HCQA Health Care Quality Assessment

Patient Safety Reporting System

2010 Summary Report

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Patient Safety Reporting System

2010 Summary Report

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Patient Safety Reporting System

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

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Patient Safety Reporting System

Executive Summary

The New Jersey Patient Safety Act (P.L.2004, c.9) requires all New Jersey licensed health care facilities 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 following types of facilities currently report to the Patient Safety Reporting System:

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

The following facility type reports to the Department of Human Services, Division of Mental Health and Addiction Services:

- State psychiatric hospitals began reporting August 2008.

Summary of reported adverse events for all facility types in 2010:

- 797 events were reported to the Patient Safety Reporting System by all facility types;
- 694 events were determined to be reportable adverse events;
- 103 deaths were associated with the adverse events.

General Acute Care Hospitals:

- Submitted 562 reportable adverse events in 2010 which was a 23.5 percent increase in the number of reports compared to 2009;
- The average number of reportable events per reporting hospital was 7.9; the average number of reportable events tended to increase with hospital size;
- There were 85 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, care management “other” events, fall events and surgery “other” events;
- The most frequently reported events were falls, pressure ulcers, retained foreign objects, and care management “other” events;
- 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 physical assessment process; 62 RCAs did not identify a systems root cause for the event;
- The most frequent consequences of the events were additional laboratory testing or diagnostic imaging, additional patient monitoring in current location, surgery, and increased length of stay.

Comprehensive Rehabilitation Hospitals:

- There were 38 reportable events and 8 deaths associated with care management “other” events, falls, and one medication error;
- The most frequently reported root causes were communication among staff and/or with the patient/family and care planning process;

Executive Summary

- Approximately 50 percent of patients had a visit to an emergency department, were admitted to the hospital, and /or transferred to a more intensive level of care.

Psychiatric Hospitals:

- There were 14 reportable events and 2 deaths associated with care management "other" events;
- The most frequently reported root cause was communication among staff and/or with the patient/family;
- Eight patients had a visit to an emergency department and/or were transferred to a more intensive level of care.

Special Hospitals:

- Six reportable events were submitted with no associated deaths;
- The most frequently reported root causes were communication among staff and/or with the patient/family, care planning process and availability of information;
- Impact of the events included additional patient monitoring in current location, additional laboratory testing or diagnostic imaging, visit to an emergency department, and disability-physical or mental impairment.

Ambulatory Surgery Centers:

- Submitted 74 reportable events with 8 deaths associated with intraoperative or Postoperative coma, death or other serious preventable events and surgery "other" events;
- The most frequent root causes were care planning process, physical assessment process, and communication among staff and/or with the patient/family;
- Of the 74 reported events, approximately 67 percent of the patients were admitted to hospitals; other frequently reported impacts were additional laboratory testing or diagnostic imaging and visit to an emergency department.

Division of Mental Health and Addiction Services:

- Overall there were 14 reportable events comprising seven falls, six attempted suicides and one medication error;
- There were no associated deaths resulting from these events.

I. Introduction

This summary 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). PSRS staff reviewed and analyzed the data from event and Root Cause Analysis (RCA) reports submitted from January 1, 2010 through December 31, 2010.

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

Health care facilities are required to report serious preventable adverse events and perform a root cause analysis (RCA) for each reportable event. The classification and definitions of serious preventable events can be found in Appendix I.

The RCA process requires the facility to provide a description of the event; determine the causes; write a corrective plan; and monitor the corrective plan of action. See Appendix 2 for the complete required components of an RCA.

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

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

This annual report summarizes the 2010 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.

The number of reportable and not reportable events submitted to the Patient Safety Reporting System for 2010 from all facilities was 797. The number of deaths was 103 or 14.8 percent of the 694 reportable events submitted.

Table 1 below shows the distribution of events reported to the New Jersey Department of Health, Patient Safety Reporting System by facility types during 2010.

Table 1: Reporting Pattern by Facility Type

Facility Type	Number of Facilities	Number of Reporting Facilities	Number of Reportable Events	Number of Not Reportable Events	Number of Deaths
General Acute Care Hospitals	72	71	562	66	85
Comprehensive Rehabilitation Hospitals	15	13	38	12	8
Psychiatric Hospitals	10	8	14	5	2
Special Hospitals	13	8	6	1	0
Ambulatory Surgery Centers	119	59	74	19	8
Total	229	159	694	103	103

III. General Acute Care Hospitals

A. Reportable and Not Reportable Events by Year

Table 2 and Figure 1 demonstrate the relationship between reportable events and not reportable events over the past six years. Not reportable events do not meet the statutory definition of a serious preventable adverse event. These include events which result in less serious injury such as small superficial lacerations and single rib fractures with no significant impact on the patient.

With the exception of 2009 and 2010, not reportable events represent less than 10 percent of the total events collected. There was a slight increase of not reportable events in 2009, to 12 percent of the total events, and to 11 percent in 2010. One of the reasons for the increase in the absolute number of not reportable events is related to a change in the process of event determination. Previously, any injury still present after seven days or at discharge resulting from a fall was accepted as a reportable event.

Beginning in 2009, consistent with the National Quality Forum (NQF) and other states' patient safety programs, only falls resulting in serious injury and with a significant impact on the patient are accepted as reportable events. These may include, but are not limited to, death, long bone fractures, hip fractures, intracranial hemorrhage or injuries that severely limit basic life functions. Consistent with this change, less serious injuries were determined to be not reportable. The change was initiated to focus root cause analysis on events that have the most severe impact on patients. Table 2 and Figure 1 show the trend over the past six years.

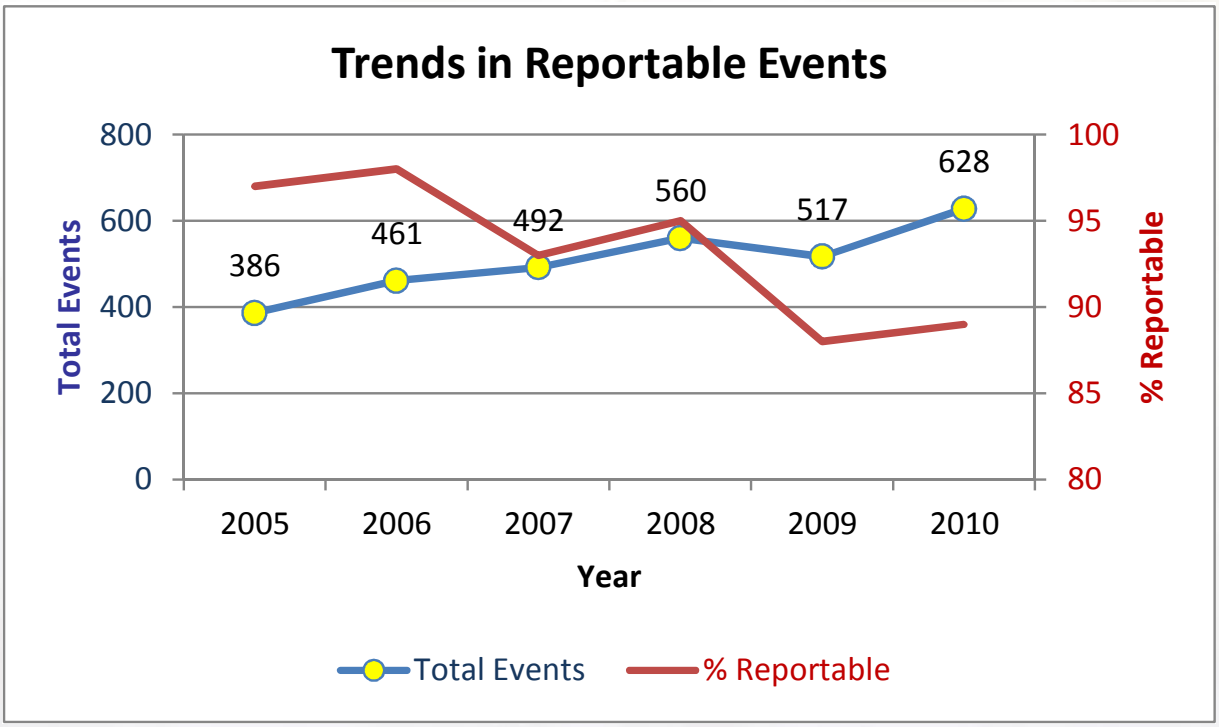
Table 2: General Acute Care Hospitals: Reportable and Not Reportable Events by Year

Year	Reportable	Not Reportable	Total Events	Percent Not Reportable	Percent Reportable
2005[a]	376	10	386	3	97
2006	450	11	461	2	98
2007	456	36	492	7	93
2008	533	27	560	5	95
2009	455	62	517	12	88
2010	562	66	628	11	89

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

III. General Acute Care Hospitals

**Figure 1: General Acute Care Hospitals:
Trends in Reportable and Not Reportable Events**



2005 Data represents 11 months of reporting since the program started on February 1, 2005

III. General Acute Care Hospitals

B. Reporting Patterns (2005-2010)

Since reporting began in February 2005, 2,832 reportable adverse events have been submitted by New Jersey general acute care hospitals to the Patient Safety Reporting System (PSRS) as of end of year 2010. In 2010, the sixth year of reporting, 562 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 23.5 percent increase in the number of reports in 2010 compared with 2009 (Table 3). In 2010, 71 of the 72 (98.6 %) general acute care hospitals in New Jersey submitted reportable events. The average number of reports per reporting hospital was 7.9 percent. This average does not take into account hospital size and bed capacity.

Table 3: General Acute Care Hospitals: Reporting Patterns (2005-2010)

Reporting Year	Number of Reportable events	Hospitals			Average 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	73	72	98.6	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

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

III. General Acute Care Hospitals

A review of reportable events by maintained bed size groupings shows that one third of New Jersey's general acute care hospitals are within the 201-300 range. The hospitals in this bed size range accounted for 30.3 percent of all events reported in 2010. This group was followed by the 10 hospitals in the 401-500 bed size group which reported 153 events, representing 27.2 percent of the total reportable events in 2010. There were five hospitals with less than 100 maintained beds each but only four reported at least one event. As a group, these hospitals reported the fewest number of adverse events—8 in total or 1.4 percent. The average number of reportable events tends to increase with hospital size as shown in Table 4.

Table 4: General Acute Care Hospitals: Reports Based on Hospital Maintained Beds

Maintained Beds	Number of Hospitals Reporting	Number of Reports	Percent of Reports	Average Reported Per Bed Size
<=100	4	8	1.4	2.0
101-200	17	69	12.3	4.1
201-300	24	170	30.3	7.1
301-400	9	55	9.8	6.1
401-500	10	153	27.2	15.3
501+	7	107	19.0	15.3
Total	72	562	100.0	7.9

III. General Acute Care Hospitals

C. Reportable Events and Associated Deaths by Event Category

As indicated earlier in the report, there were 562 adverse events reported by New Jersey general acute care hospitals in 2010 and accepted by the PSRS. There were 85 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

Environmental events were the most frequently reported events, such as falls. (Detailed analysis follows later in this report.) As a category, environmental events accounted for 30.8 percent of total events and 7.5 percent of the total deaths in 2010. Care management events, such as medication errors, pressure ulcer events and care management "other" events, accounted for 27.8 percent of reportable events and 17.9 percent of all deaths resulting from patient adverse events. The third highest category of events reported was surgery-related. As a category, it accounted for 26.2 percent of reportable events and 25.9 percent of all deaths reported in 2010. Table 5 provides an overview of reportable events in the event categories with associated deaths.

