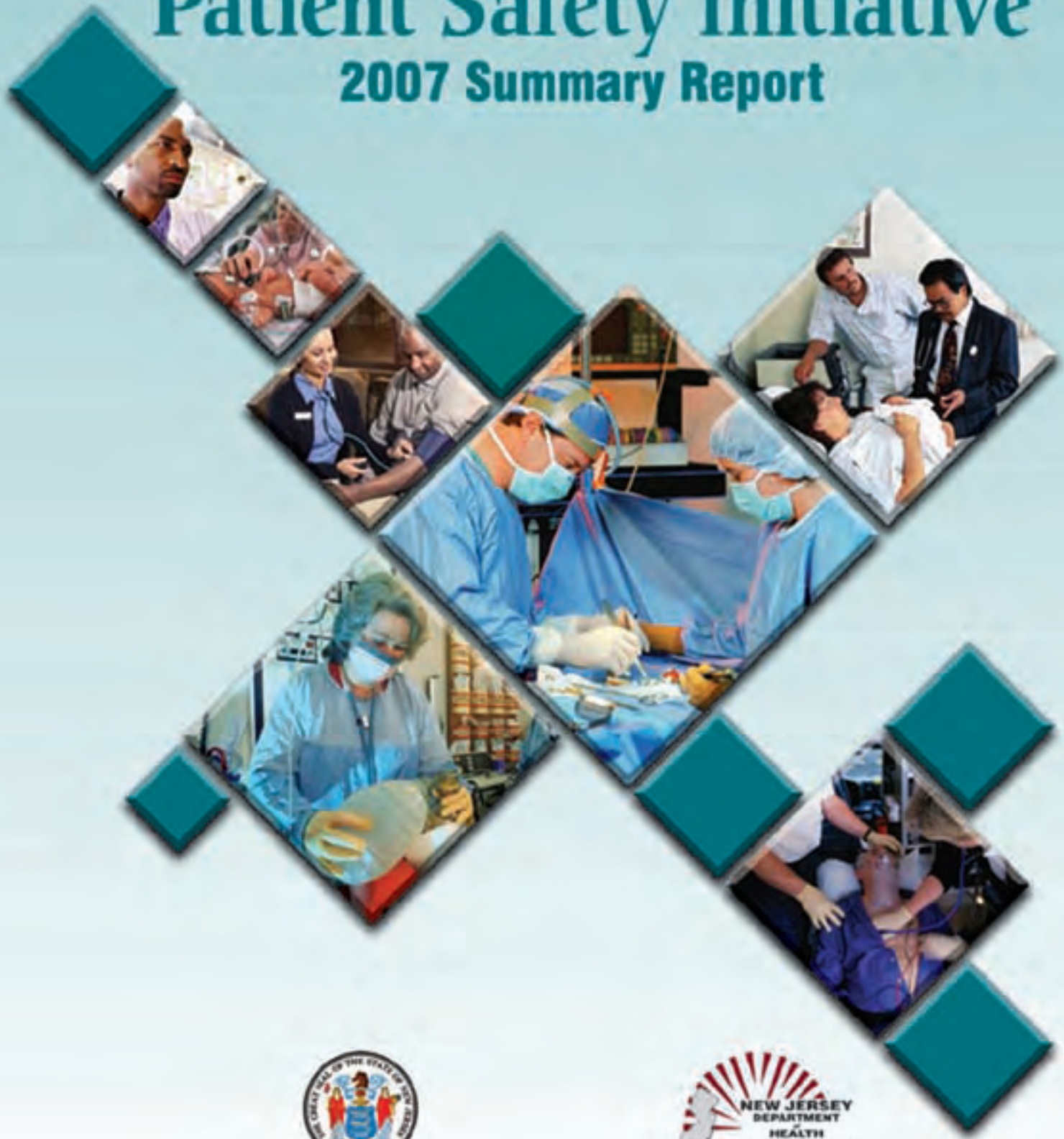
Health Care Quality Assessment
New Jersey Department of Health and Senior Services

Patient Safety Initiative

2007 Summary Report



Jon S. Corzine
Governor

Heather Howard
Commissioner

Patient Safety Initiative

2007 Summary Report

Office of Health Care Quality Assessment

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Commissioner

December 2008

Dear Friends,

I am happy to submit the third annual report summarizing activities to implement the "Patient Safety Act." Based on this legislation, we have been working with hospitals to improve the safety of health care provided to New Jersey patients. The report presents a review of the preventable adverse events reported to the Department of Health and Senior Services for 2007 as well as a comparison to earlier reporting years. Also included are recommendations on "time out" before invasive procedures and a review of ways to prevent falls.

This report summarizes the activities of the Patient Safety Initiative which was established in 2004 to implement the reporting requirements of the Act. Acute care general hospitals began reporting in 2005. Since then, we have worked to ensure a complete analysis of medical errors and to share both national "best practices" and the approaches used by other hospitals. During 2007, we have built on earlier years' experiences to expand our cooperation with hospitals on their analyses and preventive strategies. The Patient Safety Initiative 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.

The goal of the "Patient Safety Act" and the Department's implementation efforts is to ensure that patients are safe while receiving health care. In cooperation with New Jersey hospitals this year, we have made progress toward that goal. We want to acknowledge the cooperation of hospital staff in this process and to encourage a commitment of the entire hospital team in examining their own processes and working toward safe care.

Sincerely,

Heather Howard
Commissioner

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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 eight 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), enacted in 2004 continues to produce broad policy and operational changes for patient safety in New Jersey. The Act was based on the Institute of Medicine principles which support examining the systems for providing care in order to improve patient safety.[1] The entire Patient Safety Act is directed toward that goal and recognizes the need for health care facilities to make safe care a priority through evaluating and improving their own operations. This internal examination is a major commitment for the health care facility and requires the involvement of multiple disciplines.

The main statutory requirements are:

- All health care facilities are required to develop a patient safety plan, including 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.

- 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

[1] Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. Washington, DC: National Academy of Science Press; 2000.
[2] Committee on Quality of Health Care in America, Institute of Medicine, Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.

disability or loss of bodily function lasting more than seven days or present at discharge to the Department of Health and Senior Services.

- The Department of Health and Senior Services must set up a system for collecting these mandatory reports as well as voluntary, anonymous reporting for near-misses and preventable, adverse events that are not subject to mandatory reporting.

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

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

- Information in both the mandatory and voluntary reporting systems 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. National Patient Safety Updates

New approaches to improving health care quality and patient safety continue to emerge at the federal level and in other states. In August 2007 the Centers for Medicare and Medicaid Services adopted new rules stipulating that hospitals will not be reimbursed for care associated with specific preventable medical errors.[3] Some other states, including New Jersey, plan to follow this approach for their Medicaid programs.

The federal Patient Safety and Quality Improvement Act of 2005 authorized the creation of Patient Safety Organizations (PSOs) to encourage the voluntary sharing of confidential information on patient safety.[4] Organizations that are eligible to become a PSO include public and private entities, profit or not-for-profit groups, hospital chains and other entities that

[3] "Revision to Hospital Inpatient Prospective Payment Systems- 2007 FY Occupational Mix Adjustment to Wage Index; Implementation; Final Rule." *Code of Federal Regulations* Title 42 PT. 409, 410, 412, et al.; 2006 ed.

[4] Department of Health and Human Services. Patient Safety and Quality Improvement: Proposed rule, 73(29) Fed Reg. (to be codified at 42 C.F.R. pt. 3); 2008 Available at: *http://edocket.access.gpo.gov/2008/pdf/E8–2375.pdf*

establish the required special components.[5] PSOs will work with clinicians and health care organizations to identify, analyze, and reduce conditions that may lead to adverse medical errors. This will be accomplished through the voluntary reporting of adverse medical errors by clinicians and health care organizations.

C. How To Use This Report

The Patient Safety Initiative started collecting data from general acute care hospitals in February 2005 and continued this process through 2007. The compilation of this data collection from the last three years is documented in the *Patient Safety Initiative 2007 Annual Report*. 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 in *New Jersey Health Care Quality Reporting and Assessment Initiatives*.

One of the difficulties in reducing adverse medical errors is overcoming the "culture of blame" prevalent in the health care system. The requirement to report medical errors is not designed to identify and punish the involved staff. Based on the IOM strategy and the New Jersey Patient Safety Act, our objective is assisting hospitals to improve the systems for providing care. With the relatively low occurrence of medical errors, it is important to recognize that the number of reports from New Jersey hospitals may differ from year to year for a variety of reasons. A higher number of reported events do not necessarily mean that a hospital 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 Initiative, health care providers in New Jersey are aware and watching for situations involving adverse medical errors and subsequently reporting them 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.

[5] Agency for Healthcare Research and Quality. Patient Safety Overview. AHRQ; 2008 Available at: *http://www.pso.ahrq.gov/psos/overview.htm*

Resources for providers on patient safety include:

- Institute for Healthcare Improvement (IHI): http://www.ihi.org/ihi
- National Center for Patient Safety (NCPS): http://www.patientsafety.gov/tools/html
- AHRQ Patient Safety Network (PSNet): http://psnet.ahrq.gov/
- AHRQ Morbidity and Mortality Rounds: http://webmm.ahrq.gov/
- Joint Commission: http://www.jointcommission.org/

Resources for consumers on patient safety include:

- Patient Safety Information for Consumers: http://web.doh.state.nj.us/hpr/patientsafety.shtml
- 20 Tips to Help Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm
- 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 Series
New Jersey Health Care Quality Reporting and Assessment Initiatives

- **Hospital Patient Care Staffing:** Manage the reporting system for hospital direct care staffing ratios and prepare quarterly reports for the public. (http://nj.gov/health/hpcs/index.shtml)

- **Stroke Services:** Monitor the quality of services provided to acute stroke patients through analysis and reporting of patient level data collected from hospitals. (http://nj.gov/health/healthcarequality/stroke/index.shtml)

- **Cardiac Services**: Monitor the quality of **cardiac surgery** (http://nj.gov/health/healthcarequality/cardiacsurgery.shtml) and **cardiac catheterization** (http://nj.gov/health/healthcarequality/cardiaccath.shtml) services through a mandatory hospital data reporting system. Produce consumer and technical reports on open heart surgery and cardiac catheterization.

