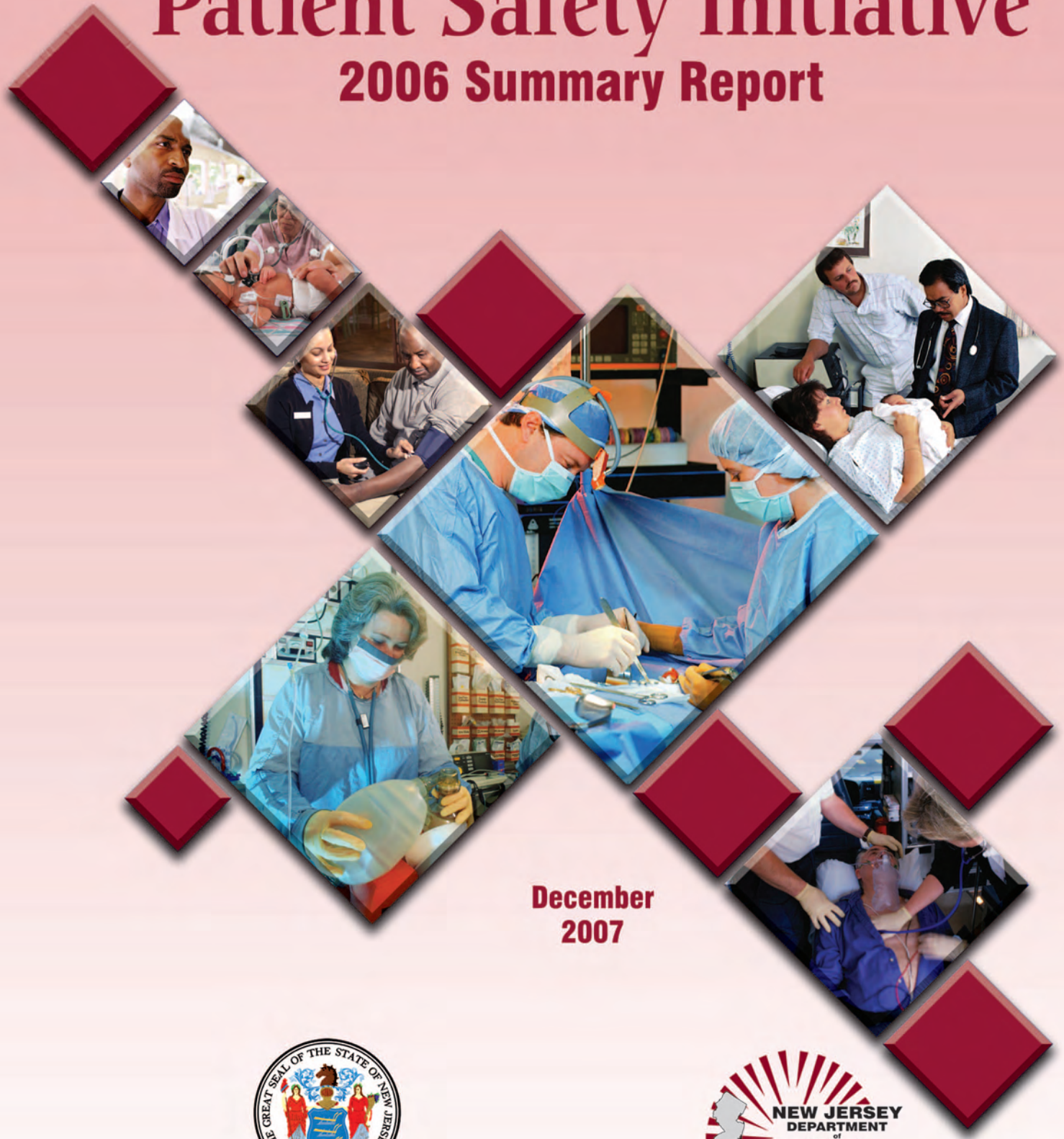
Health Care Quality Assessment

New Jersey Department of Health and Senior Services

Patient Safety Initiative

2006 Summary Report



December
2007

Jon S. Corzine
Governor

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

State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

JON S. CORZINE
Governor

FRED M. JACOBS, M.D., J.D.
Commissioner

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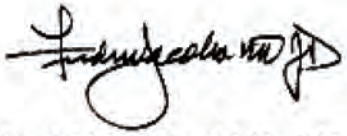
Dear Friends:

I am happy to present the second annual report reviewing implementation of the reporting system for serious preventable adverse events. The reporting system was established in response to the Patient Safety Act (P.L. 2004, c.9) which required all New Jersey health care facilities to take a comprehensive approach to patient safety. Facilities must review their own operation to ensure patient safety and report serious preventable events to the Department. The reporting system was implemented in 2005 for acute care general hospitals.

The Department established the Patient Safety Initiative to implement the reporting system and to work with health care facilities on patient safety. Building on the initial activities in 2005, there has been significant collaborative efforts in 2006. Patient Safety Newsletters and Alerts gave information back to hospitals about reported events and corrective actions. Since patient falls are the most frequently reported event, the Patient Safety Initiative developed a collaborative workshop on fall prevention and a newsletter which focused on that issue. This approach allows hospitals to evaluate their own operations in terms of national best practice models.

The objective of all these activities is simple--to make patient care safer. But the method for achieving this goal demands significant changes for the entire delivery system. The Department of Health and Senior Services looks forward to working with health care facilities to ensure that patient safety is a priority for all levels of operations. Newsletters, Alerts and additional resources developed to support patient safety in New Jersey may be found at www.NJ.gov/health/ps.

Sincerely,



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

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I. BACKGROUND

The New Jersey Patient Safety Act (P.L. 2004, c.9) initiated broad policy and operational changes for patient safety in New Jersey. The Act was based on the Institute of Medicine principles which supported an examination of systems for providing care in order to improve patient safety.[1] The entire Patient Safety Act is directed toward this 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 major statutory requirements are:

- All health care facilities are required to develop a patient safety plan, including a patient safety committee. The plan would include a process for a multidisciplinary team to conduct root cause analyses of serious preventable adverse events. 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 disability or loss of bodily function lasting more than seven days or present at discharge.

- 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 would 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 would not be subject to discoverability in any civil, criminal or administrative action or considered a public record.

Confidentiality is an important component of the Patient Safety Act. Since health care facilities must engage in review of preventable events and their own operations in order to look for ways to make care safer, it is necessary to provide a confidential way to engage in this activity. This internal review is the basis for changes in the system for providing care.

[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.

In order to implement the mandatory reporting system for medical errors, the Department of Health and Senior Services set up the Patient Safety Initiative to design the system, to collect the information and to work with health care facilities on improving patient safety. The Department started collecting medical error reports for acute care hospitals in February 2005 and continued that process through 2006. This is the second annual report covering implementation of the act during 2006.

The number of reported events is not viewed as an absolute measure of hospital quality. A facility which makes patient safety a priority through examining all events and systems is likely to report more events.

Implementation of the reporting system has been a major initiative for the Department of Health and Senior Services in supporting the quality of health care in New Jersey hospitals. This is one aspect of a broad approach to supporting quality through collecting and analyzing information on health care quality and making that information public. A summary of these activities is presented under ***New Jersey Quality Initiatives***.

New Jersey Quality Initiatives

Hospital Performance Report: This annual report ranks the performance of NJ's hospitals in delivering quality treatment to their patients with heart attack, pneumonia, congestive heart failure and prevention measures for surgical infections. (www.nj.gov/health/hpr)
Cardiac Surgery in New Jersey: This annual report on coronary artery bypass graft (CABG) surgery compares inpatient death rates for the specific NJ hospitals and the physicians performing this procedure. (www.nj.gov/health/healthcarequality/documents/cardconsumer04.pdf)
Nursing Home Report Card: This site compares New Jersey Nursing Homes for quality of care and services and is based on DHSS unannounced certified inspections conducted every 9 to 15 months. (www.state.nj.us/health/healthfacilities/hcfa/index.shtml)
Bariatric Surgery in New Jersey: This periodic report is based on patients who had bariatric surgery regardless of discharge date and examines severity, mortality, readmissions, complications, length of stay and other indicators. (www.state.nj.us/health/healthcarequality/documents/bariatricsurgeryrpt05.pdf)
Inpatient Quality Indicators: This report uses the AHRQ Inpatient Quality Indicators and hospital discharge data to review mortality, utilization and volume. (www.state.nj.us/health/healthcarequality/documents/iqi2005.pdf)
Commissioner's Quality Improvement Initiative: Six hospitals developed quality improvement initiatives for congestive heart failure and shared best practices in an effort to improve delivery of quality care.
Congestive Heart Failure Collaborative: Funded by a grant from the Healthcare Foundation of New Jersey to the Department and the Rutgers University's Center for State Health Policy and spearheaded by the Quality Institute of the NJ Hospital Association, this initiative focused on improving performance for congestive heart failure of 14 participating hospitals.

II. IMPLEMENTATION

The Department's Patient Safety Initiative uses a mandatory reporting system based on the National Quality Forum's (NQF) list of "never events."[2] The Patient Safety Act requires the Department to use national standards where 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 included only falls resulting in death but New Jersey's list also includes all falls with serious impact.

- 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 acute care survey unit.

Hospitals are required to report patient safety events within five (5) business days of discovery or when the hospital should have been aware of the event. Standard reporting forms were developed to collect basic information about the event. At this time, hospitals must fax completed forms to a confidential fax number securely housed within the Department's Patient Safety Initiative. Hospitals are also required to submit a Root Cause Analysis (RCA) for each event, due 45 days after the event was reported to the Department. The requirements for the RCA are relatively broad including a description of the event, an analysis of causality, an action plan, and a strategy for monitoring the action plan. Each RCA is reviewed by Patient Safety Initiative clinical staff. If the RCA does not meet the Department's requirements, clinical staff works with hospitals to improve their analysis and the corrective actions designed to minimize recurrence of the event.

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

Related Patient Safety Initiative Activities

In order to support patient safety in New Jersey hospitals and share information learned from hospital event reports, the Patient Safety Initiative undertook several other activities in 2006:

Event/RCA Reporting Workshops: Over the course of two years the Department has done extensive training in reporting and RCA workshops for New Jersey hospital staff. These workshops presented the basic approach of the Patient Safety Law which involves taking a systems approach to reviewing events and examining causality by looking at the systems for providing care. The workshops used lecture, real-world examples, and interactive exercises to familiarize participants with the RCA process, the new reporting requirements, and to review frequently asked questions concerning report preparation and submission standards. During 2005, hospitals were trained in event reporting and RCAs in four workshops. In addition, the Department was asked to make presentations at four hospitals. These hospital-based workshops were useful in presenting the new philosophy and approach to a broad range of hospital personnel. Department staff limitations did not allow implementation of additional on-site workshops in response to hospital requests.

Patient Safety Newsletters: *Patient Safety Initiative Updates* and *Alerts* are used to communicate with hospitals about Department activities and to share information from individual reported events/RCAs. The purpose of the newsletter is to extend the benefits of lessons learned by individual hospitals to all New Jersey hospitals. Newsletters are sent electronically to hospital CEOs, Medical Directors, Nursing Directors, quality improvement staff and patient safety staff. Hospitals have responded favorably to these communications and shared information within facilities to support review and modification of their own processes. The 2006 releases are included in Appendix 2 and covered the following topics:

- *February 2006 Updates:* Highlighted falls in New Jersey hospitals covering risk factors, prevention strategies, resources; also considered medication errors and hospital response strategies.

