 patients 44 or 62.0 percent were considered at risk and were seen by a psychiatrist. Over one-half (53.5%) of the patients had a prior suicide attempt. Sixty-three (88.7 %) of the patients saw a psychiatrist after the attempted suicide event.

At the time of the event, the following levels of observation were in place: 26 patients (36.6 %) were on 1:1; 15 (21.1%) were on 15-minute checks; 6 (8.5%) on line of sight; four on hourly visits, and the rest on other observation.

The events reported mostly occurred in the Emergency Department, the Behavioral Health Unit, the Emergency Crisis Screening/Observation Unit, Telemetry unit and Med/Surg unit. The chart below shows the distribution.

There was no death in 2018.

Figure 15: Suicide/Attempted Suicide Event Locations



2. Pressure Ulcers

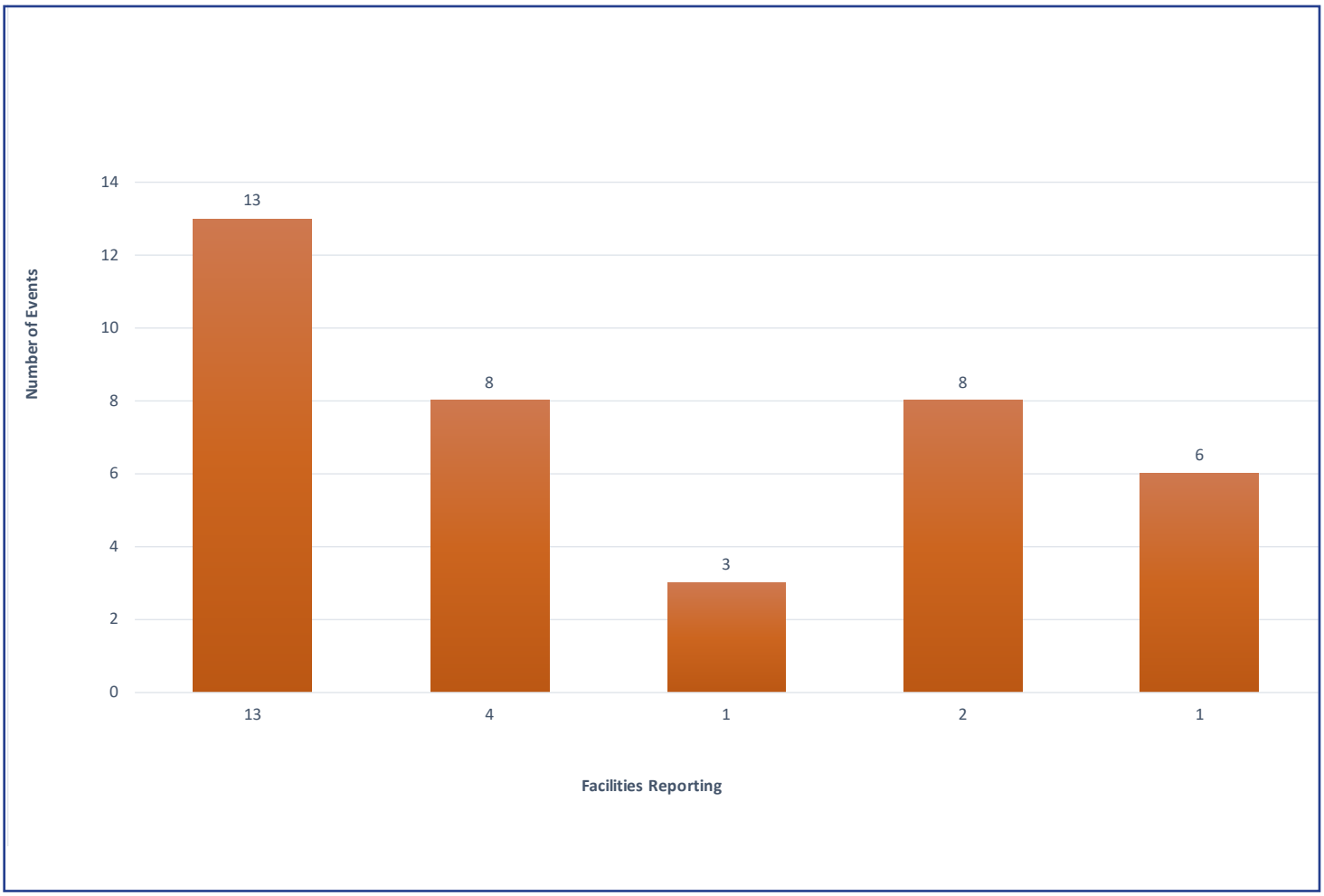
In 2018, there were 38 healthcare associated pressure ulcers compared to 40 in 2017, a decrease of two events.

The 38 pressure ulcer events were submitted by 21 hospitals. The table below shows the submission categories.

Nearly two-thirds (28) of the ulcers reported were located in the sacrum, two were on the buttocks and the rest were classified as "other".

Of the 38 events, 28 or 73.7 percent were Stage I and the rest Stage II.

Figure 16: Number of Facilities Reporting Pressure Ulcer Events

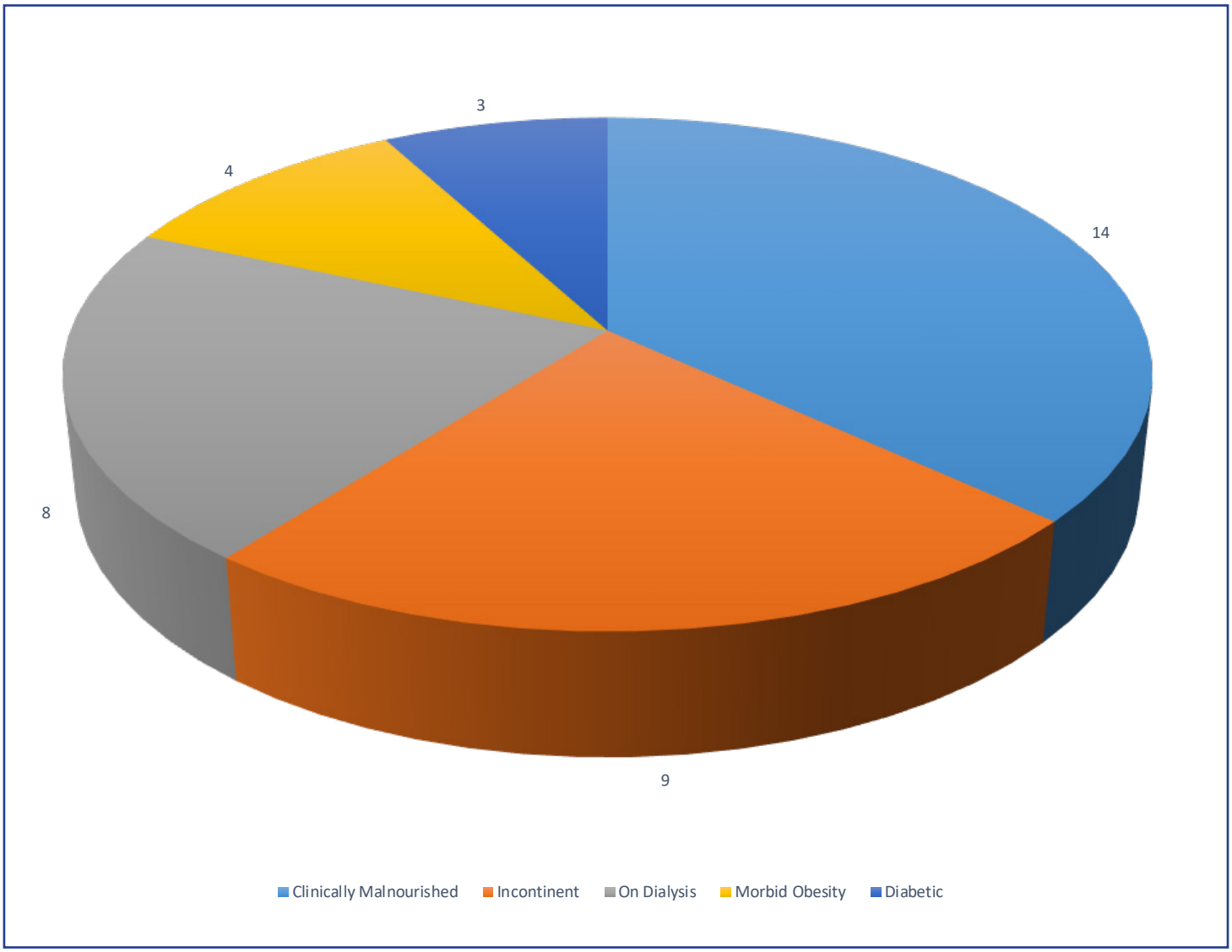


2a. Pressure Ulcer Patient Characteristics:

Over one-third of the patients (14 out of 38) who had pressure ulcer were diagnosed as being clinically malnourished. Nine of the patients were classified as incontinent, experienced heart failure as well as various neurological /neuromuscular conditions.

Eight (21.1%) of the patients received dialysis while four (10.5%0, were categorized as being morbidly obese and with a body mass index (BMI) of 40 or greater. The remaining three (7.9%) were diabetic with kidney and respiratory failures.

Figure 17: Patient Characteristics Categories



3. Retained Foreign Objects

There were 46 retained foreign object (RFO) events submitted in 2018 compared to 29 in 2017.

