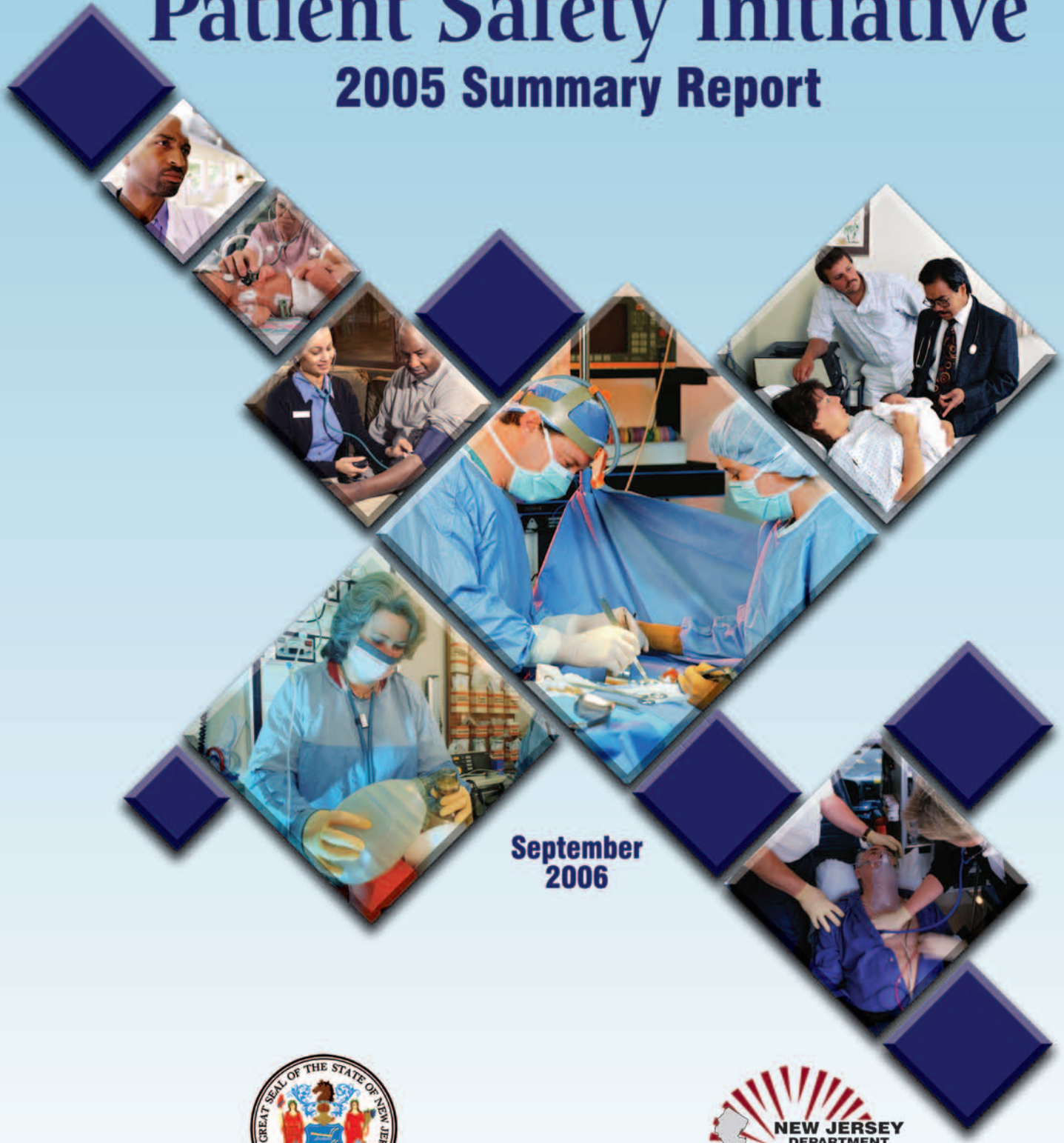
Health Care Quality Assessment
New Jersey Department of Health and Senior Services