- *May 2006 Alert*: Reviewed an event where a sandbag was filled with metal shot. The Alert suggested that hospitals review "sandbags" to ensure that they did not contain shot. Hospitals followed this suggestion and reported similar problems.

- *June 2006 Updates*: Reviewed imaging errors that had been reported in ordering, performing, reading and communicating information.

- *December 2006 Updates*: Reviewed events related to retained objects considering reasons for the errors and hospital responses.

Falls Collaborative Workshop: Based on requests from hospitals, the Patient Safety Initiative offered a two-session falls collaborative workshop. Falls are the most frequently reported events accounting for 37% of all reports in 2006 and 33% of all reports in 2005. In response to strong hospital interest, the workshop was offered three times in 2005/2006 and fifty-one hospitals participated. The workshop builds on the New Jersey experience with falls and the national perspective on fall reduction. At the introductory session, each hospital team develops a falls reduction project. Through periodic conference calls, the hospital teams were given the opportunity to ask questions and to exchange information on prevention plan resources, successes and failures. Participating hospitals were able to develop and rapidly implement their projects. At the second session, hospital teams present and review their projects. Most hospitals were successful in developing a project that led to a reduction in falls.

Patient Safety Regulations: The Health Care Administration Board approved the patient safety rules for initial publication at their October 19, 2006 meeting. Those regulations describe the requirements for each health care facility to have a patient safety plan and committee as well as the requirements for mandatory reporting of serious preventable events. The rules will be effective for different types of health care facilities following a phase-in schedule based on adoption of the rules:

- *Upon adoption:* rehabilitation, general, psychiatric and special hospitals
- *Six months after adoption:* ambulatory care, home health care, and hospice
- *One year after adoption:* assisted living, comprehensive personal care homes, long-term care, adult and pediatric day health, and residential health care.

Development of a web-based system: An RFP for a web-based patient safety system was developed to allow facilities to submit events and RCAs through the web. The system will collect more specific information on each event thereby enabling a more comprehensive tracking and analysis by both the reporting facility and the Department. Implementation of the online system is anticipated in 2010.

III. ANALYSES OF EVENT AND RCA REPORTS

The Patient Safety Initiative has reviewed and analyzed the data from event and RCA report forms for events submitted in 2005 and 2006. For events, summary information for both 2005 and 2006 is provided. Since reporting began in February 2005, initial year reporting is based on 11 months. For RCAs, the summary information is based on events reported in 2006.

A. Overall Reporting Patterns

Overall reporting patterns are presented in Table 1. Reporting increased from 376 events in 2005 to 450 events in 2006. This increase is partially due to reporting on 12 months in 2006 and 11 months in 2005. However, the increase is also probably related to growth in familiarity with the reporting process. The number of reporting hospitals increased from 83% in 2005 to 88% in 2006. Only 2 hospitals did not report during the two-year period. The average number of reports per hospital was 4.6 in 2005 and 5.6 in 2006. When reports are adjusted by 1,000 patient days, the reported events increase from .070 in 2005 to .078 in 2006.

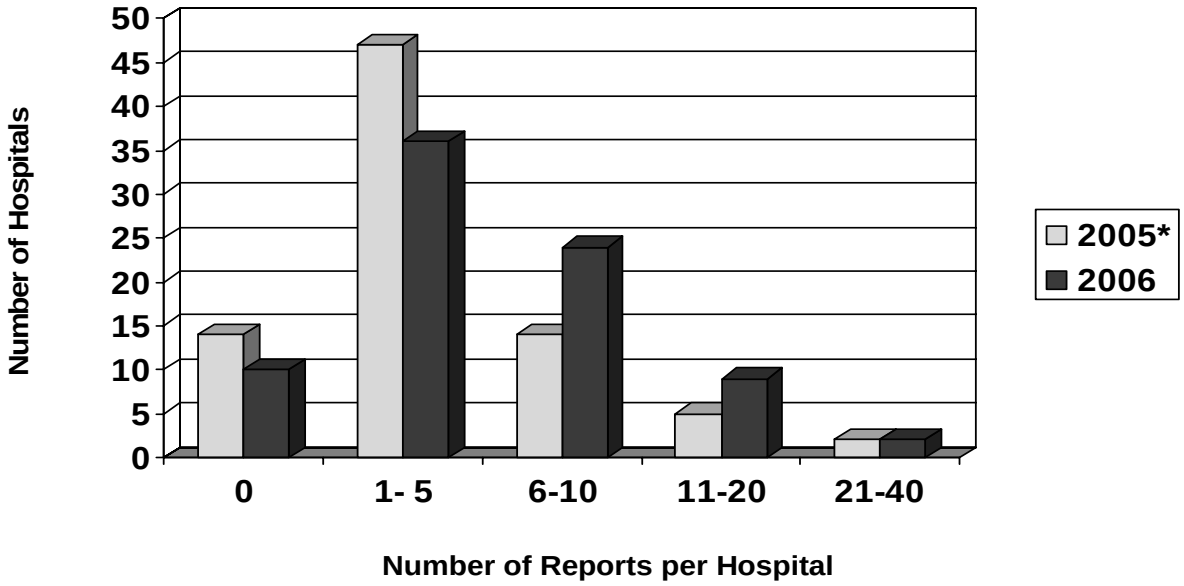
Table 1: Reporting Patterns (2005 and 2006)[a]

	2005[b]	2006
Total reported events	376	450
% of hospitals reporting	83%	88%
Number of reporting hospitals	68	71
Reported events per 1,000 patient days	0.070	0.078
Average number of reports per hospital	4.6	5.6

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

Figure 1 gives the number of events reported for each hospital in 2005 and 2006. The pattern shows that many hospitals reported between 1 and 5 events in both years. However the number of hospitals reporting between 6 and 10 reports and between 11 and 20 reports increased in 2006.

Figure 1
Frequency of Event Reports for Each Hospital (2005 and 2006)

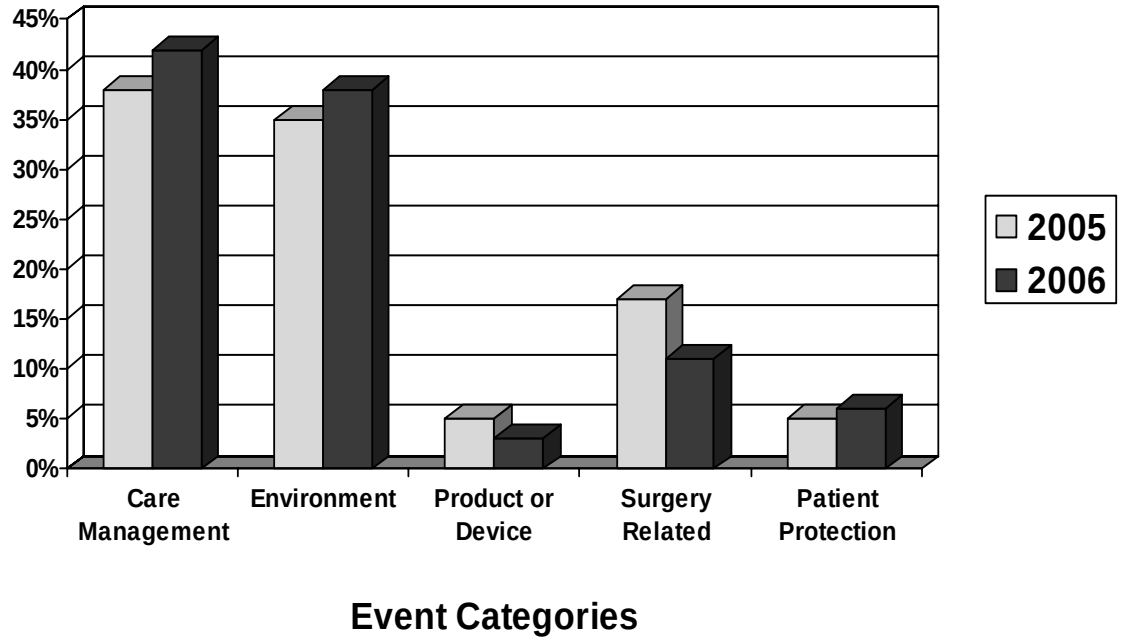


** Represents 11 months of data since the program started on February 1, 2005.*

B. Types of Reported Events

Figure 2 gives the percentage of reports for each of the five event categories for 2005 and 2006. The majority of events are in care management and environment categories for both years. These two categories account for 73% of the reports in 2005 and 81% in 2006. The distributions of reported events across categories are similar for the two reporting years.

Figure 2
Percentage of Reports by Event Category (2005 and 2006)

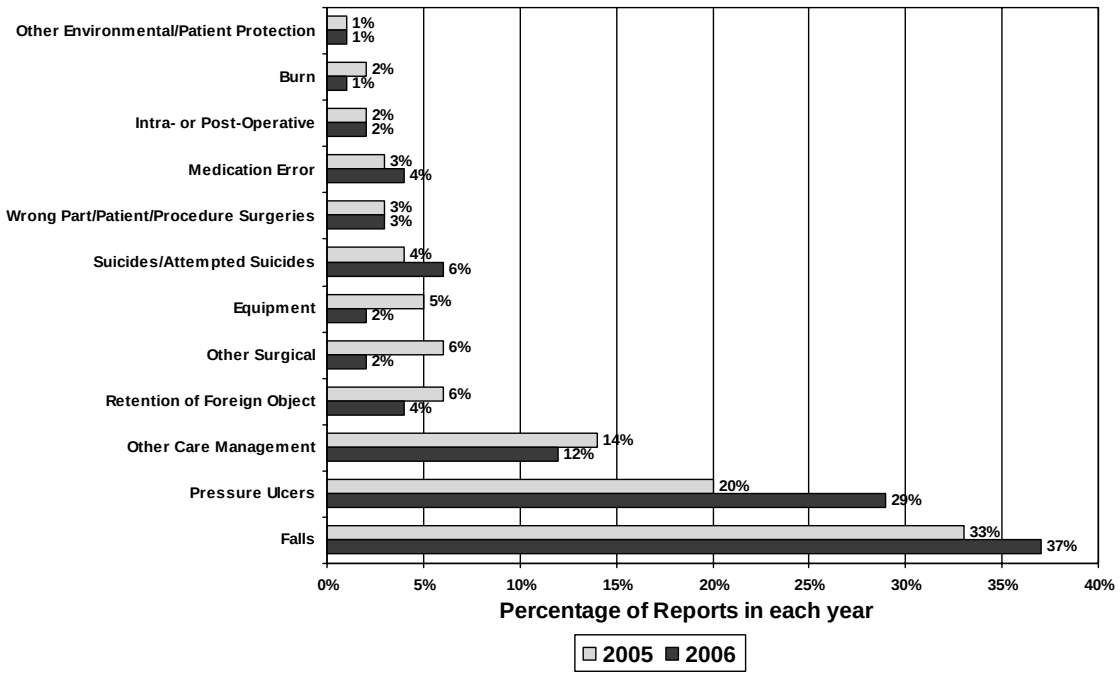


The distribution of reporting for specific types of events in 2005 and 2006 is presented in Figure 3. Falls and pressure ulcers are the most frequently reported events for both years with the overall frequency increasing in 2006 for both events. This increase may be due to increased sensitivity for these events based on the Patient Safety Initiative training on falls and the New Jersey Hospital Association pressure ulcer collaborative during this time period. Both of these training sessions would have led to increased focus on those events and, therefore, higher reporting.