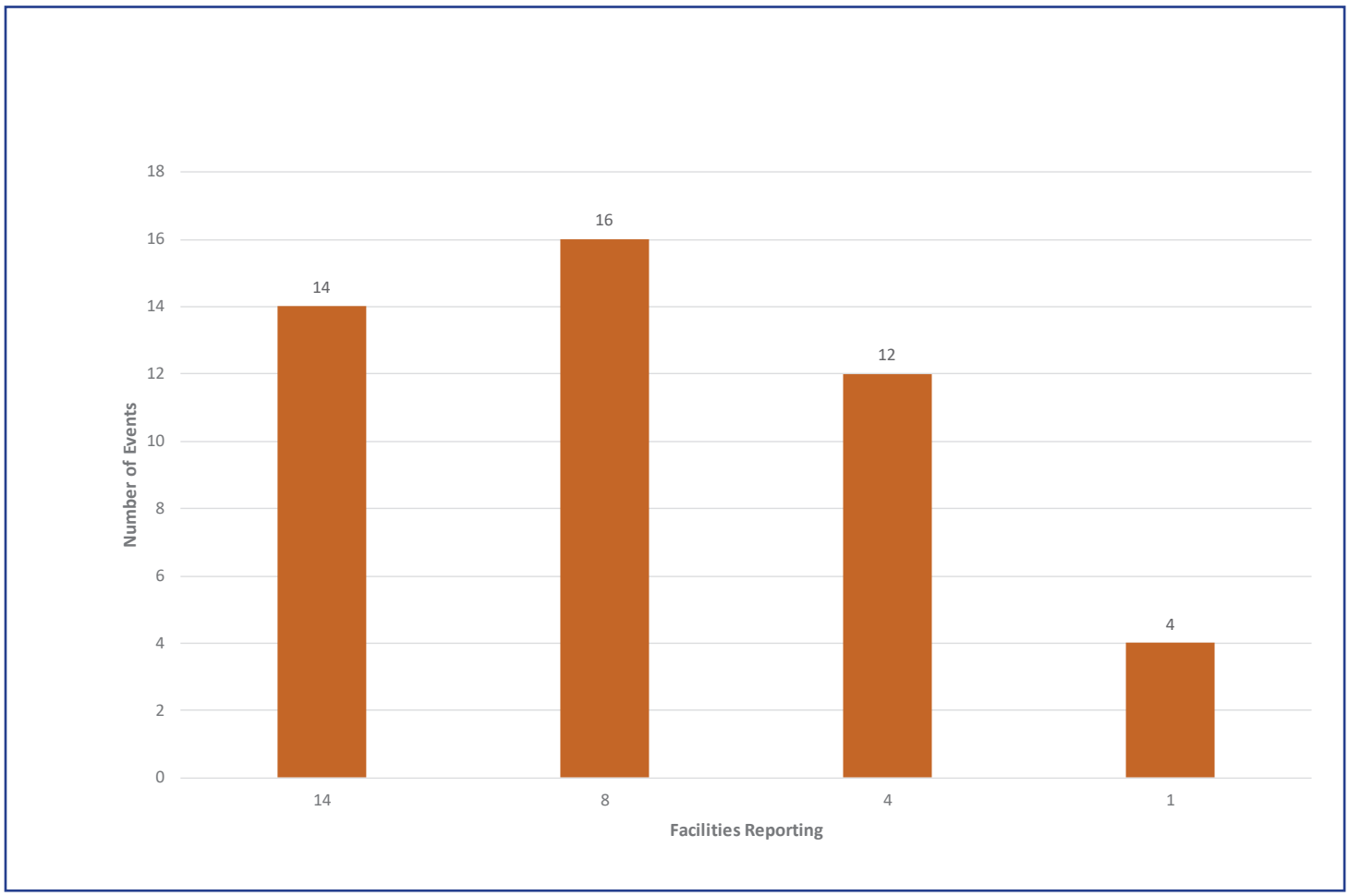
This represents an increase of 58.6 percent from 2017. There was one death associated with these events.

Figure 18 shows the number of facilities reporting the events.

Of the 46 RFOs, 12 were sponges/gauze, two were needles, one lap pad, and the rest were "other". See chart below.

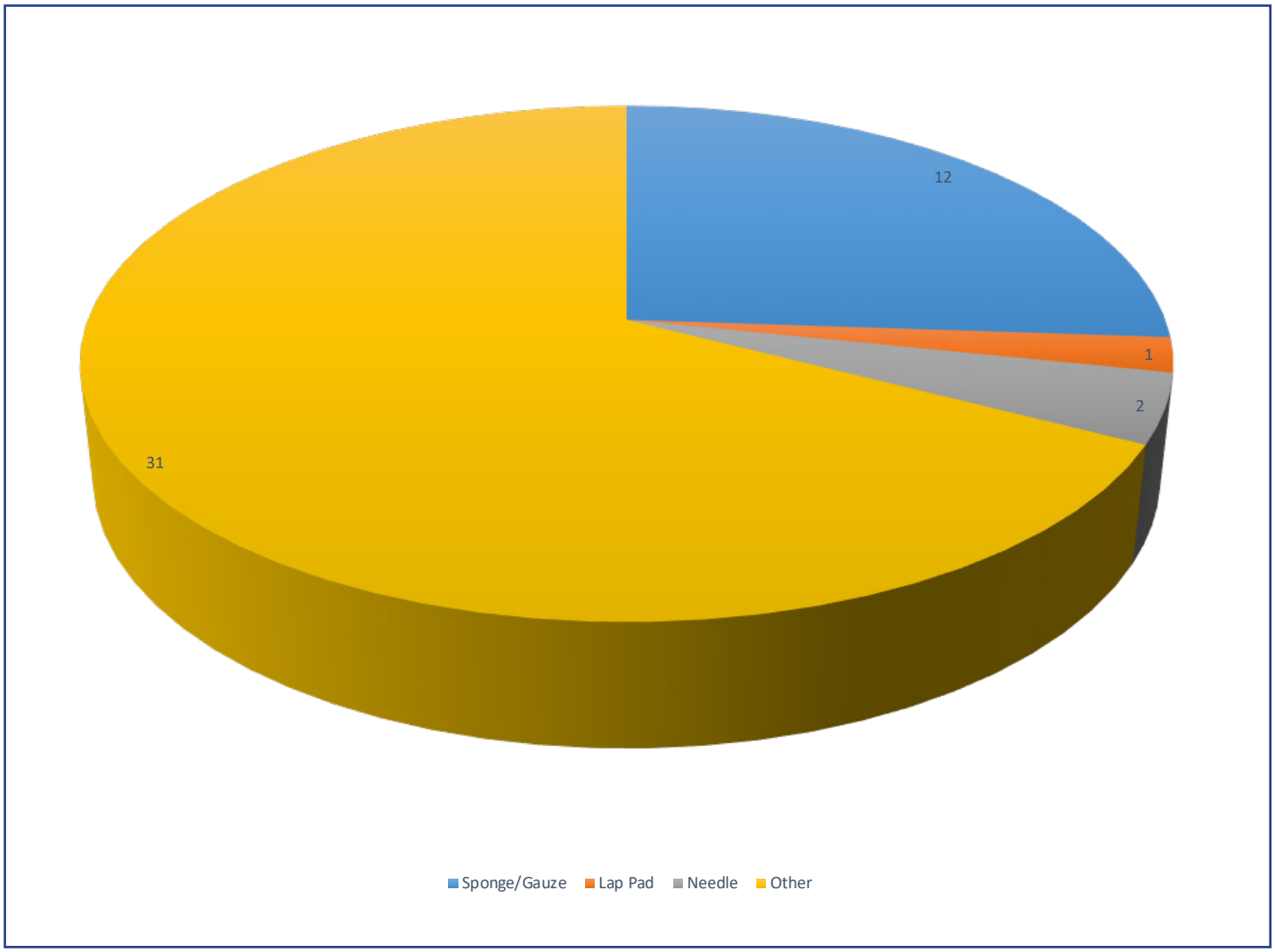
Examples of other RFOs included a surgical towel, vaginal prep stick, umbilical tape, hemovac drain, gauze inside of a glove, piece of a cardiac stent, and piece of a drain.

Figure 18: Retained Foreign Objects Events



Over two-thirds (31, 67.4%) of the 46 patients required a second surgery to remove the object.

Figure 19: Retained Foreign Object Items



E. Major Root Causes for All Events

In 2018, the most frequent root causes of adverse events reported to PSRS were care planning process (46.7%), communication among staff (24.1%), patient observation procedures (10.7%), "other" (17.4%), orientation and training of staff (14.9%), and physical assessment process (14.1%).

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	188	46.7
Communication Among Staff Members	97	24.1
"Other"	70	17.4
Orientation and Training of Staff	60	14.9
Physical Assessment Process	57	14.1
Patient Observation Procedures	43	10.7

a: Data drawn from 403 RCAs submitted for 2018 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.)*	259	64.3
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	242	60.0
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	209	51.9
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	121	30.0
Staff Factors *(May include training, experience and inadequate staffing levels.)*	93	23.1
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	92	22.8
Equipment *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	63	15.6

a: Data drawn from 403 RCAs submitted for 2018 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 75 deaths which represent 18.6% of the 403 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	187	46.4
Additional Lab Testing or Diagnostic Imaging	183	45.4
Increased Length of Stay	177	43.9
Transfer to more Intensive Level of Care	106	26.3
Disability-Physical or Mental impairment	99	24.6
Major Surgery	88	21.8
Death	75	18.6

a: Data drawn from 403 RCAs submitted for 2018 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 65 reportable events submitted from specialty hospitals in 2018 compared to 47 in 2017.