- **Hospital Quality:** Manage the data reporting system on hospital quality. Produce the New Jersey Hospital Performance Report, both in print and on the web. Interactive web site allows users to compare individual hospitals and find other consumer information. (http://web.doh.state.nj.us/hpr/)

- **Quality Indicator Measures (QIs):** Develop a summary report on health care quality measures of New Jersey hospitals that are derived from hospital discharge data. These health care quality measures are obtained by applying QI modules developed by the Agency for Healthcare Research and Quality (AHRQ). The Department has published two reports: **Inpatient Quality Indicators** (IQIs) (http://nj.gov/health/healthcarequality/qi.shtml) and **Prevention Quality Indicators** (PQIs) (http://nj.gov/health/healthcarequality/pqi.shtml). AHRQ has developed two other modules (Pediatric Quality Indicators and Patient Safety Indicators) which will be considered for future reports.

- **Bariatric Surgery**: Examines trends and outcomes of bariatric surgery using hospital discharge data. The report includes basic statistics on the bariatric surgery population including gender distribution, age distribution, health insurance status, and selected outcomes. (http://nj.gov/health/healthcarequality/bariatric.shtml)

II. Implementation

The Department developed the Patient Safety Initiative to implement the statute in 2004. Reporting for general hospitals began in February 2005 as specified in the rules. The mandatory reporting system uses the National Quality Forum's (NQF) list of "never events".[6] 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 (see Appendix 1). Some changes from the NQF categories and definitions were made:

- 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 ASA Class I patients. New Jersey's list includes events resulting in death or significant harm. The New Jersey events also include ASA Class I patients in an outpatient setting.

- 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 Patient Safety Act. These events must be reported to the Department's Office of Health Facilities Assessment and Survey.

[6] National Quality Forum. Serious Reportable Events in Healthcare: A Consensus Report. Washington, DC: National Quality Forum; 2002.

A. Overview of 2007 Activities

The New Jersey Patient Safety Initiative reviews all reported events, root cause analyses (RCAs) and corrective action plans. Based on these reports, the New Jersey Patient Safety Initiative provides guidance to hospitals on how they can strengthen their analyses and corrective actions. The Initiative also uses this information to develop alerts that communicate with hospitals about Department activities and share information from individual reported events/RCAs.

- **Sharing Knowledge**
  - April 2007 Alert: *Hypoglycemia Caused by Unintended Insulin in Total Parenteral Nutrition for an Infant in the Neonatal Intensive Care Unit* provided facilities with information about preventing errors caused by look-alike heparin and insulin vials (Appendix 2).

  - June 2007: Patient Safety Initiative clinical staff conducted Root Cause Analysis training on root cause concepts and causality for the Virtua Health System hospitals.

  - September 2007: *Standardizing Color Codes for Patient Risk Factors* (page 10). Working in conjunction with the New Jersey Hospital Association, a toolkit to standardize color-coded wristbands used across New Jersey health care facilities was released. Previously, there was no consistency across facilities in the use of color designations for clinical conditions. A task force composed of representatives from hospitals, long term care facilities, ambulatory care settings, home health providers and emergency responders agreed on standardized colors and policies.

- **Patient Safety Regulations**
  The proposed Patient Safety Rules (N.J.A.C. 8:43E-10), which implement the New Jersey Patient Safety Act, were published for comment in the *New Jersey Register* in February 2007; the final rules were approved by the Health Care Administration Board on January 31, 2008 and published in the *New Jersey Register* on March 3, 2008.

- **Strengthening the Reporting System**
  Changes were made to the *Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities* to clarify existing language and to be more consistent with the patient safety rules.

  - 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.

  - Surgery reporting should include post-operative coma, death or any other event that occurs within twenty-four hours instead of the previous requirement of twelve hours.

  - A new category was added for single-use devices that do not function as intended. Reporters must indicate whether the device was new or reprocessed.

- **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. These bids are currently under review and the selection of a vendor to design the web-based system is anticipated for 2008. Implementation of the online system is projected for 2010.

B. Clinical Review of Root Cause Analyses (RCA)

Hospitals 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. That RCA must include a description of the event, a determination of the causes of the event based on examining systems for providing care, an action plan which changes that system to minimize recurrence of the event and monitoring of that action plan to ensure that it was implemented. The Patient Safety Initiative clinical team reviews each event to ensure that the analysis and plans fulfill Department requirements and are likely to prevent the event from occurring again.

The clinical review of each RCA submitted is extensive and follows this general approach:

- The *description of the event* is reviewed to ensure that the event is completely described in detail 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) are examined to determine if they flow from the event description. The causality statements should address the underlying vulnerabilities in systems for providing care.

- *Action plans* (risk reduction strategies) are evaluated to determine if the stated actions or strategies would likely 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, be reasonable and feasible to implement. The implementation time frame and the person responsible should be specified. The actions should be initiated or completed during the 45-day period between submission of the event report and submission of the RCA.

- The *monitoring plans* (measures of effectiveness) are reviewed for their ability to measure the implementation and impact of each action. The plans should include defined time frames and the responsible person. There should be a monitoring plan for each risk reduction strategy.

For most RCAs, the Patient Safety Initiative clinical reviewer contacts hospital staff to review event specifics or to suggest alternative strategies for improving the analysis. This is an opportunity for the Department to share the strategies among hospitals which are facing the same issues. There may be discussion regarding the root causes and the need to focus on systems/processes rather than individuals. The clinical reviewer may suggest expansion of action plans and monitoring to improve effectiveness. At times consultants with specific clinical expertise are used to assist in the review process. If the case is very complicated, there may be additional discussions with the hospital.

Standardized Color Codes

Color-coded wristbands for patients in health care facilities are used to quickly communicate a certain health care state, condition, or alert. But what the different colors stand for vary from hospital to hospital resulting in near fatal mistakes. In 2005, the Pennsylvania Patient Safety Reporting System issued a Patient Safety Advisory about an incident where clinicians nearly failed to resuscitate a patient because she was incorrectly identified as "DNR" by a nurse. This nurse was working at multiple facilities where colored wristbands had different meanings.

In 2007 the New Jersey Hospital Association and New Jersey Department of Health and Senior Services began working with industry leaders to standardize communications for patient risk factors and special needs to prevent any incidents of patient harm due to confusion on color-coded wristbands occurred.

A survey sent to a wide range of health care providers in New Jersey indicated that acute care facilities had 10 colors designated for 19 different risk factors. Other facilities including specialty hospitals, nursing facilities, assisted living residents, and home health agencies used 9 different colors to represent 25 different risks.

Based on this survey it became clear that a statewide standardized color system was needed. This system includes wristbands, care plan and information stickers, and color-coded charts. Information on this system is available at http://www.njha.com/qualityinstitute/colorcodes.aspx.

Color Codes:

- ***Red-Allergy***
- ***Yellow- Fall Risk***
- ***Green-Latex Allergy***
- ***Purple-Do Not Resuscitate (DNR)***
- ***Pink-Restricted Limb***

Risk Reduction Strategies:

- Use wristbands with pre-printed text that tells what the band means.
- Remove any "Social Cause" bands on admission.
- Remove wristbands applied at another facility (if not using same color system).
- Educate patient and families on meaning and purpose of wristbands.
- Educate staff to always verify that correct color-coded wristband is being used.

Things to Consider:

- Every department should be included in the system of care process:
  - Environmental staff are commonly in patient rooms when a patient is attempting to get up or go to the bathroom. If they know yellow means fall risk and see a patient is wearing a yellow wristband, they will know to alert the nursing staff about a potential fall.
  - Dietary technicians will know if they see a patient with a red wristband to be aware of allergies, including food allergies.
  - All medical staff, including attendings, intensivists, hospitalists, residents and interns should also be educated on the color code system.

III. Analyses of Events and RCA Reports

Collecting and analyzing reports submitted from hospitals on events and RCAs are vital components of the Patient Safety Initiative. Mandatory reporting began in February 2005. Event report summary information for 2005 through 2007 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 2007.

A. Overall Reporting Patterns

Reporting has steadily increased from 376 events submitted in 2005 to 456 events in 2007 (Table 1). The percentage of reporting hospitals increased from 83% in 2005 to 94% in 2007. Only one hospital did not report during the three-year period and five hospitals did not report in 2007.* The average number of reports per hospital was 4.6 in 2005 and 5.7 in 2007. When reports are adjusted by 1,000 patient days, the rate of reported events increased from 0.070 in 2005 to 0.080 in 2007. Reporting increased over the last three years due to increases in the number of reporting hospitals and the number of reported events per hospital.

