Patient Safety Reporting System

2008 Summary Report

Office of Health Care Quality Assessment

Report Preparation Team
Cynthia M. Kirchner, MPH, Senior Policy Advisor
Emmanuel Noggoh, Director
Margaret E Lumia, PhD, MPH, Research Scientist

Patient Safety Reporting System Staff
Mary Noble, MD, MPH, Clinical Director
Margaret E Lumia, PhD, MPH, Research Scientist
Sharon Sedlak, Research Scientist
Gay Lutton, MSN, MS, RN, Health Science Specialist
Frank Lumia, MD, FACC, Consulting Physician
Adan Olmeda, Administrative Support

For further information contact:
Patient Safety Reporting System
Office of the Commissioner
Health Care Quality Assessment
New Jersey Department of Health and Senior Services
Post Office Box 360
240 West State Street
Trenton, NJ 08625-0360

Phone: (800) 418-1397
Fax: (609) 984-7707
Website: www.NJ.gov/health/ps
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I. Background

A. Overview

Patient safety continues to be one of the nation’s most challenging health care issues. It has been ten years since the landmark studies *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century* were published by the Institute of Medicine (IOM).[1,2] Since these publications, there has been a major increase in patient safety awareness among health care providers, state and federal governments, and the general public. Patient safety reporting systems are becoming more common. These reporting systems not only track medical errors, but also encourage health care providers and national/state patient safety organizations to share their experiences and to work together to prevent adverse events.

The New Jersey Patient Safety Act (P.L. 2004, c.9), passed in 2004, continues to produce broad policy and operational changes for improved patient safety in New Jersey.

The main statutory requirements are:

- All licensed health care facilities are required to develop a patient safety plan, including the formation of a patient safety committee. The plan would include a process for a multidisciplinary team to conduct analyses of serious preventable adverse events and near misses. Deliberations are confidential.

- Licensed health care facilities must submit reports of serious preventable adverse events - defined as an event that results in death or loss of a body part or disability or loss of bodily function lasting more than seven days or present at discharge - to the New Jersey Department of Health and Senior Services (the Department).

  - Facilities are required to submit a root cause analysis (RCA) for each reported event within 45 days of submitting the event as described in the Department’s guidelines.
    - RCAs must include: description of the event; determination of the causes; corrective action plan; and monitoring of the corrective action plan.
    - The Patient Safety Initiative clinical team reviews each event and RCA to ensure that the analysis and plans fulfill the Department’s requirements and are likely to prevent the event from occurring again.

  - Reports will be analyzed to detect trends or events of statewide significance.

  - The New Jersey Department of Human Services is responsible for setting up a similar system for the state psychiatric hospitals.

  - Information in the mandatory system is not subject to discoverability in any civil, criminal or administrative action or considered a public record.

  - The rules developed to implement the statute mandate a phase-in of all licensed health care facilities.
B. New Jersey Patient Safety Updates

- General acute care hospitals began reporting February 1, 2005; psychiatric, special and comprehensive rehabilitation hospitals began reporting April 1, 2008; and ambulatory surgery centers began reporting October 1, 2008.

- Serious preventable adverse event reporting began in August 2008 at state psychiatric hospitals, and they report to the Department of Human Services, Division of Mental Health Services.

- In 2009, legislation was passed requiring hospital specific data on patient safety performance and serious preventable adverse events be included in the annual New Jersey Hospital Performance Report. Currently, the Hospital Performance Report includes 12 Patient Safety Indicators (PSIs) that were approved by the New Jersey Legislature in 2009.

  - The data for PSIs are collected from the Uniform Billing (UB) data and not from the confidential serious preventable adverse event reports that are submitted to the Patient Safety Initiative. To avoid confusion and to further differentiate these two programs, the Patient Safety Initiative will now be known as the Patient Safety Reporting System.

  - The 12 PSIs were selected from the 20 PSIs developed by the Agency for Healthcare Research and Quality (AHRQ) to measure health care quality by using readily available inpatient hospital discharge data. The 12 PSIs include such serious adverse events as objects left inside patients during surgery, accidental cuts and punctures to patients, or hip fractures suffered in a post-surgery fall.

C. How to Use This Report

The Patient Safety Reporting System started collecting data from general acute care hospitals in February 2005 and continues this process to date. The compilation of this data collection from 2005-2008 is documented in the Patient Safety Reporting System: 2008 Summary Report. This data can be used to look at trends that are occurring in the area of patient safety. This report is one component of the Department’s commitment to supporting quality through collecting and analyzing information on health care quality and making this information available to the public. It is designed to provide an overview of patient safety reporting and activities. Other Department projects which focus on health care quality are listed on page four and available online at http://nj.gov/health/healthcarequality/index.shtml.

One of the difficulties in reducing serious preventable adverse events is overcoming the “culture of blame” prevalent in the health care system. The requirement to report preventable adverse events is not designed to identify and punish the involved staff. Based on the IOM strategy and the New Jersey Patient Safety Act, the objective is to
assist facilities in improving the systems for providing care. With the relatively low occurrence of serious preventable adverse events, it is important to recognize that the number of reports from New Jersey facilities may differ from year to year for a variety of reasons. A higher number of reported events does not necessarily mean that a facility is less safe and a lower number does not necessarily mean the facility is safer. In some cases, the number of events may be higher at facilities that are especially vigilant about identifying and reporting events.

Because of the Patient Safety Reporting System, health care providers in New Jersey are aware and watching for situations involving serious preventable adverse events. They are reporting these events with the intent to learn and prevent future harm to their patients. This reality is a major step forward in patient safety.

Consumers can use this report to identify situations of interest and ask their hospital or health care provider about what is being done to prevent these types of events from occurring. Consumers can also consult the New Jersey Hospital Performance Report to compare individual hospitals on their quality of care. The 2009 Hospital Performance Report includes the 12 Patient Safety Indicators mentioned on page two of this report.

**Resources for providers on patient safety include:**
- Institute for Healthcare Improvement (IHI): http://www.ihi.org/ihi
- AHRQ Morbidity and Mortality Rounds on the Web: http://webmm.ahrq.gov/
- Joint Commission: http://www.jointcommission.org/

**Resources on patient safety for consumers include:**
- New Jersey Hospital Performance Report: http://nj.gov/health/hpr
- Patient Safety Information for Consumers: http://web.doh.state.nj.us/hpr/patientsafety.shtml
- Hospital Patient Rights: http://web.doh.state.nj.us/hpr/patientrights.shtml
- Consumer Information: http://web.doh.state.nj.us/hpr/resources.shtml
Department of Health and Senior Services
New Jersey Health Care Quality Reporting and Assessment Initiatives

- **Hospital Quality**: All New Jersey acute care hospitals are required to submit data for 25 measures based on nationally accepted best practices developed by CMS for heart attack, pneumonia, heart failure and surgical care infection. **Inpatient Quality Indicators (IQIs)** compare New Jersey’s hospitals on 32 nationally recognized measures of inpatient quality care. DHSS released its first **Patient Safety Indicator (PSIs)** report on October 14, 2009 on 12 selected patient safety indicators. The PSIs report came out as part of the 2009 Hospital Performance Report. The **Hospital Performance Report’s** interactive web site allows users to compare individual hospitals and find other consumer information at: [http://nj.gov/health/hpr](http://nj.gov/health/hpr).

- **Cardiac Services**: The New Jersey Department of Health began collecting patient level cardiac catheterization data in 2001 to ensure facilities meet licensing guidelines and regulations. New Jersey hospitals licensed to operate a cardiac catheterization laboratory are required to report patient level data for each cardiac procedure on a quarterly basis. In November 1997, the Department initiated a report on **Coronary Artery Bypass Graft (CABG) surgery**. The CABG surgery report deals with quality of care provided by hospitals and surgeons performing bypass surgeries in New Jersey. Consumer and technical reports on CABG surgery are available at: [http://nj.gov/health/healthcarequality/cardiacsurgery.shtml](http://nj.gov/health/healthcarequality/cardiacsurgery.shtml).

- **Quality Indicator Measures (QIs)**: The health care quality measures are derived by applying the Agency for Healthcare Research and Quality QI Modules on the readily available New Jersey Hospital Discharge data. These measures provide health professionals, policy makers and consumers with a tool that they can use in making important health care decisions. **Prevention Quality Indicators (PQIs)** compares hospitalizations by county for the 14 PQIs. The PQI reports are available at [http://nj.gov/health/healthcarequality/pqi.shtml](http://nj.gov/health/healthcarequality/pqi.shtml).

- **Stroke Services**: The Stroke Center Act, requires the Department to designate licensed general hospitals as either Primary or Comprehensive Stroke Centers. In 2007, the DHSS Acute Stroke Data Registry was initiated to build a partnership with New Jersey’s designated Stroke Center Hospitals and create a statewide stroke data registry. The Department’s stroke registry is to be implemented on January 1, 2010 and data submission is required of all hospitals designated as Primary or Comprehensive Stroke Centers. More information is available at: [http://nj.gov/health/healthcarequality/stroke/index.shtml](http://nj.gov/health/healthcarequality/stroke/index.shtml).

- **Hospital Patient Care Staffing**: General hospitals are required to post direct patient care staffing levels and to submit aggregate data on a monthly basis to the Department. In January 2009, the first quarterly report was released to the public. This report and subsequent quarterly reports are available at: [http://www.nj.gov/health/hpcs/index.shtml](http://www.nj.gov/health/hpcs/index.shtml).

II. Implementation

The Department developed the Patient Safety Reporting System to implement the statute that passed in 2004. Reporting for general acute care hospitals began in February 2005 as specified in the rules. The mandatory reporting system is based on the National Quality Forum’s (NQF) list of “never events.”[3] The Patient Safety Act requires the Department to use national standards wherever possible. New Jersey’s system uses five general categories: care management, environment, product or device failure, surgery-related and patient protection (Appendix 1). Some changes from the NQF categories and definitions were made by New Jersey. They are:

- An “other” category was added to each of the five categories in order to allow reporting of events that meet the statutory definitions of serious harm (i.e., lasts seven days or present at discharge) but are not specifically included in the NQF list.

- The NQF list published in 2002 included only falls resulting in death. In 2007 NQF changed this requirement to include falls resulting in serious injury which is consistent with New Jersey’s list that, since inception, includes all falls with serious harm.

- The NQF list includes intra-operative and post-operative surgery events resulting in death for American Society of Anesthesiologists (ASA) Class I patients. New Jersey’s list includes events resulting in death or significant harm within twenty-four hours. The New Jersey events also include any ASA Class patients in an outpatient or same day surgery setting. This includes all patient deaths, comas, or other serious preventable adverse events in situations where anesthesia was administered and/or the planned surgical procedure may or may not have been carried out.

- In January 2007, the reporting categories were modified to distinguish between single-use and reusable devices which do not function as intended.