As noted earlier, reporting for falls is not consistent with the NQF categories. NQF restricts reporting to falls which resulted in death while the New Jersey definition includes reporting on falls with serious injury. In a revised version of its reporting categories released in 2007, NQF moved to reporting falls with serious injury. [3]

There continues to be a substantial percent of reporting in "other care management." That category includes events that relate directly to patient care, i.e., the use of radiological findings, etc. Events related to surgery including retention of foreign object, wrong part/patient, intra- or post-operative surgery and other surgeries account for 17% in 2005 and 11% in 2006. This decrease is primarily due to a lower percentage of "other surgical" events in 2006.

Figure 3
Percentage of Reports by Event Subcategory (2005 and 2006)



[3] National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update*. Washington, D.C: National Quality Forum; 2007.

C. Patient Characteristics

Table 2 presents the demographic characteristics of patients involved in events reported in 2005 and 2006. Events for the two years are very similar. In 2006, the average patient involved in a preventable event was female, Caucasian, 65 years of age, and had been admitted to the hospital 17 days prior to the event. These characteristics differ somewhat from the general population of New Jersey hospital patients where the average patient was female, Caucasian and 49 years of age.

For both 2005 and 2006, 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 likely to be associated with older patients as shown in subsequent sections of this report.

Table 2: Demographic Characteristics of Patients from Event Reports Compared to All NJ Hospital Patients (2005 and 2006)

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

[a] N = 376 for 2005 and 450 for 2006.
[b] Data drawn from Uniform Billing data 2005 and 2006 and same day surgery patients, N = 1,528,583 for 2005 and N = 1,528,097 for 2006.
[c] Inpatient only.
NA = not applicable.

D. Impact of Reported Events on Patients

Hospitals review events submitted to the Patient Safety Initiative and prepare RCAs to examine causality and ways to prevent recurrence. The hospitals also complete a form providing information on causality and patient impact. Patient Safety Initiative clinical staff reviews this information when analyzing the RCA to ensure accuracy and consistency. Based on the 450 RCAs submitted for 2006 events, the most frequent consequences of preventable adverse events on patients are additional patient monitoring, additional laboratory testing or diagnostic imaging and increased length of stay as shown in Table 3. A moderate percentage of patients also experienced major surgery and temporary/permanent physical or mental impairment.

Table 3: Impact of Events on Patients (2006)[a]

Impact / Outcome	Number of Patients 2006	Percentage of Patients[b] 2006
Additional patient monitoring	242	54%
Additional laboratory testing or diagnostic imaging	207	46%
Increased length of stay	182	40%
Major surgery	141	31%
Physical/mental impairment	135	30%
Minor surgery	66	15%
Transfer to higher level of care	57	13%
Additional diagnostic testing	43	10%
Death	42	9%
Hospital admission	25	6%
Other	24	5%
To be determined	24	5%
System/process delay	21	5%
Loss of bodily function	6	1%
Loss of body part	4	1%
Loss of sensory function	4	1%

[a] Data are drawn from 450 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one adverse outcome.

E. Root Causes

The Agency for Healthcare Research and Quality (AHRQ) has published a list of the most common causes of medical errors (www.ahrq.gov/qual/pscongrpt/psini2.htm). These common causes or factors are (in descending order of magnitude) communication problems, inadequate information flow, human problems (how standards of care are followed), patient-related issues (assessment or education of patient), organizational transfer of knowledge, staffing patterns, technical failures, and inadequate policies and procedures. Similar to the AHRQ list of causes, the major causes of system failure for the New Jersey reporting system are communication among staff, care planning, staff orientation and physical assessment as shown in Table 4.

Table 4: Root Causes (2006)[a]

Root Cause	Number of Events 2006	Percentage of Events[b] 2006
Communication among staff	226	50%
Care planning	191	42%
Staff orientation and training	152	34%
Physical assessment	116	26%
Patient observation	85	19%
Communication with family	58	13%
Equipment maintenance	54	12%
Availability of information	42	9%
Staff competence	41	9%
Other	37	8%
Physical environment	36	8%
Supervision of staff	35	8%
Behavioral assessment	32	7%
Staffing	16	4%
Patient identification	11	2%
Adequacy of technical support	8	2%
Control of medications	7	2%
Labeling of medications	4	1%
Security systems	2	0%

[a] Data are drawn from 450 RCAs submitted for 2006 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 other events.

1. Falls

Falls are the most frequently reported event submitted to the Patient Safety Initiative, constituting 37% of all reported events in 2006. An analysis of falls by location indicates that the majority of falls (80%) occurred in the patient's room (Table 5). Although lower in number, 7% of falls occurred in the emergency department and 5% of falls occurred in a hallway or other common area. As shown in Table 6, older patients appear to be especially prone to injury from falls. Of the eight falls that led to patient death, the average patient age was 74.

Table 5: Percentage of Falls by Location (2005 and 2006)

Location of Fall	2005	2006
Patient room	82%	80%
Emergency department	6%	7%
Hallway or other common area	7%	5%
ICU	1%	2%
Radiology	1%	2%
Cardiac lab	0	1%
Other	2%	1%
Rehab	1%	1%
Operating room	0	1%
Telemetry	1%	0

N = 125 for 2005 and N = 165 for 2006.

Table 6: Falls by Patient Characteristics (2005 and 2006)

Patient Characteristic	Average or Percentage 2005	Average or Percentage 2006
Age	78	78
Days since admission	5	12
Gender: female	53%	66%
Race: Caucasian	89%	92%

N = 125 for 2005 and N = 165 for 2006.

As shown in Table 7, the patient impact resulting from falls was most likely to be additional laboratory testing or diagnostic imaging, increased length of stay, physical or mental impairment and major surgery. In most of the fall events analyzed, hospitals identified care planning, communication among staff, staff orientation and training and patient observation as the major causes for falls (Table 8).

Table 7: Impact of Falls on Patients (2006)[a]

Impact / Outcome	Number of Patients 2006	Percentage of Patients[b] 2006
Additional laboratory testing or diagnostic imaging	141	85%
Increased length of stay	119	72%
Physical/mental impairment	118	72%
Major surgery	105	64%
Additional patient monitoring	63	38%
Transfer to higher level of care	21	13%
Additional diagnostic testing	20	12%
Death	8	5%
Hospital admission	7	4%
Minor surgery	5	3%
Other	5	3%
System/process delay	5	3%
To be determined	4	2%
Loss of bodily function	2	1%
Loss of sensory function	1	1%

[a] Data are drawn from 165 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one adverse outcome.

Table 8: Root Causes of Patient Falls (2006)[a]

Root Cause	Number of Events 2006	Percentage of Events[b] 2006
Care planning	97	59%
Communication among staff	61	37%
Staff orientation and training	53	32%
Patient observation	51	31%
Communication with family	34	21%
Physical assessment	32	19%
Equipment maintenance	20	12%
Physical environment	17	10%
Availability of information	9	5%
Other	8	5%
Behavioral assessment	8	5%
Staffing	5	3%
Supervision of staff	4	2%
Staff competence	2	1%
Patient identification	1	1%

[a] Data are drawn from 165 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one root cause.

Review of falls was a major focus of 2006 patient safety activities. As previously described, the Department conducted a collaborative workshop which gave hospitals the opportunity to learn national models for falls prevention and to develop their own quality improvement projects. The February 2006 *Patient Safety Initiative Updates* which focused on falls is included in Appendix 2. In addition, the Patient Safety Initiative developed a comprehensive approach to reviewing RCAs for falls. This frequently involves asking hospitals to expand their view of causality and prevention strategies. A fall RCA frequently involves looking at:

- Cultural attitudes of the patient, their family, and the hospital staff
- The emotional issues patients face when dealing with the loss, even temporarily, of independence
- Medications that have potential side effects of dizziness or orthostatic hypertension
- Staffing issues
- Clinical conditions like anemia, dehydration, fever, low blood sugar, low blood pressure, poor oxygen saturation, and cardiac arrhythmia.

A Falls Prevention Program appears to be effective in preventing serious injury from falls if a medical facility reviews their system operations during an RCA with an open mind to these and other factors that impact fall events. The entire staff, from physicians to engineering and housekeeping, can affect patient safety. A fall event is often a result of several system failures and the group responsible for conducting the RCA needs to have an interdisciplinary approach. A collaborative effort among several disciplines ensures a thorough understanding of how a particular system functions, how routine functioning of the system caused or contributed to the event, and how to create a realistic solution.

2. Pressure Ulcers

A pressure ulcer (bedsores, pressure sores, decubitus ulcers) is an injury caused by constant pressure or shearing forces on the skin and muscle. The severity ranges from mild, affecting the skin surface only, to severe, when a deep decubitus ulcer reaches down to muscle and bone. Patients with diminished or absent sensation or who are debilitated, emaciated, paralyzed, or long bedridden are most likely to develop pressure ulcers.[4]

Pressure ulcers are categorized by severity, from Stage I (earliest signs) to Stage IV (severe). Only patients with Stage III or Stage IV ulceration need to be reported to the Patient Safety Initiative. Patients with documented Stage II ulceration at admission who progress to Stage III are not reportable. Next to falls, pressure ulcers are the second most frequently reported serious adverse preventable event, constituting 29% of all reported events in 2006 (Figure 3).

In 2006, the average patient developing a Stage III or Stage IV pressure ulcer was male, Caucasian, 64 years of age, and had been admitted for 29 days prior to the event (Table 9). This is in marked contrast to the average hospital patient who is female, Caucasian and 49 years of age (Table 2). A comparison of the reporting for 2005 and 2006 indicates a movement towards younger patients and earlier pressure ulcer diagnosis. As previously noted, the percentage of pressure ulcer events also increased in 2006. An increased sensitivity to pressure ulcers resulting from the NJHA pressure ulcer collaborative might account for these results.

[4] The Merck Manual of Diagnosis and Therapy. Available at: http://www.merck.com. Accessed March 22, 2006.

The typical risk factors for developing pressure ulcers, adapted from the Braden Scale for Predicting Pressure Sore Risk[5], are:

- 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
- Requires moderate to maximum assistance in moving.

Table 9: Pressure Ulcers by Patient Characteristics (2005 and 2006)

Patient Characteristic	Average or Percentage 2005	Average or Percentage 2006
Age	69	64
Days since admission	34	29
Gender: male	55%	56%
Race: Caucasian	78%	69%

N = 77 in 2005 and N = 129 in 2006.

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

As shown in Table 10, the consequences for the patient developing advanced-stage pressure ulcers are additional patient monitoring, minor surgery (i.e., tissue debridement) and increased length of stay.

Table 10: Impact of Pressure Ulcers on Patients (2006)[a]

Impact / Outcome	Number of Patients 2006	Percentage of Patients[a] 2006
Additional patient monitoring	124	96%
Minor surgery	37	29%
Increased length of stay	24	19%
Additional laboratory testing or diagnostic imaging	11	9%
Major surgery	5	4%
Other	5	4%
Additional diagnostic testing	4	3%
Physical/mental impair	3	2%
System/process delay	3	2%
Transfer to higher level of care	2	2%
Death	1	1%
Hospital admission	1	1%
To be determined	1	1%

[a] Data are drawn from 129 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one adverse outcome.