Table 1: Reporting Patterns (2005-2007)[a]

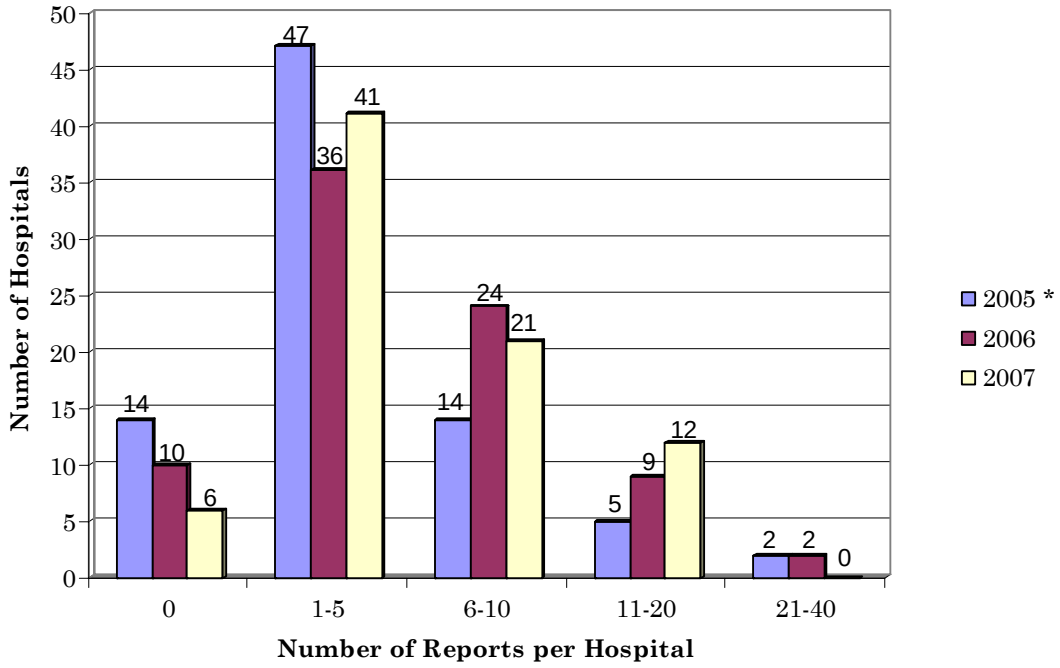
	2005[b]	2006	2007
Total reported events	376	450	456
Percentage of hospitals reporting each year	83%	88%	94%
Number of reporting hospitals	68	71	75
Reported events per 1,000 patient days	0.070	0.078	0.080
Average number of reports per hospital	4.6	5.6	5.7

a Based on 82 hospitals in 2005, 81 hospitals in 2006 and 80 hospitals in 2007
b Represents 11 months of data since the program started on February 1, 2005

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

Figure 1 presents reporting patterns for each hospital across years based on the number of reports per year. The most frequent category is between one and five events for each reporting year. However, there has been an increase in the number of hospitals which fall in the higher reporting categories (six to ten events and eleven to twenty events) since 2005.

Figure 1: Frequency of Event Reports for Each Hospital (2005-2007)



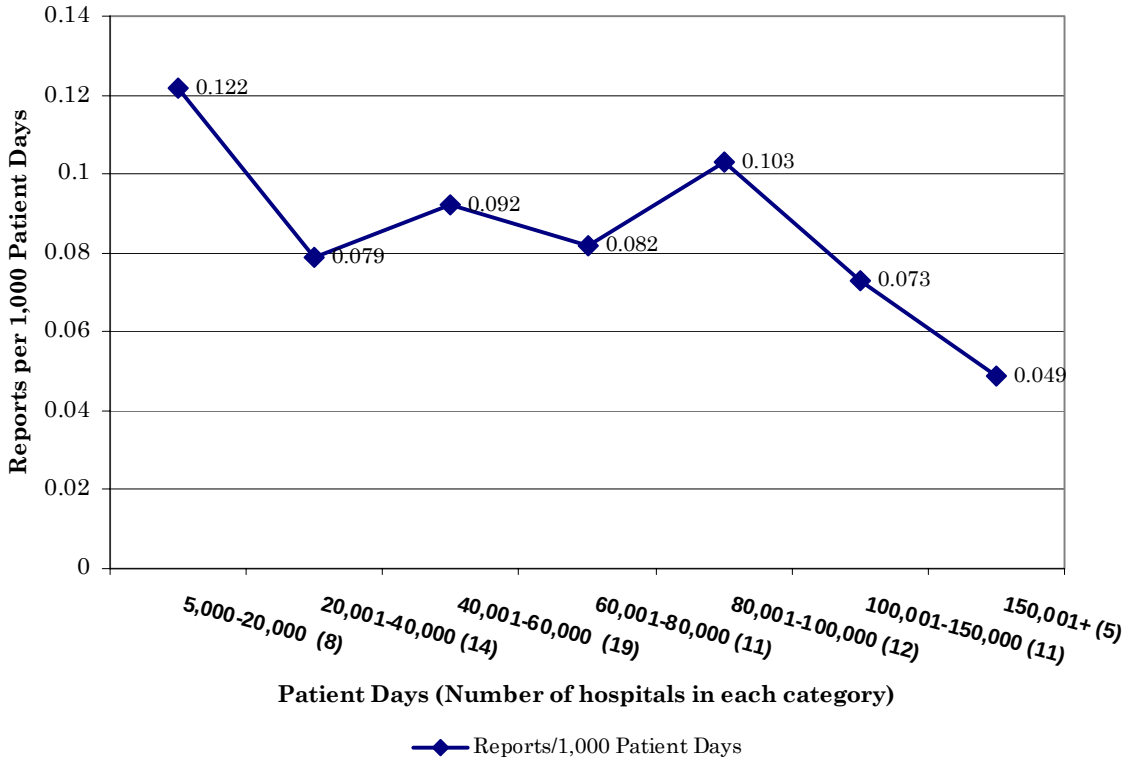
* Represents 11 months of data since program started February 2005

Reporting for 2007 shows that hospitals with an intermediate number of maintained beds (201-300 and 301-400) submitted the most reports, 54% of the total reports (Table 2). This is reasonable since 36 hospitals are in this intermediate group.

Table 2: Event Reports Based on Hospital Maintained Beds (2007)

Maintained beds	Number of Hospitals	Number of Reports	Percentage of Reports
Less than 100	8	14	3%
100-200	22	64	14%
201-300	24	138	30%
301-400	12	110	24%
401-500	8	69	15%
501+	6	61	13%
Total	80	456	99%

Figure 2: Event Reports per 1,000 Patient Days (2007)



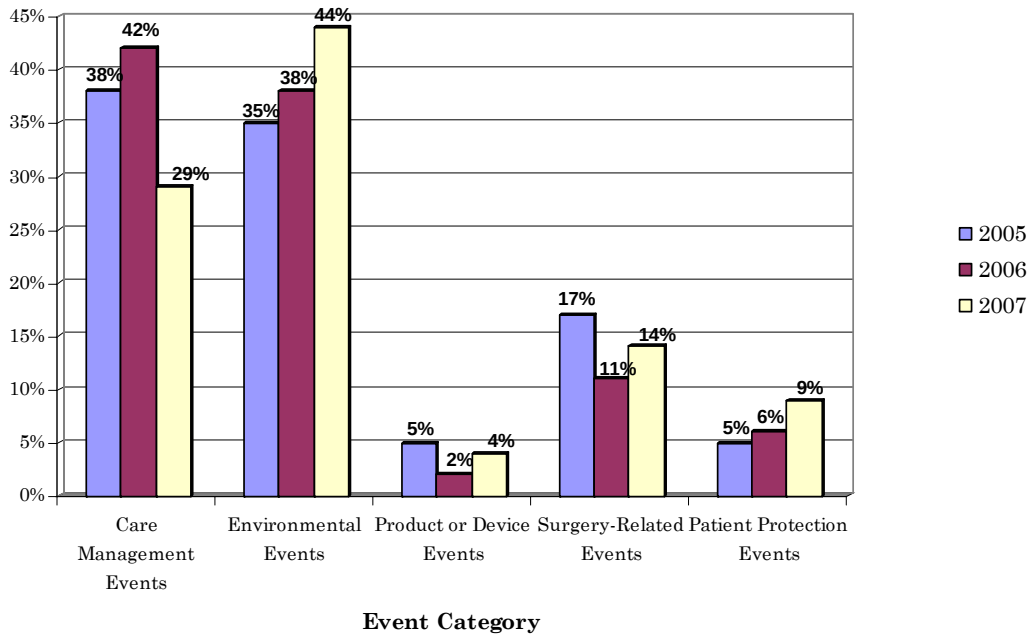
As shown in Figure 2, a somewhat different pattern emerges from considering the rate of reporting based on the number of patient days for each hospital. The reporting rate is highest for the low volume hospitals

(5,000-20,000 patient days) and lowest for the high volume hospitals (over 150,001 patient days). The reporting rates for the other hospitals are similar and fall between these two groups. This intermediate group includes most of New Jersey hospitals while the extremes include very few hospitals (i.e., eight low volume hospitals and five high volume hospitals).