- Certain criminal events are included in the NQF list but are not covered by the New Jersey Patient Safety Act. These events must be reported to the Department’s Office of Health Facilities Assessment and Survey and appropriate police authorities.

Overview of 2008 Activities

The New Jersey Patient Safety Reporting System reviews all reported events, RCAs and corrective action plans. Based on these reports and trend data from facilities, the New Jersey Patient Safety Reporting System provides guidance to facilities on how they can strengthen their analyses and corrective actions. The Reporting System also uses this information to develop newsletters and alerts that communicate with facilities about Department activities and share information from specific reported events/RCAs.

- Patient Safety Regulations
  In order to comply with the statute mandate, a phase-in approach of all licensed health care facilities to start
reporting to the Patient Safety Reporting System was employed. In April 2008, licensed psychiatric, special and comprehensive rehabilitation hospitals began reporting and in October 2008, New Jersey licensed ambulatory surgery centers began reporting.

- **Sharing Knowledge:**
  - April 2008 Newsletter: *Review of Invasive Procedures: Wrong Patient, Wrong Site, Wrong Procedure* provides a summary of "time out" procedures for both surgery and other invasive procedures. It also provides best practices and issues raised by New Jersey hospitals to avoid errors related to wrong site/procedures/patients (Appendix 2).
  
  - June 2008 Newsletter: *Suicide in the Hospital Setting* highlights suicidal behaviors and risk factors to help hospital staff identify patients with suicidal ideation and reduce the number of suicide attempts (Appendix 2).

  - Starting in December of 2008 a monthly Prevention Strategy is posted to the Patient Safety Reporting System website. Each strategy provides a summary of a reported event and the facility’s resolution to prevent the event from reoccurring.

  - June 2008: Patient Safety Reporting System staff conducted event reporting and root cause analysis training for the newly reporting facilities. In attendance were a total of 42 representatives from psychiatric hospitals, special hospitals and comprehensive rehabilitation hospitals

  - November 2008: Patient Safety Reporting System staff conducted event reporting and root cause analysis training for licensed ambulatory surgery centers. In attendance were a total of 163 representatives from ambulatory surgery centers from around the state.

- **Development of a Web-based System:**
  A Request for Proposal (RFP) for a web-based patient safety system was developed to allow facilities to submit events and RCAs through the web. The final RFP was approved and bids from various vendors were submitted. In December of 2008 a vendor was selected and awarded the contract. Development of the online system began in September 2009 and is projected for completion in 2012.
III. Analyses of Events and RCA Reports

A. General Acute Care Hospitals

Collecting and analyzing reports submitted from hospitals on events and RCAs are vital components of the Patient Safety Reporting System. Mandatory reporting began in February 2005 for general acute care hospitals. Event report summary information for 2005 through 2008 is provided in the following tables and figures (initial year reporting is based on 11 months). RCA summary information is based on events reported in 2008.

1. Continued Growth in Reporting

Since 2005, the first year of reporting, there has been a steady increase in the number of events submitted; 376 reportable events were submitted in 2005 which increased to 533 reportable events, in 2008, a 42% increase in reporting (Table 1). The number of reporting hospitals increased from 83% in 2005 to 95% in 2008. Four hospitals did not report any events in 2008.* The average number of events per hospital was 4.6 in 2005 and 7.0 in 2008. When reported events are adjusted by 1,000 patient days, the rate of reported events increased from 0.070 in 2005 to 0.095 in 2008.

* During 2008, the Department actively worked with the non-reporting hospitals to ensure understanding of the reporting process. This has resulted in more consistent reporting.

<table>
<thead>
<tr>
<th>Table 1: Reporting Patterns (2005-2008)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total reported events</td>
</tr>
<tr>
<td>376 450 456 533</td>
</tr>
<tr>
<td>% of hospitals reporting each year</td>
</tr>
<tr>
<td>83% 88% 94% 95%</td>
</tr>
<tr>
<td>Number of reporting hospitals</td>
</tr>
<tr>
<td>68 71 75 72</td>
</tr>
<tr>
<td>Reported events per 1,000 patient days</td>
</tr>
<tr>
<td>0.070 0.078 0.080 0.095</td>
</tr>
<tr>
<td>Average number of reports per hospitals</td>
</tr>
<tr>
<td>4.6 5.6 5.7 7.0</td>
</tr>
</tbody>
</table>

a: Based on 82 hospitals in 2005, 81 hospitals in 2006, 80 hospitals in 2007 and 76 hospitals in 2008
b: Represents 11 months of data since the program started on February 1, 2005
Figure 1 demonstrates the variation in the number of all reported events by quarter since the beginning of the Patient Safety Reporting System (February 1, 2005). It was expected that after four years of reporting the number of event reports submitted each month would become more consistent as hospitals became more aware of patient safety issues and began to implement measures preventing preventable events from occurring. However, this is not the case as the number of reports continue to fluctuate by quarter. As shown in Figure 1, the Patient Safety Reporting System receives an average (mean) of 113 reported events from general acute care hospitals each quarter.
Figure 2 presents reporting patterns for hospitals across years based on the number of events submitted per year. The most frequent category is between one and five events for each reporting year. However, since 2005 there has been an increase in the number of hospitals which fall in the higher reporting categories (11 to 20 events and 21 to 40 events).

Reporting for 2008 shows that hospitals with an intermediate number of maintained beds (201-300 and 301-400) submitted the most reports, 45% of the total reports (Table 2). This is reasonable since 34 hospitals are in this intermediate group.

<table>
<thead>
<tr>
<th>Maintained Beds</th>
<th>Number of Hospitals</th>
<th>Number of Reports</th>
<th>Percentage of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 100</td>
<td>8</td>
<td>10</td>
<td>2%</td>
</tr>
<tr>
<td>101-200</td>
<td>19</td>
<td>77</td>
<td>14%</td>
</tr>
<tr>
<td>201-300</td>
<td>23</td>
<td>133</td>
<td>25%</td>
</tr>
<tr>
<td>301-400</td>
<td>11</td>
<td>106</td>
<td>20%</td>
</tr>
<tr>
<td>401-500</td>
<td>9</td>
<td>112</td>
<td>21%</td>
</tr>
<tr>
<td>501+</td>
<td>6</td>
<td>95</td>
<td>18%</td>
</tr>
<tr>
<td>Total</td>
<td>76</td>
<td>533</td>
<td>100%</td>
</tr>
</tbody>
</table>
However, when looking at the number of reports submitted per 1,000 patient days by hospital patient-volume, the smaller hospitals have the highest number of reports as shown in Figure 3. This is consistent with some of the findings in 2007. Overall in 2008, there was an increase in the number of reports per 1,000 patient days. The reporting rate is highest for the low patient-volume hospitals (5,000-20,000 patient days) and lowest for the high patient-volume hospitals (over 150,001 patient days). The reporting rates for the intermediate patient-volume hospitals are similar to 2007. This intermediate group includes most New Jersey hospitals while the extremes include very few hospitals (i.e., nine low patient-volume hospitals and seven high patient-volume hospitals).

It would be expected that after adjusting for patient days there would be a similar number of events reported across all hospital sizes. However, it is the smaller hospitals that are submitting more reports per patient days.

These findings are comparable to the findings of the Pennsylvania Patient Safety Reporting System (PA-PSRS). PA-PSRS also found that the smaller hospitals had the highest submission rate.\[^4\] The reason for the higher reporting may be because of differences in how serious preventable adverse events are identified and reported. Also, there may be less of a chance of an event getting lost in the system at a smaller hospital.
2. Focusing on Specific Events

This section explores the most commonly reported events in greater detail: falls, pressure ulcers, surgical events and suicides. Also included is a review of care management “other” events and medication error events. This section will also take a closer look at the most serious outcome of an event, death.

a. Falls

Falls are the most frequently reported event submitted to the Patient Safety Reporting System in each reporting year. While there has been an increase in the overall rate of total events reported each year, there has also been an increase in the reported rate of falls. In 2005, 33% of all events reported were falls. This number increased to 40% in 2008.

The number of falls reported by acute care hospitals was analyzed using Moving Range Control Charts (Figure 4). This chart illustrates the variation of reported falls over time and makes it easier to detect trends. These trends can then be used to help predict future performance from the acute care hospitals.

In Figure 4, an average of 10 fall events per month from February 2005 to February 2006 was submitted to the Patient Safety Reporting System. There was an increase in the average number of fall events reported (16 fall events/month) from March 2006 to December 2008. A two-tailed, unpaired t-test was used to determine if this increase in fall events was statistically significant. The t-test results ($p=0.0009$) determined that there was a statistically significant increase.

![Figure 4: Moving Range Control Charts (All Falls 2005-2008)](image-url)
Figure 5: Falls by Age Groups (2008)

Figure 6: Number of Falls versus Time of Day (2005-2008)
During 2008, the typical patient who sustained a fall resulting in serious injury was an older (between 81-90 years) Caucasian female patient (Figure 5). Falls become more common as patients get older, especially over age 50. The overall death rate is 10% and appears to occur to patients 50 and older. Falls have a significant risk of death and preventing falls should be a high priority at hospitals.

Of the 213 reported falls, the majority occurred in the patient’s room (71%), usually when the patient was attempting to go to the bathroom. Other locations for patient falls, although to a lesser extent, are hallways or other common areas (8%) and the emergency department (8%). The event usually occurred within the first 7 days following admission.

The majority of falls reported in the past four years occurred in the early morning, between 12 midnight and 6 am, and late afternoon, 2 pm to 5 pm (Figure 6). This may be due to the timing of medication, especially diuretic medication. A review of the RCAs revealed that some hospitals administered medication late in the morning and again around bedtime. This increases the likelihood that the patient will need to use the bathroom or commode during night or early morning hours.

Overall, the most common serious injury was a fracture of the extremities (31%) followed by hip fractures (25%). The most common injury associated with death was from a fall with an intracranial hemorrhage (Figure 7).

In 2008, 85% of the falls resulted in additional laboratory testing or diagnostic imaging. Other common patient impacts included additional patient monitoring (78%), physical or mental impairment (55%), increased length of stay (54%), and major surgery (41%). Based on the RCA reports, one of the most pervasive causes of falls in hospitals was inadequate care planning (55%) followed by poor communication among staff (32%) and inadequate patient observation (29%).
Preventing Falls

Fall risk assessments should be conducted on admission and entered into the admission database as soon as possible. Another risk assessment should be completed if there are any changes in a patient’s status, such as physiological, functional or cognitive change or whenever a fall occurs. Conducting a fall risk assessment periodically during a hospital stay or when the patient is transported (including transfers to another patient care unit) is also recommended as a good practice in preventing falls.[5]

Corrective Actions[6]
- Communicate the patient’s “at risk” status during shift report and with other disciplines as appropriate.
- Do not leave “at risk” patients or residents unattended in diagnostic or treatment areas.
- Ensure patients or residents being transported by stretcher/bed have all side rails in the up position during transport, or if left unattended briefly while awaiting tests or procedures.
- Ensure that the pathway to the restroom and hallway is properly lighted.
- Install vertical grab bars near toilets.
- Evaluate chair and bed height.
- Install anti-slip tape or strips.