Similar to the causes of patient falls, staff communication, care procedures (i.e., care planning process, physical assessment and patient observation), and staff orientation and training were the most frequently identified causes for Stage III or Stage IV pressure ulcers (Table 11). The use of air or gel mattresses, reducing bed elevation to prevent shearing forces, using pillows or wedges with knees and ankles, and proactive education programs aimed at increasing line staff awareness and assessment skills are effective interventions in reducing hospital-acquired pressure ulcers.[6]

[6] de Laat EHEW, Scholte op Reimer WJ, van Achterberg T. Pressure ulcers: diagnostics and interventions aimed at wound-related complaints: a review of the literature. *J Clin Nurs.* 2005;14:464–472.

Table 11: Root Causes of Pressure Ulcers (2006)[a]

Root Cause	Number of Events 2006	Percentage of Events[b] 2006
Communication among staff	76	59%
Care planning	66	51%
Physical assessment	58	45%
Staff orientation and training	54	42%
Staff competence	22	17%
Other	18	14%
Supervision of staff	18	14%
Patient observation	12	9%
Equipment maintenance	10	8%
Availability of information	8	6%
Staffing	8	6%
Communication with family	7	5%
Patient identification	5	4%
Behavioral assessment	4	3%
Physical environment	2	2%

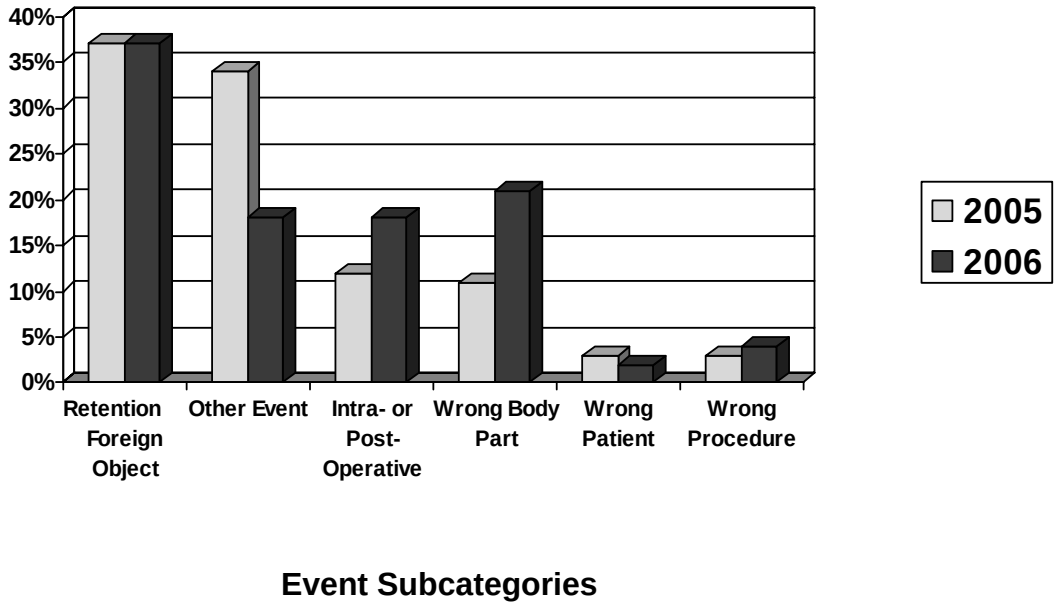
[a] Data are drawn from 129 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one root cause.

3. Surgical Events

Figure 4 presents the distribution of various types of surgery events. For both 2005 and 2006, the most commonly reported surgical event was retention of a foreign object (37% in both years). The prevalence of retained foreign objects is particularly noteworthy, as it has been identified by the Joint Commission as a target patient safety indicator for all Joint Commission accredited hospitals. Although surgical teams utilize a variety of techniques to reduce the potential for this type of event (e.g., counting each item used during surgery), a highly reliable method of prevention remains elusive. Several cases of retained objects reported to the Patient Safety Initiative resulted in serious complications requiring major surgery 41% of the time in 2006. The December 2006 *Patient Safety Initiative Updates* focused on retained objects and is included in Appendix 2.

Next to retained objects, wrong body part and intra-operative or post-operative coma were the most frequently reported surgical events. Of the nine intra- or post-operative coma or death events, seven (78%) resulted in death in 2006.

Figure 4
Percentage of Surgical Events by Subcategory (2005 and 2006)



The average person who experienced a surgical event in 2006 was female, Caucasian, 55 years of age who had been admitted to the hospital for 3 days prior to the event (Table 12). The most common consequences of experiencing a surgical event were major surgery (to minimize or repair the damage caused), additional laboratory and/or diagnostic imaging, minor surgery and additional patient monitoring (Table 13).

Table 12: Surgical Events by Patient Characteristics (2005 and 2006)

Patient Characteristic	Average or Percentage 2005	Average or Percentage 2006
Age	59	55
Days since admission	3	3
Gender: female	51%	51%
Race: Caucasian	63%	69%

N = 65 in 2005 and N = 49 in 2006.

Table 13: Impact of Surgical Events on Patients (2006)[a]

Impact / Outcome	Number of Patients 2006	Percentage of Patients[b] 2006
Major surgery	20	41%
Additional laboratory testing or diagnostic imaging	13	27%
Minor surgery	12	24%
Additional patient monitoring	10	20%
Increased length of stay	9	18%
Death	7	14%
To be determined	6	12%
Physical/mental impair	5	10%
Hospital admission	4	8%
Transfer to higher level of care	4	8%
Other	3	6%
Additional diagnostic testing	3	6%
System/process delay	3	6%
Loss of body part	2	4%
Loss of bodily function	1	2%
Loss of organ	1	2%
Loss of sensory function	1	2%

[a] Data are drawn from 49 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one adverse outcome.

Hospitals identified the following as the root causes of surgical events: communication among staff, care planning, staff orientation and training and physical assessment (Table 14).

Table 14: Root Causes of Surgical Events (2006)[a]

Root Cause	Number of Events 2006	Percentage of Events[b] 2006
Communication among staff	32	65%
Care planning	10	20%
Physical assessment	10	20%
Staff orientation and training	10	20%
Equipment maintenance	9	18%
Availability of information	7	14%
Staff competence	6	12%
Supervision of staff	5	10%
Communication with family	3	6%
Other	3	6%
Patient observation	3	6%
Physical environment	3	6%
Patient identification	1	2%

[a] Data are drawn from 49 RCAs submitted for 2006 events.
[b] Events do not total 100% since events generally have more than one root cause.

4. Other Events

Although reports of falls, pressure ulcers, and surgical errors comprised the majority of submitted preventable adverse events, the number of events reported for several other event types also warranted further review.

Other Care Management Events

Of the 36 reported preventable adverse events under the category of "other care management event," procedures (47%; *n=17)* and patient characteristics (42%; *=15)* were the dominant contributing factors to these events. Deaths occurred 44% (*n=16*) of the time for these reported events in 2006. Since a substantial number of the cases in "other care management" were due to errors related to imaging, a *Patient Safety Initiative Updates* in June 2006 focused on these events and is included in Appendix 2.

Patient Suicide / Attempted Suicide

Patient suicides/attempted suicides accounted for 4% of all reported serious events in 2005 and 6% in 2006. Death resulted from these events 8% of the time in 2006. More than half of these events occurred in the emergency department. The most frequently reported causes were behavioral assessment (76%), communication among staff (40%) and patient observation (40%).

Medication Errors

Few pharmacological errors (4%; *n=18*) have been reported to the Patient Safety Initiative in 2006. This is consistent with 2005 patterns. Some studies have estimated medication error rates as high as one medication error per hospital patient per day.[7] The difference 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 (33%) or the wrong drug (28%) to a patient.

Most of these errors occurred in the patient's room (61%). Communication among staff (61%) and orientation and training of staff (56%) were the most frequently reported causes of medication errors. Based on the 18 submitted RCAs in 2006, the most frequent consequence of medication errors were increased length of stay (56%), transfer to a higher level of care (56%) and additional testing (50%). Death resulted 22% of the time.

The February 2006 edition of the *Patient Safety Initiative Updates* newsletter provided facilities with strategies to reduce medication errors drawn from the submitted RCAs and is included in Appendix 2. The New Jersey reporting system, consistent with other research findings,[8] found that medication errors typically occurred at the point of administration as well as during the process of prescribing, transcription, dispensing and monitoring.

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

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

G. Similarities in the Identification of Root Causes

Table 15 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, communication among staff members was selected as the most frequent cause for total events, pressure ulcers and surgical errors and the second most frequent cause for fall events. The care planning process ranked in the top three causes for all categories of events. There is more variability among the importance of the mid ranked causes. For example, staff orientation and training were ranked either three or four for all categories. In contrast, staff competence is ranked fifth for pressure ulcer events but fourteenth for fall events.

Table 15: Ranking of Root Causes by Frequency for Total Events, Falls, Pressure Ulcers and Surgical Events (2006)[a]

Root Cause	Total Events Rank[b]	Falls Rank[c]	Pressure Ulcers Rank[d]	Surgical Events Rank[e]
Adequacy of technical support	16			
Availability of information	8	9	10.5	6
Behavioral assessment	13	10.5	14	
Care planning	2	1	2	3
Communication among staff	1	2	1	1
Communication with family	6	5	12	10.5
Control of medications	17			
Equipment maintenance	7	7	9	5
Labeling of medications	18			
Other	10	10.5	6.5	10.5
Patient identification	15	15	13	13
Patient observation	5	4	8	10.5
Physical assessment	4	6	3	3
Physical environment	11	8	15	10.5
Security systems	19			
Staff competence	9	14	5	7
Staff orientation and training	3	3	4	3
Staffing	14	12	10.5	
Supervision of staff	12	13	6.5	8

[a] A mean rank is assigned if two or more data values are equal.
[b] Data are drawn from 450 RCAs submitted for 2006 events.
[c] N = 165. [d] N = 129. [e] N = 49.

IV. CONCLUSION

During the second year of operations, health care facilities expanded medical error reporting. Based on experiences in submitting and reviewing events in 2005, there was a growing acceptance of the broad approach to examining medical errors in terms of systems and developing ways to make improvements. The Patient Safety Initiative was able to support this process by working with hospitals on individual RCAs and by sharing information through newsletters and Alerts. These publications were widely viewed by hospital personnel as an integral part of the reporting process and as supporting the growth of patient safety.

The results for 2005 and 2006 reporting are similar. Falls and pressure ulcers are the most frequently reported events in both years with increases in the relative frequency of both of these events. In the second year of operation, there was an increase in reporting both in terms of the number of reported events per hospital and the number of reporting hospitals.

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.

- Final adoption of the regulations implementing the Patient Safety Act.

- After final adoption of the regulations, implementation of mandatory reporting for the wide range of health care facilities.