B. Review of Reported Events

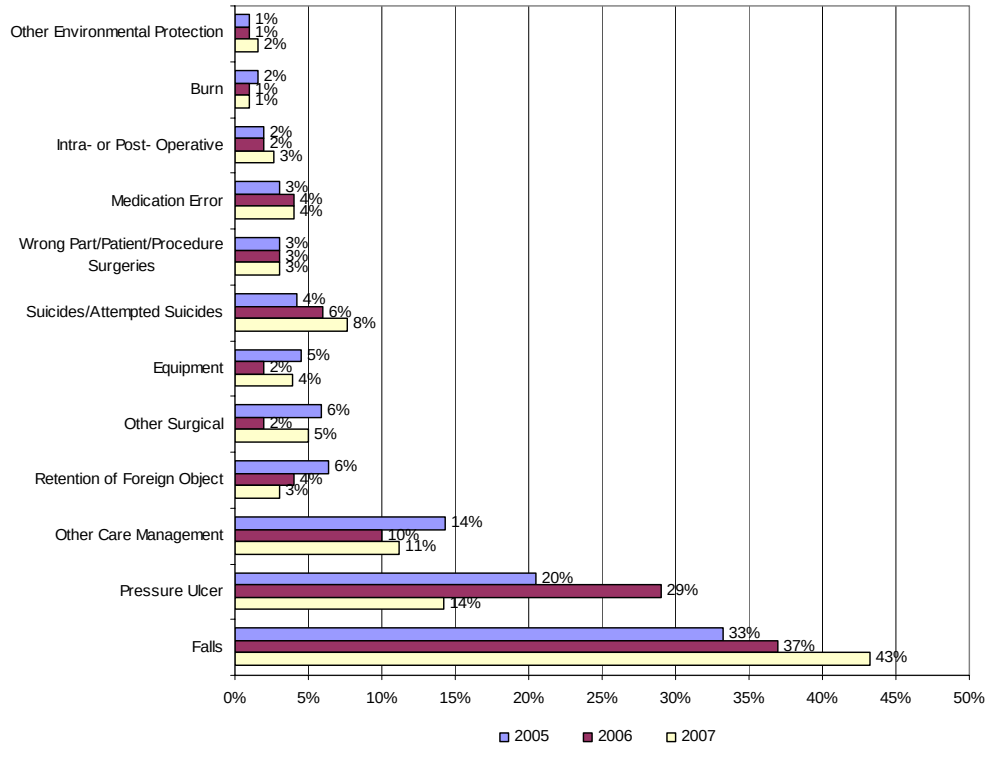
There are five main categories of events: care management, environment, product or device, surgery-related and patient protection. The percentage of event reports for each of the five event categories for 2005 through 2007 are presented in Figure 3. As in previous years, the majority of events are in the care management and environment categories. These two categories account for 73% of the reports in 2007. This year, for the first time, the number of reported events in care management decreased.

Figure 3: Percentage of Reports by Event Category (2005-2007)



The distribution of reporting for specific subcategories in each event type for 2005 through 2007 is presented in Figure 4. Falls and pressure ulcers continue to be the most frequently reported events. In 2007, the overall percentage of falls increased while the percentage of pressure ulcers decreased by half. The increase in reported falls may be related to the announcement that Medicare will not reimburse for these events. Hospitals may have responded to this additional financial liability by focusing on detecting and preventing falls. The decrease in reported pressure ulcers may be due to eliminating the reporting of pressure ulcers for patients with skin ulcers that develop as a result of an underlying vascular etiology or that develop as a result of an underlying neuropathy. There may also have been improved preventive care related to hospitals participating in the 2006-2007 collaborative on pressure ulcers sponsored by the New Jersey Hospital Association in association with the Department of Health and Senior Services.

Figure 4: Percentage of Reports by Event Subcategory (2005-2007)



There continues to be a substantial percentage of reporting in the "other care management" subcategory. That 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. The percentage of events related to suicide/attempted suicide has doubled since 2005. The number of suicide events reported increased from 16 in 2005 to 35 in 2007.

Nationally and in New Jersey, wrong site, wrong person, and wrong procedure surgery-related events continue to be an area of concern. This concern is reflected on the national level where the Joint Commission assembled a group of experts in 2007 for a summit to discuss the reoccurrence of wrong surgery events based on sentinel events submitted to them.[7] Sentinel events are an unexpected occurrence resulting in death, serious physical or psychological injury which is reported to the Joint Commission.[8] Once an event has been reported to the Joint Commission, hospitals must submit an RCA and action plan within 45 calendar days. The Joint Commission receives between five and eight new cases of wrong surgery a month, and in 2007 it became the most frequently reported sentinel event. In New Jersey the percentage of reports on combined wrong site, wrong patient and wrong procedure has remained consistent since the patient safety reporting system began.

C. Patient Characteristics

Table 3 presents the demographic characteristics of patients involved in events reported for 2005 to 2007. Events for the three years are very similar. In 2007, the average patient involved in a preventable event was female, Caucasian, 64 years of age, and had been admitted to the hospital 13 days prior to the event.

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

[7] Joint Commission. Performance of the Correct Procedure at the Correct Body Site. Second Wrong Site Surgery Summit February 23, 2007. Available at: *www.jointcommission.org*

[8] Joint Commission. Sentinel Events Policy and Procedure. Available at: *www.jointcommission.org*

Table 3: Demographic Characteristics of Patients from Event Reports Compared to All New Jersey Hospital Patients (2005-2007)

Patient Characteristics	Percentage or Average Event Reports[a] 2005	Percentage or Average Event Reports[a] 2006	Percentage or Average Event Reports[a] 2007	Percentage or Average All Patients[b] 2005	Percentage or Average All Patients[b] 2006	Percentage or Average All Patients[b] 2007
Mean Age	67	65	64	49	49	49
Less than 1 Year	1%	2%	3%	8%	8%	9%
01-24 years	3%	3%	3%	10%	10%	10%
25-34 years	4%	4%	7%	10%	10%	10%
35-44 years	6%	7%	9%	12%	12%	12%
45-54 years	10%	12%	9%	13%	13%	13%
55-64 years	14%	12%	14%	13%	13%	13%
65-74 years	19%	16%	16%	13%	12%	12%
75-84 years	27%	27%	20%	14%	14%	14%
85-94 years	15%	15%	16%	6%	7%	7%
95+ years	1%	2%	4%	1%	1%	1%
Days since admission[c]	15	17	13	NA	NA	NA
Gender: Female	51%	56%	56%	58%	58%	58%
Race: Caucasian	78%	78%	82%	64%	64%	63%
Inpatient	88%	87%	84%	NA	NA	NA

a N=376 for 2005, N=450 for 2006 and N=456 for 2007
b Data drawn from Uniform Billing Data 2005-2007 and same day surgery: N=1,528,583 for 2005, N=1,528,097 for 2006 and N=1,530,293 for 2007
c Inpatient only
NA Not Applicable

Take "Time Out" *

Correct identification continues to be an issue for surgeries and invasive procedures, specifically events related to 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 Joint Commission's *Universal Protocols*, specifically "Time Out".

"Time Out" is not just for the operating room:

This important step should be required for all operative and other invasive procedures performed in the operating room as well as in special procedure units, endoscopy, and interventional radiology suites. "Time Out" procedures should include 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.

"Time Out" must include the following elements: 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.

Tips in developing an effective "Time Out" policy:

- Include a clear description of which specific procedures require a "Time Out".
- Determine at what point during the procedure a "Time Out" is required.
- Designate who is responsible for calling the "Time Out".
- Conduct it in the location where the procedure will be done.
- During site marking, if the site is not visibly identifiable, the surgeon is to obtain an intra-operative image to mark.
- 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.
- Involve the entire operative team and require the operative team to give active confirmation for each of these elements.
- If there are any discrepancies, there should be a description of the reconciliation process.
- "Time Out" must be documented and include signatures indicating all the team members were in agreement with all the required elements.
- It is also recommended that instruments and equipment not be available until after the "Time Out" is performed.

Procedures involving more than one site and/or more than one surgeon:

- 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 they mark.
- During the "Time Out" if the procedure is being performed without assistance, it is strongly recommended 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.

* New Jersey Patient Safety Initiative April 2008 Newsletter *Review of Invasive Procedures: Wrong Patient, Wrong Site, Wrong Procedure*

D. Impact of Reported Events on Patients

Based on the 456 events and corresponding RCA reports submitted for 2007, the most frequent consequences of preventable adverse events on patients were additional laboratory testing (62%) and additional patient monitoring (59%). A moderate percentage of patients also experienced physical disability or mental impairment (41%) or an increase in their length of stay (40%) as seen in Table 4.

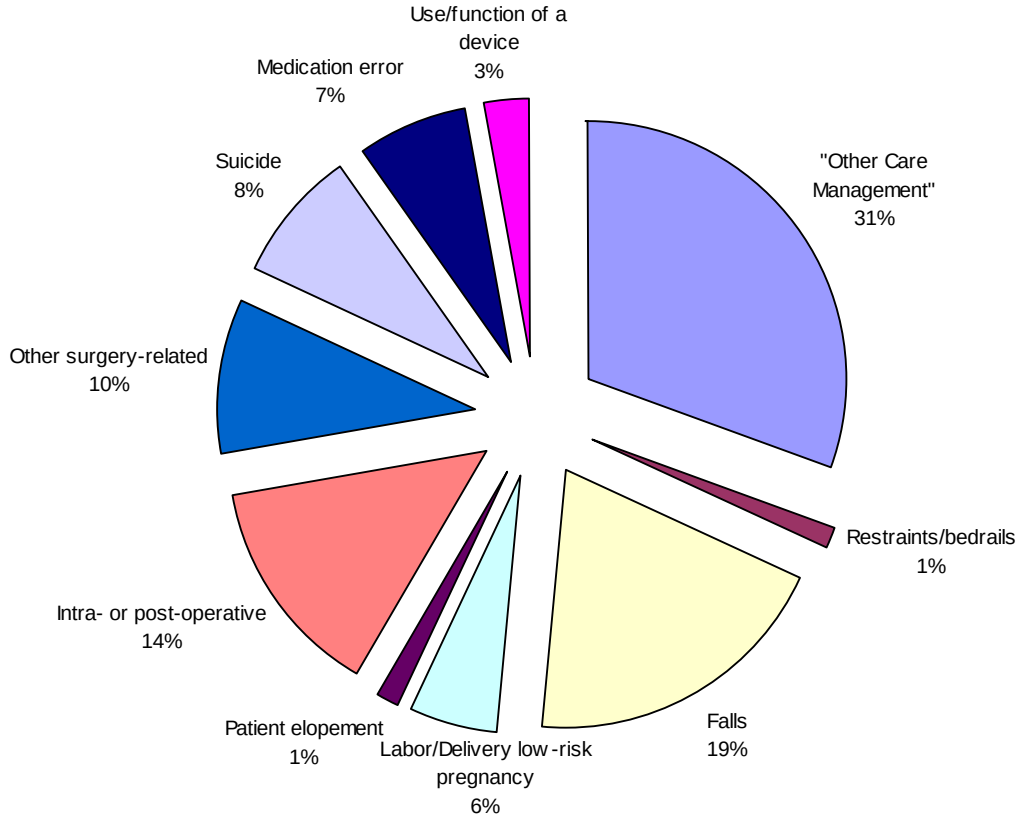
Table 4: Impact of Events on Patients (2007)[a]