Preventative Actions[6]
- Consider peak effect for prescribed medications that affect level of consciousness, gait and elimination when planning patient care.
- Educate staff to increase awareness of high risk patients.
- Use the standardized color code system to identify a high fall risk patient.
- Educate the patient and their family about the risk of falling and the patient’s limited mobility.
- Include the patient’s family in the development of an individualized safety plan.
- Instruct patients to rise slowly and take their time to make sure they are stable.
- Orient the patient to his/her bed area, location of the bathroom and how to request assistance.
- Instruct the patient or resident to request assistance as needed.

**Prevention Strategy**

**Event:** The patient fell while being transferred from the commode to the bed. The patient had a previous amputation above the knee and he refused to wear his prosthesis. The patient care technician assisted him to the commode. He pivoted toward the side of his intact leg to get to the commode but pivoted toward the side of his amputation to get back to bed. He fell during the transfer back to bed.

**Hospital Strategy:** The RCA Team discovered that training for patient care technicians included transfers but did not specifically address certain patient populations, such as amputees. The training now addresses special populations and includes role playing and demonstration of transfers. The hospital has also started a Situation-Background-Assessment-Recommendation (SBAR) report for patient care technicians to include specific information, such as the amputee status.
b. Pressure Ulcers

Pressure ulcers, sometimes referred to as bedsores, pressure sores, or decubitus ulcers, are injuries caused by constant pressure or shearing forces on the skin and muscle. The average patient who developed a Stage III or Stage IV pressure ulcer during 2008 was a 66-year-old Caucasian male who had been hospitalized for 27 days prior to the event. A little over one third of the patients reported to have a Stage III or IV pressure ulcer were under the age of 65. The majority of these patients underwent long surgeries, had multiple co-morbidities, or long lengths of stay in intensive care units (Figure 8).

According to the 2008 Uniform Billing data, the average length of stay in a hospital for a patient in New Jersey was five days. Patients are more likely to develop pressure ulcers when their length of stay exceeds five days (Figure 9).

In 2008, 98% of the pressure ulcer events required additional patient monitoring. Other common patient impacts included: physical or mental impairment (52%), minor surgery (i.e., tissue debridement) (27%), increased length of stay (21%), additional laboratory testing or diagnostic imaging (20%) and/or a system process delay (20%). Based on the RCA reports, one of the most common causes of pressure ulcers in hospitals was inadequate care planning (86%) followed by poor communication among staff (67%) and inadequate staff orientation (39%).
The severity of pressure ulcers can range from mild, affecting the skin surface only, to severe, when a deep decubitus ulcer reaches down to muscle and bone. The patients most at risk for developing pressure ulcers are those with diminished or absent sensation or who are debilitated, emaciated, paralyzed, or bedridden for an extended time period.\(^7\)

Pressure ulcers are the second most frequently reported serious preventable events, constituting 20% of all reported events in 2008.

There are five stages of severity for pressure ulcers:
- **Stage I:** Intact skin with non-blanchable redness of a localized area.
- **Stage II:** Partial thickness wound that presents as a shallow ulcer or blister.
- **Stage III:** Full thickness tissue loss.
- **Stage IV:** Full thickness tissue loss with exposed muscle, tendon or bone.
- **Unstageable:** Full thickness tissue loss, covered with slough or scabbing so that the stage cannot be determined.

Only patients with Stage III, Stage IV or Unstageable ulceration must be reported to the Patient Safety Reporting System. If at admission a patient is documented with Stage II ulceration and it progresses to Stage III, this is not considered reportable. However, a Stage II ulceration that progresses to Stage IV must be reported. Reporting for pressure
ulcers does not include skin ulcers that develop as a result of an underlying vascular etiology or that develop as a result of an underlying neuropathy. This is different from the CMS reporting requirements.

According to the Braden Scale for Predicting Pressure Sore Risk, typical risk factors for developing pressure ulcers include:[8]

- Impaired ability to respond meaningfully to pressure-related discomfort.
- High level of skin moisture due to perspiration or urine.
- Low degree of physical activity.
- Inability to change or control body position.
- Poor nutrition.

c. Surgical Events

In 2008, 65 surgery-related events were reported. The average patient who experienced a surgery-related event in 2008 was a 56-year-old Caucasian female who had been admitted to the hospital for 2 days prior to the event. Additional laboratory testing or diagnostic imaging was the most common impact of a surgery-related event (59%) followed by additional monitoring (53%), major surgery to minimize or repair the damage (35%) and increased length of stay (18%). The following areas were identified by the hospitals, during the RCA, as the root causes of surgery-related events: poor communication among staff (48%), lack of planning (29%) and inadequate staff orientation and training (17%).

Prevention Strategy

Event: The lack of a sponge count and the lack of an examination following a spontaneous vaginal delivery led to retention of a sponge in two cases. This resulted in discomfort, fever, and a foul smelling vaginal discharge, which required a repeat admission and treatment with antibiotics.

Facility Strategy: Some NJ hospitals have implemented a sponge count before and after a spontaneous vaginal delivery presenting the argument that a manual examination prior to discharge is painful to the patient. Other NJ hospitals have indicated that the sponges used during a vaginal delivery absorb more than just blood, i.e., feces, amniotic fluid and, therefore, performing a sponge count is not practical. They have instituted a manual vaginal examination in the Delivery Room. Either approach is appropriate and will help decrease the number of retained sponges after a vaginal delivery.
Figure 10 presents the distribution of the various types of surgery events. After a drop in reports of retention of a foreign object (RFO) in 2007 (14 RFO/63 surgery-related events), the number of retained foreign objects increased in 2008 (27 RFO/65 surgery-related events). This is more consistent with reporting of RFOs in 2005 and 2006 (24 RFO/65 surgery-related events and 18 RFO/49 surgery-related events, respectively). The second most reported subcategory is the surgery-related “other” events (23%). There was a slight decrease in the number of wrong body part and intra-operative or post-operative coma or death events from 2007. Wrong patient and wrong procedure reported events remained the same as 2007.

Retained Foreign Objects

Retention of foreign objects, such as sponges and instruments, is considered by the National Quality Forum and other national organizations to be a preventable adverse event that should never happen. The Centers for Medicare and Medicaid Services includes the retention of foreign objects in its list of non-reimbursed hospital-acquired conditions. In 2005, The Joint Commission added retained foreign objects to its list of sentinel events. In 2008, retained foreign objects was the seventh most frequently reported sentinel event nationally and the fourth most frequently reported event in New Jersey.¹⁹

A retained foreign object can result in post-procedure infections, bowel
perforations, abscess, undue pain, return to surgery and even death.\[^9\]  A. Gawande et al. conducted a retrospective case-control study on patients with retained instruments or sponges following a procedure. Sixty cases were identified; 54 of these cases confirmed to have a retained object. Sixty-nine percent of these cases identified the retained objects as sponges. Over half of these objects were retained in the abdomen or pelvis and 22% were retained in the vagina. \[^{10}\]

In the four years that the Department has been collecting serious preventable adverse events, retention of foreign objects has been the most frequently reported surgery-related event type. Since 2005, there have been 111 retained foreign object events. In 2008 the majority of the retained foreign objects were surgical sponges; most often retained in the patient’s abdominal cavity or chest cavity (Figure 11).

There have been several studies conducted on the reliability of surgical counts.\[^{11}\] These studies have found this practice to be unreliable or insufficient. One study on retained objects discovered that the majority of the retained objects were associated with a count that was erroneously thought to be correct, which is consistent with New Jersey DHSS’s findings.\[^{10}\] The incorrect counts were due to limitations in the counting procedures, such as additions, incorrect documentation, or miscounting. These studies concluded that manual counts are not reliable enough to be used without concurrent manual visual checks. Any count discrepancy should prompt a thorough search and reconciliation and should never be ignored.\[^{12}\]

There is technology available to help assist in the detection and prevention of retained objects. To augment the manual count, radio-frequency (RF), radio-frequency identification (RFID) and bar coded detectable sponges, gauze, and laparotomy pads are available.\[^{11}\] Use of this technology will help with early detection of retained objects, prevention of additional surgery to retrieve the objects, and the need for x-rays to locate retained objects.
d. Suicide/Attempted Suicide

The fourth leading event reported by hospitals to the New Jersey Patient Safety Reporting System in 2008 was in the Patient/Resident Protection Category, specifically suicides and attempted suicides. These events represent 3% of all deaths from adverse events reported in 2008.

An analysis of these suicide/attempted suicide events by location revealed that 52% occurred in the patient’s room and 39% occurred in the emergency department (Figure 12). These numbers may reflect the increasing trend of behavioral health patients using the emergency department for psychiatric and general medical services.

The average person who committed or attempted suicide in 2008 was a 41-year-old Caucasian male who had been admitted to the hospital for 11 days prior to the event. This differed from 2005 and 2006 when the average patient was female. Additional patient monitoring was the most common (79%) consequence of suicide/attempted suicide followed by additional laboratory testing (30%), transfer to higher level of care (15%), and hospital admission (15%).

A review of the 2008 RCA reports revealed that some of the most recurrent causes of suicide/attempted suicide in hospitals were due to inadequate patient observation (55%), behavior assessment (45%) and poor communication among staff (39%).

Clinicians should remember that denial of suicidal ideation is not sufficient to rule out the presence of suicidal risk.[13] Collateral questions should be asked based on the patient’s suicidal risk factors including symptoms of depression or mania, psychosis, delirium and dementia, losses (especially recent ones), substance abuse, and any family...
members or friends who have died or attempted to kill themselves. Reliance on “no-suicide” contracts should not be considered a sufficient intervention strategy. However, a patient’s refusal to sign such a contract may offer insight into a patient’s potential for suicidal behavior. According to the Minnesota Office of the Ombudsman, such contracts were in place for almost every suicide that occurred in an inpatient, acute care facility.

e. Care Management “Other”

There were 61 reported preventable adverse events under the subcategory of care management “other”. Most of these events were related to the process for managing care. Of the 61 events in this category, 38% were the result of lack of attention to detail and failure of follow-up on laboratory tests, imaging studies and procedures in a timely manner.

The following is an example of a care management “other” event due to a delay in treatment. A female patient arrived in the emergency department complaining of neck pain and an inability to move her upper extremities. An MRI was ordered in the morning and was not completed due to patient movements. The incomplete MRI was not reported to the emergency department physician or nurse. In the late afternoon, an MRI was attempted a second time and completed with a diagnosis of epidural abscess and spinal cord compression. The patient was taken to surgery late that same evening. The patient remains on a ventilator and unable to move her extremities.