Table 5: General Acute Care Hospitals: Reportable Events and Associated Deaths by Event Category

Event Category	Total Events	Percent of Total Events	Total Death Events	Deaths per 100 Events
A: Care Management	156	27.8	28	17.9
B: Environmental	173	30.8	13	7.5
C: Product or Device	49	8.7	1	2.0
D: Surgery-Related	147	26.2	38	25.9
E: Patient Protection	37	6.6	5	13.5
Total	562	100.0	85	15.1

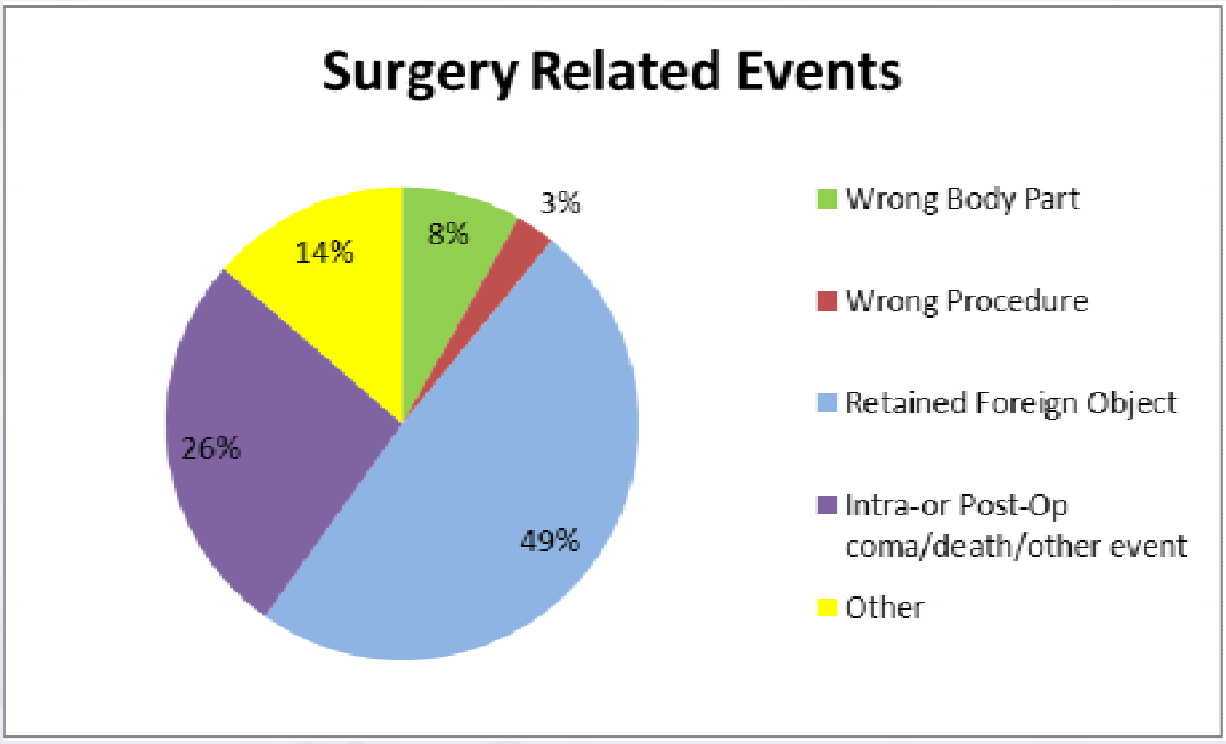
III. General Acute Care Hospitals

As Table 5 demonstrates, the surgery-related event category had the highest number of associated deaths (38) and deaths per 100 events (25.9).

In 2010, general acute care hospitals reported 147 surgery-related events, which accounted for 26.2 percent of total events reported (Table 5). Retention of foreign object, intraoperative or Postoperative coma, death or other serious preventable adverse events and surgery "other" events were the most frequently reported surgical events. These three event types accounted for 23 percent of all reportable events submitted by general acute care hospitals. There were 37 deaths associated with the three event types, representing over 42 percent of all reportable deaths across all facility types in 2010.

There were 39 intraoperative or Postoperative events with 25 associated deaths. Of the 20 reported surgery "other" events, 11 resulted in death (55%). There were 12 wrong body part events reported in 2010, which resulted in four deaths. This represents a decrease of over 27 percent of reported wrong body part events compared to 2009. Additionally, there were four events reported for wrong surgical procedures with no associated deaths. There were no wrong patient events reported in 2010.

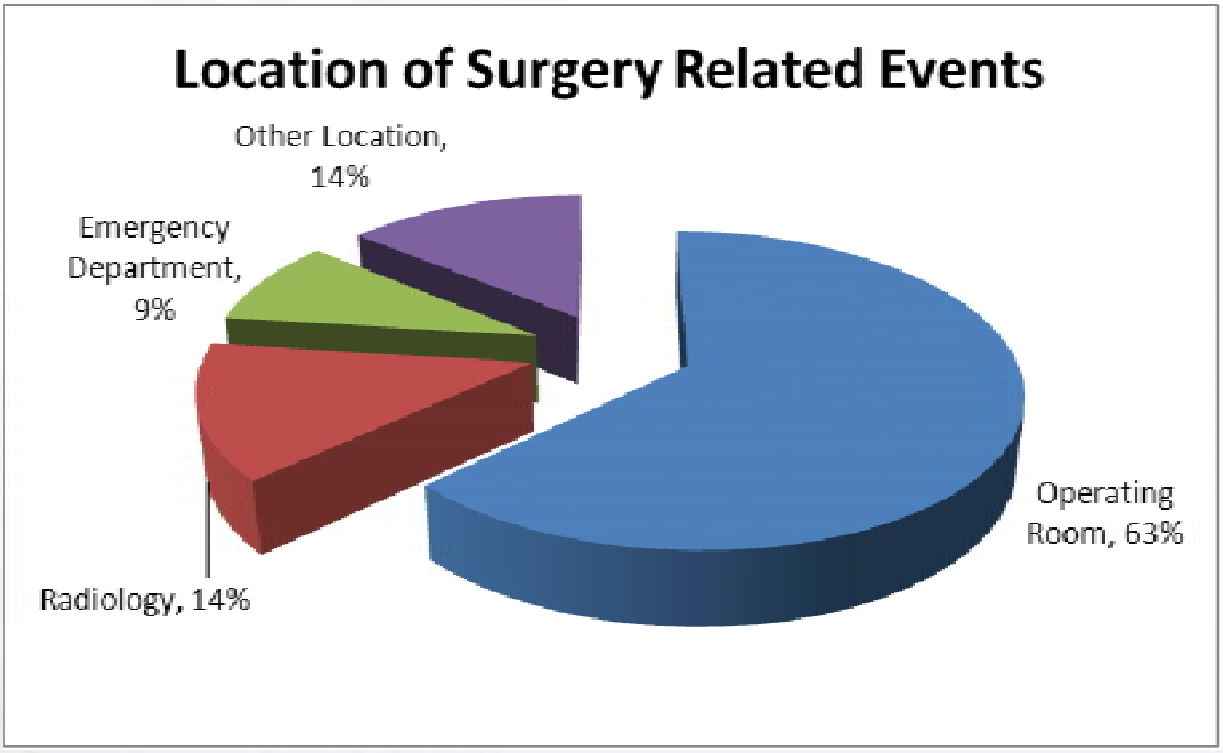
Figure 2: General Acute Care Hospitals: Distribution of Surgery-Related Events



III. General Acute Care Hospitals

As would be expected, most of these surgery-related adverse events occurred in the operating room. The remainder of the surgery-related events occurred in the radiology department, emergency department, or other location (Figure 3).

Figure 3: General Acute Care Hospitals: Location of Surgery-Related Events



D. Events Types Associated with Highest Percent Deaths

The table below shows the event types with the highest percent of deaths. As shown below, the highest percent of deaths was associated with intraoperative or Postoperative coma, death or other serious preventable adverse events. Of the 39 patients in this event type, 25 died, which accounted for 64.1 percent of the events in this event type. The second highest event type was surgery "other" with 20 events and 11 deaths (55%). Care management "other" was the third highest in terms of percent of deaths. There were 46 reportable events and 21 deaths, representing 45.7 percent of the patients in the care management "other" event type. Patient or resident suicide or attempted suicide accounted for 37 events and 5 deaths. The percent of deaths in this event type was 13.5.

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
Intraoperative or Post-Operative Coma, Death or Other Event	39	25	64.1
Care Management "Other" Event	46	21	45.7
Falls	166	12	7.2
Surgery "Other" Event	20	11	55.0
Suicide/Attempted Suicide	37	5	13.5
All Other Event Types	254	11	4.3
Total	562	85	15.1

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 were high in 2010 compared to the previous years. There were 39 events from general acute care hospitals accepted by the PSRS in 2010, which accounted for 6.9 percent of total events. In 2009, there were 23 events compared to 11 events in 2008.

A major factor contributing to the increased number of reported events in 2010 relates to a more consistent classification of events in this category. Part of the language in the above noted definition includes: '…intraoperative or postoperative coma, death or other serious preventable adverse event…' Additional education was provided to facilities regarding the need for consistency to include other serious events in this event type in addition to death and coma.

Of the 39 reportable intraoperative or postoperative coma, deaths or other events in 2010, there were 25 deaths, which represents 29.4 percent of total deaths (85) in all event types in 2010.

2. Care Management "Other" Events

Among care management events, the second highest number of reported event types was care management "other." 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 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, and failure to implement appropriate treatment.

In addition, care management "other" events include failure to perform any of the above tasks in a timely manner. For example, an elderly patient fell and hit her head. The order for the CT scan of the head was entered into the computer as a routine order and it was scheduled for the following day. In the evening on the day of the fall, the patient became unresponsive. Following successful resuscitation, a CT scan demonstrated a large acute subdural hematoma. This would be considered a care management "other" event.

There were 46 care management "other" events reported out of a total of 156 in the care management category. This represents 29.5 percent. Twenty-one deaths were associated with the care management "other" event type, representing 24.7 percent of all deaths in 2010.