Eleven comprehensive rehabilitation hospitals submitted 26 reportable events. This was an increase of five from 2017. The average event reports per this facility type was 2.4. There was one death associated with this facility type.

Seven psychiatric hospitals submitted 25 reportable events in 2018; an average of 3.6 per facility. There were three deaths associated with this facility type.

Five special hospitals submitted 14 reportable events averaging approximately 2.8 reports per facility. There were two deaths associated with this facility type.

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 type.

Table 11: Specialty Hospitals: Overall Reporting Pattern, 2018[a]

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	26	2.4	1
Psychiatric	11	7	25	3.6	3
Special Hospitals	14	5	14	2.8	2
Total	39	23	65	2.8	6

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

A. Comprehensive Rehabilitation Hospitals

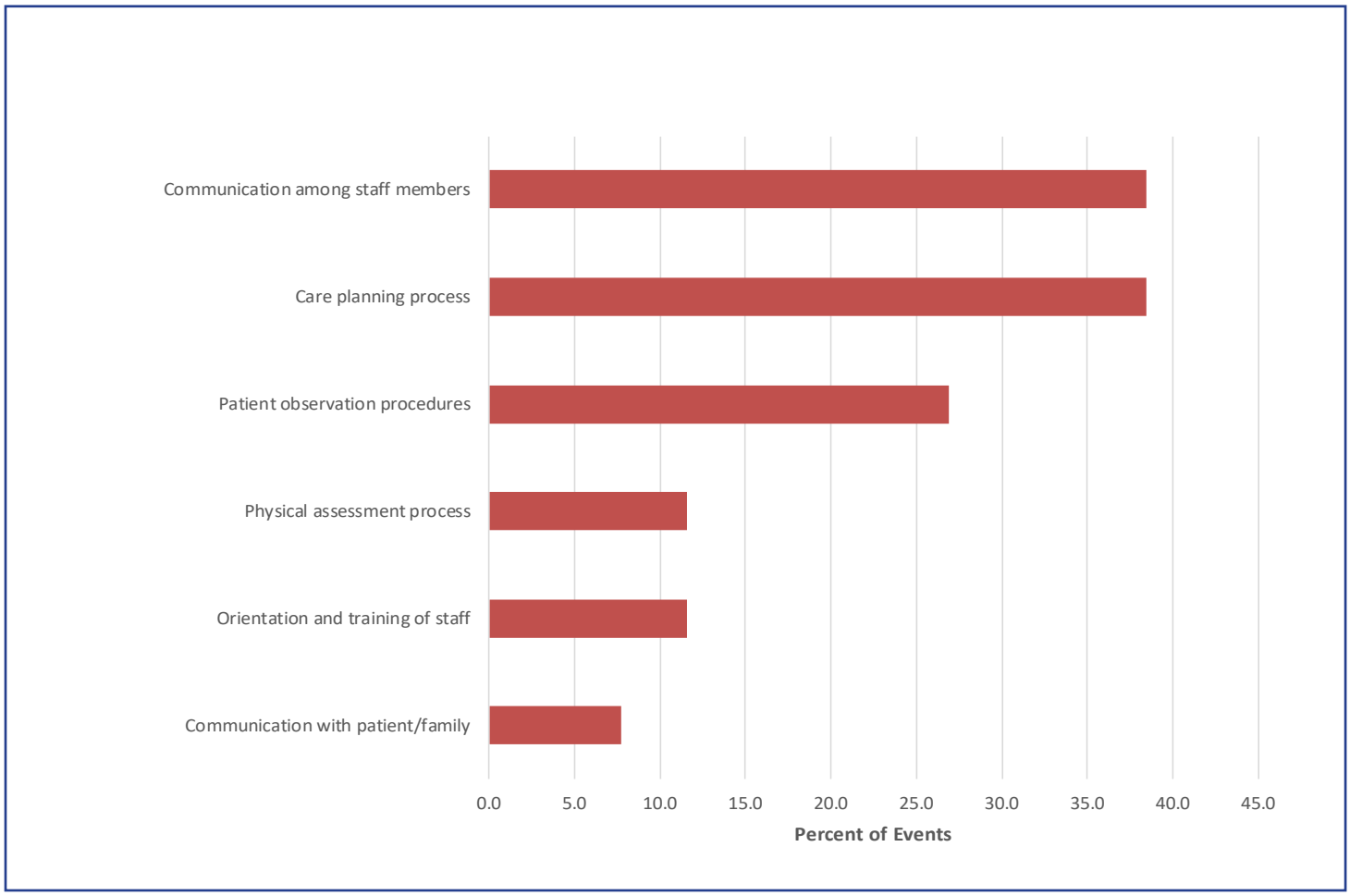
Of the 14 comprehensive rehabilitation hospitals in the state, 11 reported at least one event in 2018. There were 26 reportable events and one death from these facilities. The death was related to a restraint.

Most frequently reported event types were 18 falls, five pressure ulcers, two care management "other" events and one restraint. These events are similar to previous years' reporting.

1. Root Causes for All Events

Figure 20 shows the major causes for the events reported by this facility type.

Figure 20: Comprehensive Rehabilitation Hospitals: Root Causes for All Events[a]



a: Data drawn from 26 RCAs submitted for 2018 events.

2. Contributing Factors to All Events

In 2018, the most frequently reported contributing factors were task factors (61.5%), team factors (57.7%), patient characteristics (53.8%), staff factors and equipment factors each at 26.9 percent.

Table 12 shows the results.

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

Contributing Factors	Number of Events	Percent of Events
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	16	61.5
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	15	57.7
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	14	53.8
Staff Factors *(May include training, experience and inadequate staffing levels.)*	7	26.9
Equipment *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	7	26.9

a: Data drawn from 26 RCAs submitted for 2018 events.

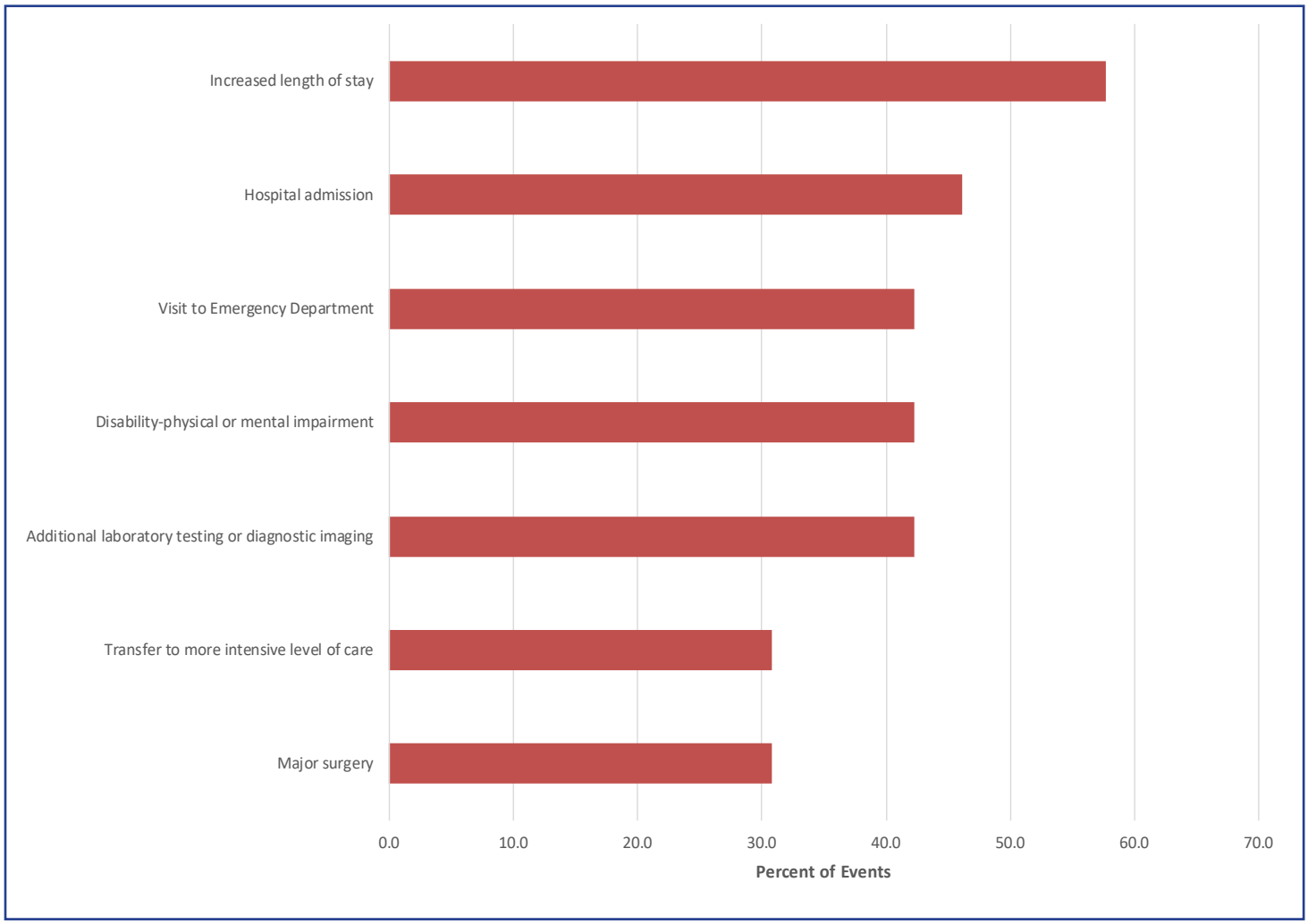
3. Impact of All Events

As a result of these adverse events, more than one-half (57.7%) of the patients experienced increased length of stay while others were admitted to a hospital (46.2%). Other impacts included additional laboratory testing or diagnostic imaging as well as a visit to the emergency room.