The following is another example of a care management “other” event where the lack of follow-up resulted in death. A male was brought to the emergency department by EMS and admitted to the psychiatric unit for paranoid schizophrenia. Two weeks later, the patient was found unresponsive in bed. The Rapid Response Team was called and the patient gradually became responsive and was transferred to a medical floor. One week later, the patient returned to the psychiatric unit and a medical consult was done the following day. Four days later a second medical consult was done with plans to follow the patient daily. There was no evidence that the daily follow-up was implemented. Three days later, the patient was found to be unresponsive, CPR was unsuccessful and he expired.

Poor communication among staff members (56%), inadequate care planning (36%) and lack of physical assessment (34%) were the most frequent root causes of these events. Patient characteristics (54%), procedures (46%) and team factors (38%) were the most common contributing factors to these events. The impact of care management events for patients can be significant, with deaths occurring 51% of the time in 2008.

f. Medication Errors

Consistent with the previous three years, there were few pharmacological errors (4%; n=19) reported to the Patient Safety Reporting System in 2008. Studies have estimated medication error rates as high as one medication error per hospital patient per day. The difference in New Jersey’s rate is likely due to the vast majority of medication
errors resulting in either near misses or minimal patient impact. Of the medication errors reported to the Patient Safety Reporting System, the majority involved administering the wrong dose (42%) or there was a monitoring error (26%).

Communication among staff (68%) and staff orientation/training and availability of information (both 47%) were frequently reported as causes of these errors. Hospital policies and procedures (79%) were the most reported contributing factor to these events. The most common consequences of medication errors, based on the 19 submitted RCAs in 2008, were additional testing (63%), increased length of stay (58%), additional patient monitoring (53%) and transfer to a higher level of care (37%). Death resulted 21% of the time. The New Jersey Patient Safety Reporting System, consistent with other research findings, found that medication errors typically occurred at the point of administration as well as during the process of prescribing, transcribing, dispensing and monitoring.\[16\]

**g. Events Resulting in Death**

The most serious outcome of a preventable adverse event on a patient is death. There were 75 deaths in 2008 related to serious preventable adverse events. Similar to 2007, in 2008 the majority of the deaths (n=31; 42%) were attributed to the care management “other” subcategory followed by falls (n=20; 27%) and intra- or post-operative (n=7; 9%) events (Figure 13). When looking at the root causes of the 31 care management “other” events that resulted in death, one of the most common causes is poor communication among staff followed by inadequate care planning (Table 3).

![Figure 13: Deaths by Subcategory (2008)](image-url)
### Table 3: Root Causes of Care Management “other” Events Resulting in Death

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Number of Events</th>
<th>Percentage of Events&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication among staff</td>
<td>18</td>
<td>58%</td>
</tr>
<tr>
<td>Care planning</td>
<td>13</td>
<td>42%</td>
</tr>
<tr>
<td>Physical assessment</td>
<td>13</td>
<td>42%</td>
</tr>
<tr>
<td>Staff orientation/training</td>
<td>11</td>
<td>35%</td>
</tr>
<tr>
<td>Patient observation</td>
<td>8</td>
<td>26%</td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td>6</td>
<td>19%</td>
</tr>
<tr>
<td>Availability of information</td>
<td>6</td>
<td>19%</td>
</tr>
<tr>
<td>Supervision of staff</td>
<td>6</td>
<td>19%</td>
</tr>
<tr>
<td>Staff competence</td>
<td>6</td>
<td>19%</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>10%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Data drawn from 31 care management other events with death RCAs submitted for 2008 events

<sup>b</sup> Events do not total 100% since events generally have more than one root cause.

### 3. Overall Reporting Patterns

There are five main categories of events: care management, environment, product or device, surgery related and patient protection. The percentage of event reports for each of the five event categories for 2005 through 2008 is presented in Figure 14. As in previous years, the majority of events are in the care management and environment categories. These two categories account for 77% of the reports in 2008.

The distributions of reporting for specific types of subcategories in each event type for 2005 through 2008 are presented in Figure 15. Falls and pressure ulcers continue to be the most frequently reported events. In 2008, the overall percentages of each event subcategory have remained consistent with a few exceptions. There was an increase in the percentage of retention of foreign objects, care management “other” and pressure ulcers. However, in 2008 the percentages of suicides/attempted suicide, surgery-related “other” and falls decreased from 2007.
Figure 14: Percentage of Reports by Event Category (2005-2008)
As with the previous years, there continues to be a substantial percentage of reporting in the care management “other” subcategory. This subcategory includes events that relate directly to general patient care events that are not covered in other categories, e.g., timely follow-up of laboratory studies and imaging studies, delay in treatment etc.
4. Impact of Reported Events on Patients

A review of the 533 events and corresponding RCA reports submitted for 2008 revealed that the most frequent consequences of serious preventable adverse events on patients were additional patient monitoring or diagnostic imaging (74%) and additional laboratory testing (59%). A moderate percentage of patients also experienced physical disability or mental impairment (37%) or an increase in their length of stay (34%) as shown in Table 4.

<table>
<thead>
<tr>
<th>Impact/Outcome</th>
<th>Number of Patients</th>
<th>Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional patient monitoring or diagnostic imaging</td>
<td>394</td>
<td>74%</td>
</tr>
<tr>
<td>Additional laboratory testing</td>
<td>316</td>
<td>59%</td>
</tr>
<tr>
<td>Physical disability or mental impairment</td>
<td>197</td>
<td>37%</td>
</tr>
<tr>
<td>Increased length of stay</td>
<td>182</td>
<td>34%</td>
</tr>
<tr>
<td>Major surgery</td>
<td>132</td>
<td>25%</td>
</tr>
<tr>
<td>Transfer to higher level of care</td>
<td>104</td>
<td>20%</td>
</tr>
<tr>
<td>Death</td>
<td>75</td>
<td>14%</td>
</tr>
<tr>
<td>Minor surgery</td>
<td>54</td>
<td>10%</td>
</tr>
<tr>
<td>Other additional testing</td>
<td>50</td>
<td>9%</td>
</tr>
<tr>
<td>System/process delay</td>
<td>49</td>
<td>9%</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>45</td>
<td>8%</td>
</tr>
<tr>
<td>To be determined</td>
<td>19</td>
<td>4%</td>
</tr>
<tr>
<td>Loss of bodily function</td>
<td>12</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td>Loss of sensory function</td>
<td>6</td>
<td>1%</td>
</tr>
</tbody>
</table>

Table 4: Impact of Events on Patients (2008)

*a Data drawn from 533 RCAs submitted for 2008 events
b Events do not total 100% since events generally have more than one adverse outcome
5. Root Cause Analysis

All facilities are required to submit a root cause analysis (RCA) for each reported event within 45 days of submitting the event. Each RCA is reviewed by the Patient Safety Reporting System staff to ensure that the analysis and corrective action plans meet the requirements and are likely to prevent the event from occurring again.

RCAs must include:

- The **facts of the event**. A detailed account of the event including the date/time/location. There must be a clear description of how the event occurred which is the basis for further analysis to determine causality.

- The **causality statements** which identify root causes and address the underlying vulnerabilities in systems for providing care.

- **Action plans** (risk reduction strategies) which include stated actions or strategies to prevent or reduce the probability of future events, or reduce the harm caused by such events. The risk reduction strategies should specifically address each identified root cause and be feasible to implement. The implementation time frame and the person responsible should be specified.

- **Monitoring plans** that include defined time frames and the responsible person. There should be a monitoring plan for each risk reduction strategy.

According to the Agency for Healthcare Research and Quality (AHRQ), the most common causes of preventable adverse events include communication problems, inadequate information flow, human problems, patient-related issues (assessment or education of patient), organizational transfer of knowledge, staffing patterns, technical failures, and inadequate policies and procedures.[17]

In 2008, the major causes of events reported to the Patient Safety Reporting System were care planning, communication among staff, staff orientation and physical assessment of the patient as shown in Table 5.
Table 5: Root Causes (2008)*

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Number of Events</th>
<th>Percentage of Eventsb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care planning</td>
<td>279</td>
<td>52%</td>
</tr>
<tr>
<td>Communication among staff</td>
<td>245</td>
<td>46%</td>
</tr>
<tr>
<td>Staff orientation/training</td>
<td>154</td>
<td>29%</td>
</tr>
<tr>
<td>Physical assessment</td>
<td>129</td>
<td>24%</td>
</tr>
<tr>
<td>Patient observation</td>
<td>112</td>
<td>21%</td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td>94</td>
<td>18%</td>
</tr>
<tr>
<td>Communication with family</td>
<td>65</td>
<td>12%</td>
</tr>
<tr>
<td>Availability of information</td>
<td>64</td>
<td>12%</td>
</tr>
<tr>
<td>Supervision of staff</td>
<td>57</td>
<td>11%</td>
</tr>
<tr>
<td>Behavioral assessment</td>
<td>46</td>
<td>9%</td>
</tr>
<tr>
<td>Physical environment</td>
<td>44</td>
<td>8%</td>
</tr>
<tr>
<td>Staff competence</td>
<td>38</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>30</td>
<td>6%</td>
</tr>
<tr>
<td>Staffing</td>
<td>19</td>
<td>4%</td>
</tr>
<tr>
<td>Patient identification</td>
<td>18</td>
<td>3%</td>
</tr>
<tr>
<td>Security systems</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td>Adequacy of technical support</td>
<td>7</td>
<td>1%</td>
</tr>
<tr>
<td>Control of medication</td>
<td>4</td>
<td>1%</td>
</tr>
<tr>
<td>Labeling of medication</td>
<td>3</td>
<td>1%</td>
</tr>
</tbody>
</table>

*a Data drawn from 533 RCAs submitted for 2008 events

b Events do not total 100% since events generally have more than one root cause.
6. Patient Characteristics

Table 6 presents the demographic characteristics of patients involved in events reported for 2005 to 2008. Events for the four years are very similar. In 2008, the average patient involved in a preventable event was a 65-year-old female Caucasian who had been admitted to the hospital 11 days prior to the event.

For all four years, the patients involved in preventable events were older than the general hospital population. This is due to the types of events reported. Many of the reported events were falls and pressure ulcers which are more likely to be associated with older patients as shown in subsequent sections of this report.