Impact/Outcome	Number of Patients	Percentage of Patients[b]
Additional laboratory testing	283	62%
Additional patient monitoring	270	59%
Physical disability or mental impairment	185	41%
Increased length of stay	183	40%
Major surgery	121	27%
Transfer to higher level of care	91	20%
Death	72	16%
Minor surgery	53	12%
Other additional testing	38	8%
System/process delay	38	8%
To be determined	35	8%
Hospital admission	23	5%
Loss of bodily function	13	3%
Other	13	3%
Loss of sensory function	10	2%
Loss of organ	4	1%

a Data drawn from 456 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one adverse outcome

There were 72 deaths related to adverse medical errors in 2007. The largest category of deaths (31%) were a result of "other care management events". The other large portion of deaths occurred from falls (19%) and intra- or post-operative events (14%) as shown in Figure 5.

Figure 5: Event Categories Resulting in Death (2007)



E. Root Causes

When a preventable adverse event occurs, the hospital is required to submit an initial report of the event to the Patient Safety Initiative. Once that event is accepted as a reportable event, the hospital then conducts a Root Cause Analysis (RCA) to examine causality and ways to prevent recurrence. During the RCA process, the hospital assembles a team to examine the factors that led up to the event. According to the Agency for Healthcare Research and Quality (AHRQ) the most common causes of medical errors 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 (www.ahrq.gov/qual/pscongrpt/psini2.htm).

After the RCA is concluded, the hospital completes an RCA form providing information on causality and patient impact. This form, along with the completed RCA report, is reviewed by the Patient Safety Initiative clinical staff to ensure accuracy and consistency. The major causes of reported events are care planning, communication among staff, staff orientation and physical assessment as shown in Table 5.

Table 5: Root Causes (2007)[a]

Root Cause	Number of Events	Percentage of Events[b]
Care planning	247	54%
Communication among staff	202	44%
Staff orientation/training	168	37%
Physical assessment	109	24%
Patient observation	95	21%
Communication with family	64	14%
Availability of information	57	13%
Equipment maintenance	56	12%
Physical environment	42	9%
Supervision of staff	34	7%
Staff competence	33	7%
Other	30	7%
Behavioral assessment	28	6%
Patient identification	17	4%
Staffing	11	2%
Adequacy of technical support	9	2%
Security systems	5	1%
Control of medication	4	1%

a Data drawn from 456 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one root cause

F. 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 the less frequent events ("other care management" and medication errors).

1. Falls

Falls were the most frequently reported event submitted to the Patient Safety Initiative in each reporting year and constituted 43% of all reported events in 2007. Most falls occurred in the patient's room (77%). Other locations for patient falls, although to a lesser extent, are hallways or other common areas (7%) and in the emergency department (6%) as shown in Table 6.

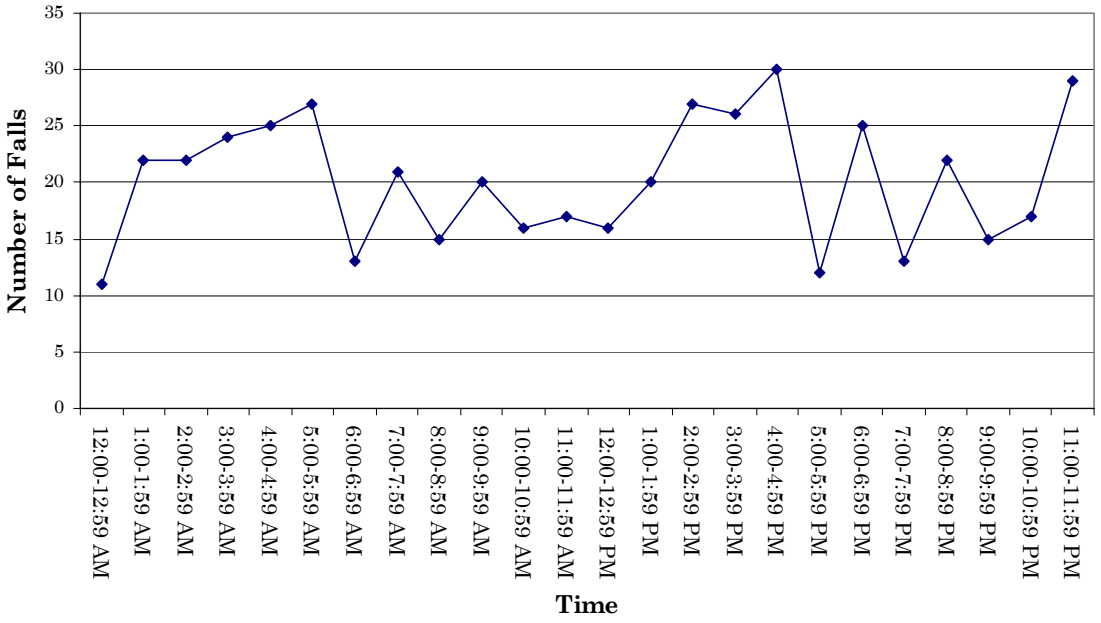
Table 6: Percentage of Falls by Location (2005-2007)

Location of Fall	2005	2006	2007
Patient Room	82%	80%	77%
Hallway	5%	7%	7%
Emergency Department	6%	7%	6%
Radiology	1%	2%	2%
ICU/CCU/TCU	1%	2%	2%
Telemetry Unit	1%	0%	2%
Cardiac Catheterization Laboratory	0%	1%	1%
Rehabilitation Areas	1%	1%	1%
Other	2%	1%	1%

N=125 for 2005, N=165 for 2006 and N=197 for 2007

The majority of falls reported in the past three years occurred between 11 pm and 6 am, and late afternoon, between 2 pm and 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.

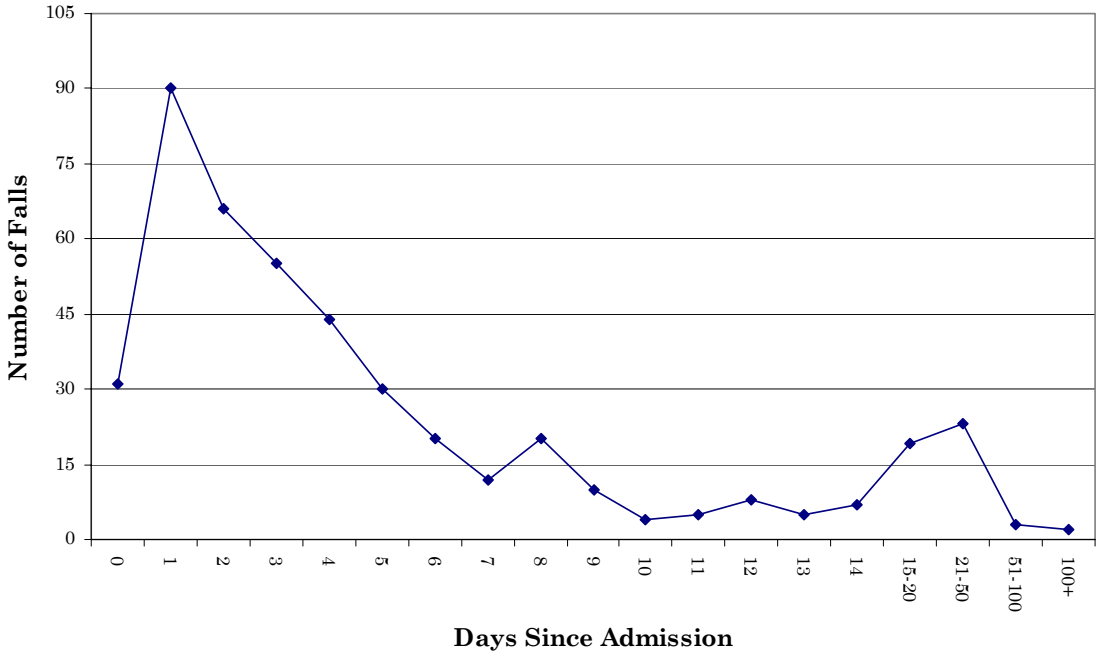
Figure 6: Number of Falls versus Time of Day (2005-2007)*



*Excluding ED events

Proper assessment of the patient upon admission, at regular intervals, and especially following a previous fall has been shown to be most effective in identifying the risk factors for future falls. Data from the last three years revealed that the first two days, especially the first day after admission, are the most critical. From 2005 to 2007, 90 of the 455 falls occurred on the day after admission (Figure 7).