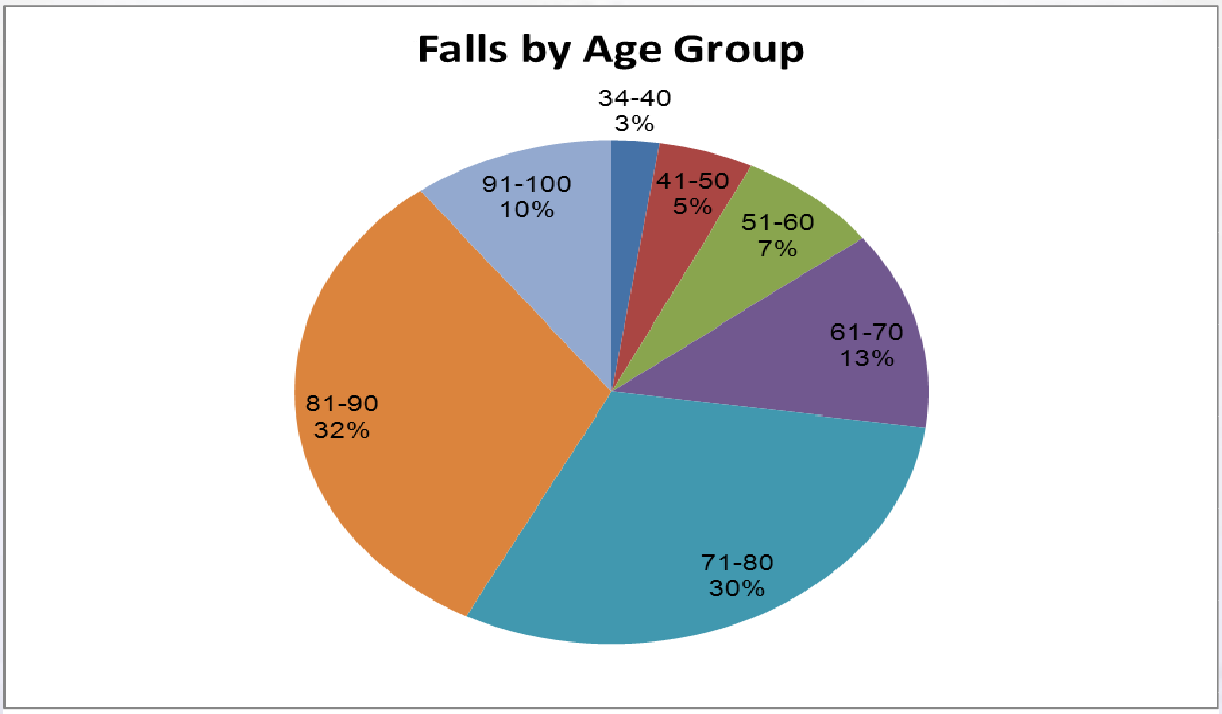
3. Fall Events

Falls continue to be the most frequently reported event submitted to the Patient Safety Reporting System. In 2010 there were 166 fall events resulting in 12 deaths. Falls accounted for 29.5 percent of total events reported. Falls represented 96.0 percent of the environmental events (173).

Falls are more common in older patients, especially over age 60. A review of the reportable fall events resulting in serious injury submitted by general acute care hospitals showed that 62 percent of the patients were in the age group between 71 and 90 years old. Specifically, 30.3 percent of the patients were in the 71-80 age groups while 32.1 percent were aged between 81 and 90 years (Figure 4).

The overall death rate for falls was 14.1 percent. As one might expect, fall related deaths appear to be associated with increasing age. Falls have a significant risk of death and fall prevention should be a high priority for general acute care hospitals.

Figure 4: General Acute Care Hospitals: Percent of Total Falls by Age Group



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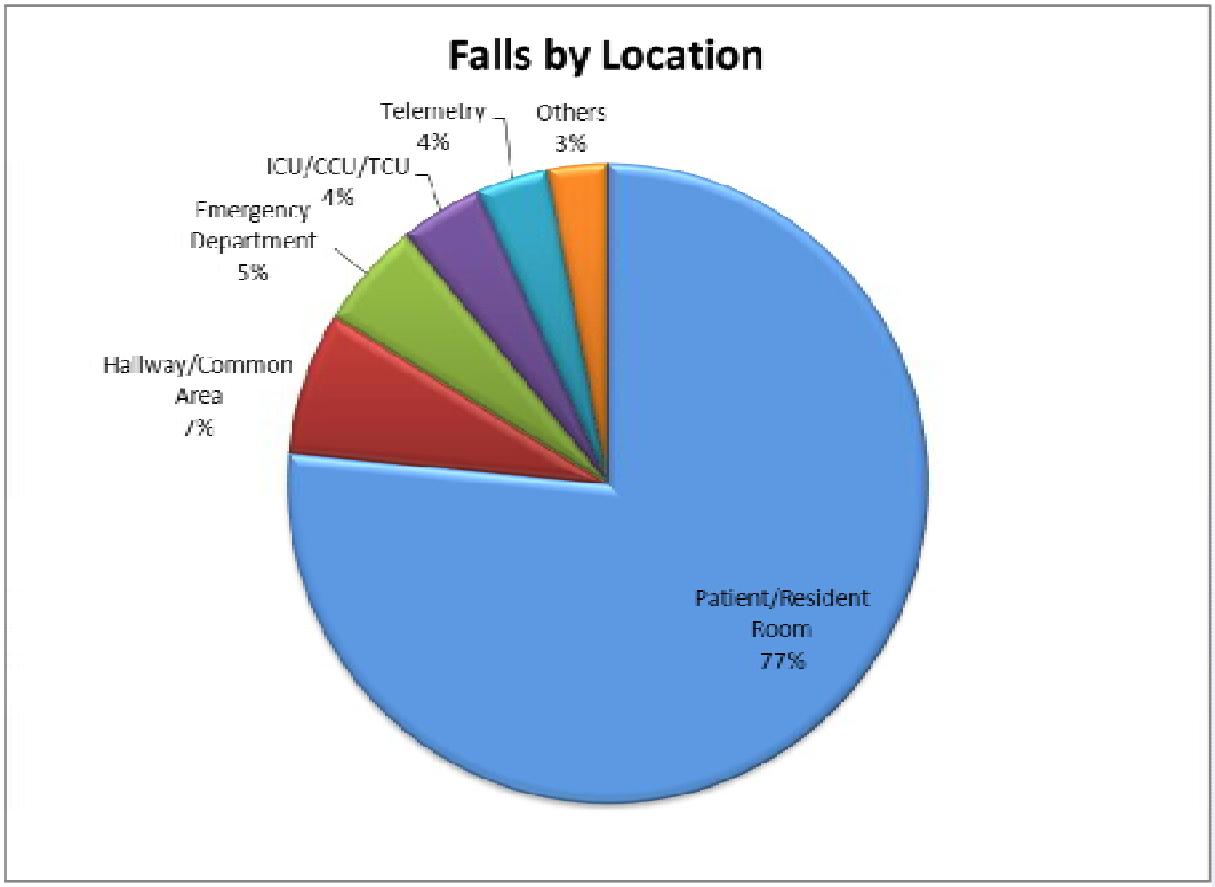
Of the 166 reportable falls, the majority occurred in the patient's room (76.5%), usually when the patient was attempting to go to the bathroom (Figure 5). Other locations for patient falls, although to a lesser extent, were hallways or other common areas (7.2%), emergency departments (5.4 %) and ICU/CCU/TCU (4.2%). The adverse event usually occurred within the first 7 days following admission.

Figure 5: General Acute Care Hospitals: Percent of Total Falls by Location



Patient/Resident Room refers to nursing units not otherwise specified.

III. General Acute Care Hospitals

4. Surgery "Other" Events

There were 147 surgery-related events reported in 2010. Of this total, there were 20 events categorized as surgery "other." Surgery "other" events include surgery-related events which do not meet the definition of the specific surgery event types, such as intraoperative or postoperative events and wrong body part events. As an example, surgical site infections which manifest themselves more than 24 hours post-op and meet the statutory definition of a serious preventable adverse event would fit into this event type. Also included would be serious post-op bleeding requiring intervention which occurs more than 24 hours following surgery.

This event type is the fourth most frequently reported event and represents 13.6 percent of the events in the surgery-related category. Eleven of the 20 events resulted in death (55%). These deaths represent 13 percent of all deaths in 2010.

5. Suicide/Attempted Suicide Events

There were 37 reportable adverse events for this event type and these represent 100% of all Patient Protection events and 3.6 percent of all reportable events. There were 5 completed suicides, which is 13.5 percent of deaths in all categories. Four of the deaths occurred in the patients' rooms. The other death occurred offsite when the patient was granted a one day pass. The facility failed to provide for appropriate oversight of the patient during the offsite visit.

E. Most Frequently Reported Event Types

Upon review of the specific event types submitted in 2010, falls, pressure ulcers, retained foreign objects, and care management "other" events represent the four most frequently reported event types in order of frequency. Fall events and care management "other" events have been discussed in detail in the "Specific Events with Highest Number of Associated Deaths" section.

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

Event Type	Number of Reported Events	Percent of Total Events
Falls	166	29.5
Pressure Ulcers	92	16.4
Retained Foreign Objects	72	12.8
Care Management "Other" Events	46	8.2
Intraoperative or Post-operative Coma, Death or Other Adverse Events	39	6.9
Suicide/Attempted Suicide	37	6.6

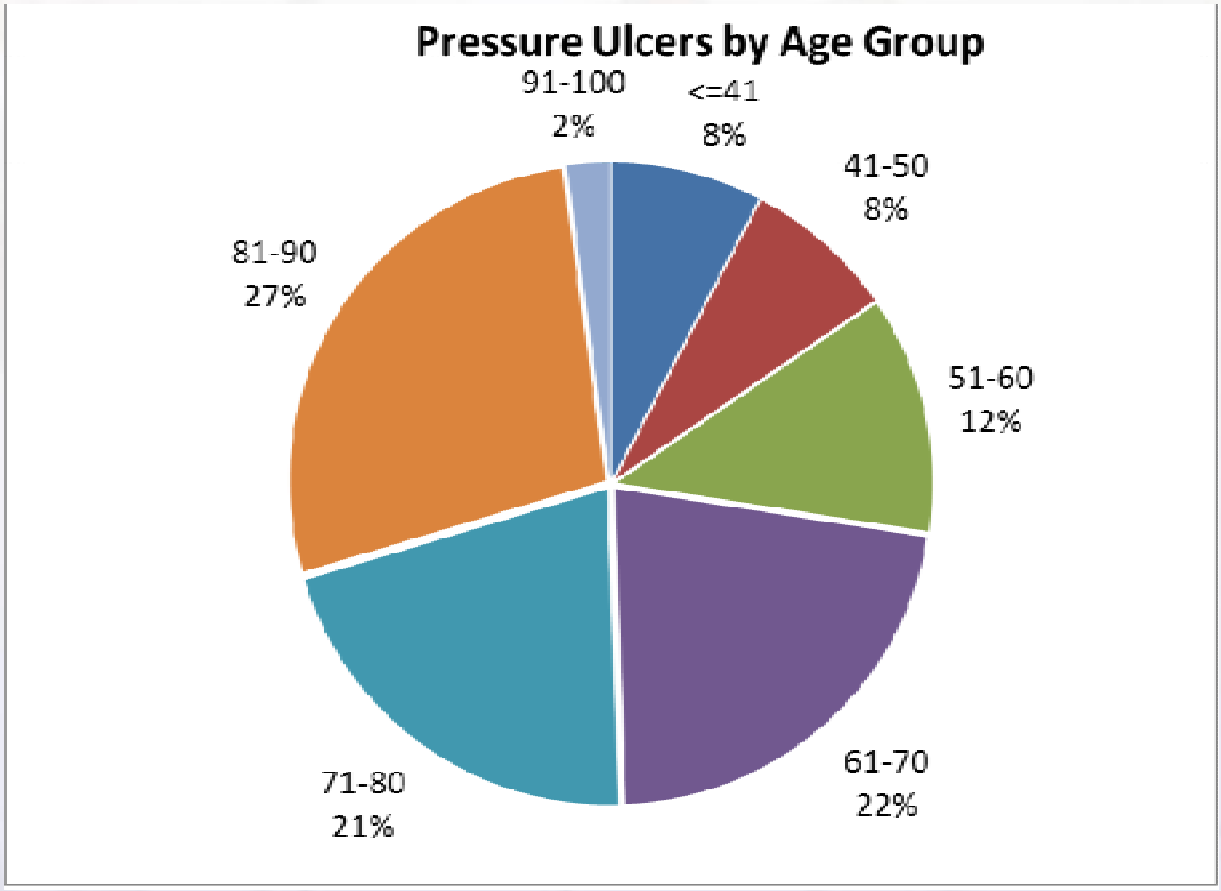
III. General Acute Care Hospitals

1. Pressure Ulcers

In 2010, there were 92 Stage III and IV pressure ulcers accepted as reportable by the Patient Safety Reporting System. This number represents 59 percent of all reportable events in the category of care management and accounted for 16.4 percent of total reportable events submitted by New Jersey general acute care hospitals. There were no deaths attributable to pressure ulcer events.