**Table 6: Demographic Characteristics of Patients from Event Reports Compared to All New Jersey Hospital Patients (2005-2008)**

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Percentage or Average Event Reports&lt;sup&gt;a&lt;/sup&gt; 2005</th>
<th>Percentage or Average Event Reports&lt;sup&gt;a&lt;/sup&gt; 2006</th>
<th>Percentage or Average Event Reports&lt;sup&gt;a&lt;/sup&gt; 2007</th>
<th>Percentage or Average Event Reports&lt;sup&gt;a&lt;/sup&gt; 2008</th>
<th>Percentage or Average All Patients&lt;sup&gt;b&lt;/sup&gt; 2005</th>
<th>Percentage or Average All Patients&lt;sup&gt;b&lt;/sup&gt; 2006</th>
<th>Percentage or Average All Patients&lt;sup&gt;b&lt;/sup&gt; 2007</th>
<th>Percentage or Average All Patients&lt;sup&gt;b&lt;/sup&gt; 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>67</td>
<td>65</td>
<td>64</td>
<td>65</td>
<td>49</td>
<td>49</td>
<td>49</td>
<td>49</td>
</tr>
<tr>
<td>Less than 1 Year</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>8%</td>
<td>8%</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>01-24 years</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
<td>4%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>25-34 years</td>
<td>4%</td>
<td>4%</td>
<td>7%</td>
<td>5%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>35-44 years</td>
<td>6%</td>
<td>7%</td>
<td>9%</td>
<td>7%</td>
<td>12%</td>
<td>12%</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>45-54 years</td>
<td>10%</td>
<td>12%</td>
<td>9%</td>
<td>13%</td>
<td>13%</td>
<td>13%</td>
<td>13%</td>
<td>14%</td>
</tr>
<tr>
<td>55-64 years</td>
<td>14%</td>
<td>12%</td>
<td>14%</td>
<td>10%</td>
<td>13%</td>
<td>13%</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>65-74 years</td>
<td>19%</td>
<td>16%</td>
<td>16%</td>
<td>18%</td>
<td>13%</td>
<td>12%</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>75-84 years</td>
<td>27%</td>
<td>27%</td>
<td>20%</td>
<td>22%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>85-94 years</td>
<td>15%</td>
<td>15%</td>
<td>16%</td>
<td>16%</td>
<td>6%</td>
<td>7%</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>95+ years</td>
<td>1%</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Days since admission&lt;sup&gt;c&lt;/sup&gt;</td>
<td>15</td>
<td>17</td>
<td>13</td>
<td>11</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Gender: Female</td>
<td>51%</td>
<td>56%</td>
<td>56%</td>
<td>53%</td>
<td>58%</td>
<td>58%</td>
<td>58%</td>
<td>58%</td>
</tr>
<tr>
<td>Race: Caucasian</td>
<td>78%</td>
<td>78%</td>
<td>82%</td>
<td>79%</td>
<td>64%</td>
<td>64%</td>
<td>63%</td>
<td>69%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>88%</td>
<td>87%</td>
<td>84%</td>
<td>87%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

<sup>a</sup> Data drawn from Uniform Billing Data 2005-2008 and same day surgery: N=1,528,583 for 2005, N=1,528,097 for 2006, N=1,530,293 for 2007 and N=1,560,304 for 2008

<sup>b</sup> Data drawn from Uniform Billing Data 2005-2008 and same day surgery: N=1,528,583 for 2005, N=1,528,097 for 2006, N=1,530,293 for 2007 and N=1,560,304 for 2008

<sup>c</sup> Inpatient only

NA Not Applicable
B. Comprehensive Rehabilitation, Psychiatric and Special Hospitals

The Department has taken a phase-in approach of implementing the Patient Safety Act to all licensed health care facilities. Mandatory reporting of these specialty hospitals began April 1, 2008. Event and RCA report summary information for the initial year of reporting (8 months) is provided in the following tables and figures. Over the life of this program, additional data will be collected and analyzed to determine patient safety event trends.

1. Overall Reporting Patterns

There were 70 reportable events submitted from specialty hospitals in the eight months of reporting in 2008. The number of reported events varied by month and by specialty type. Comprehensive rehabilitation hospitals submitted the most events, averaging four event reports per month (Table 7). Special hospitals were the lowest reporters, averaging one event report per month. Variation in reporting may relate to the size and patient population of the facility.

2. Types of Events Reported

The breakdown of reported events by event type from April to December 2008 is illustrated in Figure 16. The majority of the events were falls (57%) followed by suicide/attempted suicide (16%) and care management “other” (11%). This is similar to some of the most commonly reported event types seen by the general acute care hospitals.

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Number of Hospitals</th>
<th>Number of Reports</th>
<th>Percentage of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive Rehabilitation</td>
<td>15</td>
<td>35</td>
<td>50%</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>10</td>
<td>27</td>
<td>39%</td>
</tr>
<tr>
<td>Special</td>
<td>13</td>
<td>8</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>38</strong></td>
<td><strong>70</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*8 month reporting period

Figure 16: Frequency of Reported Events by Category
3. Impact of Reported Events on Patients

Based on the 70 events and corresponding RCA reports submitted for 2008, the most frequent consequences of preventable adverse events on patients were additional patient monitoring (77%) and physical disability or mental impairment (56%). About half (51%) of patients were admitted to a general acute care hospital. Forty-nine percent needed additional laboratory testing and 41% had an increase in their length of stay (Table 8).

4. Root Cause Analysis

A review of the 70 RCA reports revealed that the most common cause of all events in the specialty hospitals was inadequate care planning (54%). This was followed by poor communication among staff (43%), insufficient patient observation (30%) and a deficient physical assessment (26%) (Table 9).

<table>
<thead>
<tr>
<th>Table 8: Impact of Events on Patients (2008)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact/Outcome</td>
</tr>
<tr>
<td>Additional patient monitoring</td>
</tr>
<tr>
<td>Physical disability or mental impairment</td>
</tr>
<tr>
<td>Hospital admission</td>
</tr>
<tr>
<td>Additional laboratory testing</td>
</tr>
<tr>
<td>Increased length of stay</td>
</tr>
<tr>
<td>Transfer to higher level of care</td>
</tr>
<tr>
<td>Major surgery</td>
</tr>
<tr>
<td>Other additional testing</td>
</tr>
<tr>
<td>Minor surgery</td>
</tr>
<tr>
<td>System/process delay</td>
</tr>
<tr>
<td>Death</td>
</tr>
</tbody>
</table>

* Data drawn from 70 RCAs submitted for 2008 events

b Events do not total 100% since events generally have more than one adverse outcome

<table>
<thead>
<tr>
<th>Table 9: Root Causes (2008)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root Cause</td>
</tr>
<tr>
<td>Care planning</td>
</tr>
<tr>
<td>Communication among staff</td>
</tr>
<tr>
<td>Patient observation</td>
</tr>
<tr>
<td>Physical assessment</td>
</tr>
<tr>
<td>Behavioral assessment</td>
</tr>
<tr>
<td>Staff orientation/ training</td>
</tr>
<tr>
<td>Availability of information</td>
</tr>
<tr>
<td>Communication with family</td>
</tr>
<tr>
<td>Physical environment</td>
</tr>
<tr>
<td>Supervision of staff</td>
</tr>
<tr>
<td>Staff competence</td>
</tr>
<tr>
<td>Staffing</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Equipment maintenance</td>
</tr>
<tr>
<td>Patient identification</td>
</tr>
<tr>
<td>Control of medication</td>
</tr>
</tbody>
</table>

* Data drawn from 70 RCAs submitted for 2008 events

b Events do not total 100% since events generally have more than one root cause
C. Ambulatory Surgery Centers

On October 1, 2008, in accordance with the New Jersey Patient Safety Act (P.L. 2004, c.9) phase-in approach, ambulatory surgery centers began reporting of serious preventable adverse events. Event and RCA report summary information for the initial year of reporting (3 months) is provided in the following tables and figures.

1. Overall Reporting Patterns

There were 111 licensed ambulatory surgery centers in 2008. Twelve (11%) of these centers reported thirteen events in the three reporting months.

2. Types of Events Reported

The majority of the reported events were surgery-related “other” (8) followed by wrong procedure (2) as shown in Table 10. Different types of events that may be categorized as a surgery-related “other” include, but are not limited to: perforation of an organ, cardiac and/or respiratory related problems, moderate to severe bleeding, serious infections, prolonged decrease in oxygenation and/or blood pressure all of which required intervention.

3. Impact of Reported Events on Patients

Based on the 13 events and corresponding RCA reports submitted for 2008, the most frequent consequences of preventable adverse events on patients were additional laboratory testing (62%) and minor surgery (46%) followed by additional patient monitoring (38%).

4. Root Cause Analysis

The 13 RCA reports showed that one of the most frequent causes of all the events reported by ambulatory surgery centers was poor communication among staff members (38%) followed by inadequate staff orientation and training (31%).

<table>
<thead>
<tr>
<th>Event Category</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Management “other”</td>
<td>1</td>
</tr>
<tr>
<td>Wrong Body Part</td>
<td>1</td>
</tr>
<tr>
<td>Retention of a Foreign Object</td>
<td>1</td>
</tr>
<tr>
<td>Wrong Surgical Procedure</td>
<td>2</td>
</tr>
<tr>
<td>Surgery-related “other”</td>
<td>8</td>
</tr>
</tbody>
</table>

Data drawn from 13 events submitted for 2008
IV. Conclusion

In the fourth year of the Patient Safety Reporting System, the mandatory reporting of serious preventable adverse events expanded to comprehensive rehabilitation, psychiatric, and special hospitals in April 2008 and to ambulatory surgery centers in October 2008.

In August 2008, State Psychiatric Hospitals began reporting serious preventable adverse events to the Department of Human Services, Division of Mental Health Services. The analysis of these events and RCAs are found in Section V of this report.

Over the last four years, the Patient Safety Reporting System has been able to develop a more comprehensive relationship with hospitals to support improvements in patient care. The Department’s Patient Safety clinical staff can now draw upon their experience to provide more direct guidance to the facilities and share the successful strategies from these facilities.

The Department’s Patient Safety staff continues to develop an understanding of each general acute care hospital's unique culture and organizational structure. These hospitals also continue to expand their understanding of the requirements for RCAs and increase the complexity of their analysis and preventive actions. This results in better collaboration and a more productive relationship between the hospitals and the Department’s Patient Safety staff.

The reporting results remain similar to previous years. There is still inconsistent reporting across hospitals by patient-volume. The smallest patient-volume hospitals are the largest reporters of events. However, reporting, both in terms of the number of reported events per hospital and the number of reporting hospitals, continues to increase each year despite the number of hospital closures.

Falls continue to be the most frequently reported events with a steady increase in the relative frequency of falls. Most of the reported falls occurred to patients between the ages of 81 and 90 and a fracture of extremities (i.e., legs or arms) was the most common injury. Pressure Ulcers is still the second largest reported event category. The data suggests that there is an increase in the potential of developing a pressure ulcer for patients that have a longer than average length of stay in a hospital. Retained foreign objects events continue to be the largest subcategory of the surgery-related events. This is consistent with national trends.

The collaborative efforts and willingness to share knowledge between the Department and the general acute care hospitals allowed for an easier integration of the new reporting facilities in 2008. The analysis of the data from these facilities is preliminary, reflecting events reported in a period of a few months. The event trends will vary over time as additional data are received and analyzed throughout the life of this program.

Future development for the Patient Safety Reporting System involves addressing the following issues:
Development of a web-based reporting system allowing for more detailed event/RCA reporting and additional analytical capacity for both health care facilities and the Department.

Initiation of additional cooperative projects with health care facilities that support the growth of patient safety and use of the information collected through the reporting system.