Patient Safety Initiative

2005 Summary Report



September
2006

Jon S. Corzine
Governor

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

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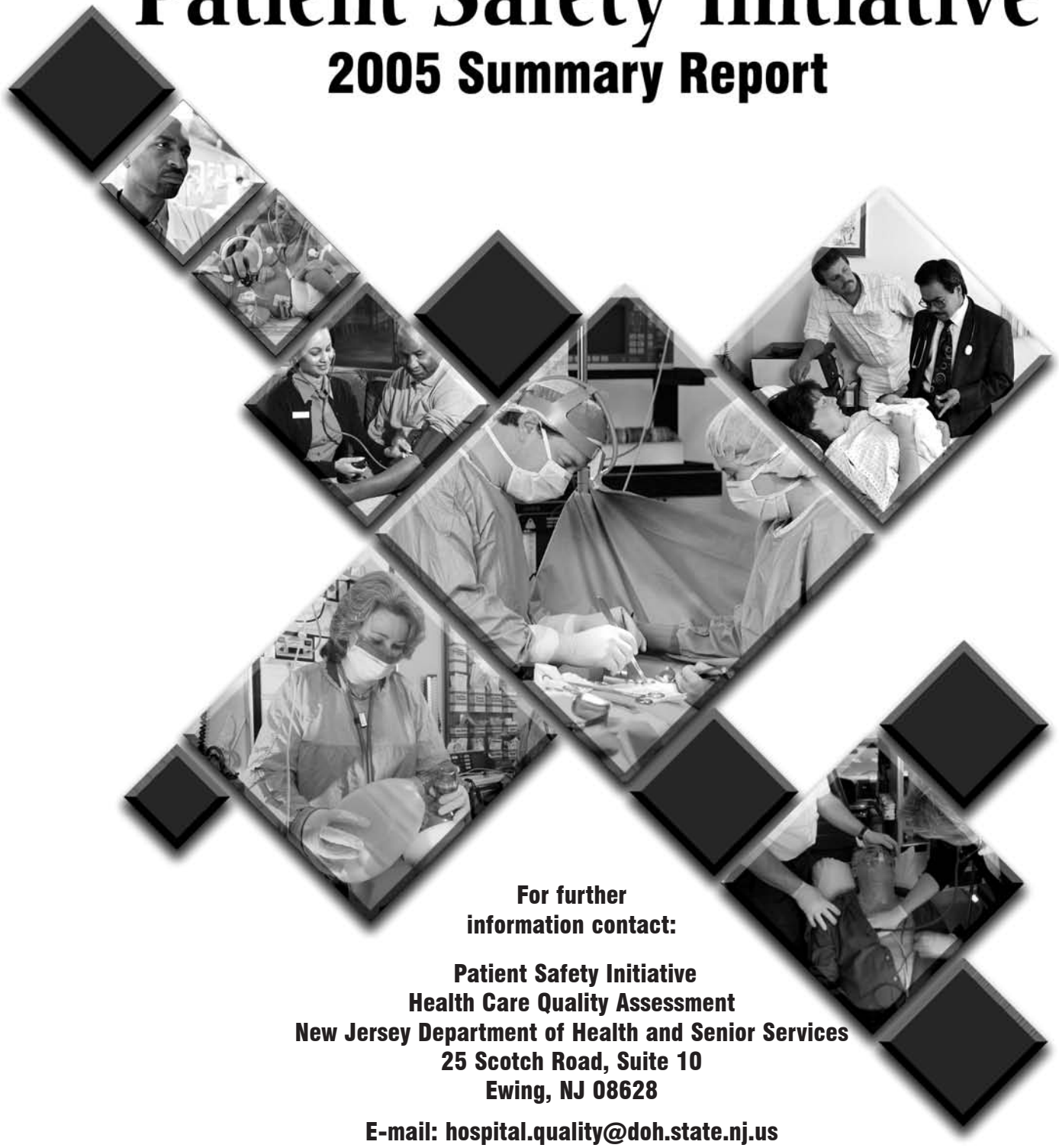

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FRED M. JACOBS, M.D., J.D.
Commissioner

September 2006

Dear Friends:

Recent Institute of Medicine reports have focused national attention on problems with health care safety and quality. In response, the New Jersey Legislature developed the Patient Safety Act (P.L. 2004, c.9) that provides a framework for improving the safety of health care in New Jersey. Following the Institute of Medicine's approach, the legislation emphasizes the importance of making changes in the underlying systems for delivering safer health care. As a result, the Department created the Patient Safety Initiative and a system for hospitals to report serious preventable adverse events. This report is a result of the initial year of operations and includes a summary of the events reported and the hospitals' analyses of those events.