Figure 7: Number of Falls versus Days Since Admission (2005-2007)*



*Excluding ED events

The typical patient who has a fall resulting in injury is an older Caucasian female patient (Table 7). Of the fourteen falls that led to patient death in 2007, the average patient age was 72 and many of these falls happened within the first week after admission.

Table 7: Falls by Patient Characteristics (2005-2007)

Patient Characteristics	Average or Percentage 2005	Average or Percentage 2006	Average or Percentage 2007
Age	78	78	76
Days since admission	5	12	6
Gender: Female	53%	66%	62%
Race: Caucasian	89%	92%	92%

N=125 for 2005, N=165 for 2006 and N=197 for 2007

In 2007, 90% of the falls resulted in additional laboratory testing (Table 8). Other common patient outcomes included physical or mental impairment, additional patient monitoring, increased length of stay, and major surgery. Based on the RCA reports, one of the most pervasive causes of falls in hospitals was the lack of care planning (74%) followed by inadequate staff orientation and training (40%) and poor communication among staff (32%) as shown in Table 9.

Table 8: Impact of Falls on Patients (2007)[a]

Impact/Outcome	Number of Patients	Percentage of Patients[b]
Additional laboratory testing	178	90%
Physical or mental impairment	148	75%
Additional patient monitoring	146	74%
Increased length of stay	134	68%
Major surgery	94	48%
Transfer to higher level of care	39	20%
Other additional testing	17	9%
Death	14	7%
System process delay	14	7%
Minor surgery	9	5%
Hospital admission	8	4%
To be determined	7	4%
Loss of bodily function	7	4%
Loss of sensory function	2	1%
Other	1	1%

a Data drawn from 197 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one adverse outcome

Table 9: Root Causes of Patient Falls (2007)[a]

Root Cause	Number of Events	Percentage of Events[b]
Care planning	145	74%
Staff orientation and training	79	40%
Communication among staff	72	32%
Patient observation	55	28%
Physical assessment	43	22%
Communication with patient/family	42	21%
Availability of information	25	13%
Equipment maintenance	20	10%
Physical environment	14	7%
Other	12	6%
Behavioral assessment	6	3%
Supervision of staff	4	2%
Staff competence	4	2%
Staffing	4	2%
Patient identification	1	1%
Security systems	1	1%

a Data drawn from 197 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one root cause

Falls

A fall by a hospitalized adult is not a rare event. Based on the total events submitted to the New Jersey Patient Safety Initiative in 2007, 197 were falls. Since 68% of the falls require increased length of stay and 48% result in major surgery, preventing falls is an increasingly important part of inpatient care. The Joint Commission has recognized this and initiated in 2006 the addition of Goal 9B "Fall Prevention Reduction Programs" in its National Patient Safety Goals.

Most falls can be categorized as one of three types of falls:[1]

1. **Accidental falls:** This type of fall is an unintentional fall, such as, when a patient trips, slips, or falls because of an external problem due to either defective equipment or an object in their path.
2. **Unanticipated physiologic falls:** This type of fall occurs because of a patient's risk factors (fainting, a seizure, or a pathological fracture of the hip) which are not identified during the fall risk assessment.
3. **Anticipated physiologic falls:** This type of fall occurs in patients who were identified during the risk assessment [e.g., Morse Fall Scale (MFS)] that they are at risk of falling. Some of the common characteristics in this type of patient include a prior fall, weak or impaired gait, use of a walking aid, intravenous access, or impaired mental status.

Common causes of falls[2]

Due to patient's condition:

- Previous fall
- Reduced vision
- Unsteady gait
- Musculoskeletal system
- Mental status
- Acute illnesses
    - rapid onset of symptoms associated with seizures, stroke, orthostatic hypotension, and febrile conditions
- Chronic illnesses
    - arthritis, cataracts, glaucoma, dementia, diabetes and Parkinsonism

Due to environment:

- Medications
    - affecting the central nervous system, such as sedatives and tranquilizers, benzodiazepines, and the number of administered drugs
- Height of bathtubs and toilets
- Design of furnishings
- Condition of ground surfaces
- Poor illumination conditions
- Type and condition of footwear
- Improper use of devices
    - bedside rails and mechanical restraining devices that may actually increase fall risk in some instances
- Inadequate assistive devices
    - walkers, wheelchairs and lifting devices

[1] Morse, J M, Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control. 2002; 30(6): 376-80.*
[2] Premier HealthCare Alliance™. Fall Prevention. Available at: *http://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/*

Effective Fall Prevention and Corrective Actions

Risk Assessment
Research has shown there is a reduction in the number of falls when a fall risk assessment is used as a screening tool to determine which intervention methods best fits the individual patient.[1] This assessment is usually performed by the nurse and utilizes a system that assigns points or a level of specific risk factors.

Fall risk assessments should be conducted on admission.[2] This data should then be 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.

Tips on Developing an Effective Fall Prevention Program[3]

Corrective Actions:
- Consider peak effect for prescribed medications that affect level of consciousness, gait and elimination when planning patient care.
- 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.
- Vertical grab bars near toilets.
- Evaluate chair and bed height.
- Install anti-slip tape or strips.

Preventative Actions:
- Education for staff to increase awareness of high risk patients.
- Use the standardize color code system to identify a high fall risk patient.
- Education for 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.
- Orientate the patient to their bed area, location of the bathroom and how to request assistance.
- Instruct the patient or resident to request assistance as needed.

[1] Becker, C., Kron, et al. Effectiveness of a Multifaceted Intervention on Falls in Nursing Home Residents. *J Am Geriatr Soc; 2003 51(3): 306-313.*
[2] Premier HealthCare Alliance™. Fall Prevention. Available at: *http://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/*
[3] University of Texas Health Science Center. Policies and Procedure for Fall Prevention/Intervention Strategies; 2003. Available at: *http://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/downloads/S-09-uthsc-pol-procedures.doc*

2. 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 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.[9]

There are four stages of severity for pressure ulcers, Stage 1 (earliest signs) to Stage IV (severe). Patients with Stage III or Stage IV ulceration need to be reported to the Patient Safety Initiative. However, if at admission a patient is documented with Stage II ulceration and it progresses to Stage III, this is not considered reportable. Pressure ulcers are the second most frequently reported serious events, constituting 14% of all reported events in 2007 (Figure 4).

According to the Braden Scale for Predicting Pressure Sore Risk, typical risk factors for developing pressure ulcers include:[10]

- 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
- Require moderate to maximum assistance in moving.

The average patient who developed a Stage III or Stage IV pressure ulcer during 2007 was a 69-year old Caucasian male who was hospitalized for 33 days prior to the event (Table 10).

[9] The Merck Manual of Diagnosis and Therapy. Available at: *http://www.merck.com*

[10] Ayello EA, Braden B. How and why to do a pressure ulcer risk assessment. *Adv Skin Wound Care. 2002;15(3):125-132.*

Table 10: Pressure Ulcers by Patient Characteristics (2005-2007)

Patient Characteristics	Average or Percentage 2005	Average or Percentage 2006	Average or Percentage 2007
Age	69	64	69
Days since admission	34	29	33
Gender: male	55%	56%	52%
Race: Caucasian	78%	69%	83%

N=77 for 2005, N=129 for 2006 and N= 65 for 2007

In 2007 almost all of the patients (98%) that developed Stage III or IV pressure ulcers required additional patient monitoring (Table 11). Other consequences for the development of advanced-stage pressure ulcers were additional laboratory testing and minor surgery (i.e., tissue debridement).

Table 11: Impact of Pressure Ulcers on Patients (2007)[a]

Impact/Outcome	Number of Patients	Percentage of Patients[b]
Additional patient monitoring	64	98%
Additional laboratory testing	22	34%
Minor surgery	18	28%
Physical or mental impairment	12	18%
Increased length of stay	11	17%
System process delay	6	9%
Major surgery	2	3%
Other additional testing	2	3%
To be determined	2	3%
Other	2	3%
Transfer to higher level of care	1	2%
Loss of organ	1	2%

a Data drawn from 65 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one adverse outcome

As with patient falls, lack of care planning, inadequate staff orientation/training, poor staff communication and limited physical

assessments were the most frequently identified causes for Stage III or Stage IV pressure ulcers (Table 12).

Tips for reducing hospital-acquired pressure ulcers include:[11]

- Identify patients at risk and develop an individualized care plan.
- Frequently reposition the patient in bed and when sitting in a chair.
- Alternate the use of special foam mattresses and pressure overlays.