Continue to work with health care facilities to ensure consistent reporting.
V. Department of Human Services, Division of Mental Health Services

A. Background

Prior to 2003, incidents at State Psychiatric Hospitals were prepared on a template and e-mailed by the Risk Management departments to the Division of Mental Health Services (the Division) central office staff. Each hospital had its own database for tracking incidents. Since October 2003, however, the hospitals have been reporting unusual incidents into a centralized database system referred to as Unusual Incident Reporting Management System (UIRMS).

All reporting of incidents and investigations related to service recipient care in any Department of Human Service operated facility must be reported in this system. Incidents are reported in this system by type of incident and further classified by severity of incident (from A+ to C); for example, an allegation of physical abuse, with major injury, would be classified as an A+; an attempted suicide resulting in minor injury would be classified a C.

B. Implementation

A new feature was added to the UIRMS that includes a Patient Safety Act tab (PSA) that when clicked, elevates an incident to an A+. Therefore, any suicide attempt would automatically be upgraded to an A+ when the PSA tab is clicked.

The Division of Mental Health Services has a patient information database where specific data related to a patient is entered. Since the advent of the Patient Safety Act, an additional feature has been added to this database that includes information related to patient safety events. At the completion of the root cause analysis (RCA), information is entered into the patient’s individual database related to the event.

Data collected includes incident specific information from the Unusual Incident Report (UIR), such as date and time of the incident and how the event was discovered. Also included is the Department of Health and Senior Services’ classification and type of serious preventable adverse event and RCA specific information, the impact of the event on the patient, contributing factors, root cause, description of the root cause, event description, and immediate action taken.

C. Overall Reporting Patterns

From August 30, 2008 through December 31, 2008, five Patient Safety Act events were reported by two out of the five state psychiatric hospitals. Ten additional incidents were reported state-wide, but these did not meet the definition of a patient safety event. The events were analyzed with the following results.

Focusing on Specific Events

During the four months of reporting, the majority of the events (four of the five) were attempted suicides.
### Table 11 Root Causes of Attempted Suicide

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Number of Events</th>
<th>Percentage of Events&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral assessment</td>
<td>2</td>
<td>40%</td>
</tr>
<tr>
<td>Physical environment</td>
<td>2</td>
<td>40%</td>
</tr>
<tr>
<td>Staff orientation/training</td>
<td>1</td>
<td>20%</td>
</tr>
<tr>
<td>Care planning</td>
<td>1</td>
<td>20%</td>
</tr>
<tr>
<td>Communication among staff</td>
<td>1</td>
<td>20%</td>
</tr>
<tr>
<td>Availability of information</td>
<td>1</td>
<td>20%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Data drawn from 5 RCAs submitted for 2008 events
<sup>b</sup> Events do not total 100% since events generally have more than one root cause

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**a. Suicide/Attempted Suicide**

The average person who attempted suicide in the four months of reporting was a 36-year-old female of either Caucasian or African American descent. The majority of the suicide attempts occurred in the bathroom (3 out of 4). All the patients required additional patient monitoring as a consequence of the attempted suicide. Additional laboratory testing, transfer to higher level of care, and hospital admission were also impacts of the attempted suicide.

A review of the 2008 RCA reports revealed some of the causes of suicide/attempted suicide in hospitals as shown in Table 11.

**Preventing Attempted Suicides**

The following examples present some of the findings and corresponding prevention strategies that the two reporting hospitals discovered while conducting the root cause analysis.

**i. Finding:** A patient’s previous diagnoses and treatment prior to admission were not known to the receiving unit. In addition, there was a reliance on the medical record as a form of communication when changing from one psychiatrist to the next.

**Prevention Strategy:** At least one month of a patient’s medical record/progress notes when sent from a facility, other than short term care, will be sent at the time of transfer (including history and course of treatment). A copy of the patient’s discharge summary or transfer notes upon admission to a unit will be available within 72 hours and the final progress note or summary describing the course of care will be included when psychiatrists change.

**ii. Finding:** The assessment of patients’ suicidal behavior was not adequate to detect the seriousness of the behaviors. Also, there was undue reliance on the patients contracting for safety and statements that she/he was not suicidal for determining level of precautions for suicide risk.

**Prevention Strategy:** The Suicide Risk Reassessment tool and a more individualized in-depth assessment and treatment options will be developed for modifiable risk factors. Suicide risk assessment is the responsibility of the psychiatrist and is not to be delegated.

**iii. Finding:** A patient’s visiting parents were able to slip in a bottle of Tylenol.
Prevention Strategy: Visiting areas were changed from the patients’ living cottage to a business occupancy building in order to have more control and monitoring capabilities of the visits. Visiting hours were changed so that they will not conflict with staff breaks in order to have sufficient staff to monitor visits.

iv. Finding: A patient used several PRNs (medication taken as needed) in the weeks preceding discharge placement visits, indicating the patient was not clinically stable. This information was not communicated to the team, nor was it communicated as to how the brief visits went.

Prevention Strategy: Morning briefings will now include uses of PRNs, the precipitating factors as well as discussions of how well the pre-discharge placement visits went. The staff will strategize prior to the brief discharge placement visits on how to get patients, who may be fearful/reluctant, ready for discharge.

b. Falls

During the four months of reporting in 2008, there was one fall by a 63-year-old Caucasian male who had been in the facility for more than 20 years. The patient fell while getting up from a chair. There was no indication that the patient was at risk for falling. The result of this fall caused the patient to have a hospital admission, major surgery and the loss of bodily function. The RCA revealed the root cause of this event to be a lack of staff orientation and training. The facility has implemented “Slow and Go” technique training for patients and staff.

D. Conclusion

In 2008, the State Psychiatric Hospitals did not share the completed root cause analyses with the Division of Mental Health Services. Because of this, all the incidents and risk reduction activities were hospital-specific, not Division-wide. In the spring of 2009, the Division began requiring that the completed root cause analyses be shared with the Division and any questions were sent back to the respective hospital for response. This system-wide review of risk reduction activities and dissemination of the lessons learned will improve patient safety in the future. Training also began on documenting the root cause analysis process at one of the hospitals.

Each hospital uses a separate format for conducting root cause analyses and at various levels of intensity. In 2010, the Division will be requiring the use of a standardized format for documenting the root cause analysis process. Training on how to conduct a root cause analysis will be given to all hospitals.

E. Improvements


i. Clinical Review Team (composed of Discipline Heads and outside consultants, if necessary) – to review difficult cases.

ii. Morning briefings to include review of PRN use.

iii. Enhance communication:
  1. From previous facility to hospital – month of progress notes including history and course of treatment.
2. From provider to provider – within hospital: course of treatment, medications, etc.
3. From hospital to placement – brought into discharge planning (how is the patient doing on brief visits, reluctance for discharge).

iv. Contraband: Policy change made regarding contraband and contraband checks.

v. Enclosure of exposed piping under sinks in patient bathrooms.

vi. Addition of tamper-proof screws.

vii. Addition of visitor security system.


1. All patient areas were assessed; potential hazards identified and assigned a risk level from low risk to extremely high risk.
2. Each identified hazard was further categorized by the type of action to be taken (control, accept or eliminate); prioritized with the recommended action for controlling or eliminating the hazard and then presented to the senior leadership for acceptance.
3. Many of the identified hazards were eliminated; most notably was the enclosure of the piping under many of the sinks.
4. Additionally, vendors have been contacted in order to assess other hazard risk reducers (i.e.: door handles that nothing can be strung to, suicide-proof doors).

b. System Wide Improvements (2009-2010)

i. Longitudinal training of clinical teams on suicide and parasuicidal behavior will be at least yearly.

ii. Continue the work on the suicide risk assessment tools.

iii. Investigate the feasibility of a visitor security system at the 2 remaining hospitals where this is not in place.

iv. Continue environmental suicide risk assessments at all the hospitals with necessary action taken.

v. Continue enclosing exposed pipes under bathroom sinks at the remaining hospitals.

vi. Continue replacing screws with tamper proof screws at remaining hospitals where this is not in place.

Department of Human Services, Division of Mental Health

Report Preparation Team

Rosita M. Cornejo, MPH, RD, CPRP
Director of Quality Management
Office of State Hospital Management

Alberto Regalado
Quality Assurance Coordinator
Office of State Hospital Management

Robert Eilers, M.D.
Medical Director

Gregory P. Roberts
Assistant Division Director
Office of State Hospital Management
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Appendix I: Classification of Serious Reportable Adverse Events

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.

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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).

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 body part, disability, or loss of bodily function lasting more than seven days or still present at 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.

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: Patient Safety Reporting System Newsletters

- June 2008: Suicide in the Hospital Setting
- April 2008: Review of Invasive Procedures: Wrong Patient, Wrong Site, Wrong Procedure
Patient Safety Initiative Update

• The second annual report, Patient Safety Initiative: 2006 Summary Report (link to http://www.nj.gov/health/ps/documents/ps_report_2006.pdf) was released in January 2008 covering 2006 reporting and Patient Safety Initiative activities. Overall reporting has increased both in terms of the number of reports and the number of hospitals making reports. Falls and pressure ulcers continue to be the most frequently reported events.

• The rules implementing the Patient Safety Act (PL. 2004, c.9) were approved by the Health Care Administration Board in January 2008 and published in the New Jersey Register in March 2008. Those rules establish a time frame for implementation of the rules for all licensed health care facilities. In addition, the rules define the requirements for each licensed facility to develop a patient safety committee and a patient safety plan.

• Based on approval of the rules, psychiatric, special and comprehensive rehabilitation hospitals began mandatory reporting on April 1, 2008. Those facilities have been notified regarding the initiation of reporting. General hospitals continue to report as required under the earlier system. Additional materials on how to prepare an RCA have been provided to all reporting facilities. A special training session on event reporting and RCA development will be offered in June for special, psychiatric and comprehensive rehabilitation hospitals.

• A revised Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities (link to http://www.nj.gov/health/ps/documents/final_directions_march08.pdf) is available on the Patient Safety site. This manual reflects the passage of the rules and the implementation of the reporting system for all acute care hospitals. The only change in the rules is that hospitals are required to report an event within five days after discovery. The requirement that hospitals report within five days of when the event should have been discovered was deleted from the rules.

Invasive Procedures: Wrong Patient, Wrong Site, Wrong Procedure

The Patient Safety Initiative has received reports of Surgery-Related Events from various hospitals across New Jersey. Specifically, there were reports of surgeries and invasive procedures performed on the wrong body part, the wrong patient and incidents where the wrong procedure was conducted. These are errors that can be avoided by consistent use of widely accepted universal protocols. This issue of Patient Safety Initiative Updates considers the problem of correct identification for invasive procedures in the operating room as well as other locations.