As the chart below shows, most of the patients who developed pressure ulcers were the elderly, between the ages of 61-90 years. In aggregate, this age group accounted for 64 cases and 70.0 percent of the total pressure ulcer events (Figure 6).

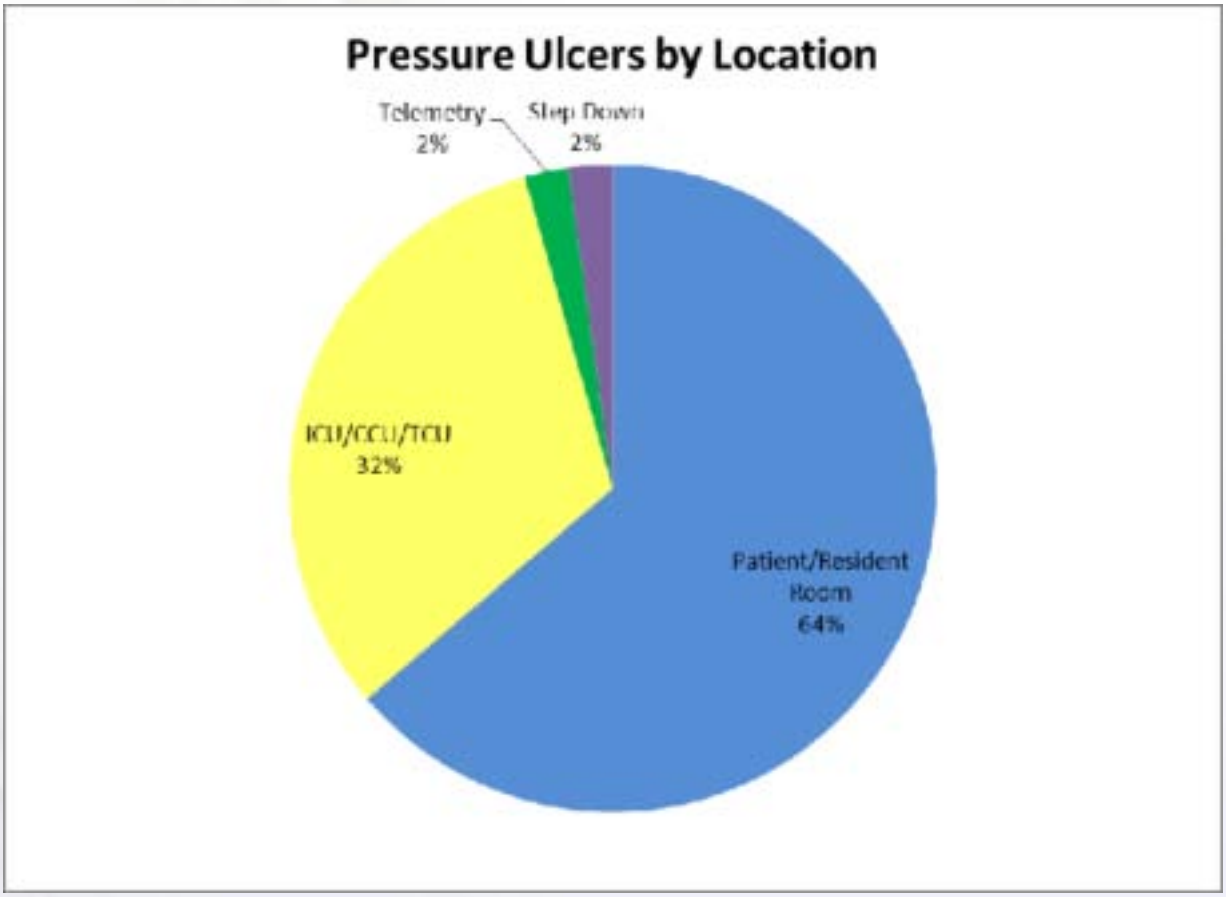
Figure 6: General Acute Care Hospitals: Pressure Ulcers by Age Group



III. General Acute Care Hospitals

Most of the patients who developed pressure ulcers while hospitalized were located in a patient/resident room (58 or 64%). Of the total 92 pressure ulcer events, 29 occurred in ICU/CCU/TCU units. This represents 31.5 percent of pressure ulcer events.

Figure 7: General Acute Care Hospitals: Location of Pressure Ulcer Events*



*** Event locations are based on event reporting forms in use in 2010**
• Patient Resident/Room refers to nursing units not otherwise specified.

2. Retained Foreign Objects (RFOs)

Retention of a foreign object in a patient after surgery was the third most frequently reported event type in 2010. There were 72 reportable RFO events, representing 12.8 percent of all general acute care hospital events. This is an increase from 2009 when RFOs represented five percent of total events.

Examples of RFOs include sponges (including vaginal sponges), instruments, needles, guide wires, and catheters. There was one associated death. This event type excludes objects intentionally implanted as part of a planned intervention, objects present prior to surgery that were intentionally retained, and retained broken microneedles.

F. Major Root Causes for All Events

In 2010, the most frequent root causes of adverse events reported to PSRS were care planning process (46.4%), communication among staff and/or with the patient/family (44.8%), orientation and training of staff and supervision of staff (31.9%) and physical assessment process of the patient (26.5%). (Table 8)

In sixty-two RCAs, "Other" was identified as the root cause. This option is available when the facility does not identify one of the specific root causes (such as care planning process or patient observation procedures). In effect, this designation indicates that the facility identified no systems cause of the event. This represents 8.2 percent of all general acute care hospital reportable events. Forty-two events that had a root cause of "other" were associated with death. This represents 67.7% of all events with a root cause "other" and 49.4% of all deaths.

The 62 root cause "other" RCAs were submitted by 30 hospitals. One hospital submitted 7 RCAs with a root cause of "other" which included 5 deaths. Ten hospitals each submitted 2 RCAs with the root cause "other."

In a few of these RCAs, facilities further defined the root cause of "other" as hand-off procedures, availability of equipment, and medication ordering. These root causes could have been classified as one or more of the specific root causes, such as care planning process. Some RCAs identified the patient and the patient's clinical condition as the root cause of the event.

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

Root Cause	Number of Events	Percent of Events
Care Planning Process	261	46.4
Communication among Staff and/or Patient/ Family	252	44.8
Orientation and Training of Staff and Supervision of Staff	179	31.9
Physical Assessment Process	149	26.5
Patient Observation Procedures	108	19.2
Equipment Maintenance/Management	77	13.7
Availability of Information	59	10.5
Other	46	8.2

a: Data drawn from 562 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one root cause.

G. Contributing Factors to All Events

Patient characteristics were the most frequently reported contributing factor to the events (56.6%). This category can include the patient's confusion, co-morbidities and the patient's choice to refuse care. Task factors (tasks performed or omitted by any member of the care team that contribute to the event) were contributing factors in approximately one third of events (32.2%). The third most frequent contributor to events was team factors (29%); this includes failure of the care team to work together and to communicate appropriately (Table 9).

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

Contributing Factors	Number of Events	Percent of Events
Patient Characteristics	318	56.6
Task Factors	181	32.2
Team Factors	163	29.0
Procedures	152	27.0
Patient Records Documentation	100	17.8
Equipment	89	15.8

a: Data drawn from 562 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one contributing factor.

H. Impact of All Events on Patients

A review of the 562 events and corresponding Root Cause Analysis (RCA) reports for 2010 revealed that similar to 2009, the most frequent consequences of serious preventable adverse events on patients included additional laboratory testing or diagnostic imaging (45.6%) and additional patient monitoring in current location (45.0%). Over 40 percent of the patients (42.7%) received either major or minor surgery. About a third of the patients also experienced physical disability or mental impairment (33.1%) or an increase in their length of stay (36.7%) as shown in Table 10. There were 85 deaths reported, which accounted for 15.1 percent of all affected patients.

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

Impact/Outcome	Number of Patients	Percent of Patients[c]
Additional Lab Testing or Diagnostic Imaging	256	45.6
Additional Patient Monitoring in Current Location	253	45.0
Surgery – Major and Minor	240	42.7
Increased Length of Stay	206	36.7
Disability-Physical or Mental Impairment	186	33.1
Death	85	15.1
Loss of Bodily Function	16	2.8
Loss of Sensory Function	7	1.2
Loss of Body Parts	3	0.5

a: Data drawn from 562 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one outcome.

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 April 1, 2008. This report is the second full year of reporting for these hospitals.

There were 58 reportable events submitted from specialty hospitals in 2010. Comprehensive rehabilitation hospitals submitted 38 reportable events, averaging about three event reports per month. Psychiatric hospitals submitted 14 reportable events while special hospitals submitted 6 (Table 11).