Figure 21 shows other impacts associated with adverse events from comprehensive rehabilitation hospitals.

There was one death reported from this facility type and was associated with restraint.

Figure 21: Comprehensive Rehabilitation Hospitals: Impact of All Events[a]



a: Data drawn from 26 RCAs submitted for 2018 events.

B. Psychiatric Hospitals

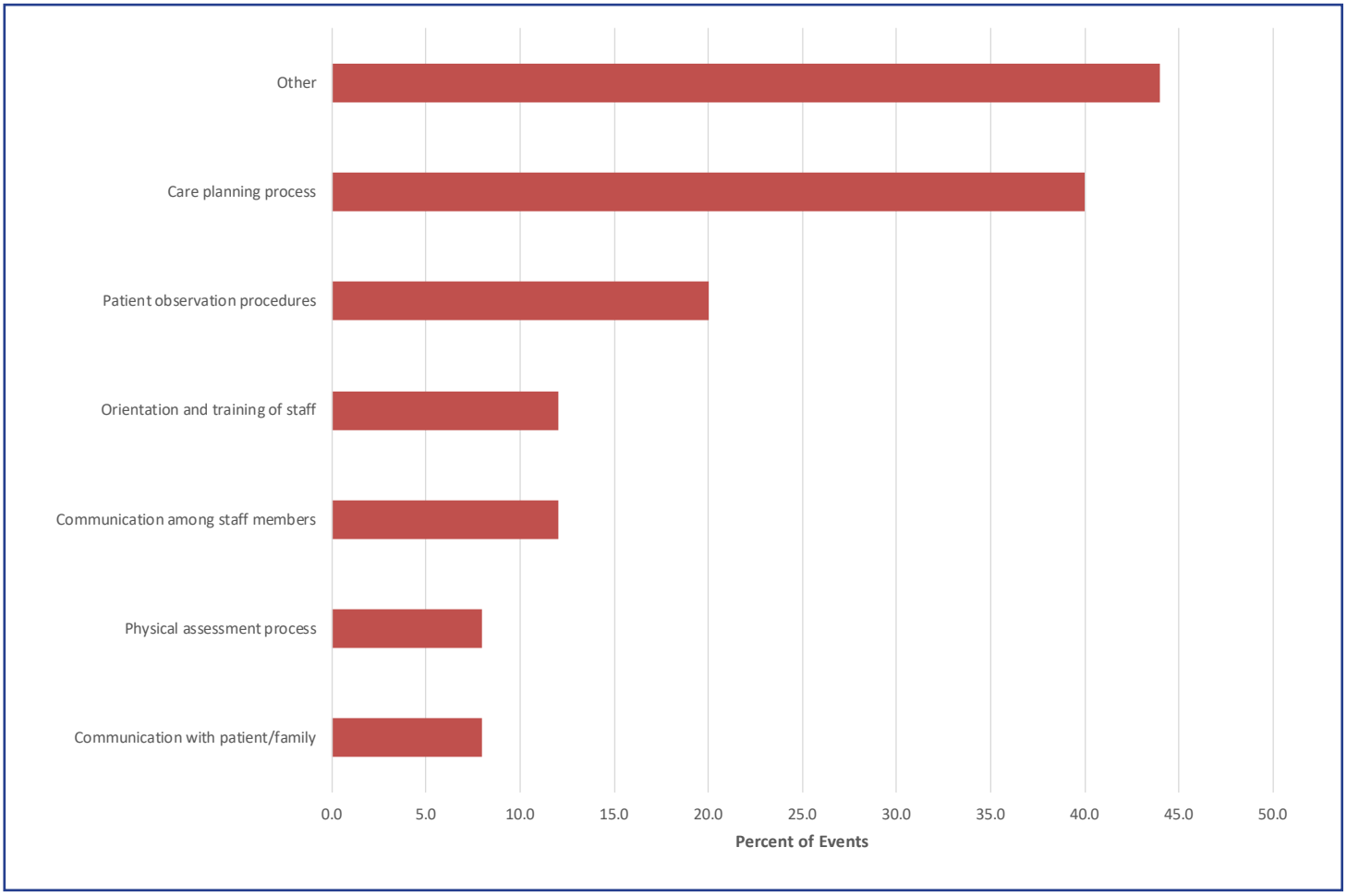
Seven out of 11 psychiatric hospitals reported at least one event during 2018. A total of 25 reportable events were submitted to the Patient Safety Reporting System. Of the 25 events reported, eighteen were falls, four were care management "other" events and one each for medication error, suicide/attempted suicide and protection "other".

The average submission by this facility type was 3.6. There were three reported deaths for this facility type and all were related to care management "other".

1. Root Causes for All Events

Figure 22 shows the most reported root causes for the events that occurred in Psychiatric hospitals.

Figure 22: Psychiatric Hospitals: Root Causes for All Events[a]



a: Data drawn from 25 RCAs submitted for 2018 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]

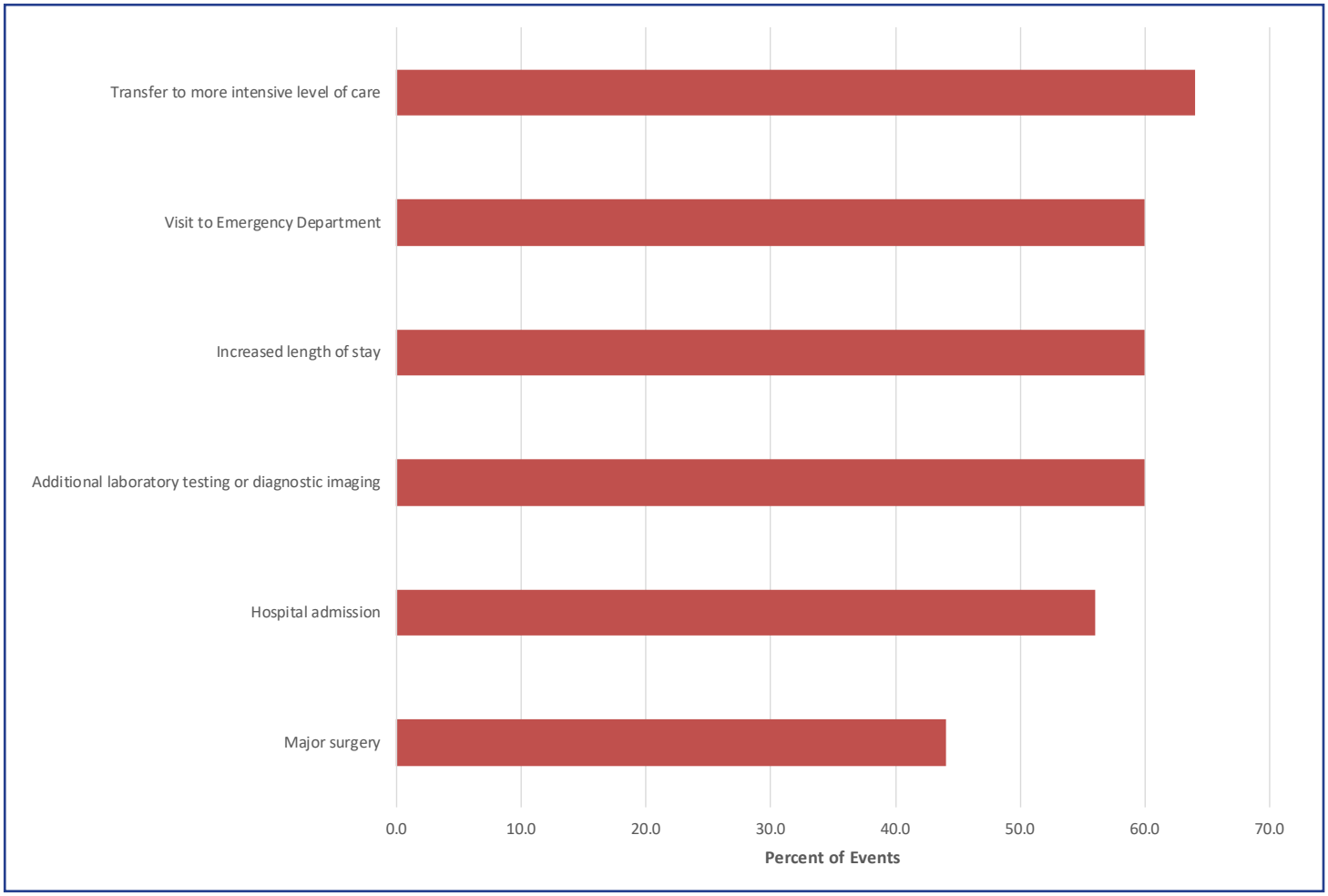
Contributing Factors	Number of Events	Percent of Events
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	18	72.0
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	11	44.0
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	10	40.0
Staff Factors *(May include training, experience and inadequate staffing levels)*	7	28.0
Other Factors *(May Includes factors not identified in the other categories.)*	6	24.0

a: Data drawn from 25 RCAs submitted for 2018 events.