Ensuring the Correct Surgery and Invasive Procedure

In 2004 the Joint Commission required all accredited organizations to comply with the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. The purpose of this protocol is to ensure communication between and among the surgical staff and the patient to verify the correct procedure on the correct patient and the correct site. The main components of this protocol include:
• **Preoperative verification process**: verification of patient’s identity, determination that all relevant documents (e.g., history and consent), studies, and images are properly labeled and available before the start of the procedure, and any required equipment or implants are available.

• **Marking the operative site**: an unambiguous mark, such as, initials or “yes”, should be placed at or near the incision site in indelible ink that is visible after the patient is prepped and draped.

• **Time out immediately before the start of the procedure**: must be conducted in the location where the procedure will be done and involve the entire operative team; should be documented and include correct patient identity, correct side and site, agreement on procedure being performed, correct patient position, availability of correct implants and any special equipment.

• **Adaptation of the requirements to non-operating room settings, including bedside procedures**: must include verification, site marking, and “time out” procedures.

### Second Looks:
#### Review of Events and RCAs

Despite the presence of a *Universal Protocol* that is available to hospitals and patient care providers, for quite some time now, there are reports of events which demonstrate the protocol is not being consistently applied. The following are some examples of reports and follow-up by those involved.

#### Events in the Operating Room

1. **A patient was admitted with a diagnosis of a left hip fracture.** The patient went to the operating room for surgical repair of his left hip and the surgery was incorrectly started on the right hip. During the preoperative interview the nurse verified the correct surgical site but did not mark it; this failure to mark the correct site created a critical ambiguity that was not corrected. The “time out” procedure was incomplete and conducted while the patient was still in bed and not in the operating room. The fact that the site was not marked was clear and obvious to the staff; however this was not corrected during the time out procedure.

   **Response**: To prevent this type of error from reoccurring, the Wrong Procedure/ Wrong Patient policy for this facility was revised and strengthened. The physicians performing the procedure are now required to mark the site with their initials in indelible ink and are responsible for initiating the “time out” and ensuring that it occurs in the location where the procedure is being conducted. The completion of a “time out” is now documented.

2. **A patient was admitted for open reduction and internal fixation of the right fourth finger fracture.** During the preoperative interview the correct site was verified and marked “yes” by the physician with the patient. During the patient preparation for surgery, the right hand of the patient was scrubbed with a betadine solution which removed the site mark. The surgeon began the surgery and incorrectly made an incision on the right third finger. The nurse manager recognized the mistake and informed the surgeon, who then closed the incision and initiated the procedure on the correct fourth finger.

   **Response**: To avoid this type of error from occurring in the future, the markers have been replaced with Association of periOperative Registered Nurses (AORN) indelible markers. All “time out” procedures now include assurance that the site marking is visible after the skin preparation. This facility also initiated a hospital-wide “time out” day and distributed “time out” posters to all the departments and staff in an effort to raise awareness.

#### Events in a Non-Operating Room Setting

Wrong site, wrong patient, wrong procedure surgery is not just an issue for the operating room; it can occur during any invasive procedure performed in an office, ambulatory setting, or at the bedside.

3. **A patient was scheduled for an esophagogastro-duodenoscopy (EGD) in the endoscopy unit.** During the preoperative interview, the nurse questioned the patient about what procedure he was having and the patient replied that he was having a colonoscopy. This information was not
verified and the “time out” procedure was not performed resulting in a colonoscopy being performed instead of the EGD.

Response: This facility now only accepts written orders for confirmation of procedures. The endoscopy staff was re-educated on the Universal Protocol and on conducting a “time out”. The “time out” documentation was revised to include the names of those participating in it and requires two signatures verifying the completion of the “time out”.

4. A patient went to the emergency department with dyspnea. The patient was evaluated by a physician who decided that a thoracentesis was needed on the right side; however, he inserted the thoracentesis needle on the left side. The physician immediately realized his mistake and repeated the procedure on the correct side. The correct site was not marked prior to the procedure and a “time out” was not conducted.

Response: An online Universal Protocol education module is being developed and all medical staff are required to complete and pass this module prior to appointment and/or reappointment. Residents and rotating residents would also be required to complete and pass the Universal Protocol training. This facility also posted “time out” stop signs throughout the departments starting with the emergency department.

Effective Corrective Actions

Several healthcare organizations have developed recommendations to supplement the Joint Commission’s Universal Protocol in preventing surgery related events. The Partnership for Health and Accountability in Georgia’s Successful Practices for Correct Site Surgeries/Procedures recommends that facilities’ “time out” procedures include a clear description of which specific procedures require a “time out” and at what point during the procedure a “time out” is required. The policy should designate who is responsible for calling the “time out”. The “time out” must include confirmation of correct patient identity, correct site and side, agreement on the procedure to be performed, correct patient position, and availability of correct implants and special equipment. Also, the surgical team must give active confirmation for each of these elements. If there are any discrepancies, there should be a description of the reconciliation process. Finally, the “time out” must be documented and include signatures indicating that all the team members were in agreement with all the required elements. To help implement the “time out”, it is recommended that facilities require the nurse to withhold or hide the scalpel until the “time out” is completed.

The Department of Veterans Affairs, Veteran Health Administration developed “Seven Absolutes to Avoid Surgical Site Errors”. These absolutes include having the operating room office schedule each procedure involving laterality with a right or left designation; having the nurse verify each correct surgery site with the operating room schedule and the patient’s current medical record; and having the patient verify each surgical site in the presence of a nurse and if possible mark the site. The surgical team should interview the patient; review the patient’s current medical record and the results of any diagnostic tests and verbally verify each surgical site and procedure. After the patient is draped, the surgical team must pause and verbally confirm each site prior to incision. The nurse will document the verification process in the patient’s medical record.

The New York State Department of Health also developed a policy for surgical and invasive procedures.
procedure protocol. This policy incorporates the same standard guidelines as Joint Commission, Veteran Health Administration and Georgia’s Partnership Accountability. However, the protocol expands the scope of the policy to include all operative and other invasive procedures performed in the operating room as well as in special procedure units, endoscopy units, and interventional radiology suites. This protocol covers invasive procedures that involve punctures and incisions of the skin, the introduction of any instrument or foreign material into the patient, such as, percutaneous aspirations, biopsies, and catheterizations. The preoperative/pre-procedural verification process is required for invasive procedures in all clinical settings, including endoscopy units, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, and emergency departments.

This policy also expands on specific steps within the protocol. During site marking, if the site is not visibly identifiable, the surgeon is to obtain an intraoperative image to mark. When multiple surgical procedures are being performed by different surgeons, all the sites must be marked prior to the start of the initial surgery. Each surgeon must be present for the site marking and participate in the “time out” for each procedure he/she marked. During the “time out” if the procedure is being performed without assistance, the protocol strongly recommends that an observer or assistant participate in the “time out”. If a new surgeon arrives and is assuming primary responsibility for the procedure, another “time out” is to be conducted. For procedures that require radiological images to be displayed, a second team member must confirm that the image belongs to the patient, that the image is oriented correctly, and that the proper site is marked. It is also recommended that instruments and equipment not be offered until after the “time out” is performed.

In Conclusion

All facilities and patient care providers performing invasive procedures should adopt the Universal Protocol including the “time out” procedure to ensure the safety of their patients. The processes are straightforward but demand strong hospital procedures, effective communication, and constant adherence to the protocols. This is especially true for invasive procedures that occur outside the operating room where this process is not as widely accepted as routine practice.

References


Patient Safety Initiative Update

On April 1, 2008 mandatory reporting of adverse patient safety events took effect for psychiatric, special and comprehensive rehabilitation hospitals. General hospitals continue to report as required under the reporting system in effect since 2005. On June 6, 2008 the Patient Safety Initiative conducted a special training session for these newly reporting hospitals on event reporting and RCA development. In attendance were a total of 42 staff representatives from psychiatric hospitals, special hospitals, and comprehensive rehabilitation hospitals.

Overview: Suicide in the Hospital Setting

Clinical Rationale

Suicide is a key public health problem in the United States. It is the 11th leading cause of death in America and the 3rd leading cause of death among American youth. This high rate of suicide is also a significant issue for hospitals. According to The Joint Commission, suicide has been the most frequently reported type of sentinel event for patients in a “staffed, around-the-clock care setting” since 1996.¹

At least 90% of those who commit suicide had an underlying mental illness and/or substance abuse disorder.² A retrospective matched-case study was conducted for three hospitals in Mobile, Alabama.³ This study found that the rate of suicide in general hospitals was three times higher than in the general population, 32/100,000 versus 12/100,000 respectively. Among the suicides committed in the hospitals, 73% had been diagnosed with mental illness and/or substance abuse disorder and only 1 of the 44 subjects (both cases and controls) had been referred for psychiatric consultation.

Location of Events

The elevated suicide rate in acute care facilities supports the need for special focus on suicide prevention policies and programs. The Joint Commission recognized this need in its 2008 National Patient Safety Goal 15A. Health care facilities are required to identify patients at risk for suicide. This includes performing a risk assessment to identify specific factors or features that may increase or decrease risk of suicide.¹

Suicidal Behaviors

The first step toward identifying at-risk patients is understanding the different forms of suicidal behavior, which exist or occur on a continuum:
Suicidal ideation: thinking or talking about committing suicide. This can include actually planning the suicide. Activities associated with suicidal ideation include making a will, getting affairs in order, unexpectedly visiting family and friends, buying a gun or rope, writing a suicide note, and visiting a primary care physician. Passive suicidal ideation is when a patient states that they wish they were dead, but would never intentionally try to commit suicide.

Suicidal gesture: making an unusual, but nonfatal, behavioral bid for help. This can include cutting and attempting to overdose. These behaviors should be treated as suicidal. If the patient is not satisfied with the outcome of the gesture, he/she may move on to more lethal measures.

Suicide attempt: an intentional act that causes self-harm. This act will be fatal if direct intervention does not occur. A suicide attempt is not a harmless effort to gain attention, it is an extreme expression of distress.

Risk Factors
There are a number of risk factors that may predispose a patient to suicide, including patient demographics, medical condition and life experiences.

Mental Illness and Substance Abuse
Mood disorders (e.g., major depression or bipolar disorder) and a stressor (e.g., death of a loved one or divorce) are closely linked to suicide. Those at highest risk for suicide are patients with a combination of substance abuse and mood disorder. Patients who exhibit schizophrenia also have a high rate of suicide. In particular, patients with schizophrenia may become vulnerable for suicide when they realize they have a mental illness or that they are different from other people. Also, these patients may experience hallucinations such as hearing voices commanding them to kill themselves.

Medical Condition
Studies have found evidence of an increased risk of suicide in patients with protracted, painful, progressive medical conditions (e.g., AIDS, cancer, multiple sclerosis, and quadriplegia). Patients with AIDS are 16 to 36 times more likely to commit suicide than the general population. The combination of older patients with cancer also increases the risk of suicide.