Supporting health care facilities in developing patient safety programs has been a high priority for this administration. The Department has established the Patient Safety Initiative to manage the event reporting system and support hospitals in creating a safe environment. We have been working with hospitals to ensure that response to a medical error limits the possibility of recurrence. Our patient safety newsletters share information on events and hospital actions for improving patient care systems. Collaborative workshops train hospitals in national models for "best practices" and encourage the development of quality improvements.

I look forward to a continuation of this cooperative relationship with hospitals and expansion of the process to other health care facilities. Information on the Patient Safety Initiative may be found at www.NJ.gov/health/hcqo/ps.

Sincerely,

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

Contents

List of Tables

List of Figures

I. Background

The release of the Institute of Medicine's (IOM) publications, *To Err is Human: Building a Safer Health System,* in 2000 and *Crossing the Quality Chasm: A New Health System for the 21st Century*, in 2001 focused considerable public attention on the quality and safety of health care delivery systems. The 2000 report estimated that between 44,000 and 98,000 patients die each year in the U.S. as a result of medical errors.[1] This number pales in comparison to the number of patients for whom additional tests, procedures, lengthened hospital stay, and temporary or permanent disability are unanticipated outcomes. For example, in one study of 51 hospitals in New York, injuries resulting from care processes occurred in 3.7% of all patients that were hospitalized.[2]

One aspect of the IOM report was its emphasis on collecting and analyzing the important metrics of physician and hospital performance. Data gathered from a variety of sources could be used to encourage quality and safety improvements in patient care by identifying specific issues associated with high risk of poor outcomes. The IOM report thus encourages individual providers and government agencies to develop data gathering and analytical tools to monitor and inform quality improvement and patient safety strategies.

To this end, the State of New Jersey enacted the Patient Safety Act (P.L. 2004, c.9; "the Act") to improve patient safety within New Jersey health care facilities. The Act recognizes the importance of designing systems to improve the safety of heath care delivery. Health care facilities are given the responsibility of working to improve safety through a patient safety committee. The committee is charged with developing a patient safety plan for the facility, as well as internal tracking of medical error trends and comprehensive analysis of the causes of serious errors. The committee is responsible for correcting the underlying causes of error and for reporting serious errors to the New Jersey Department of Health and Senior Services (Department).

The Department is required to set up both mandatory and voluntary reporting systems:

- **Mandatory:** Facilities are required to report all serious errors, defined as serious preventable adverse events resulting in death or loss of bodily function lasting more than seven (7) days or present at discharge or loss of a body part or disability or loss having an impact which lasts for seven (7) days or until discharge.

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

[2] Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice study. *N Engl J Med.* 1991;324:370-376.

- **Voluntary:** Health care professionals are encouraged to report near misses or less serious events. This reporting system is anonymous.

All reporting under the Act is confidential. Information for both the mandatory and voluntary reporting systems is not subject to discoverability in any civil, criminal or administrative action or considered a public record. Likewise, the work of a facility's patient safety committee is confidential and non-discoverable. Confidentiality is considered an essential component for a successful patient safety system, since health care professionals must feel confident that their reports of serious events will not be used against them.

In order to implement the Act, the Department worked with stakeholders to develop detailed regulatory guidance. Proposed rules should be published for formal public comment in the near future. Since hospitals were already required by rule and Departmental policy to report serious preventable adverse events to the Department, the hospital industry agreed to a Department initiative to handle such reporting within a new framework provided for by the Patient Safety Act, in advance of formal rule adoption. The new, confidential reporting system was launched for general hospitals on February 1, 2005. This report describes the implementation of the reporting system and related activities as well as the results of the initial operations during 2005.

II. Implementation

The Department's Patient Safety Initiative staff designed a new mandatory reporting system employing event categories based on the National Quality Forum's (NQF) list of "never events."[3] 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). Some changes from the NQF categories and definitions were made in order to comply with the State statute:

- 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., last seven days or are 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. They are instead required to be reported non-confidentially.

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 professional clinical staff. If the RCA does not meet the Department's requirements, clinical staff works with hospitals to improve their analysis and corrective actions that minimize the likelihood that the event will reoccur.

Related Patient Safety Initiative Activities

In addition to developing the reporting system, the Patient Safety Initiative took several additional steps to support the patient safety systems in New Jersey hospitals:

Event Reporting and RCA Workshops: In February and March 2005, four workshops were offered to New Jersey hospitals to train them not only on what types of events to report but,

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

more importantly, on how to conduct a Root Cause Analysis (RCA) of a medical error. All of New Jersey's acute care hospitals registered for the training. In addition, the Patient Safety Initiative staff was invited by several hospitals to provide four workshops on-site, training another 150 hospital staff. The workshops used lecture, real-world examples, and interactive exercises to familiarize the participants with the RCA process and new reporting requirements, and to review frequently asked questions concerning report preparation and submission standards. These workshops also served to build trust between the Patient Safety Initiative's staff and hospitals around the reporting system's confidentiality.