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

Facility Type	Number of Hospitals	Number of Facilities Reporting	Number of Event Reports	Number of Deaths
Comprehensive Rehabilitation	15	13	38	8
Psychiatric [a] Hospitals	10	8	14	2
Special Hospitals	13	8	6	0
Total	38	29	58	10

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

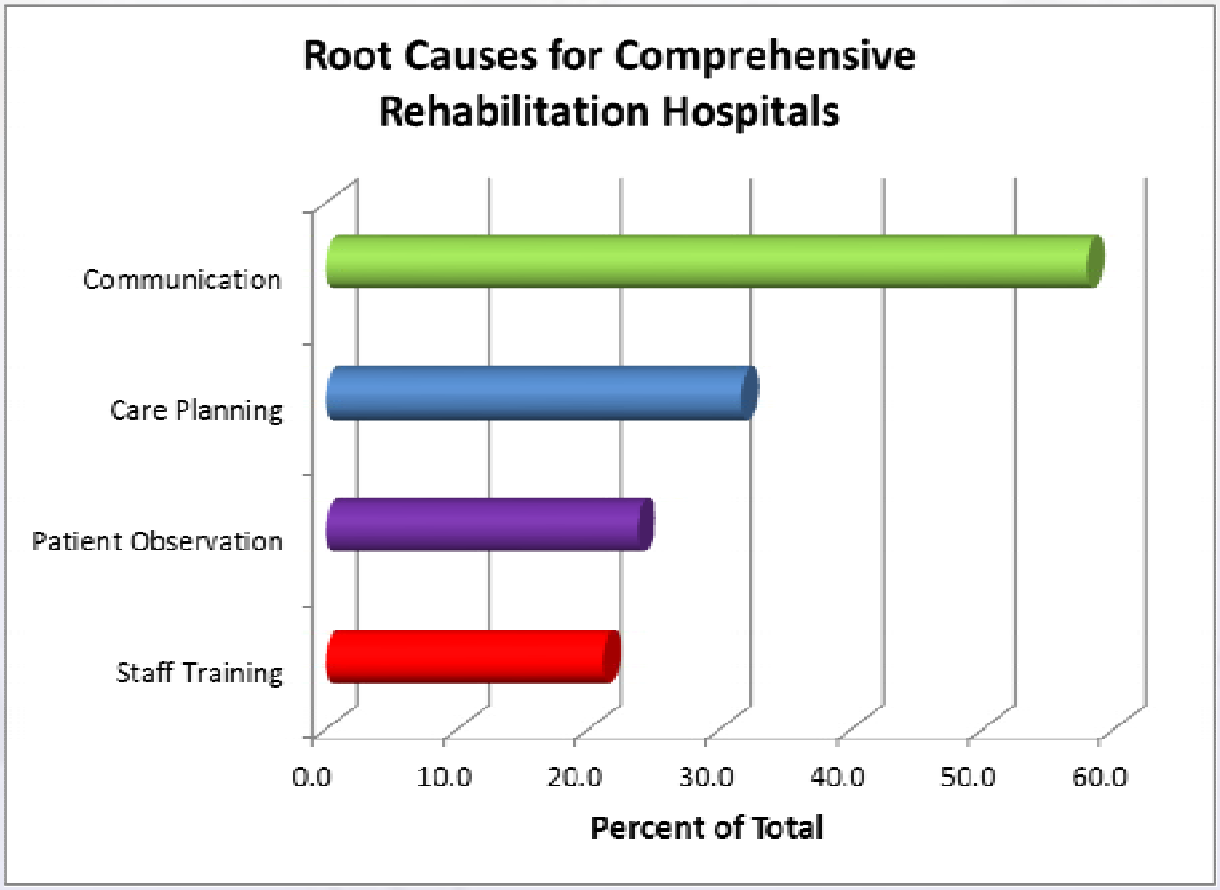
Of the 15 comprehensive rehabilitation hospitals in the state, 13 (86.7%) reported at least one event in 2010. As noted earlier, there were 38 reportable events from these hospitals. There were 29 fall events, representing 76.3 percent of the total reportable events submitted by comprehensive rehabilitation hospitals. Care management "other" events were the second highest number of reportable events (7 events or 18.4% of the total). There was one reportable medication error and one reportable pressure ulcer event submitted.

There were eight (8) reportable deaths submitted by comprehensive rehabilitation hospitals. One-half (4) were associated with care management "other" events and three were related to falls. The remaining one death was attributed to a medication error.

1. Root Causes for All Events

Most of the 38 events (22 or 57.9%) submitted had a root cause related to communication among staff and/or with patient/family. This was followed by care planning process, patient observation procedures and orientation and training of staff (Figure 8).

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



a: Data drawn from 38 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one root cause.

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

2. Contributing Factors to All Events

The most frequently reported contributing factors were patient characteristics (63.2%), task factors (26.3%) and team factors (23.7%). Additional factors reported were procedures, equipment and patient record documentation (Table 12).

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

Patient Factors	Number of Events	Percent of Events
Patient Characteristics	24	63.2
Task Factors	10	26.3
Team Factors	9	23.7
Equipment	8	21.1
Patient Record Documentation	8	21.1
Procedures	6	15.8

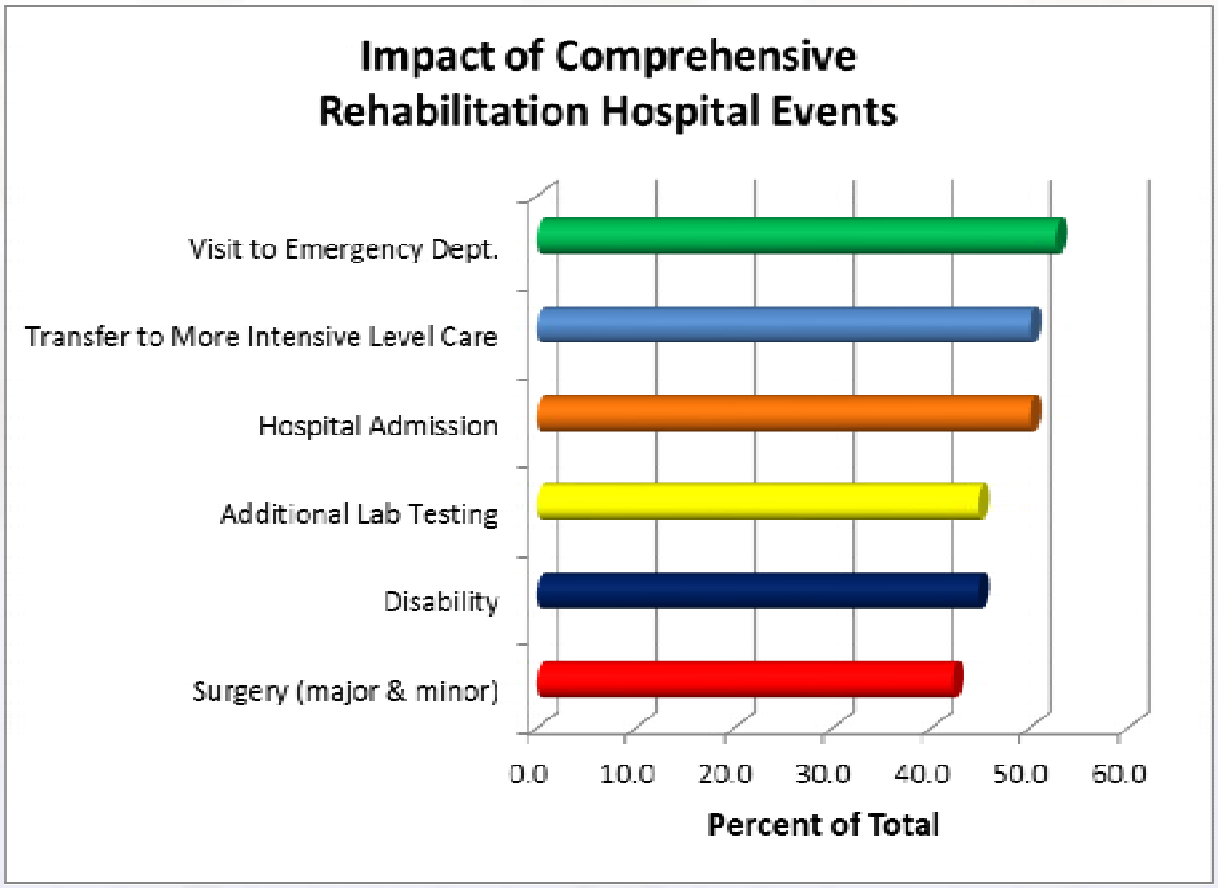
a: Data drawn from 38 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one contributing factor.

3. Impact of All Events

Due to the adverse event, about 50 percent of the patients had a visit to an emergency department, were admitted to the hospital, or transferred to a more intensive level of care.

Other major impacts included disability-physical or mental impairment. Additional laboratory testing or diagnostic imaging and surgery were also observed as impacts for these patients (Figure 9).

Figure 9: Comprehensive Rehabilitation Hospitals: Impact of All Events[a]



a: Data drawn from 38 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one outcome.

B. Psychiatric Hospitals

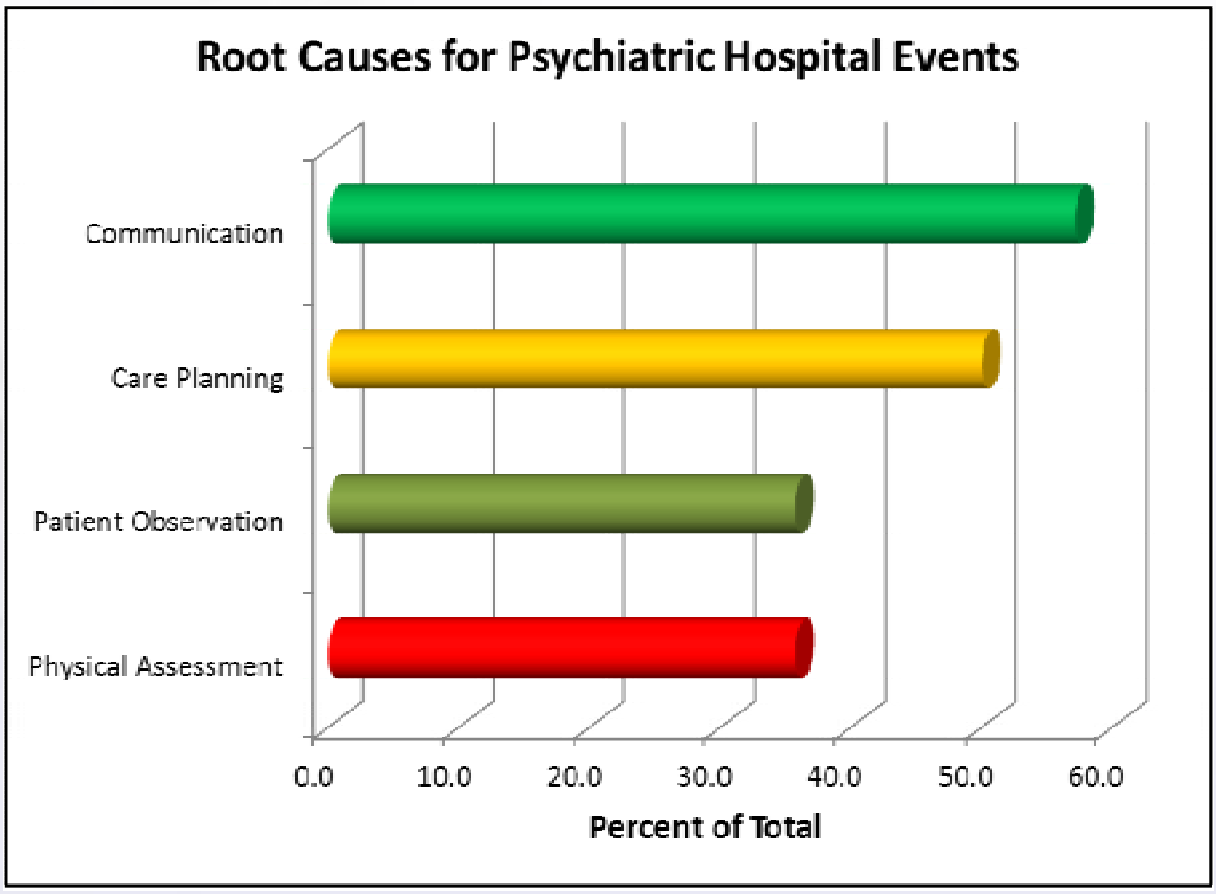
Eight out of the 10 psychiatric Hospitals reported at least one event during 2010 (80.0%). A total of 14 reportable events were submitted to the Patient Safety Reporting System. Of the 14 events, eight (57.1%) were falls, three were care management other events (21.4%) and three were patient or resident suicide or attempted suicide (21.4%).