Table 12: Root Causes of Pressure Ulcers (2007)

Root Cause	Number of Events	Percentage of Events[b]
Care planning	51	78%
Staff orientation and training	33	51%
Communication among staff	29	45%
Physical assessment	24	37%
Equipment maintenance	6	9%
Staff competency	5	8%
Other	4	6%
Patient observation	3	5%
Communication with patient/family	3	5%
Patient identification	3	5%
Availability of information	1	2%
Supervision of staff	1	2%

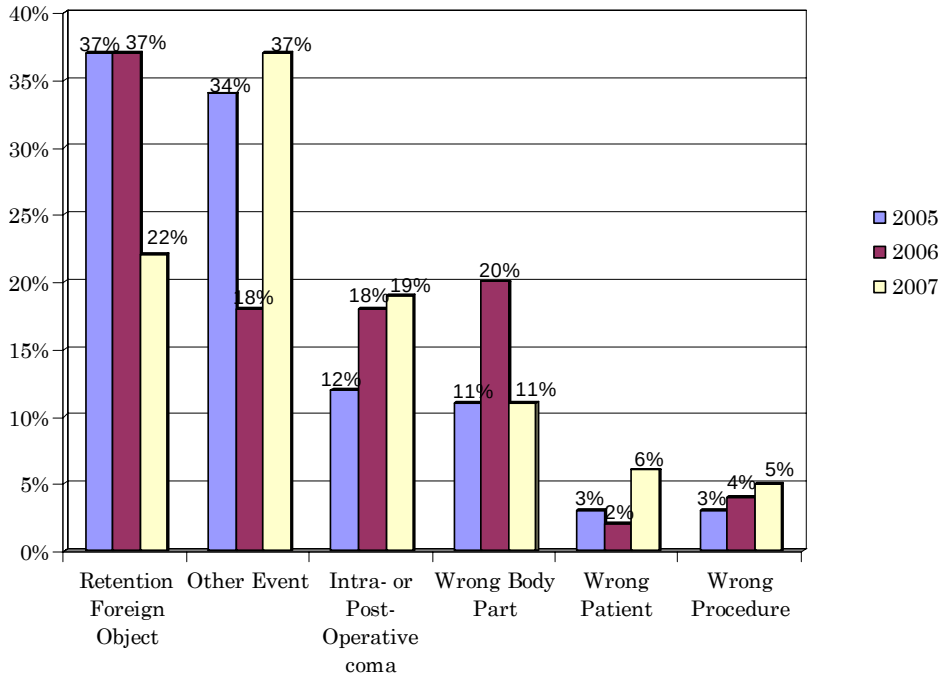
a Data drawn from 65 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one root cause

3. Surgical Events

Figure 8 presents the distribution of various types of surgery events. In 2007 the most commonly reported surgical event was the "other surgery event" category (37%). For both 2005 and 2006, the most commonly reported surgical event was retention of a foreign object (37% in both years). However, reports of retention of a foreign object dropped to 22% in 2007. In contrast, wrong patient events increased slightly from 2006. Of the twelve intra- or post-operative events, ten (83%) resulted in death in 2007.

[11] Wann-Hansson C, Hagell P, Willman A. Risk factors and prevention among patients with hospital-acquired and pre-existing pressure ulcers in an acute care hospital. *J Clin Nurs. 2008;17(13):1718-1727.*

Figure 8: Percentage of Surgical Events by Subcategory (2005-2007)



The average person who experienced a surgical event in 2007 was a 53-year old Caucasian female who had been admitted to the hospital for 2 days prior to the event (Table 13). Additional laboratory testing was the most common result (41%) followed by death (27%), major surgery to minimize or repair the damage caused (24%) and minor surgery (24%) as shown in Table 14.

Table 13: Surgical Events by Patient Characteristics (2005-2007)

Patient Characteristics	Average or Percentage 2005	Average or Percentage 2006	Average or Percentage 2007
Age	59	55	53
Days since admission	3	3	2
Gender: Female	51%	51%	52%
Race: Caucasian	63%	69%	75%

N=65 for 2005, N=49 for 2006 and N=63 for 2007

Table 14: Impact of Surgical Events on Patients (2007)[a]

Impact/Outcome	Number of Patients	Percentage of Patients[b]
Additional laboratory testing	26	41%
Death	17	27%
Minor surgery	15	24%
Major surgery	15	24%
Increased length of stay	12	19%
Additional patient monitoring	11	17%
To be determined	11	17%
Transfer to higher level of care	10	16%
System process delay	8	13%
Physical or mental impairment	7	11%
Other additional testing	7	11%
Hospital admission	7	11%
Other	5	8%
Loss of sensory function	3	5%
Loss of bodily function	3	5%
Loss of organ	2	3%
Loss of body part	2	3%

a Data drawn from 63 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one adverse outcome

The following areas were identified by the hospitals during the RCA as the root causes of surgical events: poor communication among staff, limitations in physical assessment, inadequate staff orientation and training (Table 15).

Table 15: Root Causes of Surgical Events (2007)[a]

Root Cause	Number of Events	Percentage of Events[b]
Communication among staff	36	57%
Physical assessment	16	25%
Staff orientation and training	15	24%
Availability of information	10	16%
Supervision of staff	9	14%
Equipment maintenance	8	13%
Staff competency	8	13%
Communication with patient/family	7	11%
Care planning	6	10%
Other	6	10%
Patient identification	6	10%
Patient observation	3	5%
Physical environment	3	5%
Staffing	2	3%
Adequacy of technical support	2	3%
Security	1	2%

a Data drawn from 63 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one root cause

4. Suicides/Attempted Suicides

Suicide is a key public health problem in the United States.[12] 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. Suicides and attempted suicides were the fourth leading event reported by hospitals to the New Jersey Patient Safety Initiative in 2007. The number of suicides/attempted suicides has doubled since reporting began in 2005.

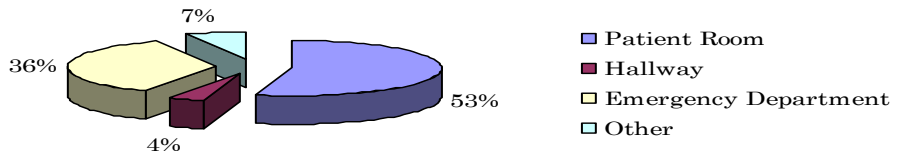
These events represent 6% of all deaths from adverse events reported from 2005 to 2007. An analysis of these suicides/attempted suicide events by location revealed that 53% occurred in the patient's room and 36% occurred

[12] The Joint Commission 2008 National Patient Safety Goals, 15A. Available at: *http://www.jointcommission.org*

in the emergency department (Figure 9). These numbers may reflect the increasing trend of behavioral health patients using the emergency department for psychiatric and general medical services.

National studies indicate that at least 90% of those who commit suicide had an underlying mental illness and/or substance abuse disorder.[13] A retrospective matched-case study was conducted for three hospitals in Mobile, Alabama.[14] 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.

Figure 9: Location of Suicide/Attempted Suicide Events (2005-2007)



The average person who committed or attempted suicide in 2007 was a 42-year old Caucasian male who had been admitted to the hospital for 5 days prior to the event (Table 16). This differed from 2005 and 2006 where the average patient was female. Additional patient monitoring was the most common (66%) consequence of suicide/attempted suicide followed by transfer

[13] Office of Disease Prevention and Health Promotion. Healthy People 2010 Chapter 18 Mental Health and Mental Disorders. Available at: *http://mentalhealth.samhsa.gov/features/hp2010/objectives.asp*

[14] Dhossche D, Ulusarac A, Syed W. A Retrospective Study of General Hospital Patients who Commit Suicide Shortly After Being Discharged from the Hospital. *Arch Intern Med. 2001;161:991-994.*

to higher level of care (23%), additional laboratory testing (20%) and death (17%) as shown in Table 17.

Table 16: Suicide Events by Patient Characteristics (2005-2007)

Patient Characteristics	Average or Percentage 2005	Average or Percentage 2006	Average or Percentage 2007
Age	45	43	42
Days since admission	6	3	5
Gender: female	56%	64%	37%
Race: Caucasian	56%	40%	69%

N=16 for 2005, N=25 for 2006 and N=35 for 2007

Table 17: Impact of Suicide Attempts on Patients (2007)[a]

Impact/Outcome	Number of Patients	Percentage of Patients[b]
Additional patient monitoring	23	66%
Transfer to higher level of care	8	23%
Additional laboratory testing	7	20%
Death	6	17%
Increased length of stay	5	14%
Other	3	9%
Other additional testing	2	6%
Minor surgery	2	6%
Hospital admission	2	6%
Loss of sensory function	1	3%
System process delay	1	3%

a Data drawn from 35 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one adverse outcome

A review of the 2007 RCA reports revealed that some of the most pervasive causes of suicide/attempted suicide in hospitals were due to lack of patient observation (57%), behavior assessment (49%) and poor communication among staff (43%) as shown in Table 18.

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.[15] 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.[16]

Also, 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.[15] 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.[17]

The inadequacy of denials of suicide intent is illustrated by an event that occurred at a New Jersey hospital. For the fourth time in two months, a patient was brought to the hospital after a suicide attempt. 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.

[15] American Association of Suicidology. Recommendations for Inpatient and Residential Patients Known to be at Elevated Risk for Suicide; 2005. Available at: *http://www.suicidology.org/associations/1045/files/FinalRecommendations.pdf*

[16] Soreff S. Suicide. eMedicine; 2006. Available at: *http://www.emedicine.com/med/topic3004.htm*

[17] Office of the Ombudsman for Mental Health and Mental Retardation, State of Minnesota. February 2002 Suicide Prevention Alert. Available at: *http://www.ombudmhmr.state.mn.us/alerts/suicidepreventionalert.htm*

Table 18: Root Causes of Suicide Events (2007)[a]

Root Cause	Number of Events	Percentage of Events[b]
Patient observation	20	57%
Behavioral assessment	17	49%
Communication among staff	15	43%
Care planning	12	34%
Staff orientation and training	12	34%
Physical environment	12	34%
Staff supervision	5	14%
Communication with patient/family	4	11%
Availability of information	3	9%
Staffing	3	9%
Other	2	6%
Staff competency	2	6%
Patient identification	2	6%
Security	1	3%
Control of medication	1	3%

a Data drawn from 35 RCAs submitted for 2007 events
b Events do not total 100% since events generally have more than one root cause

5. "Other Care Management Events"

There were 43 reported preventable adverse events under the category of "other care management event." These events include events related to the process for managing care, (e.g., laboratory tests or x-rays that were ordered but not implemented). Communication among staff members (63%; *n=27)* and physical assessment (42%; *n=18*) were the most frequent root causes of these events. Team factors (60%; *n=26*) and patient characteristics (58%; *n=25)* were the most common contributing factors to these events. The impact of care management events for patients can be significant with deaths occurring 51% (*n=22*) of the time in 2007.