3. Impact of All Events

Figure 23 shows the most frequently reported impact of the events. There were three deaths reported from the 25 reportable events and were attributed to Care Management "Other".

Figure 23: Psychiatric Hospitals: Impact of All Events[a]



a: Data drawn from 25 RCAs submitted for 2018 events.

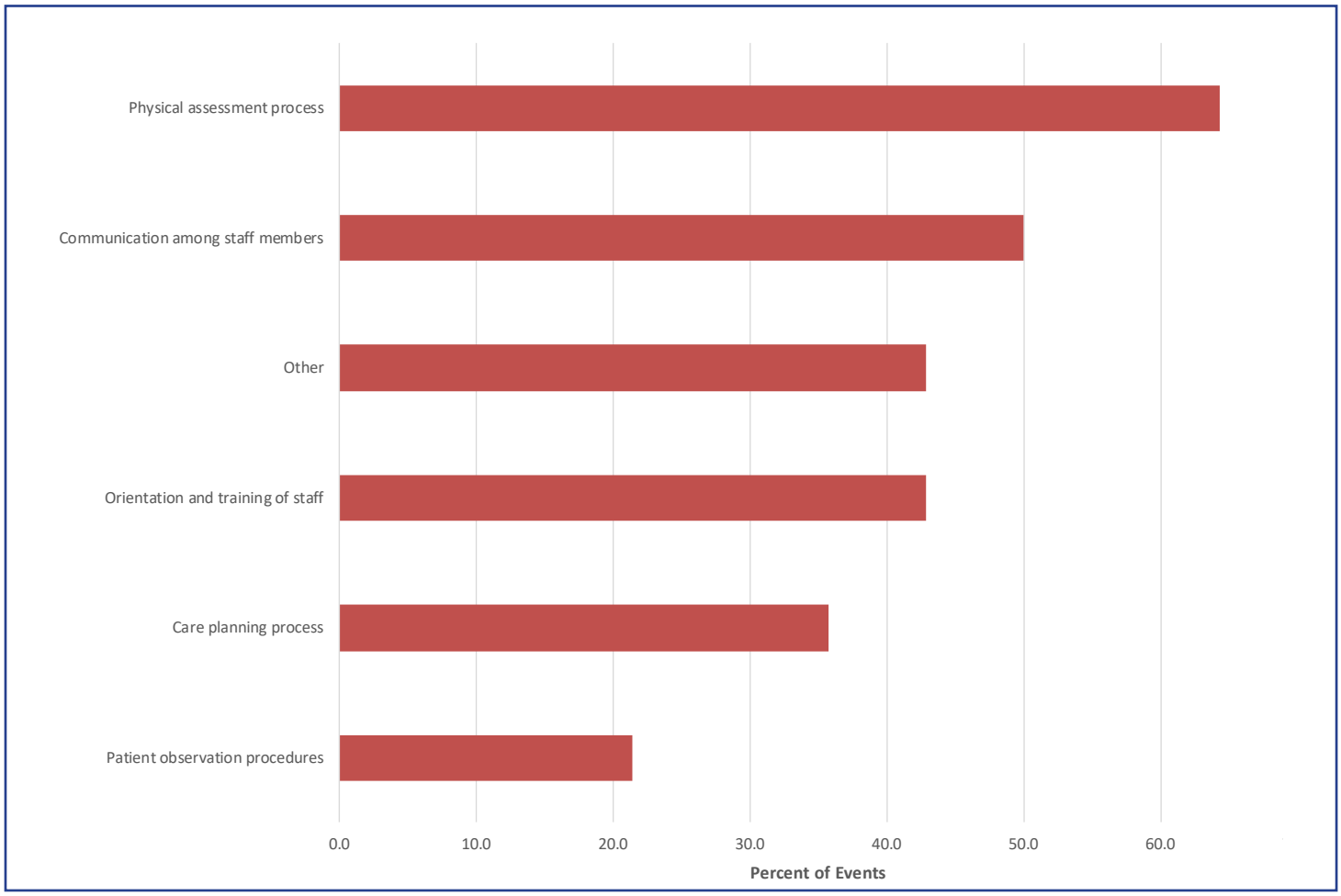
C. Special Hospitals

There were five submitted reportable events from special hospitals in 2018. This low reporting is consistent with prior years. There were two deaths reported for this facility type.

1. Root Causes for All Events

Figure 24 shows the most frequent root causes of events in this facility type.

Figure 24: Special Hospitals: Root Causes for All Events[a]



a: Data drawn from 14 RCAs submitted for 2018 events.

2. Contributing Factors to All Events

Table 14 shows the most frequent contributing factors to the events reported by special hospitals in 2018. The most frequently reported contributing factors were team factors (71.4%), patient characteristics (57.1%), task factors (57.1%), patient record documentation (57.1%) and staff factors (42.9%).

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

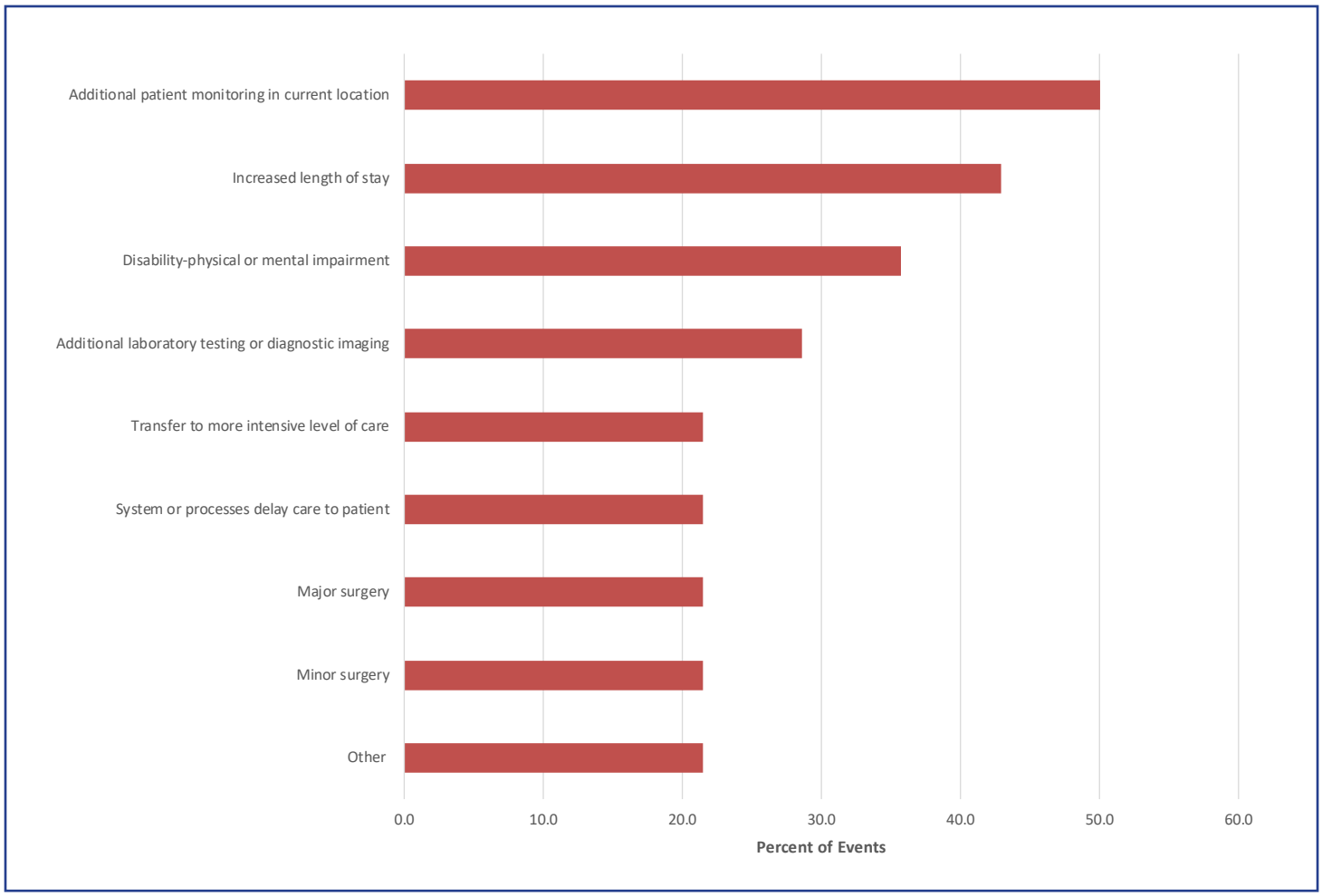
Contributing Factors	Number of Events	Percent of Events[a]
Team Factors *(May include factors which interfere with the care team working together, such as inadequate communication.)*	10	71.4
Patient Characteristics *(May include confusion, co-morbidities and the patient's choice to refuse care.)*	8	57.1
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	8	57.1
Patient Record Documentation *(May include missing or inaccurate information in the medical record.)*	8	57.1
Staff Factors *(May include training, experience and inadequate staffing levels.)*	6	42.9
Organization/Management *(May include unclear policies and a lack of support from leadership.)*	4	28.6
Medical Devices *(May include inappropriate use and malfunction of items such as stretchers, bed alarms and wheelchairs.)*	3	21.4

a: Data drawn from 14 RCAs submitted for 2018 events.