There were a total of two deaths which were associated with care management "other" events.

1. Root Causes for All Events

Communication among staff and/or with patient/family, and care planning process were the major causes of adverse events within psychiatric hospitals. Others root causes included physical assessment process and patient observation procedures (Figure 10).

Figure 10: Psychiatric Hospitals: Root Causes for All Events[a]



a: Data drawn from 14 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one root cause.

2. Contributing Factors to All Events

Procedures (50%) and patient characteristics (42.9%) were the most frequently reported contributing factors to events occurring in psychiatric hospitals. The next most frequently reported contributing factor was staff factors (35.7%). Team factors, task factors, and other factors each represented 21 percent of the total contributing factors (Figure 13).

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

Patient Factors	Number of Events	Percent of Events
Procedures	7	50.0
Patient Characteristics	6	42.9
Staff Factors	5	35.7
Team Factors	3	21.4
Task Factors	3	21.4
Other Factors	3	21.4

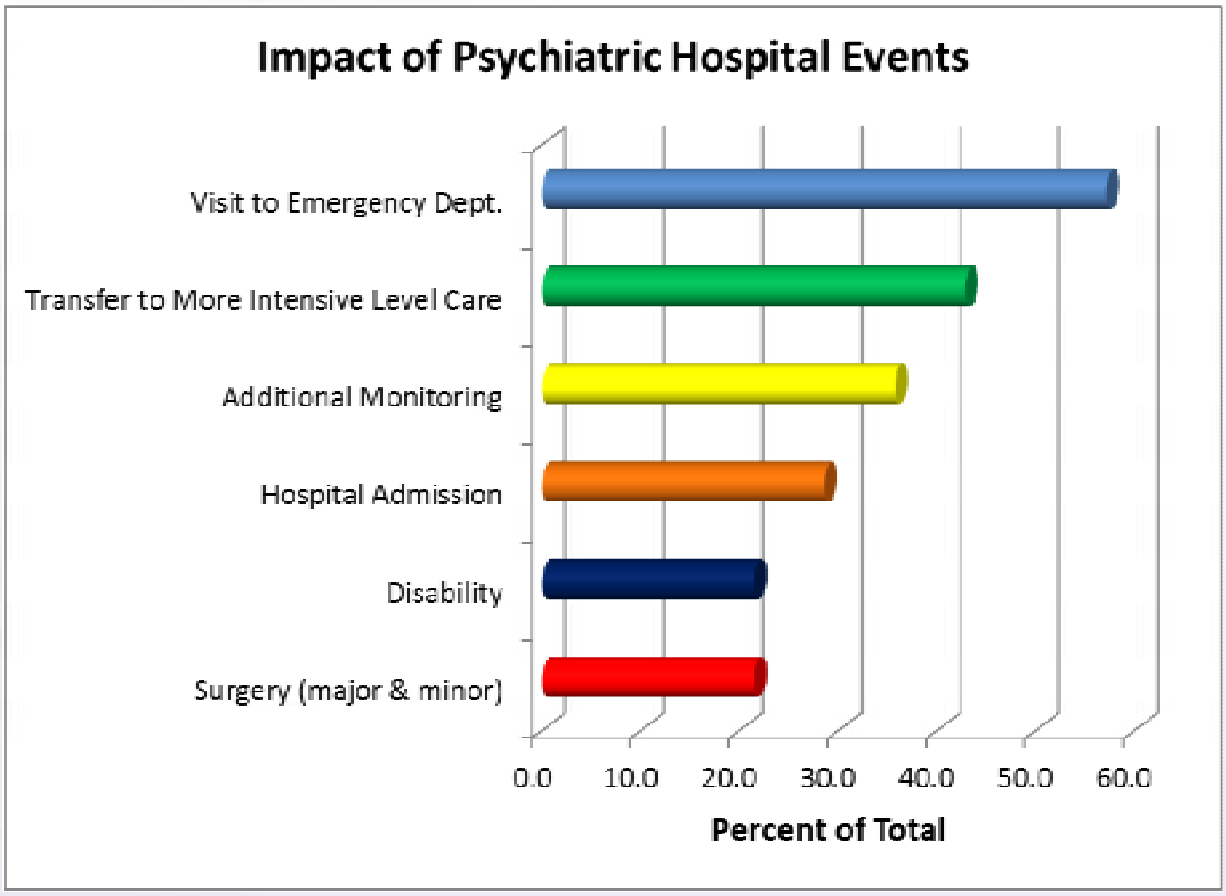
a: Data drawn from 14 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one contributing factor.

3. Impact of All Events

Eight of the 14 events (57.1%) resulted in the patient being sent to the emergency department or transferred to a more intensive level of care. Additional patient monitoring, surgery and disability-physical or mental impairment were also reported.

As noted earlier, there were two deaths reported and both deaths were associated with care management "other" events (Figure 11).

Figure 11: Psychiatric Hospitals: Impact of All Events[a]



a: Data drawn from 14 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one outcome.

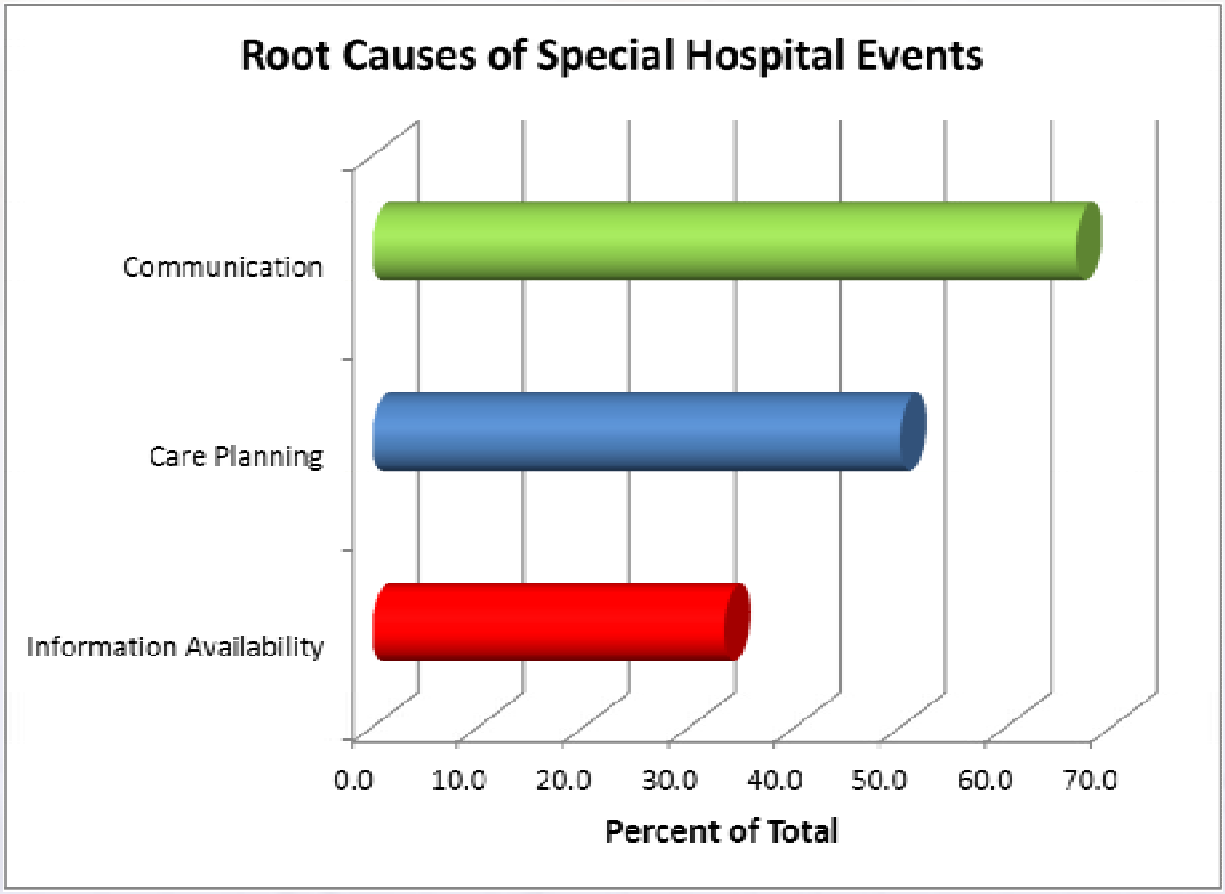
C. Special Hospitals

Eight of the 13 (61.5%) special hospitals reported at least one event in 2010. This is consistent with prior years. Six reportable events were submitted to the PSRS in 2010 and seven reportable events were submitted in 2009. Variation in reporting may relate to the size and patient population of the facility. Five of the events were from the care management category: pressure ulcers (2) and care management "other" events (3). There was one event reported as a fall. None of the events reported by special hospitals resulted in death.

1. Root Causes for All Events

The primary root causes were communication among staff and/or with patient/family. These were followed by care planning process and availability of information (Figure 12).

Figure 12: Special Hospitals: Root Causes for All Events[a]



a: Data drawn from 6 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one root cause.

2. Contributing Factors to All Events

The most frequently reported contributing factor was patient characteristics (83.3%), followed by team factors and patient record documentation (33.3% each). Additional reported factors included task factors, procedures, equipment, and staff factors (Table 14).

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

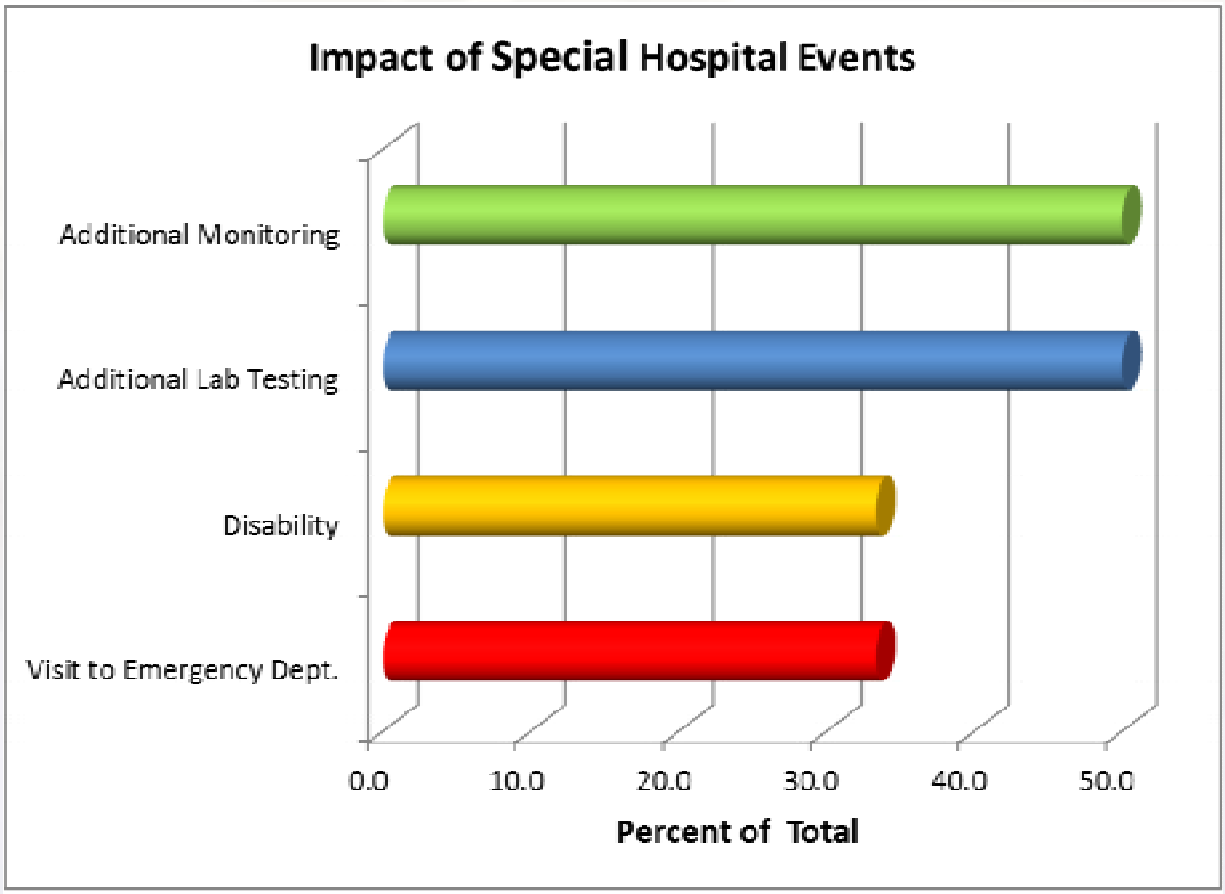
Patient Factors	Number of Events	Percent of Events
Patient Characteristics	5	83.3
Team Factors	2	33.3
Patient Record Documentation	2	33.3
Task Factors	1	16.7
Procedures	1	16.7
Equipment	1	16.7
Staff Factors	1	16.7