Patient Safety Newsletter: In November 2005, the Department released its first *Patient Safety Initiative Updates* newsletter. A special section, *Second Looks*, describes specific events and how hospitals have analyzed event causes and improved their processes as a result. The purpose of the newsletter is to extend the benefits of lessons learned by individual hospitals to the whole industry. Some hospitals have advised Patient Safety Initiative staff that the newsletter caused them to introduce changes to their policies proactively. In February 2006, the Patient Safety Initiative released a second newsletter and a third was released in June.

Development of the Patient Safety Web Site: A website to support Patient Safety Initiative activities (www.NJ.gov/health/hcqo/ps) went live in November 2005. In addition to providing all forms and instructions for patient safety reporting, the website provides resources for patient safety programs and includes copies of all previous *Patient Safety Initiative Update*s newsletters.

Falls Collaborative Workshop: Falls are the most frequently reported type of adverse event and a number of hospitals asked the Patient Safety Initiative for help in designing and implementing falls prevention strategies. As a result, the Patient Safety Initiative developed a two-day workshop that began with an initial group session, held in November 2005. Each participating hospital team, with assistance from the workshop leaders, developed a falls prevention project to be piloted in their hospital. Through regular conference calls, a collaborative approach was fostered. Teams were given the opportunity to exchange information on successes and challenges, as well as specific strategies and resources. They could ask each other and the technical experts for ideas on how to address their specific challenges. A follow-up session gives hospital teams the opportunity to present and assess their efforts. Due to ongoing interest from other hospitals in this collaborative, in 2006 the Patient Safety Initiative is conducting two more workshop cycles. In all, it is anticipated that 40 teams representing 51 hospitals will participate in the falls collaborative (note: some teams represent systems that include multiple hospitals).

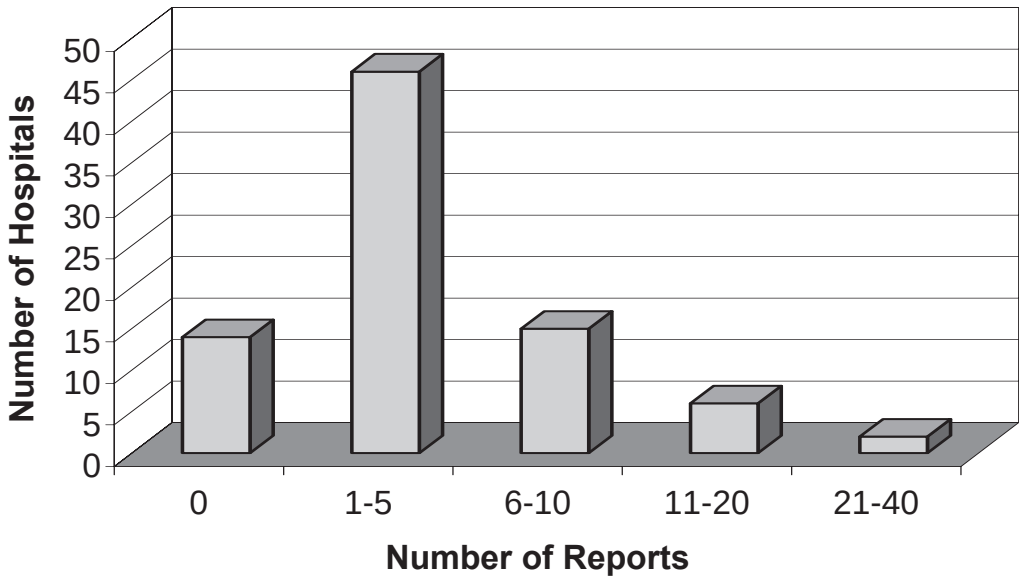
III. Analyses of Event and RCA Reports

The Patient Safety Initiative has reviewed and analyzed the data from event and RCA report forms for events submitted between February 1, 2005 and December 31, 2005.