3. Impact of All Events

Figure 25 exhibits the most frequently identified impact from the reportable adverse events submitted by special hospitals.

Figure 25: Special Hospitals: Impact of All Events[a]



a: Data drawn from 14 RCAs submitted for 2018 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 218 ambulatory surgery centers in New Jersey, 89 facilities submitted events in 2018. A total of 287 events were submitted of which 163 were deemed reportable (56.8%).

There were six deaths related to intra-op or post-op coma, death or other serious preventable adverse events. The other additional death was associated with a Spinal event. The average number of events submission by this facility type was 2 in 2018.

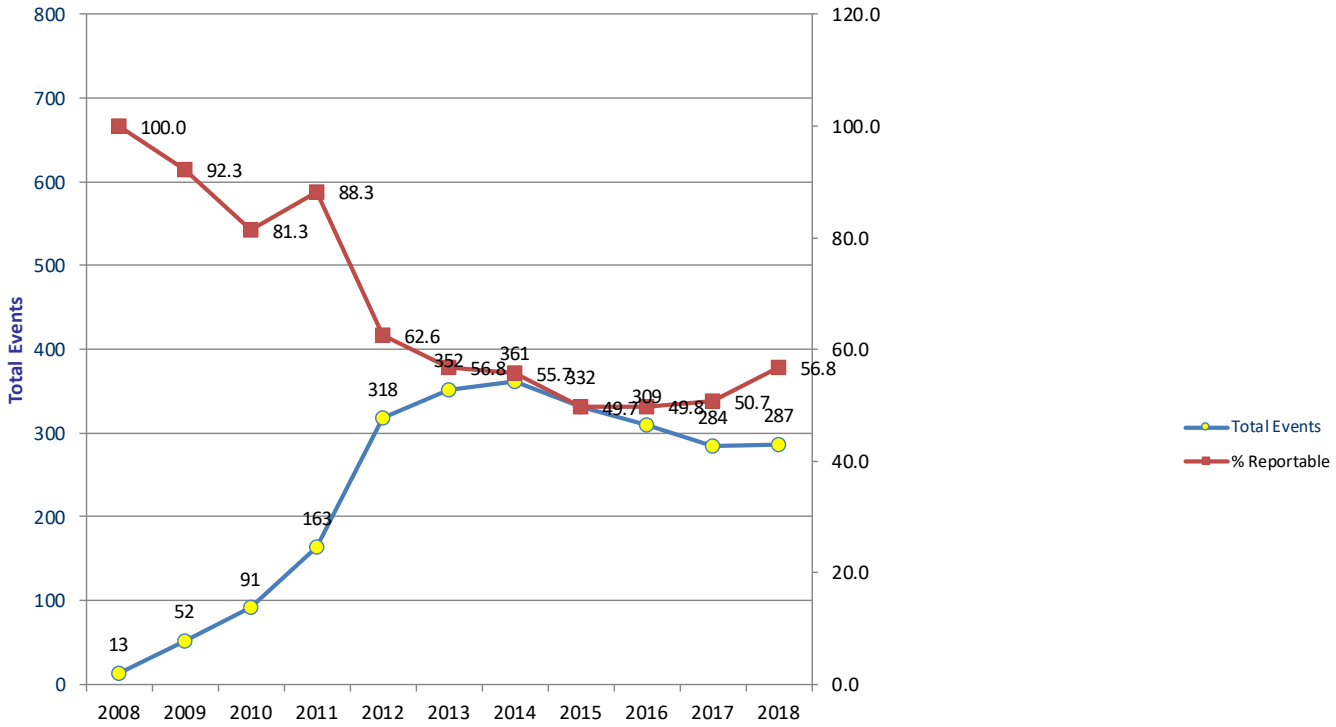
Table 15 and Figure 26 show the reporting patterns for the period 2008 to 2018.

Table 15: Ambulatory Surgery Centers: Reporting Patterns (2008-2018)[a]

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
2017	144	10	130	284	49.3	50.7
2018	163	10	114	287	43.2	56.8

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

Figure 26: ASC Trends in Reportable and Not Reportable Events 2008-2018



V. Ambulatory Surgery Centers

As shown in Table 16 below, 107 (65.6%) 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 42 cases or 25.8 percent of the total events reported from ambulatory surgery centers.

These two event types accounted for 149 cases or 91.4 percent of the total events reported (n = 163).

There was a total of seven deaths reported and six were associated with intraoperative or postoperative coma, death or "other" serious preventable adverse events type.

The other death was related to a Spinal procedure.

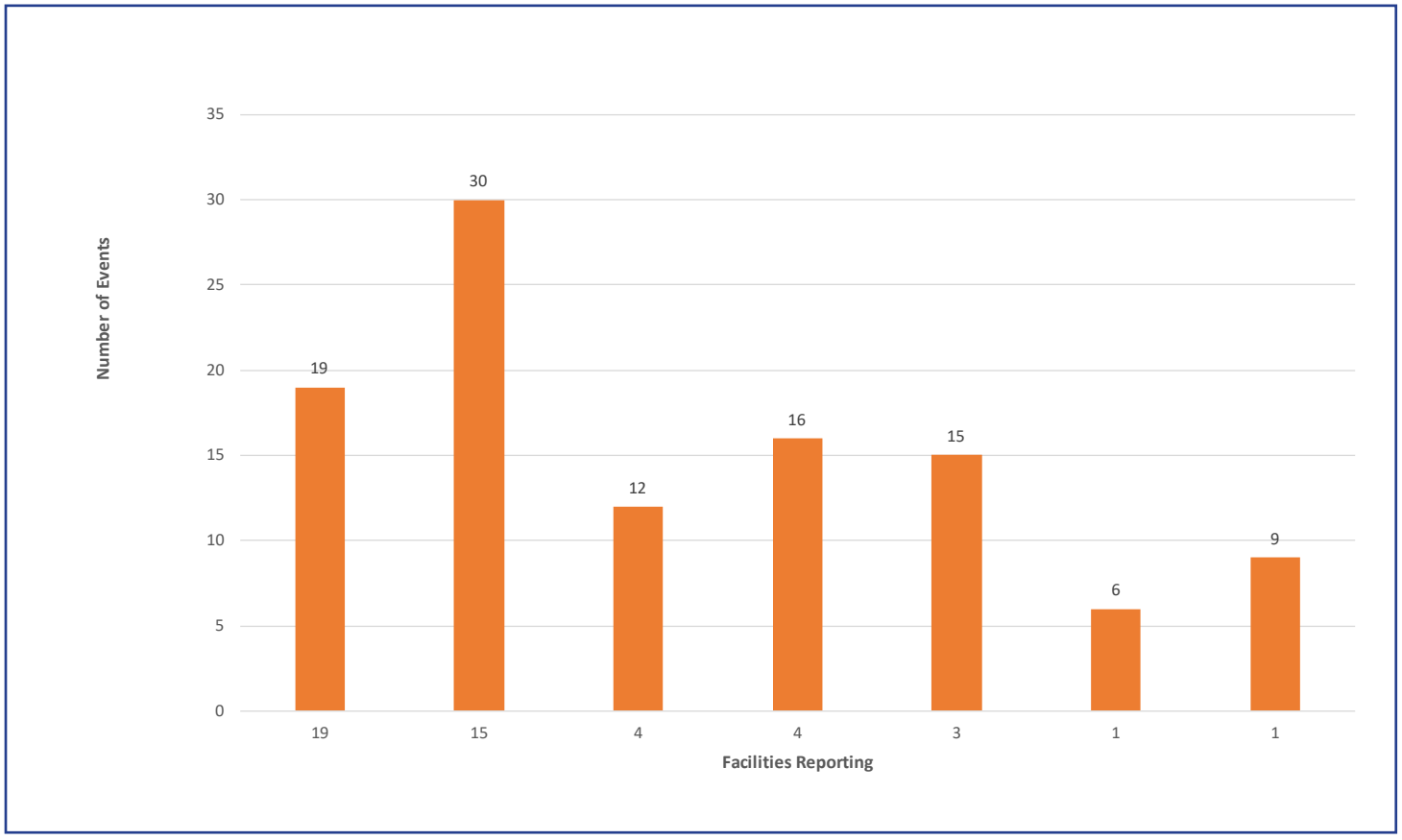
Table 16: Ambulatory Surgery Centers: Events Reported in 2018

Event Type	Number of Events	Percent of Total Events	Number of Deaths
Intra-Operative or Post-Operative Coma, Death or "Other" serious preventable adverse event	107	65.8	6
Surgery-Related "Other" Event	42	25.8	0
Wrong Site	5	3.1	0
Care Management- Spinal	3	1.8	1
Wrong Procedure	2	1.2	0
Retained Foreign Object	2	1.2	0
Pressure Ulcer	1	0.6	0
Device Malfunction	1	0.6	0
Total	163	100.0	7

V. Ambulatory Surgery Centers

As stated earlier, there were 107 intra-operative/ post-operative events submitted by 47 ambulatory surgery facilities. The chart below shows the reporting pattern of reporting by ambulatory surgery facilities. For example, 19 facilities reported one event each while 15 facilities reported a total of 30 events. (i.e. 2 per facility)