Demographic Factors
There are many demographic factors that influence suicidal behavior, including sex, age, ethnicity, sexual orientation, socioeconomic status, geography and the season. In the United States, men commit completed suicide four times as frequently as women. However, women attempt suicide approximately three to four times as frequently as men. In 2005, 25,907 men committed suicide in the U.S. compared with 6,730 women. In terms of frequency, overdose, poisoning and suffocation tend to be the method of suicide for women, while men use firearms as a means of death.

Suicide rate increases with age. People over 65 years have the highest rate of suicide. In younger populations it is rare for a child to attempt suicide before age 10. However, in 2004, suicide was the third leading cause of death in adolescents; 12.9% percent of deaths among 15 to 24 year olds were due to suicide. Furthermore, gay, lesbian and bisexual (GLB) youth are between two and six times more likely than heterosexual adolescents to think about and to attempt suicide. Although the relationship between sexual orientation and suicide remains largely unknown, GLB youth are more likely to be victimized at school. Studies have shown that GLB youth also have higher rates of substance abuse and psychiatric disorders including major depression, generalized anxiety disorder, and conduct disorder.

In the United States, the non-Hispanic Caucasian and American Indian/Alaskan Native populations have the highest rate of suicide, approximately 12.9 per 100,000 and 12.4 per 100,000 respectively. Poverty and low income, with fewer options and opportunities for medical and mental health treatment, correlate with suicide. Geography and the season also play an important role in the rate of suicide for Americans. Rural western states, such as Wyoming, Montana, Nevada, Alaska and New Mexico, are the top five states in terms of suicide rates. Suicides occur more often during spring and summer, notably in May, with a secondary peak in the fall, not during the winter holidays.
Life Experiences

Life experiences also play an important role in the risk of suicide. Personal issues like the recent loss of a job, a family member or friend, loss of a romantic interest, or divorce can be so devastating that patients feel they can never recover. A previous suicide or suicide attempt by the patient or a friend, or a family history of suicide can provoke the patient into duplicating the event. Unlike the patient’s medical condition, the negative factors of a patient’s life experience are typically transitory and only discoverable through direct questioning. Of all the factors to consider, the recent death of a family member or friend by suicide is the strongest life event linked to the act of committing suicide.

Recommendation: Identification of the At-Risk Patient

There is no proven method for suicide risk assessment and no method is completely accurate. Upon admission, every patient’s family history of mental illness and suicide should be carefully assessed, and clinicians should explore whether the patient is contemplating suicide. Some clinicians have difficulty inquiring about potential suicidal behavior since they erroneously believe that the question itself may be too intrusive or may provide the person with the idea of suicide. However, most patients appreciate having a clinician ask them about suicidal ideation as they tend to perceive this as evidence that the clinician cares about the patient.

If the patient does give a positive response to a question about suicide ideation, the clinician should follow up with questions about any plans to commit suicide. The mental health literature shows that more specific plans indicate greater risk. A common misconception in assessing suicidal risk is assuming that less lethal means (e.g., pills) indicate a less intense desire to commit suicide. Prior attempts are the most important factor for suicide risk.

Since suicidal patients frequently seek to hide their true intentions, clinicians should remember that denial of suicidal ideation is not sufficient to rule out the presence of suicidal risk. Collateral questions should be asked based on the patient’s suicidal risk factors including symptoms of depression or mania, psychosis, delirium and dementia, losses (especially recent ones), substance abuse, and any family members or friends who have died or attempted to kill themselves.

1. After being rescued from her burning house, the patient was brought to the hospital and admitted for treatment of smoke inhalation. Family members told staff that the patient had a history of depression and were concerned that she would try to kill herself when she learned of the death of her family. Security was alerted. She was transferred to a med/surg floor; other family members arrived and went straight into her room and told her of the deaths. The patient became distraught, tied a bed sheet around her neck and declared that she wished to be with her children. Her nurse entered and cut the sheet from her neck.

Response: As a result of the RCA process, the hospital created a multidisciplinary Behavioral Health Response Team to respond immediately to a patient on the med/surg floor in a behavioral health crisis and perform an immediate evaluation before any visitors are permitted.

Recommendation: Interventions/Protection

Several methods for reducing the potential for suicide in hospitals have been proposed. The first is the use of 1:1 or continuous observation (CO). This can be highly effective provided that the person observing the suicidal patient does not become distracted or implementation of the observation is not delayed, as can frequently happen in a hectic environment such as the ED. It is also critically important to ensure the person conducting the observation is trained to do so.

2. A patient was brought to the ED for evaluation of seizure-like activity. After she attempted to pull out her IV and stated “they want to kill me,” an order for a 1:1 observation and a psychiatric consultation was written by the ED attending physician. Seventy minutes later the patient was found with nasal cannula tubing wrapped around her neck. The 1:1 had yet to be initiated. The psychiatrist noted that the patient had a history of chronic bipolar illness and multiple suicide attempts.

Response: Although this patient suffered no physical harm from this attempt, the RCA team developed a process for immediate implementation of the 1:1 order.
Frequent observation (i.e., q 15 rounding) is another commonly used technique and allows for staff to observe several patients while performing other duties. The Department has received reports, however, of patients timing their suicidal behavior to coincide with the rounding pattern. This can be addressed through altering rounding patterns occasionally (e.g., 5 – 15 minutes).

3. A patient presented to the hospital for voluntary admission to the psychiatric floor for recurrent, severe depression and suicidal ideation. A treatment plan of therapy, medications and q 15 minute checks was implemented. Six days later he was found with a sheet around his neck, hanging from the side of his bed. CPR was initially successful; however the patient died several hours later.

Response: After performing the RCA, the hospital made a series of changes to ensure safety: changed the q 15 minute checks to “Status Checks” to be performed at staggered, random intervals; developed a mandatory Open Door Policy when a patient is in the room and a Locked Door Policy when patients are in group or at meals; and placed half-dome security mirrors outside Nurses’ Stations to increase visualization.

Recommendation: Identifying Environmental Risks

Hospitals reporting attempted or completed suicides by patients have identified a number of environmental risk factors that contribute to suicidal behavior. Patients have hung themselves using bed sheets tied to door knobs, door hinges and exposed pipes in the lavatory. Older hospitals tend to have bathroom door locks, allowing the patient to commit suicide without anyone being able to intervene. Windows in patient rooms or hallways have been broken, allowing patients to cut themselves and/or jump. Video surveillance cameras have failed to observe all areas of a room, allowing patients to avoid detection. These risk factors can be addressed through architectural changes to patient rooms or holding areas.

Overall Recommendations

Hospital policies for the oversight of actively or potentially suicidal patients should be clear. When identified, a suicidal patient must not be left alone. In the ED, this recommendation may be handled by hospital security personnel. Contraband, such as knives and pills or any potentially lethal personal item such as drawstrings, belts, etc. should be removed before initiating an intervention. In some cases, necessary authorization may be required before searching the belongings or person.

4. A day after being discharged from the hospital’s Behavioral Health Unit (BHU) after a suicide attempt by overdosing, the patient was brought by the police to the closest hospital for an apparent overdose. After medical stabilization, she was transferred back to the original hospital and readmitted to the BHU. The next day, she was found unresponsive, an overdose was suspected and she was successfully revived. A search of her room revealed a bag of medications hidden under her mattress.

Response: During the RCA investigation, the hospital found that the medications were transported from the other hospital, they had not been identified and secured upon the patient’s admission, and the daily room search for medications and items that might be used for self-injury was not done. The hospital immediately developed a new policy and began careful monitoring the interventions to assure that they were consistently performed.

Reliance on “no-suicide” contracts should not be considered a sufficient intervention strategy. However, a patient’s refusal to sign such a contract may offer insight into a patient’s potential for suicidal behavior.11 According to the Minnesota Office of the Ombudsman, such contracts were in place for almost every suicide that occurred in an inpatient, acute care facility.13

5. For the fourth time in two months, the patient was brought to the hospital after a suicide attempt. The first time, he had cut his wrist with a razor and the other three times were drug overdoses. His admitting diagnosis was drug overdose, major depressive disorder and a history of drug abuse. During his admission and throughout his hospitalization, he consistently
denied active suicidal ideation or a desire to harm himself or others. On the sixth day, he was found on the bathroom floor, without a pulse or respirations, with a belt tied around his neck and the plumbing pipes. He was resuscitated, intubated and placed on a ventilator; however the patient died two weeks later.

Response: After the RCA team conducted its investigation and analysis, it was discovered that the patient’s family had brought her a bathrobe with a belt and this had not been catalogued and secured as per the existing policy. They also found that because this floor had initially been designed and used as a med/surg floor and converted to a Behavioral Health Unit, there were still some door knobs, exposed pipes and other potential hazards. The day after this event, the hospital conducted a walk-through inspection and has already begun the environmental changes.

Recent Joint Commission guidelines have criticized the use of seclusion and physical/chemical restraints for actively suicidal patients stating that these measures are overly restrictive. Instead, they recommend continuous face-to-face or one-to-one observation by an assigned staff member. This technique, termed continuous observation (CO), is also known by other terms including 1:1, special observation and maximum observation.

Some hospitals have been reluctant to implement widespread use of CO due to the increased cost. This has been addressed in some hospitals by requiring psychiatric consultations to authorize CO. Staff members engaged in CO should be relieved of other duties and made aware of the potential for distractions, especially within the ED.

The potential for suicides in hospitals could be reduced by improving hospital staff awareness of more accurate assessments based on risk factors, developing environmental protections and better interventions.

Documentation Recommendation

Documentation is important for protecting patients, staff, and the healthcare facility. The following recommendations for recordkeeping were written by Christos Ballas, MD and supplemented by Daniel J. Reidenberg, Psy.D., FAPA, Executive Director of Suicide Awareness Voices of Education:

- Be clear and avoid making inferences, hypothesizing or theorizing.
- Report your clinical judgment based on the facts that led you to your assessment.
- Assessment should lead clearly to your intervention and subsequently to your plan.
- Document risk factors assessed and patient’s strengths.
- Whenever possible, use quotes from patient, staff, or family members.
- Document what you did and why.
- Document what alternatives you did not choose and why.
- Make your report logical, organized and complete.
- Write less about the symptoms and more about your assessment and clinical judgment.
- Document who you talked to or consulted.

Resources on Suicide Prevention

American Association of Suicidology available at: http://www.suicidology.org

American Foundation for Suicide Prevention available at: http://www.afsp.org


National Suicide Prevention Lifeline 1-800-273-TALK

Suicide Awareness Voices of Education available at: http://www.save.org

Suicide Prevention Resource Center available at: http://www.sprc.org

Wisconsin Department of Health and Family Services “Clarification: Environmental Suicide Prevention” available at: http://dhfs.wisconsin.gov/rl_DSL/Hospital/Hosp01-032.htm
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For more information or comments on this issue or past issues of the Patient Safety Initiative Updates please contact:

Patient Safety Initiative Tel: (609) 530-7473
Patient Safety Web Site: www.NJ.gov/health/ps