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

Appendix 1:

Classification of Serious Reportable Adverse Events[9]

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

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

1. Patient 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, wrong time, wrong rate, wrong preparation, wrong route of administration, etc.);
2. Patient 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 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 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 upon admission;

[9] 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 care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for 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 death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with an electric 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 contains the wrong gas or is contaminated by toxic substances and results in patient death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge;
3. Patient 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 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 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 death, loss of a body part, disability, or loss of bodily function lasting for 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 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. Use or function of a device in patient 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 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. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for 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, but initiated on this patient;
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. Intra-operative or post-operative (i.e. within twelve hours) coma, death or other serious preventable adverse event for any ASA Class I inpatient or any same day surgery patient (all ASA classes). 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 for more than seven days or still present at the time of discharge not included within the definitions above.

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

1. Discharge of an infant to the wrong person, excluding patient abductions;
2. Any patient death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient elopement;
3. Patient 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 protection-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

Appendix 2:

Patient Safety Initiative Reporting Initiative Updates and Alerts

- *February 2006 (Issue 2)*: Falls and Medication Errors
- *May 2006 (Alert)*: MRIs and Metal Shot
- *June 2006 (Issue 3)*: Imaging Errors
- *December 2006 (Issue 4)*: Retained Objects and Lost Specimens

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

PATIENT SAFETY REPORTING INITIATIVE

Updates - February 2006

2006: Issue 2

Patient Safety Act Update

Based on the New Jersey Patient Safety Act (P.L. 2004, C.9), general acute care hospitals began reporting serious preventable adverse events in February 2005. Other licensed health care facilities will begin reporting after the regulations are approved. Rules to implement the law are expected to be proposed within the next several months.

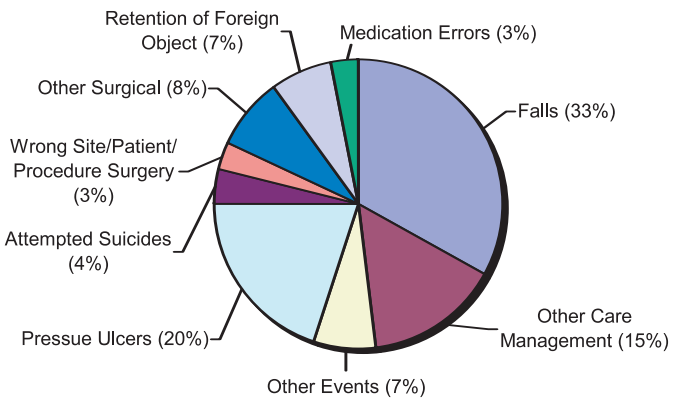
A summary of the reporting specifications are available at ***www.NJ.gov/health/hcqo/ps.*** That web site also provides links to national resources useful for ensuring patient safety.

Event Reporting

Review of events and root cause analyses (RCAs) during the initial 11 months of system operation has shown that:

- The majority of reported events were classified as either falls (33%) or hospital-acquired pressure ulcers (20%). The relative frequencies of reported event types can be seen in Figure 1. Total surgery-related (18%) and "other care management" events (15%) comprise most of the remainder of the submitted event reports.

Figure 1: Frequency of Reported Events



- The top five root causes identified by hospitals as factors in precipitating an event were poor or inadequate staff communication, staff orientation and training, physical assessment of the patient, the care planning process and patient observation. Studies of preventable adverse events conducted by the Veterans Administration and the Agency for Healthcare Research and Quality have reported similar results.[1,2]

- In general, patients experienced longer hospital stays (39%), major surgery (30%), and additional monitoring and diagnostic testing (25%) as a result of a preventable adverse event. A moderate percentage (19%) also experienced temporary to permanent physical or mental impairment. Since hospitals report multiple effects for each event, the percentage totals more than 100%.

Current Activities: Falls Collaborative

In response to the high percentage of falls reported, the Department of Health and Senior Services (DHSS) developed a collaborative workshop on fall prevention. The primary faculty for the workshop are Lisa Mazzia, MD, Senior Physician Specialist with the Patient Safety Reporting Initiative, and Deanna Gray-Miceli, DNSc, a specialist in falls with the Department's Long-Term Care Division. Based on strong hospital interest, the workshop is being offered three times. We anticipate that 40 hospital teams representing 51 hospitals will participate in the collaborative.

Continued on Page 2

Also in this issue:

The two-session workshop builds on the New Jersey experience with falls and the national perspective on fall reduction. At the introductory session, each hospital team develops a falls reduction project. Through biweekly conference calls, the hospital teams are given the opportunity to ask questions and to exchange information on prevention plan resources, successes, and failures. Participating hospitals have been able to develop and rapidly implement their projects. The initial results are encouraging. At the second session, hospital teams present and review their projects.

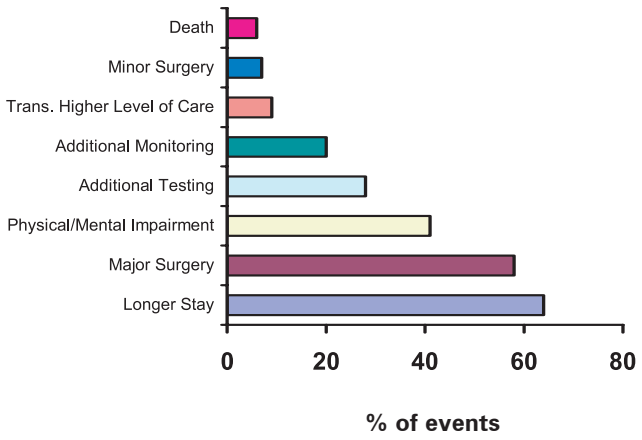
Highlighting Falls in New Jersey Hospitals

A fall is the inadvertent landing to the lowest level or ground surface. According to several studies, falls among hospitalized adults have an incidence of 2.3 to 7 falls per 1,000 patient-days.[3] Since an injury is sustained in about 30% of falls, and a serious injury in approximately 4%-6% of cases, preventing falls is an increasingly important component of inpatient care.[4]

Fall with injury is the most frequent serious preventable adverse event reported to the Patient Safety Reporting Initiative, constituting 33% of all reported events. The majority of reported falls took place within the patient's room (82%). The emergency department (7%), a corridor/hallway (6%), or "other" area (6%) captured the remainder of the reported falls.

Hospitals report that increased length of stay, major surgery, temporary or permanent disability, and additional testing/monitoring were the most likely outcomes associated with injury sustained in a preventable fall episode (Figure 2). Hospitals may code multiple impacts; therefore, percentages total more than 100%.

Figure 2: Impact of Falls



The most frequently cited root causes of falls reported to DHSS are staff communication, staff training/orientation, patient observation and the care planning process. Together these causes highlight the importance of improving staff awareness, training, and response to the common risk factors preceding patient falls.

Patient Risk Factors for Falling

Patient risk factors for falling include weakness, poor cognitive status, elimination-related activities, gait disturbances, and being on medications that contribute to somnolence or confusion.[5] Hospital falls occur in roughly equal numbers when the patient is transitioning (e.g., bed to chair) or the patient is ambulating without assistance. This is especially true for younger patients, who may believe that they do not need assistance. Several studies have shown that patients under the age of 65 are just as likely to suffer a fall-related injury as patients 65 years of age or older.[6]

It is important to discover the underlying cause of a fall, such as muscle weakness, dehydration or multiple medications, and it is also important to ask the patient why he or she attempted to get up or move. Studies have shown that at least 50% of the actions are motivated by bowel or bladder urgency.[7] Other reasons given by patients are reaching for water or reading glasses, and changing position due to pain.

What Hospitals Are Doing to Prevent Falls

Many of the acute care general hospitals in New Jersey have recognized the importance of initiating a fall prevention program. An informal survey of New Jersey hospitals revealed that several different fall prevention programs are currently in use; however, due to the multi-factorial etiology of a fall, a patient may fall even if the hospital has such a program.

Continued on Page 3

• Targeted Rounding

Several facilities have initiated regular targeted rounding on high-risk patients. During the rounds, the patient is specifically asked a series of questions: Do you need anything? Are you in pain? Is your position comfortable? The patient then is proactively toileted: "We are going to the bathroom now…." Although these plans have been in effect for only a few months, hospitals report that the preliminary results in decreasing falls are encouraging.

• Medication Timing

In addition to the well-documented problem of polypharmacy, several facilities found that the timing of medication administration was a factor in increasing the risk for a fall. This was especially true for diuretic administration. After performing the RCA, one hospital found that diuretics scheduled every 12 hours were administered at 9 AM and 9 PM thereby increasing the likelihood that the patient would need to void and get up and go to the bath room or use the commode during night hours. Its action plan was to change the administration times to earlier in the day.

• Pre- & Post-Fall Risk Assessment

Proper assessment of the patient upon admission, at regular intervals, and especially following a fall has been shown to be most effective in identifying the risk factors for future falls. Several risk assessment tools are available for identifying fall-prone patients (see Oliver et al. in **Fall Prevention Resources**). Clinical trials that used screening assessments on which to base the choice of interventions showed a successful reduction in falls when multi-factorial interventions were tailored to patients' changing needs.[8]

Many facilities found that even if patients were initially identified as at high risk, and interventions were initiated, as patients moved through the hospital's levels of care they were never reassessed and the initial assessment may have been lost. A patient may be admitted through the Emergency Department, assessed as a high fall risk on a Med-Surg floor, then go to the operating room, ICU, step-down unit and back to a different Med-Surg floor in the course of a few days. Each one of these transfers is an opportunity for critical patient information to be lost.

Successful action plans include educating all staff, including those in the critical care and step-down units, about the importance of an initial fall assessment, reassessing the patient each shift to incorporate the relatively rapid changes in physical and mental status that often accompany an inpatient admission, and repositioning the assessment and risk on either the paper medical record or the on-line charting. The key action here is effectively communicating the patient's risk status.

• Specific Interventions

After the patient has been identified as a fall risk, specific interventions, such as bed alarms, hip protectors and ambulating aids, are often employed. Some facilities found that the interventions were not consistently being used, because staff was not aware of the prevention program. In other cases, the bed alarms did not work or there were many different types with which staff was unfamiliar. These causes were addressed through staff education, the addition of a checklist to the assessment tool to match the risk with the intervention, and regular environmental rounds to check equipment availability and functioning.

Fall Prevention Resources

Perell, K.L., Nelson, A., Goldman, R.L., et al. (2001). Fall Risk Assessment Measures: An Analytic Review. J Geron Med Sci, 56A(12): M761-766.

Oliver, D., Daly, F., Martin, F.C., & McMurdo, M.E. (2004). Risk Factors and Risk Assessment Tools for Falls in Hospital In-Patients: A Systematic Review. Age and Ageing, 33(2):122-130.

National Center for Patient Safety: 2004 Falls Toolkit available at **www.patientsafety.gov/safetytopics/fallstoolkit/index.html**

Centers for Disease Control (2003). Various materials available at **www.cdc.gov/doc.do/id/0900f3ec80277b9c**

Second Looks: Review of Medication Errors

This issue of the **Patient Safety Reporting Initiative Updates** examines medication errors and RCAs that have been reported to us. We invite you to take a "second look" at your facility with these events and potential solutions in mind.

Those who are involved in direct patient care should always be aware that errors can and do occur. When the system, through our co-workers, check-lists and alerts, asks us to re-think our actions, we should take a deep breath and review our actions before continuing with what we were doing.