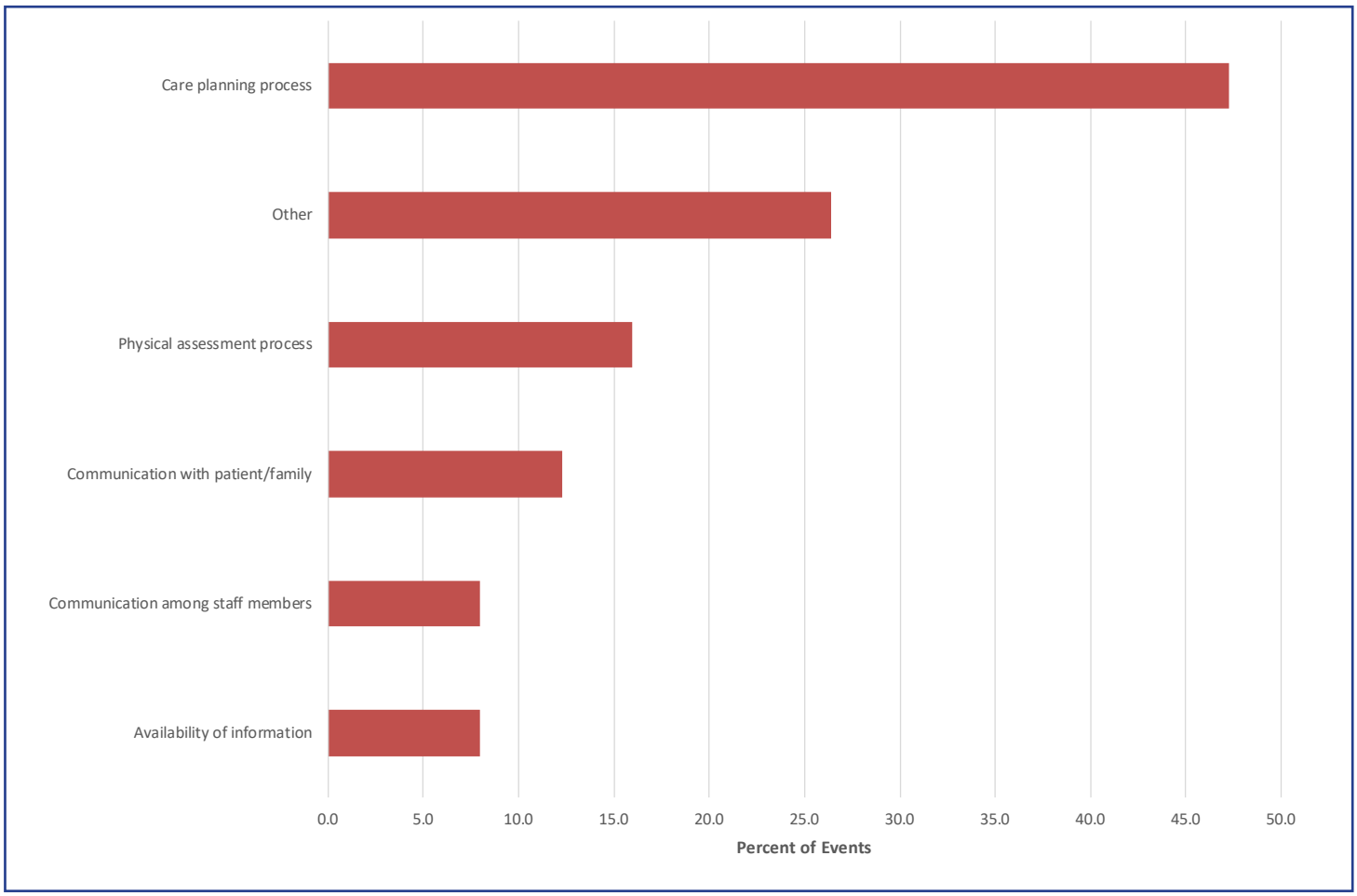
Figure 27: Ambulatory Surgery Centers: Intra-Op/Post-Op Death and Coma



A. Root Causes for All Events

Figure 28 shows the most frequently identified root causes of the events reported by ambulatory surgery centers in 2018.

Figure 28: Ambulatory Surgery Centers: Root Causes for All Events[a]



a: Data drawn from 163 RCAs submitted for 2018 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]

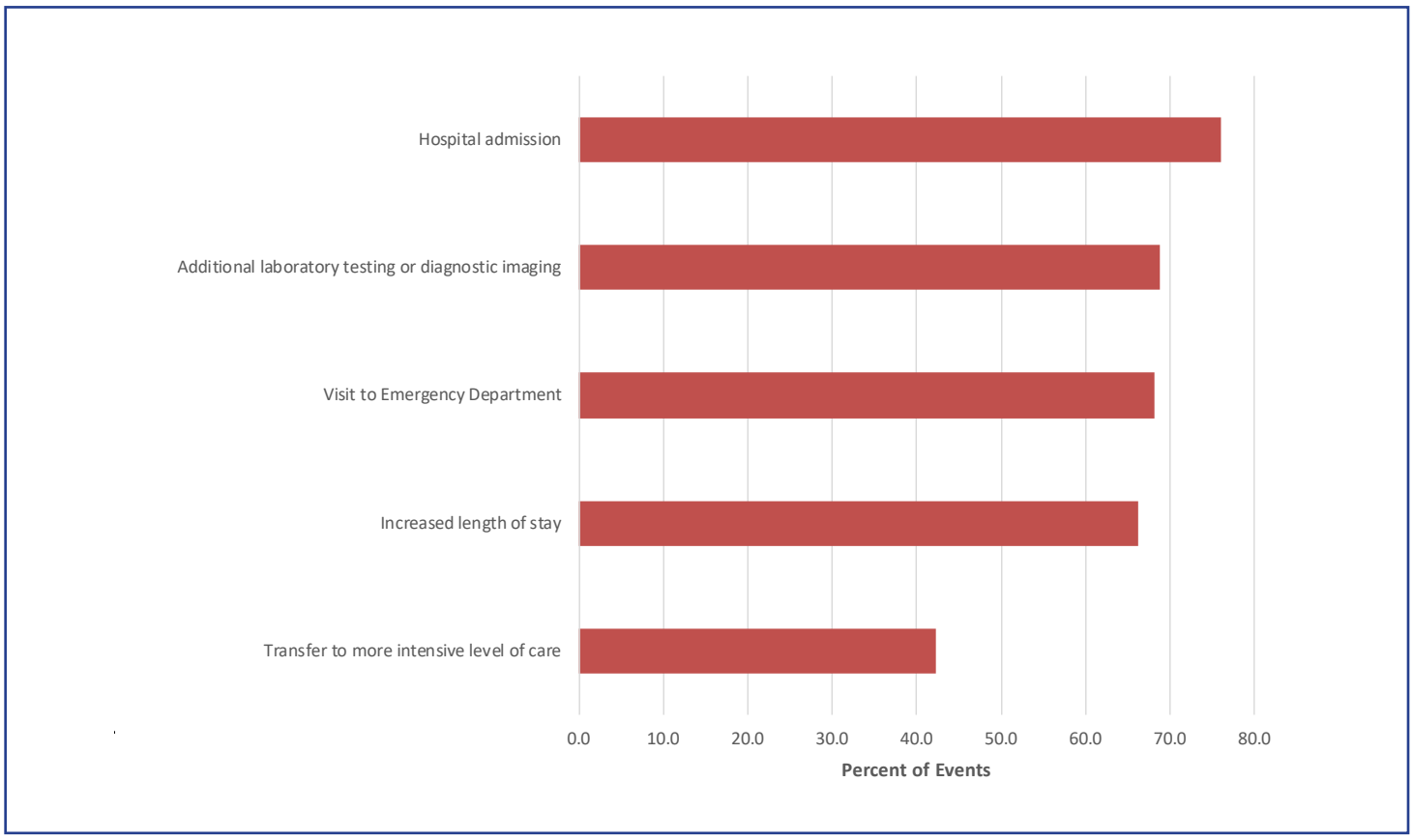
Contributing Factors	Number of Events	Percent of Events[a]
Patient Characteristics *(May include confusion, co-morbidities and the Patient's choice to refuse care.)*	107	65.6
Procedures *(May include diagnostic or therapeutic interventions that contribute to the event.)*	103	63.2
Task Factors *(May include tasks performed incorrectly, omitted or characteristics of the task such as complexity.)*	72	44.2
Team Factors *(May include factors which interfere with the care teamworking together, such as inadequate communication.)*	33	20.2
Other Factors *(May Include factors not identified in the other categories.)*	29	17.8
Medications *(May include inappropriate administration, dose and prescribed medications not administered.)*	19	11.7

a: Data drawn from 163 RCAs submitted for 2018 events.

C. Impact of All Events

Figure 29 displays the most frequently reported impact of adverse events at ambulatory surgery centers.

Figure 29: Ambulatory Surgery Centers: Impact of All Events[a]



a: Data drawn from 163 RCAs submitted for 2018 events.

Department of Health
Division of Behavioral Health Services
Annual Patient Safety Act Report
January 1, 2018 through December 31, 2018

Implementation

The Division of Behavioral Health Services (DBHS/Division) Patient Safety Act (PSA) advisory committee continues to receive and review the Root Cause Analyses (RCAs) submitted under the Patient Safety Act by the three (3) regional NJ state psychiatric hospitals and one (1) forensic psychiatric center. A log of PSA related events is maintained by the Division to monitor the timely submission and review of submitted RCAs.