An example of an "other care management event" that resulted in death was an event involving a patient in an acute care hospital with chronic obstructive pulmonary disease exacerbation. The patient was receiving oxygen via BiPap machine when he transferred to a med/surg unit. Since his nurse was unfamiliar with the BiPap model that the patient was using, the respiratory therapist provided a brief review of the machine. During lunch the patient was removed from the machine. After lunch the nurse placed the

patient back on the machine. About 90 minutes later, the patient was in respiratory distress. When the respiratory therapist responded, he discovered that the machine was in the standby mode.

6. Medication Errors

Consistent with 2005 and 2006, there were few pharmacological errors (4%; *n=17*) reported to the Patient Safety Initiative in 2007. Studies have estimated medication error rates as high as one medication error per hospital patient per day.[18] 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. While these events do not meet the New Jersey standard for mandatory reporting of serious preventable adverse events, they will be reportable under the voluntary system. Of the medication errors reported to the Patient Safety Initiative, the majority involved administering the wrong dose (35%) or the wrong drug (18%) to a patient.

Communication among staff (65%) and availability of information (41%) were frequently reported as causes of these errors. Team factors (59%) were the most frequently reported contributing factor to these events. The most frequent consequences of medication errors, based on the 17 submitted RCAs in 2007, were additional testing (71%), transfer to a higher level of care (47%) and increased length of stay (35%). Death resulted 29% 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. [19]

The April 2007 Alert: *Hypoglycemia Caused by Unintended Insulin in Total Parenteral Nutrition for an Infant in the Neonatal Intensive Care Unit* provided facilities with information about preventing errors caused by look-alike heparin and insulin vials (Appendix 2).

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[18] Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human – Building a Safer Health System. Washington, DC: National Academy of Science Press; 2000.

[19] Hicks RW, Cousins DD, Williams RL. The Quest for Quality. Summary of Information Submitted to MEDMARX in the Year 2002. Rockville, MD: *USP Center for the Advancement of Patient Safety; 2003.*

G. Similarities in the Identification of Root Causes

Table 19 lists the identified root causes of preventable adverse events by total reports, falls, pressure ulcers, and surgical errors. These data are ranked by frequency of selection by hospitals in their submitted RCAs. There is a consistent pattern for the most important causes. For example, care planning process was selected as the most frequent cause for total events, pressure ulcers and fall events. Communication among staff members ranked as the most frequent cause of surgical events and was in the top three causes for the other two categories of events. There is more variability among the importance of the middle ranked causes. For example, staff orientation and training were ranked either two or three for all categories. In contrast, control of medication is ranked sixth for pressure ulcer events but thirteenth for fall events.

Table 19: Ranking of Root Causes by Frequency for Total Events, Falls, Pressure Ulcers and Surgical Events (2007)[a]

Root Cause	Total Events Rank[b]	Falls Rank[c]	Pressure Ulcers Rank[d]	Surgical Events Rank[e]
Adequacy of technical support	17			14.5
Availability of information	6	7	11.5	4
Behavioral assessment	13	11		
Care planning	1	1	1	10
Communication among staff	2	3	3	1
Communication with family	9.5	6	9	8
Control of medications	11	13	6	6.5
Equipment maintenance	14.5	17.5		
Labeling of medications	7	8	5	6.5
Other	19	17.5		
Patient identification	12	10	7	10
Patient observation	14.5	15.5	9	10
Physical assessment	5	4	9	12.5
Physical environment	4	5	4	2
Security systems	8	9		12.5
Staff competence	18	15.5		16
Staff orientation and training	3	2	2	3
Staffing	16	13		14.5
Supervision of staff	9.5	13	11.5	5

a Mean rank is assigned if two or more data values are equal
b Data are drawn from 456 RCAs submitted for 2007 events
c N=197
d N=65
e N=63

IV. Conclusion

Building on its initial two years of operations, the Patient Safety Initiative has been able to develop a more comprehensive relationship with hospitals to support improvements in patient care. The Department of Health and Senior Services' patient safety clinical review staff can now draw on their experience with reviewing multiple RCAs to provide more direct guidance and sharing of successful strategies from other facilities. Over the course of the three years, clinical review staff has developed an understanding of each hospital's unique culture and organizational structure. This means that the patient safety staff responded with more specificity to the hospital's unique circumstances. Hospitals also expanded their understanding of the requirements for RCAs and increased the complexity of their analysis and preventive actions. This led to better collaboration and a more productive relationship between the facility and the Department's clinical review staff.

The reporting results for the last three years are consistent. Falls and pressure ulcers continue to be the most frequently reported events with a steady increase in the relative frequency of falls. However, during 2007 there was a decrease in the number of reported pressure ulcer events. Reporting, both in terms of the number of reported events per hospital and the number of reporting hospitals, continues to increase each year the Patient Safety Initiative is operational.

Future development for the Patient Safety Initiative 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.
- Implementation of mandatory reporting for other types of licensed facilities based on final adoption of the rules in 2008.
- Initiation of additional cooperative projects with health care facilities that support the growth of patient safety and use the information collected through the reporting system.
- Working with health care facilities to ensure consistent reporting.

Appendix 1

Classification of Serious Reportable Adverse Events[20]

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.

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

7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility.
8. Other patient/resident care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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

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

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

1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge,

associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product.

2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use or function of a device in patient/resident care in which the device is used or functions other than as intended, including but not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
3. Intravascular air embolism that occurs while the patient/resident is in the facility. However, this does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with use of a new single-use device or a reprocessed single-use device in which the device is used or functions other than as intended. All events related to single-use devices should be reported in this category. Indicate whether the device was new or had been reprocessed.
5. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

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 2

Patient Safety Initiative Alert

- *April 2007 (Alert):*Hypoglycemia Caused by Unintended Insulin in Total Parenteral Nutrition for an Infant in the Neonatal Intensive Care Unit

Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE
Alert - April 2007

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

Fred M. Jacobs, M.D., J.D.
Commissioner

2007

Hypoglycemia Caused by Unintended Insulin in Total Parenteral Nutrition for an Infant in the Neonatal Intensive Care Unit

The New Jersey Department of Health and Senior Services' Patient Safety Initiative has received a report of a Serious Preventable Adverse Event involving a bag of total parenteral nutrition (TPN) that contained insulin instead of heparin.

A blood glucose level of 17 mg/dL was reported for a premature baby in the NICU, six hours after a TPN infusion had been started. Despite multiple bolus doses of glucose and an infusion of dextrose 20% in sodium chloride 0.45% (1/2 NS), the hypoglycemia did not completely resolve until the TPN was discontinued. The concerned neonatologist requested that the remaining TPN be sent for analysis, which revealed that the fluid contained insulin instead of heparin. The long-term impact on the neonate has yet to be determined. This hospital receives TPN from a contracted national vendor and an investigation into the event is underway.

The Institute for Safe Medication Practices (ISMP) reports that similar events –particularly mix-ups between heparin and insulin – have occurred in other states. The most common factors associated with these errors include:

- similar packaging of insulin and heparin in 10 mL vials
- placement of insulin and heparin vials, both typically used each shift/day, next to each other on a counter, drug cart, or under a pharmacy IV admixture hood
- mental slips leading to confusion between heparin and insulin, especially since both drugs are dosed in units.

If you administer TPN solutions, the Department strongly recommends that you check with your supplier, whether it is your own pharmacy or an outside vendor, to ensure that a similar heparin/insulin error could not occur. Additionally, if there are cases of unexpected and unexplained hypoglycemia, consider the possibility of a medication error as part of the differential diagnosis and take the following steps: discontinue all current infusions and hang new solutions, treat the patient as necessary and check for unintended additives by sending the bag(s) for analysis. (In addition to an error with insulin, oral hypoglycemic agents mistakenly administered to non-diabetic patients may also cause significant hypoglycemia.) Early identification of an error involving insulin (or an oral hypoglycemic) can provide a window of opportunity to mitigate harm.

ISMP recommends the following additional strategies to reduce the risk of potentially harmful mix-ups between heparin and insulin:

- **To prevent errors caused by look-alike heparin and insulin vials:**
  - Do not keep insulin and heparin vials alongside one another on top of counters or drug carts on the nursing unit or under the laminar flow IV admixture hood in the pharmacy. When insulin is needed for an IV, it should be retrieved and added separately from other ingredients and returned to the appropriate storage area immediately after use.
  - Require an independent check by a second person for all IV insulin materials and final preparations.
  - Require an independent check of all TPN solutions, including an initial independent check of the vials gathered for all additives that must be added manually before they are added, and an independent check of the finished solution comparing the label and the original order.
  - Use systems with bar code scanning for automated compounders.
  - Have the Pharmacy and Therapeutics Committee and neonatologists determine whether heparin is absolutely necessary in infant TPN solutions, or set criteria for when its use is indicated.
- **To detect errors between heparin and insulin at the point of administration before they reach the patient:**
  - Always compare the indication for heparin or insulin with the patient's diagnoses/condition to ensure they match before dispensing or administering insulin or heparin.
  - Read back verbal orders for heparin and insulin to verify understanding and accuracy.
  - Require an independent double check of all IV insulin preparations.

Many organizations do not allow insulin near any location where TPN is being prepared and administer it separately from TPN.