a: Data drawn from 6 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one contributing factor.

3. Impact of All Events

The impacts from the reportable adverse events were additional laboratory testing or diagnostic imaging, additional patient monitoring in current location, visit to the emergency department, and disability-physical or mental impairment (Figure 13).

Figure 13: Special Hospitals: Impact of All Events[a]



a: Data drawn from 6 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one outcome.

V. Ambulatory Surgery Centers

New Jersey licensed ambulatory surgery centers (ASCs) began reporting serious preventable adverse events to PSRS as of October 1, 2008. Therefore, 2010 was the second full year of reporting. Since October 1, 2008 a total of 135 reportable and 21 not reportable events have been submitted (Table 15).

Table 15: Ambulatory Surgery Centers: Reportable and Not Reportable Events by Year

Year	Reportable	Not Reportable	Total Events	Percent Not Reportable	Percent Reportable
2008[a]	13	0	13	0	100
2009	48	4	52	8	92
2010	74	17	91	19	81

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

In 2010 there were 74 reportable adverse events submitted by 41 of 119 licensed ASCs (34.5%). The number of reportable events increased by 54.2 percent compared to 2009.

A majority of the cases were surgery-related, and these accounted for 68 cases or 91.9 percent of the total. Intraoperative or postoperative coma, death or other serious preventable adverse events accounted for 43 events or 58.1 percent of ASC adverse events, while surgery "other" events numbered 20, which is 27.0 percent of the total reported events. Fifty out of the 74 patients (67.6%) were admitted to hospitals.

There were eight deaths reported: six from intraoperative or postoperative coma, death or other serious preventable adverse events (75.0%) and two due to surgery "other" events (25.0%) (Table 16).

Table 16: Ambulatory Surgery Centers: Events Reported

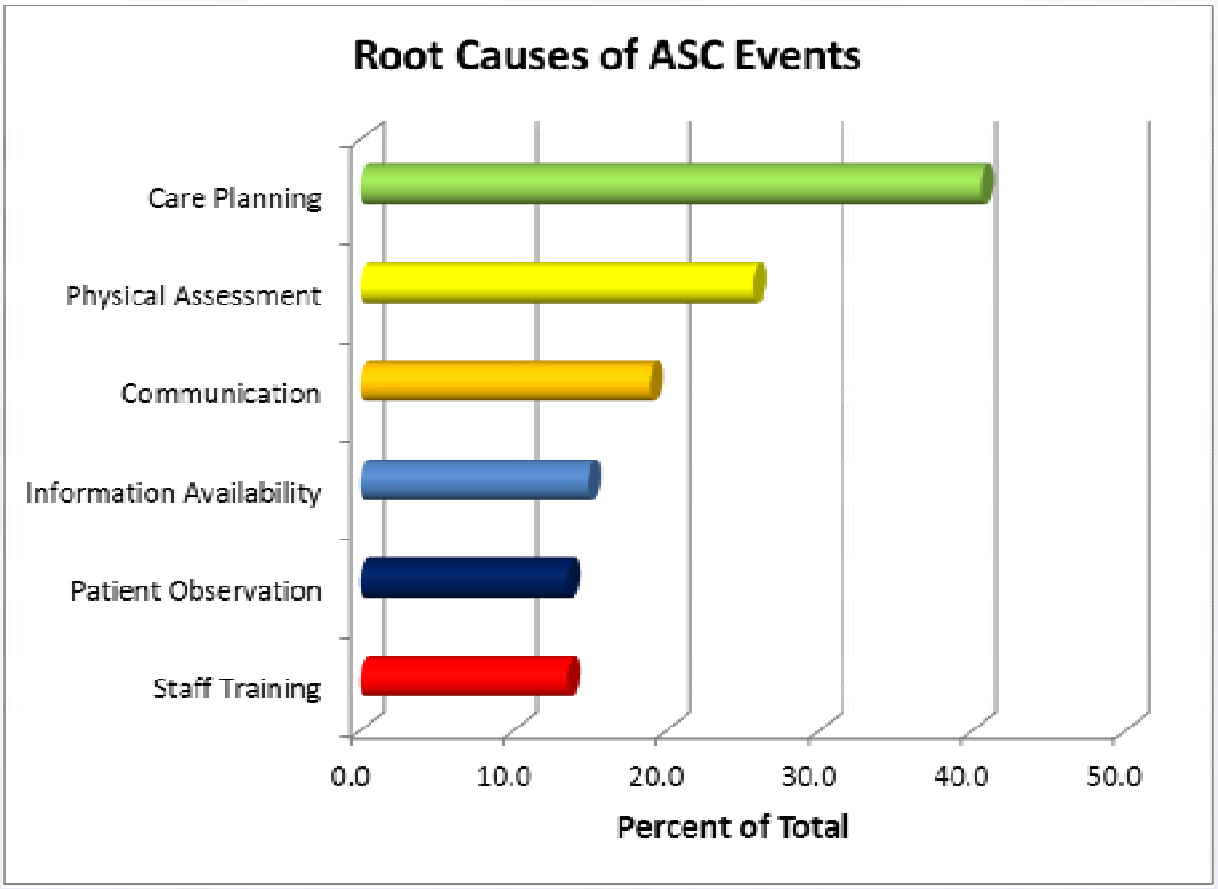
Event Category	Number of Events	Percent of Events	Number Admitted to Hospital	Number of Deaths
Intraoperative or Post-Operative Coma, Death or Other Serious Preventable Adverse Event	43	58.1	37	6
Surgery "Other" Event	20	27.0	10	2
Retention of a Foreign Object	2	2.7	0	0
Falls	2	2.7	1	0
Wrong Body Part	2	2.7	0	0
Wrong Procedure	1	1.3	0	0
Medication Error	1	1.3	1	0
Air Embolism	1	1.3	0	0
Burn	1	1.3	1	0
Care Management "Other" Event	1	1.3	0	0
Total	74	100.0	50	8

V. Ambulatory Surgery Centers

A. Root Causes for All Events

The 74 RCA reports showed that the most frequent causes of all the events reported by ambulatory surgery centers were care planning process, physical assessment process, and communication among staff and/or with patient/family. Availability of information, orientation and training of staff, and patient observation procedures were also identified as root causes (Figure 14).

Figure 14: Ambulatory Surgery Centers: Root Causes for All Events[a]



a: Data drawn from 74 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one root cause.

V. Ambulatory Surgery Centers

B. Contributing Factors to All Events

The most frequently reported contributing factors were patient characteristics (52.7%), procedures (47.3% of events), and other (25.7%). Task factors, staff factors and team factors were also identified as contributing factors (Table 17).

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

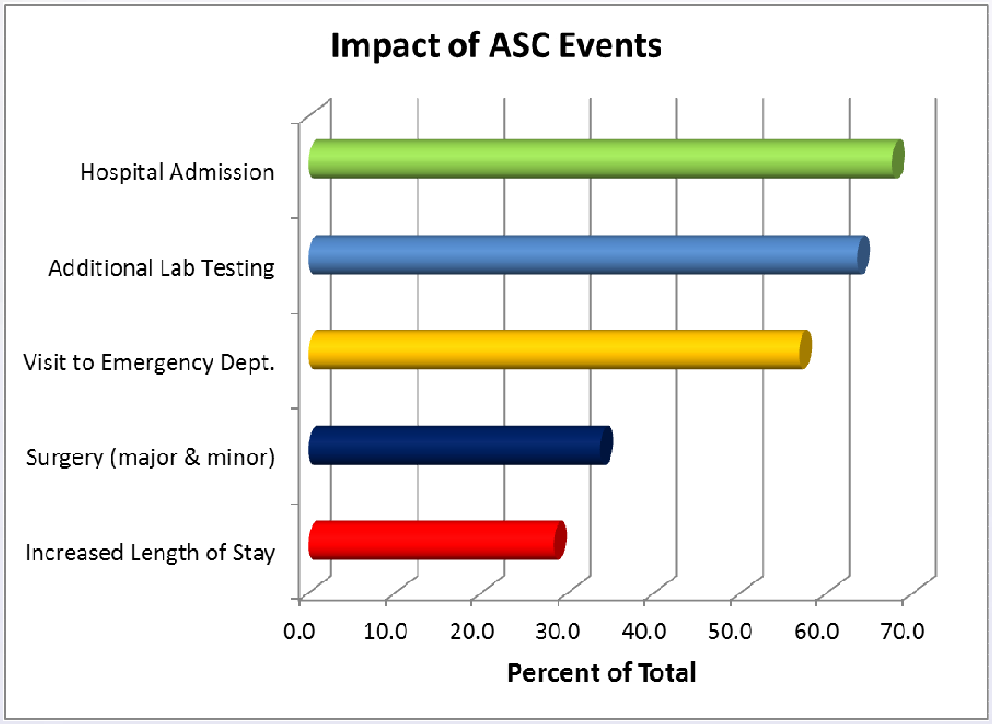
Patient Factors	Number of Events	Percent of Events
Patient Characteristics	39	52.7
Procedures	35	47.3
Other Factors	19	25.7
Task Factors	16	21.6
Staff Factors	12	16.2
Team Factors	11	14.9

a: Data drawn from 74 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one contributing factor.

C. Impact of All Events

Seventy-four reportable events were submitted. Of these events, 67.6% were hospitalized. Additional laboratory testing/diagnostic imaging was provided to 63.5% and 56.8% visited the ED. Patients also had an increased length of stay and about 30% required additional surgery (Figure 15).