DOSAGE

1. *A post-operative order for pain control was written as ".4 mg of Dilaudid IV" and was read as "4 mg of Dilaudid IV." The patient was given this dosage, suffered a respiratory arrest and was successfully resuscitated with assisted ventilation and Narcan administration.*

Comment: Legibility of handwritten medication orders and correct interpretation of the amount ordered has long been a concern, and several procedures have been developed to decrease misreadings. Use of a trailing "0" is banned and a leading "0" for dosages less than "1" is required to prevent errors such as this one. This facility, which does not currently have Computerized Physician Order Entry (CPOE), re-educated the medical and nursing staff, and also implemented random chart monitoring to ensure compliance with procedures.

2. *The neurologist ordered "Phenobarbital 20 mg IV" for a pediatric patient with seizure activity. The nurse drew up and administered 1000 mg IV. The patient became apneic and was successfully resuscitated.*

Comment: Information from the RCA revealed that this was not the nurse's usual work station, she was an adult critical care nurse, and that the medication was stored in multi-dose vials on the floor. The combination of the nurse's unfamiliarity with a pediatric patient, the sense of urgency to control the seizure activity and the presence of multi-dose vials increased the probability that an incorrect dose would be given. The hospital has developed a list of high-risk medications that require a "double check" by two RNs, removed multi-dose vials from the floor and hired additional RNs to cover that ICU. The use of multi-dose vials has been a factor in several medication error reports.

3. *An order was written as "magnesium today" in the recovery room by the physician for a 39 year-old female post-operative trauma patient. The order was acted upon by staff in the step-down unit approximately 9 hours later. Utilizing the CPOE system, the practitioner entered an order for "IV Magnesium Sulfate…Drip: D5LR 1000ml, Mag Sulfate 40 gm, 5g/h, cont until dc'd." Three hours after the first dose was hung, the patient was found unresponsive and resuscitation was unsuccessful.*

Comment: Utilizing CPOE is no guarantee that medication errors will not occur. After performing the RCA, the hospital found that both the pharmacist and the nurse questioned the dosage, but the practitioner was insistent. Furthermore, the CPOE system allowed this dosage, appropriate for a preeclamptic patient on Labor and Delivery, to be ordered without checking other admitting diagnoses or generating an alert. The hospital also found that in the push to implement CPOE, some staff members with prescription privileges were provided with sign-on codes but not with training and credentialing in the system.

While CPOE can indeed reduce medication errors, it is important to remember that it will create different ones. This case also illustrates the importance of medication reconciliation as the patient moves through different levels of care within the hospital. Had the original order been clarified when the patient was transferred, this event might not have occurred.

ROUTE OF ADMINISTRATION

4. *A post-operative patient who had been transferred to the floor complained of pain. The RN paged the surgeon who was already scrubbed in another case. The call was patched through to the OR and the surgeon gave a verbal order for "IM Demerol 75 mg + Vistaril 25 mg." The nurse called back and said that the patient didn't want an IM injection; the surgeon changed the verbal order to 50 mg Demerol IV. The nurse heard Demerol 75 mg + Vistaril 25 mg IV, entered the order on the CPOE system and gave the medications IV push. The patient was found unresponsive and expired.*

Continued on Page 5

Comment: After performing the RCA, the hospital found that communication, staff education and loopholes with the CPOE system were factors in this event. The OR did not have speaker phones, so the circulating nurse held the phone to the surgeon's ear for the first order. When the floor RN called the second time, the message was relayed to the surgeon, who gave his order to the circulator who gave it to the floor nurse. The level of noise in the OR also increased the likelihood that the order would not be correctly heard.

The RCA also revealed that some staff had become so accustomed to administering certain medications, that they had become desensitized and no longer noticed the warning labels on the bottles about the danger of IV versus IM administration.

The hospital found that the CPOE system allowed staff to work around programmed safeguards and order medication for a non-approved administration route, and that CPOE safety factor education was not part of orientation or staff continuing education.

As a result of this information, the hospital changed its verbal order procedures, added safety factor education to orientation, changed the CPOE screen to only allow Vistaril to be ordered PO or IM and assembled a multi-disciplinary team to review high risk medications and suggest changes to the CPOE screen.

References:

[1] Mills, P.D., Neily, J., Luan, D., Stalhandske, E., & Weeks, W.B. (2005). Using Aggregate Root Cause Analysis to Reduce Falls and Related Injuries. Jt Comm J Qual Patient Saf, 31(1):21-31.

[2] See **www.ahrq.gov/qual/pscongrpt/psini2.htm**

[3] Hitcho, E.B., Krauss, M.J., Birge, S., W.C., et al. (2004). Characteristics and Circumstances of Falls in a Hospital Setting. J Gen Int Med, 19:732-739.

[4] Ash, K.L., MacLeod, P., & Clark, L.A. (1998). Case Control Study of Falls in the Hospital Setting. J Gerontol Nurs, 24(12):7-15.

[5] Hitcho et al. (2004), op. cit.

[6] Hitcho et al. (2004), op. cit.

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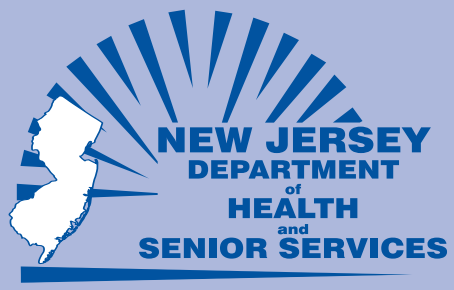

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NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

PATIENT SAFETY INITIATIVE
Alert - May 2006

2006

MRIs & Sandbags Filled with Metal Shot

The New Jersey Department of Health and Senior Services (Department) has received a report of a Potentially Serious Adverse Event, a “Near Miss” involving a sandbag that was filled with metal shot, not sand.

Immediately following a cardiac catheterization, a patient required an emergency MRI. As is the standard practice, pressure utilizing a towel-wrapped sandbag was applied to the groin, the site of catheter access, before leaving the catheterization lab.

When the MRI started, the bag moved towards the patient’s head and became adherent to the rim of the machine. Staff was able to remove the patient who, fortunately, sustained no serious injuries.

Examination of the sandbag revealed that it was filled with metal shot. The hospital also reported that all documentation, original order forms, invoices and packing slips, stated that the product was “sandbags” and the product number was that for sandbags, not metal shot bags.

The Department strongly recommends that all “sandbags” are carefully examined to ascertain that they are indeed filled with sand and that you also check with your vendors to ensure that there are no miscommunications about orders. If you have metal shot filled bags, and there is any possibility that a patient could leave an area with the bag and go for an MRI, or any other procedure where the presence of metal is contraindicated, you should remove all of the metal shot bags at your facility and replace them with sand-filled ones. Your cooperation in this will ensure that a similar event, perhaps with a more tragic outcome, will not occur.

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

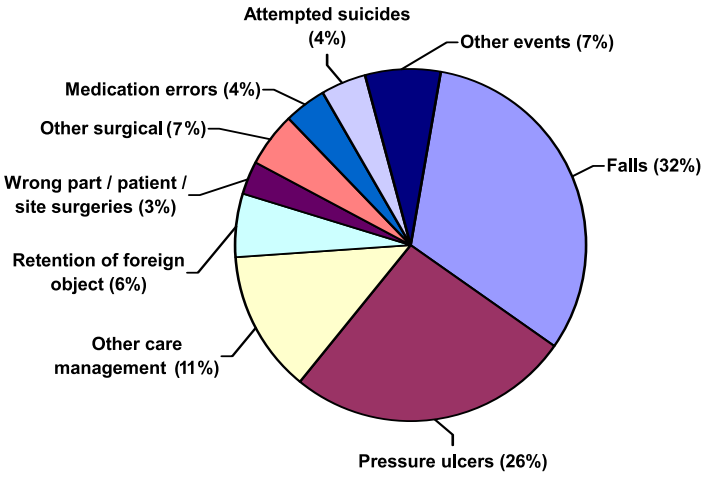
PATIENT SAFETY INITIATIVE:
Updates - June 2006

2006: Issue 3

Hospital Reporting Update

The New Jersey Department of Health and Senior Services (Department) received 528 serious preventable adverse event reports from hospitals between February 1, 2005 and March 31, 2006. Of these reported events, 503 met the statutory criteria for an event subject to mandatory reporting. The frequency of event reports by event category is illustrated in Figure 1. Falls and pressure ulcers are the most commonly reported events, accounting for 58% of all submitted event reports. This has been a consistent pattern since the start-up of the Patient Safety Initiative.

Figure 1: Frequency of Reported Events



Current Activities

The Department has planned several ongoing or new projects:

- The second cycle of the *Falls Prevention Collaborative Workshops* ended in May and the third cycle will begin in June. The two-session workshop builds on New Jersey's experience with falls and the national perspective on falls reduction. Based on concepts presented in the first session, hospitals work on quality initiatives related to falls, and report on their progress in a second follow-up session. More information on the project was presented in the February 2006 *Patient Safety Initiative Updates.*

- The Department is in the early stages of developing a web-based Patient Safety Event Reporting System. The system will collect more specific information on each event, thereby enabling more comprehensive tracking and analysis by both the reporting facility and the Department. This web-based system will include the voluntary anonymous reporting system required under the Patient Safety Act (P.L. 2004, C.9) for less serious adverse events and near misses. At this stage of the process, a firm timetable for start-up of the web-based system is not possible.

Overview: Imaging Errors

Imaging studies are frequently an essential component of the diagnostic process. This issue of the *Patient Safety Initiative Updates* focuses on diagnostic imaging.

New imaging modalities, lab tests and testing recommendations have allowed for speedier and more accurate evaluation of a patient's clinical presentation. Such improvements in diagnostic testing, however, are not without their pitfalls.

Of the 55 serious preventable adverse events reported under the category of "other care

Continued on Page 2

Also in this issue:

management event," seven events involved diagnostic imaging. While this represents only a small percent of the total events reported to the Department, these errors often have very serious consequences for the patient.

The imaging studies process can be broken down into: ordering of studies, performance of studies, reading/interpretation of studies, and communicating the results of studies. These areas overlap but the categories allow us to examine the process.

Ordering

Despite technological advances in imaging studies, they remain highly vulnerable to ordering errors that affect the diagnostic process.[1,2] Problems fall into several categories: tests that were ordered but not performed; and tests ordered that did not include scans of critical diagnostic areas. These issues led to delayed or incorrect diagnoses, resulting in injury or death of patients.

Patient sustained a fall and complained of hip pain. The physician ordered an x-ray and the clerk transcribed left lower extremity. The error was discovered and the patient's left hip fracture was diagnosed 12 hours after the initial x-ray.

Performing

Delays in performing diagnostic tests due to the failure to note or communicate the necessity for immediate testing were responsible for significant patient harm. In other cases, poor or incorrect patient positioning resulted in a need to redo tests, delaying diagnosis. In one case the level of noise generated by an MR imager led to miscommunication between the patient and the technician, resulting in patient injury. A study by Moelker, Mass and Pattynama describes specific interventions that may be implemented by hospitals to improve verbal communication between technicians or between patient and technician in areas of high acoustic noise.[3]

Reading/Interpreting

Many imaging errors reported to the Department occurred during the reading/interpreting phase. In several cases the diagnostic image was misread when the clinician identified the primary condition and missed the secondary and life-threatening condition. The clinician reading the image was generally not a radiologist or senior radiology resident.