The review committee, which consists of members of various disciplines including psychiatry, psychology, nursing and rehabilitation services, assesses the Root Cause Analyses for timeliness, thoroughness, and credibility. Questions or concerns of the committee are shared with the RCA team/facilitator as well as the Director of Quality Assurance and Risk Manager of the facility where the event occurred. Facility staff review and provide responses to these questions/concerns and may be asked to reconvene the RCA committee as needed. If necessary, a revision to the RCA is requested.

During 2018, system initiatives/improvements that are expected to decrease the number of incidents reportable under the PSA in the hospitals included the following:

- Utilizing a Lean Management system approach to identify and eliminate waste and improve patient care by initiating improvement activities and monitoring to control improvements to ensure sustainability.
- Assessed each hospital's staffing plans and developed a standard for the number of psychiatrists required at each facility.
- Implemented the Division's first step in electronic medical records, a Physician Ordering Electronic System that allows for the review, tracking, and adjustment of patient medication and will assist in the prevention of possible ordering/administration errors. Current features include but are not limited to admission/transfers/discharge tracking, medications ordering with alerts to support physician decision making, improved electronic medication reconciliation, automation of tracking of medication administration process, electronic monitoring of restraints/seclusions, and improved communication with each hospital's pharmacy. To date, the Division continues to update the piloted system with additional modules as its implementation is rolled out across the system.
- Conducted a survey of each hospital's Culture of Safety as one (1) essential component of preventing or reducing errors and improving overall health care quality. Surveys will allow for the identification of strengths and areas for improvement with the development of a corresponding action plan.

- Developed a methodology that promotes the implementation of increased active treatment by psychologists, who are focusing on patients identified as at a high risk for suicide or self-injurious behavior; discharge resistant; in need for motivation towards treatment or in need of repeated use of restraints; and seclusion or 1:1 observation.
- Developed a standardized central policy to provide guidance on items to be included on emergency carts at all hospitals and training and mock code drills.
- Provided specialized refresher training specific to Compressions, Airway, & Breathing (CAB) and the use of CPR and Log Roll was conducted at all hospitals and completed by 4,565 staff." Implementation of Dialectical Behavioral Therapy to assist patients in recognizing triggers that prompt harmful behavior and allow for the development of adaptive coping skills. Statewide Steering Committee formed.
- Developed Ancillary Response Teams with specialized training in assisting patients who are in crisis/ distress to utilize positive coping skills, as well as provide training to staff on managing these situations.
- Revised Suicide Risk Assessment and the screening processes to include use of an evidence-based assessment tool that is used to assist in determining a patient's risk for suicide at various points in care. Policies and procedures regarding suicide risk assessments were revised and began implementation in June of 2019. To date, monthly meetings are held to monitor the implementation and to assess where the Division can continue to increase evidence-based practice.
- Implemented Safety Plans for Suicide Prevention to assist patients in coping strategies and sources of support to be used by those who have been assessed to be at high risk for suicide. Exploring a nationally recognized suicide prevention safety plan for use across the system. Work toward identifying and mitigating ligature risks continues. Each facility continues to monitor possible risks and improve the environment of care for patients by systematically assessing ligature resistant in areas of; environmental improvements, hardware upgrades and complete room renovations. Additionally, in accordance with Joint Commission Standards, each facility conducts a Hazard Vulnerability Analysis (HVA) to identify potential emergencies (i.e. ligature points), the likelihood of those events occurring, and the consequences of those events. As a result of that analysis, dedicated hospital staff review and recommend projects and hardware upgrades based on most current best practices to continue to improve safety conditions on all units. Subsequently, the hospital continues to mitigate ligature points as they arise."

Overall Reporting Patterns

From January 1, 2018, through December 31, 2018, a total of nine (9) events were reported and reviewed. Seven (7) out of the nine (9) events occurred at one (1) facility, the remaining two (2) were dispersed between two (2) other facilities. The events consisted of; five (5) suicide attempts (a 37% reduction from 2017) one (1) unexpected death, and three (3) patient falls which resulted in major injuries.

Focus on Specific Events

a.Falls

There were three (3) falls in 2018 which resulted in major injuries to patients. A 68-year-old woman who was on fall precautions fell when walking without her prescribed adaptive equipment, the incident resulted in a left humeral fracture. A 71-year-old man on fall precautions stated he fell when attempting to get up from his Broda® chair without assistance, the incident resulted in the fracture of his right femur and jaw. An 84-year-old woman with a hearing impairment asked for water, couldn't hear the staff's request to wait, so attempted to get out of bed to get it herself and fell, sustaining a right hip fracture.

Root Cause:

- Procedural gaps identified in Fall Prevention and hand-off communication policies.
- Lack of staff competency related to fall prevention and safe transfers of patients who cannot self-transfer to/from a Broda® chair.
- Lack of knowledge of resources available to staff.
- Incomplete documentation in treatment plan to reflect fall precaution actions.
- Face check rounds not completed per protocol, to include utilization of two (2) staff during unit rounds.
- Failure to identify necessary fall precaution interventions on patient's comprehensive individualized treatment plan.
- Failure to utilize assistive device (Amplifier) to communicate response to patient's request for assistance.

Prevention Strategies:

- Falls prevention and hand-off communication policies were revised to include new procedural directives addressing identified gaps.
- Inservice provided on all three (3) shifts to address prevention protocols and additional resources available to staff.
- Staff training on safe transfers of patients who cannot self-transfer.
- Training on treatment plan documentation to include fall precaution interventions.
- Training on protocol for face and safety checks, and subsequent monitoring by nursing supervisors.
- Collection and analysis of fall data to assess patterns/trends and areas for improvement.
- Retraining on use of assistive devices with demonstrated competency.

b. Attempted Suicides

There was a total of five (5) suicide attempts in 2018. All involved female patients with ages ranging between 20 and 71; with a mean age of 32.4, a median age of 24, and mode of 24.

Three (3) suicide attempts occurred at one (1) hospital, and the remaining two (2) were split at two (2) different hospitals. All five (5) events involved patients tying objects around their necks; either an article of clothing, a string, or electrical wiring pulled from under the ceiling tiles. Three (3) events occurred in the bathroom, one (1) in a patient's bedroom and one (1) was in the common area of the unit.

Root causes

- After hours Medical Officer on Duty did not place patient being admitted, who was at an increased risk for suicide on precautions.
- A crisis event on the unit during the admission process caused nursing staff to not properly conduct search of patient's belongings.
- Lack of familiarity with admission process due to patient transfer and admission after regular business hours.
- Improper de-escalation techniques and application of patient's safety plan.
- Removable ceiling tile in patient areas identified as ligature points.
- Staffing levels insufficient to diffuse situations occurring during staff breaks/lunch.
- Lack of clear policy guidelines for contraband searches of rooms of patients identified at for suicide.
- Lack of clear policy guidelines for assessment of patient with behavioral changes following consent to take medications on a voluntary basis.
- Lack of training and demonstrated competency regarding implementation of special level of observation protocols.
- Gaps identified in procedures for conducting patient searches in off unit areas.

Prevention strategies

- Review/revise procedure for placing patients on a specialized level of observation.
- Review and reeducate all nursing staff on policy and procedures regarding contraband checks.
- Revise transfer/admission criteria/protocol with other State psychiatric hospitals to include admissions accepted only prior to 2 PM on regular business days.
- Provide simulation training to all nursing staff to practice de-escalation techniques.
- Develop specialized teams to intervene/engage with the most difficult patients when they pose a danger to self/others.
- Implement a trauma support response team for staff who have been assaulted by patients.
- Continue to conduct ligature point assessments and mitigate identified areas of risk, including ceiling tiles.
- Nursing Supervisor to monitor assignment sheet to ensure sufficient coverage during staff lunches and breaks.
- Revise policy regarding contraband for those patients at increased risk of suicide.
- Develop procedure for sweeps/room searches of patients placed on observation for increased risk of suicide and train staff on revised procedures.
- Revise procedure to include special treatment team sessions when patients begin to take medication voluntary.
- Revise procedure to include continuation of medication education and counseling after a patient is placed on voluntary medication status after longstanding refusals.
- Implement procedure of team assessment of SR for suicidal ideation prior to granting increased levels of independence on grounds.
- Provide training and assess competency of staff implementation of observation of patient at an increased risk of suicide.
- Revise procedure to include searches and safety checks of off unit areas.
- Assign additional staff to monitor off unit area.

c. Unexpected Deaths

There was one (1) unexpected death which occurred during 2018; a 57-year old male for whom the cause was determined to be acute pulmonary embolism because of deep vein thrombosis.

Root causes:

- Patient history of pulmonary embolism and DVT was not listed on physical exam during admissions process.
- Failure to follow code blue policy and respond to change in patient condition.

Prevention strategies:

- Peer Review process was developed/implemented to review that all diagnoses are entered on patient histories of every newly admitted patient. Quality management will conduct random reviews of peer review form to ensure compliance.
- Re-education of staff on policies and procedures involving code blue medical emergencies and responding to changes in patients' condition.
- Medical physicians re-educated to review all medical diagnoses and ensure documented on proper forms.
- The implementation of the POES will ensure that all past medical history information will be reviewed by admitting physician

VI. Division of Behavioral Health Services 2018 Report

DBHS Report Preparation Team

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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.

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.
   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.

Appendix 2: Required Components of a Root Cause Analysis

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.

Patient Safety Reporting System (PSRS) Contact Information

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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's website at www.nj.gov/health/ps.