Figure 15: Ambulatory Surgery Centers: Impact of All Events[a]



a: Data drawn from 74 RCAs submitted for 2010 events. Percent does not total 100% since events generally have more than one outcome.

VI. Division of Mental Health and Addiction Services

A. Implementation

The process for each hospital's risk management department coding applicable incidents as patient safety act events continued this year. To ensure adherence, members of the Division of Mental Health and Addiction Services' Patient Safety Act Event Oversight Committee monitors incident reports from all five state psychiatric hospitals to ascertain if an incident entered into the Unusual Incident Reporting Management System (UIRMS) should have been categorized as a Patient Safety Act Event and tracks to ensure that a root cause analysis is conducted.

This committee is tasked with assessing the root cause analysis for thoroughness and credibility using the Joint Commission criteria as well as the requirements of the Patient Safety Act. Inquiries are made to obtain clarification or more information and recommendations are sent back to the facilities with regards to systems and process issues. There continued to be emphasis on re-education of Risk Managers, Directors of Quality Management, and Medical Directors regarding processes. This committee continued to seek clarification regarding reportability on some fall events from the Department of Health.

This committee also evaluates system-wide or hospital-specific patient safety issues and makes additional recommendations to reduce the risk to patient. Tracking these to completion was, and continues to be, a challenge. A log is maintained and timeliness of completion and review of the cause analysis is tracked.

The plan is to continue with training in 2012.

B. Overall Reporting Patterns

From January 1, 2010, through December 31, 2010, fourteen (14) events meeting the definition of Patient Safety Act event were reported by the 5 State Hospitals. The majority of these events (Seven out of fourteen, 50%) were falls with major injury. Suicide attempts, (6 out of 14, 42%) and one medication error (8%) accounted for the rest.

C. Focus on Specific Events

1. Falls (7)

Of the seven falls, three of the patients were male and four were female. All were over the age of 60 with the average age of 70. Five of the seven events were hip fractures, two were other extremities. Six of the seven patients had a history of falls. Six of the seven patients had multiple psychotropic medications ordered.

Root Causes:

- The fall risk assessment and reassessment process was not systematically implemented and persons using the tool were not using it correctly resulting in a lower score.
- Physical Therapy assessment and follow-up was problematic.
- In two cases equipment to mitigate the risk of harm to patients was not ordered or not checked to see if functioning.
- Polypharmacy and use of antipsychotic medications in the elderly was felt to be a contributing factor.
- Hand-off communication among care providers in relation to falls risk.

VI. Division of Mental Health and Addiction Services

Prevention Strategies:

- Multi-factorial causes and one of the two major interventions implemented have resulted in a major impact in reducing falls or reducing impact. It was decided that an ad hoc group needed to review best practices and evidenced based practices for reducing fall risks.
- Preventative routine environmental rounds to ensure the proper functioning of falls preventative devices were instituted.
- Continued emphasis was placed on the need to decrease polypharmacy, especially in the elderly. The committee planned for a 2011 webinar, with the New Jersey Hospital Association, on Aging, Mental Illness and Antipsychotics with Dr. Stephen M. Scheinthal, Board Certified Geriatric Psychiatrist, Associate Director and Chief of Geriatric Behavioral Health, Associate Professor, Psychiatry at UMDNJ-SOM Institute for Successful Aging in Stratford, N.J.

2. Attempted Suicide (6)

The second leading event reported by Division hospitals was attempted suicide. Of the 6 reported events in the patient protection category, all six events were by females with two females making two attempts each during the reporting period. Two of the females were 27 and 28 years old, the remaining females were both 55 years old at the time of the event.

A review of the Root Cause Analysis Reports show that some of the recurrent root causes continued to be the areas of behavioral assessment /reassessment, patient observation procedures and communication among staff.

Root Causes:

- Assessment and Reassessment process
- Care Plan

Prevention Strategies:

- Have at least one 'safer' bedroom per unit near nurses' station
- Massive training held in the fall of 2010 with Dr. Shawn Christopher Shea on ***Interviewing Techniques for Assessing Suicide Risk***
- Continue assessing for suicide risk in the environment

c. Medication Error (1)

There was one medication error reported of a patient receiving the wrong medication which resulted in a critical analysis of the medication administration process.

Root Causes:

- The medication administration process for morning medications was assigned to night shift and day shift nurses which resulted in a patient receiving the wrong medication.

Prevention Strategies:

- Reassign the administration of morning medications to day shift nurses.

Report Preparation Team

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Appendix I: Classification of Serious Reportable Adverse Events[1]

The definitions below indicate the general classification and type of serious preventable adverse event.

A. Care management-related events include, but are not limited to:

1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient/resident, wrong time, wrong rate, wrong preparation, wrong route of administration, etc.).
2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a hemolytic reaction due to the administration of ABO-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/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the health care facility.
5. Death or kernicterus associated with failure to identify and treat hyperbilirubinemia 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/resident to a health care facility. This does not include skin ulcers that develop as a result of an underlying vascular etiology, including arterial insufficiency, venous insufficiency and/or venous hypertension; or develop as a result of an underlying neuropathy, such as a diabetic neuropathy. Also excludes progression from Stage II to Stage III, if Stage II was recognized and documented upon admission.
7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility.
8. Other patient/resident care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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

1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with any shock while being cared for in a health care facility. Excludes events involving planned treatments, such as electric counter shock (heart stimulation).

1 Adapted from National Quality Forum. Serious Reportable Events in Healthcare: A Consensus Report. Washington, DC: National Quality Forum; 2002.

Appendix I: Classification of Serious Reportable Adverse Events[1]

2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances and results in patient/resident death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge.
3. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a burn incurred from any source while in a health care facility.
4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a fall while in a health care facility.
5. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with the use of restraints or bedrails while in a health care facility.
6. Other environmentally-related adverse preventable events resulting in patient/resident death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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

1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product.
2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use or function of a device in patient/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/resident is in the facility. However, this does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with use of a new single-use device or a reprocessed single-use device in which the device is used or functions other than as intended. All events related to single-use devices should be reported in this category. Indicate whether the device was new or had been reprocessed.
5. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

Appendix I: Classification of Serious Reportable Adverse Events[1]

D. Surgery-related events (i.e., any invasive manual or operative methods including endoscopies, colonoscopies, cardiac catheterizations, and other invasive procedures) include but are not limited to:

1. Surgery initiated (whether or not completed) on the wrong body part.
2. A surgical procedure (whether or not completed) intended for a different patient of the facility.
3. A wrong surgical procedure initiated (whether or not completed) on a patient.
4. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
5. Intraoperative or postoperative (i.e., within twenty-four hours) coma, death or other serious preventable adverse event for an ASA Class I inpatient or for any ASA Class same day surgery patient or outpatient. Includes all patient deaths, comas or other serious preventable adverse events in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
6. Other surgery-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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

1. Discharge of an infant to the wrong person, excluding patient/resident abductions.
2. Any patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient/resident elopement.
3. Patient/resident suicide or attempted suicide while in a health care facility. However, this does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility.
4. Other patient/resident protection-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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.

Patient Safety Reporting System (PSRS) Contact Information

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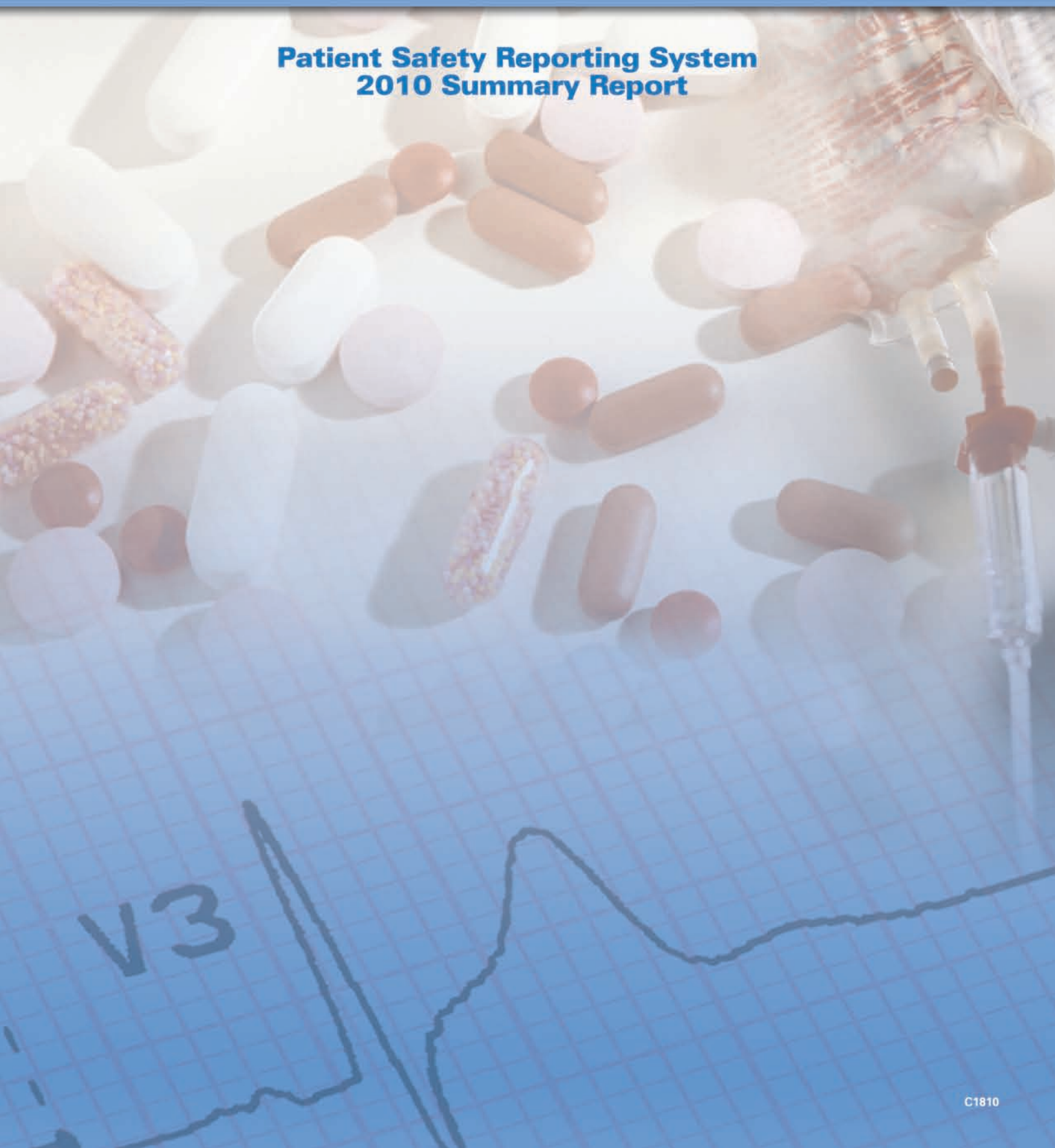
Limited copies are available by writing to the New Jersey Department of Health, Office of Health Care Quality Assessment, P.O. Box 360, Trenton, NJ 08625, by calling (800) 418-1397, by e-mailing hcqa@doh.state.nj.us or by fax at (609) 984-7735. The report is also posted on our website at www.nj.gov/health/ps.

Patient Safety Reporting System
2010 Summary Report



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