Patient was admitted after falling off his roof onto a ladder. On the second hospital day, he was noted to be tachycardic and tachypnic. The work-up included a chest x-ray that was read by the surgery resident as positive for a left pleural effusion. Later that day, the CT of the pelvis revealed free intra-peritoneal air and the patient was taken to the OR for chest tube placement and small bowel resection secondary to perforation. A second reading of the chest x-ray noted a subphrenic lucency, "rule out free air."

To address these problems, some hospitals have developed a list of critical or "don't miss" diagnoses and have had senior radiologists conduct training for residents, ED staff, and other critical care staff who read imaging studies. Such lists have included, at a minimum, aortic rupture, ectopic pregnancy, hemopericardium with cardiac tamponade, simple pneumothorax, tension pneumothorax, hemothorax, spinal epidural abscess, and thoracic spine fracture.[1,4]

Disagreements between clinicians, technical limitations (e.g., the inability of some patients to be positioned for optimal contrast) and the lack of patient history resulted in several incorrect diagnoses. In one case, a radiograph was ordered to rule out the presence of a specific retained object. Although the radiologist noted that the specific object was not present, he failed to communicate to the OR the presence of a different type of object.

The introduction of digital radiology and teleradiology that have enabled smaller facilities to have 24/7 coverage has introduced new challenges to the reading/interpretive process. Hospitals may find that off-site radiologists have difficulty in contacting the treating physicians and receiving critical patient information, leading to missed or incorrect results. Facilities should implement procedures to ensure that off-site radiologists have access to the same level of information and clinical specialists available to those in the hospital. Note that Department Licensure Standards (NJAC 8:43G-28.8) require that a radiologist must arrive at the hospital within 30 minutes upon being summoned.

Communicating

Radiologists are frequently at the center of the information exchange among clinicians. Therefore, the ability to clearly and consistently communicate the results of tests is critical to ensuring optimal patient care. In several cases reported to the Department, patient harm occurred due to incomplete communication of the results. This includes

Continued on Page 3

the imaging studies being read but the results not communicated, a delay in the communication of the results, or the results were communicated indirectly or to the wrong person.

An 18-year-old patient was admitted for pyelonephritis. She slowly responded to treatment and by the fifth hospital day was preparing for discharge when she complained of dyspnea. A CT scan was ordered to rule out a pulmonary embolus. This was performed and read by the radiologist at noon. The reading "Negative for PE, apparent CHF with bilateral pleural effusions" was faxed to the floor and not noticed until 11 PM that night. In the interim, the patient arrested and resuscitation was unsuccessful.

To minimize communication errors, the American College of Radiology in its practice guidelines encourages direct communication between clinicians utilizing methods to assure the receipt of the diagnostic report.[5] Some hospitals have initiated systems that require confirmation of receipt of the report by the treating physician. If confirmation is not received within a given time frame appropriate for the diagnosis, radiologists, or their designated representatives, notify the clinician again and document follow-up.

In exploring the causes of imaging errors drawn from RCAs submitted to the Department, staff communication, staff orientation and training, and the physical assessment process were the most frequently identified root causes. Team factors and hospital procedures were the most frequently identified contributing factors.

This emphasis on communication and practitioner skill is not unique to imaging errors. Staff communication and staff orientation/training are also the most frequently cited root causes of all adverse events reported to the Department. Poor communication, however, is not simply the result of inadequate transmission or exchange of information. The complex dynamics of health care delivery in a hospital setting, including multiple diagnostic tests/procedures and hierarchical differences among staff, inhibit clear communication and can lead to patient disability or death. Exploration of these issues, along with re-engineering information technology to address system weaknesses, may promote optimal treatment.

Imaging Resources

Several free resources are available for improving quality and safety in diagnostic imaging:

The American College of Radiology provides a number of materials, including appropriateness criteria, standards, and news bulletins. Available at **www.acr.org**

The Agency for Healthcare Research & Quality Morbidity and Mortality Rounds on the Web is an online journal and forum for patient safety and health care quality that has addressed several radiology-specific issues. Available at **www.webmm.ahrq.gov/**

An internet-based search engine for radiology and other medical specialties covering over 4500 PubMed journals and 864 HighWire-hosted journals is available at **http://highwire.stanford.edu/cgi/search**

Second Looks: Imaging

In this issue, we look at serious preventable adverse events related to imaging that, while not common, resulted in poor outcomes for the patient. In the interest of sharing this information and decreasing the probability of a similar event happening at your facility, we invite you to take a "Second Look" at your facility with these types of events in mind.

Ordering

1. *The infectious disease consulting physician ordered an echocardiogram to rule out vegetation in a septic patient. The patient improved clinically until 2 weeks later when he had sudden onset of shortness of breath and arrested. The autopsy showed fulminant endocarditis, vegetation of the valves, and valve rupture. The echo had never been performed.*

Comment: During the RCA process, the hospital discovered that the order for the echo had been entered into the computer for another patient,

Continued on Page 4

for whom, coincidentally, an echo had also been ordered. The hospital worked with its IT staff to redesign the order screen to require a yes/no second verifier for patient identification, and to reconcile the order number with the number on the test request. They also developed a method to verify that duplicate orders are valid.

The other striking finding of the hospital's investigation was that no one involved in the patient's care followed up on the echo: not the consulting physician who ordered the study, the attending physician, house staff physicians, nurses or case manager. Critically ill patients often have multiple specialists participating in their care and it is the role of the primary attending physician to ensure that there is complete, continuous and timely communication among the health care team. It is also generally agreed that it is the responsibility of the practitioner who orders a study to follow-up on the results.

Performing

2. *A patient who received epidural anesthesia for surgery developed a pulmonary embolus post-operatively and received anti-coagulation therapy. Several days later she complained of leg weakness and the neurologist ordered an emergency, "STAT," MRI. The study was performed 16 hours later and read 40 hours after the original order. The radiologist noted a subacute epidural hematoma and despite immediate surgical intervention, after the results were communicated, the patient became paraplegic*

Comment: During its RCA investigation, the hospital found that the ordering physician had not been told that the imaging technician had left for the day; the covering physicians did not communicate with each other; and the "STAT" status of the order was not recognized in radiology. The hospital's senior medical leadership is now emphasizing communication among the health care team, as in the previous event, and monitoring the response to "STAT" requests across the system.

Reading/Interpreting

3. *A chest x-ray was read in the Emergency Department as "WNL"; the patient was discharged with a diagnosis of bronchitis and sent to the waiting room for her family to pick her up. Four hours later she was found unresponsive and resuscitation was unsuccessful. The radiologist's final reading noted free intra-peritoneal air.*

Comment: The Department has received several event reports involving misread imaging studies. These were usually read by an ED attending or non-radiology resident, and the most frequent missed finding was free intra-peritoneal air. As discussed in the previous section, there are some critical findings that must not be missed if the patient is to have the best chance of a good outcome. To decrease the probability of a wrong or missed diagnosis, this hospital's Radiology Department, in consultation with other disciplines, developed a list of critical findings and then developed learning sessions, with periodic competencies, for those practitioners most likely to be doing emergency readings.

Communicating

4. *A Foley catheter was inserted into the stoma to maintain patency after the patient pulled out the PEG tube and a gastrografin abdominal x-ray was done to confirm placement. The resident read the film as "normal," confirmed it with a junior radiology resident and reordered the tube feedings. Seven hours later the patient was noted to be unresponsive, was resuscitated, transported to the ICU and placed on a ventilator.*

Comment: Information from the RCA revealed that shortly after the resident read the film, the senior radiology resident began to do the assigned preliminary reading of x-rays, read the patient's abdominal x-ray and reviewed it with the attending radiologist. They noted contrast in the stomach but could not rule out intra-peritoneal contrast and faxed the report to the floor where its receipt was unrecognized.

The Department has had several event reports involving critical imaging findings that were not directly communicated to the practitioners caring for the patient. Faxing such reports presumes there is someone at the fax machine to receive the report, but the evidence suggests this presumption is often wrong. Communicating critical results to someone other than the primary practitioner, such as a nurse, may also result in a delay of receipt of the information. This time delay can result in a delay in the patient receiving lifesaving care. The hospitals involved in such events have examined their communication protocols and many have implemented a protocol requiring direct physician to physician communication of these critical results.

Conclusion

A key factor in all of these events was the communication failure uncovered during the RCA process. Medical technology and medical informatics are rapidly evolving in sophistication and capacity. However all the refined images and enhanced diagnostic capacity will be of little benefit to the patient unless there are reliable and timely means of communicating imaging results and incorporating them in the patient's care plan. The 3"x 5" index card used to be the "gold standard" for recording information, following up on tests and results, and signing off to colleagues. Newer tools such as the PDA, Blackberry, cell phone, and laptops with wireless internet connection have virtually replaced those cherished index cards but fancier gadgets don't, on their own, assure clear channels of communication. The February *Patient Safety Initiative Updates* noted this same caution for Computerized Physician Order Entry (CPOE), another technological advance.

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NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

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Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE
Updates - December 2006

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

2006: Issue 4

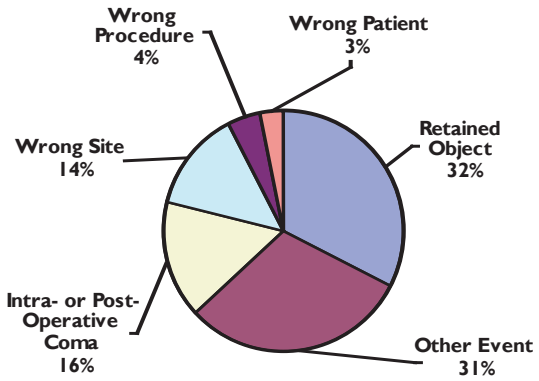
Patient Safety Initiative Update

- The first annual report for the Department of Health and Senior Services (Department) patient safety activities was released in October. That report, **Patient Safety Initiative: 2005 Summary Report**, describes the activities of the Patient Safety Initiative during 2005. It also presents a summary of events reported and related hospital analyses for that period including root cause and impact for the patient. Special emphasis is given to the most frequently reported events: falls, pressure ulcers and surgical events.
- The Health Care Administration Board approved the patient safety rules for initial publication at their October 19, 2006 meeting. Those regulations describe the requirements for each health care facility to have a patient safety plan and committee as well as the requirements for mandatory reporting of serious preventable events. The rules will be effective for different types of health care facilities following a phase-in time table based on adoption of the rules:
  - *Upon adoption:* rehabilitation, general, psychiatric and special hospitals;
  - *Six months after adoption:* ambulatory care, home health care and hospice;
  - *One year after adoption:* assisted living, comprehensive personal care homes, long-term care, adult and pediatric day health, residential health care.
- A new **instructions manual** for hospital reporting of significant events was released in early November. The changes focus primarily on clarifications of the existing instructions. For example, the root cause analysis (RCA) section has been reformatted to provide examples and to make the requirements more clear. Several changes in the reporting categories were made in order to be consistent with the proposed regulations. These changes in reporting include: special categories for new and reprocessed single-use devices; exclusion of reporting on pressure ulcers which developed as a result of underlying vascular etiology; extension in time frame for impact of surgical post-operative death or post-operative coma from 12 hours to 24 hours after surgery. The new instructions manual is effective on January 1, 2007.
- The last of three groups of hospitals finished the Falls Collaborative Workshop in September. Teams representing 51 hospitals participated in the two-session workshop designed to discuss the national perspective on fall prevention. Hospitals were successful in initiating quality improvement projects designed to prevent falls.

Overview: Retained Objects

The incidence of unintentionally retained objects during surgery is estimated to be one in 1,500 operations.[1] Reports of retained objects constitute 4% of all reports received by the New Jersey Patient Safety Initiative and are the most common surgical event reported as shown in Figure 1.

Figure 1: Frequency of Types of Surgical Events



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Also in this issue:

It is important to note that the New Jersey Patient Safety Initiative codes reports of retained objects resulting from broken instruments or supplies as device failures. This includes events related to broken catheters, bone hooks, laser tips and orthopedic hardware.

Similar to the findings from national studies,[1] the majority of retained objects reported to the Patient Safety Initiative are surgical pads and sponges. Retained pads and sponges are known as gossypiboma, derived from gossypium (Latin: "cotton") and boma (Swahili: "place of concealment"). Complications resulting from a retained sponge include pain, infection, granulomatous response with abscess development, fistula formation and/or intestinal obstruction.[2] Other types of retained objects, such as clamps, needles and retractors, may cause organ damage, bowel perforation, sepsis and severe pain.

The most commonly identified causes of retained objects are the rapid pace of emergency procedures, unexpected changes in the operation, and high patient body mass index (BMI).[1] Under these conditions, staff may be rushed, distracted, or may need to introduce new equipment during the surgical procedure, disrupting the standard counting process.

Surgeons and operating room teams routinely rely on sponge and instrument counts as a means to prevent retained objects.[3] The Association of periOperative Registered Nurses (AORN) recommends four separate counts of surgical sponges and supplies: the first before the procedure begins, the second before closure of a cavity within a cavity, the third before wound closure begins, and a final count during skin closure.[4] They also recommend counts when the OR team is relieved.

Use of these recommendations, however, is not universal or standardized and is often modified according to individual hospital policy.[3]

Reasons for a Falsely Correct Count

A recent study published in the *New England Journal of Medicine* found that in nearly 90% of cases of retained foreign objects, the counting procedure showed that all equipment and supplies were accounted for.[1] Reasons for a falsely correct count when objects are actually missing include staff fatigue, distractions, interruptions and the use of relief teams.

Three days after an exploratory laporatomy that involved multiple emergency blood transfusions, several surgeons and relief OR teams, a KUB was ordered to differentiate a post-operative ileus from an obstruction. At surgery, a sponge was removed.

Introduction of equipment and supplies during surgery but not communicated to the circulating nurse and therefore not added to the count sheet may also result in a retained object with a "correct" count.

Patient underwent an emergency exploratory laporatomy with lysis of adhesions and detorsion of a small bowel volvulus. Three weeks later he complained of abdominal pain and a CT scan showed a foreign object. At surgery a "Fish®" bowel protector was removed. This object was called for at the end of the case and not added to the count sheet.

Response to an Incorrect Count

If 90% of the cases of retained objects involve falsely correct counts, that leaves 10% where the counts did not match. Why was the object not removed for these patients? In some of the cases, surgery must be ended in order to immediately stabilize the patient. But in the other cases, the issue may be a culture where the inequities of power between surgical team members did not allow challenging a count or the violation of operating room protocols. In one study of medical malpractice claims, incorrect sponge counts were accepted prior to closure either due to the surgeon dismissing the count without re-exploring the wound, or to the nursing staff allowing the incorrect count to be accepted.[5]

The needle count was incorrect at the end of a coronary artery bypass surgery (CABG). Although the surgeon did not believe the count was truly incorrect, an intra-operative x-ray was taken. The surgeon completed the procedure and moved the patient to the recovery area before he had the result. Later that day, the patient was taken back to the OR and the retained needle was removed.

In the cases reported to the Department, some of the factors are physician refusal to believe the count, removing the patient from the OR before the x-ray result is obtained, incorrect reading of the x-ray by a

Continued on Page 3

non-radiologist and the radiologist only reporting on the absence of the object noted on the requisition and not the additional one seen.

At final count a needle was missing and could not be found. An intra-operative x-ray was ordered and the requisition read "rule-out lost needle." The radiologist called the OR and reported directly to the surgeon that there was no needle. When the final report was received, it was noted that there was a retained object. The patient was taken to the OR and a sponge was removed.

Procedures Outside OR

Lack of standard procedures and policies regarding post-operative notes and count sheets for procedures performed outside the main operating room may lead to an increased risk of retained objects. Sponge and needle counts are routine for cesarean deliveries but not for vaginal deliveries. Similarly, intra-cardiac devices (ICD) are implanted in the Cardiac Catheterization Lab and central lines are placed in patients on the units and on the floors. Preventing retained guidewires is the goal since detection after insertion may be difficult.[6]

Two months after implant of a pacemaker, the patient was readmitted for an infected surgical pocket. The pocket was opened and a 4x4 gauze sponge removed. There was no count procedure in the Cardiac Catheterization Lab.

In General

Some hospitals are investigating an emerging technology that involves electronically tagging all equipment and supplies. Retained objects can then be detected by a wand that is passed over the patient. Such technology may be an efficient way to reduce the retention of foreign objects. It is not, however, a cure-all. Technology and established procedures are only effective in reducing medical errors when all members of the treatment team understand the importance of and compliance with hospital policies. This in turn requires that hospital policies are appropriate and serve to promote safety and quality improvement.

Overview: Lost Surgical Specimens

The Department has received a few reports of lost surgical specimens and, while this represents a very small percentage of the total number of reports, the potential harm to the patient is significant.

The path of the surgical specimen from generation in the OR to documentation of the final reading and diagnosis in the medical record is a long one with many steps. The pre-analytic phase includes the specimen generation, collection, labeling, recording, storing and transport to the pathology laboratory's receiving unit. The analytic portion includes the lab's documentation of receipt, preparation and staining of the tissue, reading the slide and rendering a diagnosis, documenting the reading and diagnosis and transmitting this to the patient's chart.

Errors can occur at every step of this process and are not rare. One article estimates that pre-analytic errors may occur in as many as 6% of cases.[7] The resulting consequences may be minor and have no harmful impact for the patient. If a specimen is labeled with the wrong day, that error is unlikely to cause the patient harm. The impact may be catastrophic if the wrong patient's name is on the label or if the specimen is lost prior to diagnosis.

During the planned surgery for a buccal cyst, the surgeon decided to remove a small nodule on the tongue that "he knew" was benign and placed it on a piece of gauze. At the end of the case, the gauze with the nodule could not be found.

The Association of periOperative Registered Nurses (AORN) recommends immediately placing the specimen in a labeled container to secure it as one of the steps to decrease the likelihood of losing it.[4]

Hospitals and other health care facilities are encouraged to analyze their own process for specimen handling before there is a significant incident that impacts their patients' care. One hospital that did so in response to a lost specimen found multiple points in the process that were vulnerable to failure. By implementing a rapid cycle improvement strategy, Plan-Do-Study-Act (PDSA),[8] they were able to significantly improve their process.

Second Looks: Retained Objects and Lost Specimens

In this issue, we extend the Overview sections on retained objects and lost specimens to examine reports to the Patient Safety Initiative and hospitals' responses to these events. Retained objects and lost specimens have potentially catastrophic results for the patient. In the interest of sharing this information and decreasing the probability of a similar incident happening at your facility, we invite you to take a "Second Look" at your facility with these events in mind.

1. *Ten days after a long, complicated gastrointestinal surgery, the patient complained of abdominal pain and was taken back to the OR where a lap pad was removed. The first surgery had required multiple nursing relief teams. Towards the end of the procedure, the surgeons were rushing to get the patient off the table and expressed the need for speed to the nurses as they were doing the final counts.*

Comment: The use of counts to reduce the incidence of retained foreign objects is clearly not always sufficient. Hospitals are continuously focusing on promoting effective communication and implementing procedures that help prevent human error. After their analysis of this event, this hospital implemented the use of wall boards and began addressing the issues of clear communication and the culture of mutual respect at a systems level. Use of wall boards with clear plastic bags in the count procedure may serve as an additional visual cue and thus reduce the likelihood of a miscount.

2. *The surgeon placed the cervical cone biopsy specimen on a piece of gauze; the assistant surgeon placed the gauze on the sterile OR table where they both later examined it and left it on the table. The nurse then retrieved a specimen cup from the cabinet and at the end of the procedure the cup was sent to the laboratory. Five hours later, after the patient had been discharged from the facility, the lab called stating that the cup was empty.*

Comment: During its investigation, the hospital found that cup had not been prepared in advance and was very small; so small, in fact, that the label completely covered the cup making visualization of any contents very difficult. They also examined the entire process, as Slavin[8] has suggested, and found that there were several "points" of vulnerability for failure. As a result of this analysis, the hospital assigned one staff person to transport specimens to the lab on a scheduled basis, provided larger specimen cups, and required the surgeon and the nurse to visually confirm the container's contents. To insure that these actions are implemented, the hospital is monitoring them by direct observation and reviewing the documentation tools.

3. *A suture reel was missing at the end of a 7-hour procedure that was complicated by extensive hemorrhage and required surgeons from three specialties to scrub in. The x-ray technician took the intra-operative film to the radiologist and then called the OR to report "no reel seen." One month later the patient presented to her physician's office complaining of flank pain. A CT scan showed an abdominal abscess and lap sponges; two sponges were removed at an exploratory laporatomy. The radiologist's final report after the initial surgery had noted the presence of the sponges.*

Comment: The Department has received more than one report where only the lack of the queried object and not the presence of another foreign body was communicated to the surgeon. During their RCA investigation, this hospital found that there was no standard protocol for reporting intra-operative x-ray results and immediately required direct radiologist to surgeon communication. As discussed in the June 2006 issue of *Patient Safety Updates*, the incomplete or delayed communication of imaging results can cause harm to the patient. Perhaps adding the inclusive phrase "any foreign body/object" to the requisition, in addition to the missing object, will decrease incomplete reporting.

4. *Two weeks after a femoral line was inserted at the bedside the patient was readmitted for shortness of breath. After several chest x-rays, whose interpretation was difficult because of multiple leadwires on the chest, a foreign body was detected and the guidewire was removed from the subclavian vein.*

Comment: Insertion of central lines is a common occurrence in the acute care setting and often takes place outside of the main OR where procedures offer some protection from retained objects. The Department

Continued on Page 5

has received several reports of retained guidewires that required the patient involved to undergo an additional procedure for removal. Because the guidewire comes with the catheter and is not separately introduced, as a retractor is during surgery, it is more likely to be overlooked after the successful insertion of the line. During the RCA process, the hospital decided to require a post-operative note, based on those done after major cases, that specifically documents the removal of the guidewire.

Adopting procedures designed for patient safety from the main operating room to all other locations where invasive procedures are formed will decrease the incidence of retained sponges, pads, "peanuts" and instruments.

In Conclusion

A "blame free" culture that rewards staff for reporting risks and taking responsibility for mistakes does not mean that staff is not held accountable. Retained objects and lost surgical specimens are frequently the result of miscommunication and failure to follow standard protocols. Hospitals should actively monitor compliance with their existing policies and examine their process improvement opportunities. A multifaceted approach to error prevention can reduce or eliminate the prevalence of retained objects with their associated complications and the incidence of lost surgical specimens.

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

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**

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