A. Frequency of Reported Events

There were 397 event reports submitted during 2005. Some hospitals submitted events that, upon analysis, did not qualify as a reportable event. A total of 376 events met the statutory criteria for mandatory reporting. The number of reports submitted by month varied from a low of 15 (February) to a high of 61 (August). The majority of hospitals submitted between one and five reports during 2005 (see Figure 1). These numbers, however, should be interpreted with great caution since many factors influence the number of reports and types of reports submitted by a hospital. A hospital with a higher number of reports may be a larger hospital, a less safe hospital, or a more safe hospital that is vigilant about finding and reporting serious medical errors. Currently, there is no available research that has objectively established an "expected" or benchmark event rate applying across all hospital activities and settings. The volume of events reported to the Patient Safety Initiative does not permit drawing conclusions about whether or not a hospital has a strong, effective patient safety program.

Figure 1
Frequency of Event Reports by New Jersey Hospitals (Feb. 1 – Dec. 31, 2005)



Based on reportable events, large hospitals submitted more reports on average than small and medium hospitals (see Table 1).

Table 1
Average Number of Event Reports by Hospital Size
(Feb. 1 – Dec. 31, 2005)

Hospital Size	Maintained Beds[a]	Average Number of Reports
Small	≤150	3
Medium	151 – 299	4
Large	≥300	8

[a] Maintained beds are licensed beds that are staffed.

B. Types of Reported Events

The breakdown of reported events by event type for 2005 is illustrated in Figure 2. The majority of events fall into care management (38%; this includes, for example, pressure ulcers) and environmental (35%; this includes, for example, falls) events. These two general categories account for 73% of all submitted event reports.

Figure 2
Frequency of Event Reports by Event Category

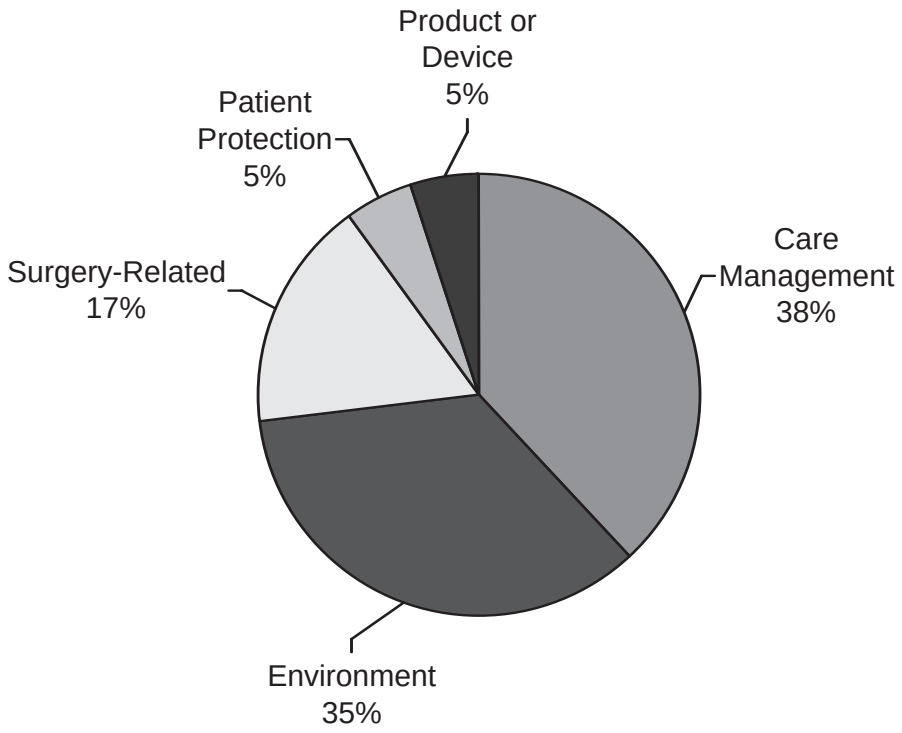


Figure 3 further breaks these categories down into more specific areas in which errors have been reported. Falls and pressure ulcers are the most commonly reported events, accounting for 54% of all submitted event reports. The high frequency of reported falls and pressure ulcers may be related to the prevalence of older adults within the general hospital population. These patients tend to be frail and have more chronic illnesses associated with an increased risk of falls and pressure ulcers.[4,5] Nationally, patients over 65 years of age represent 38% of all inpatient hospitalizations.[6] In the future, the Patient Safety Initiative will be refining the criteria for reportable pressure ulcer events to exclude those that are directly related to the patient's underlying disease and focus on those that are more related to their care in the hospital and are preventable.

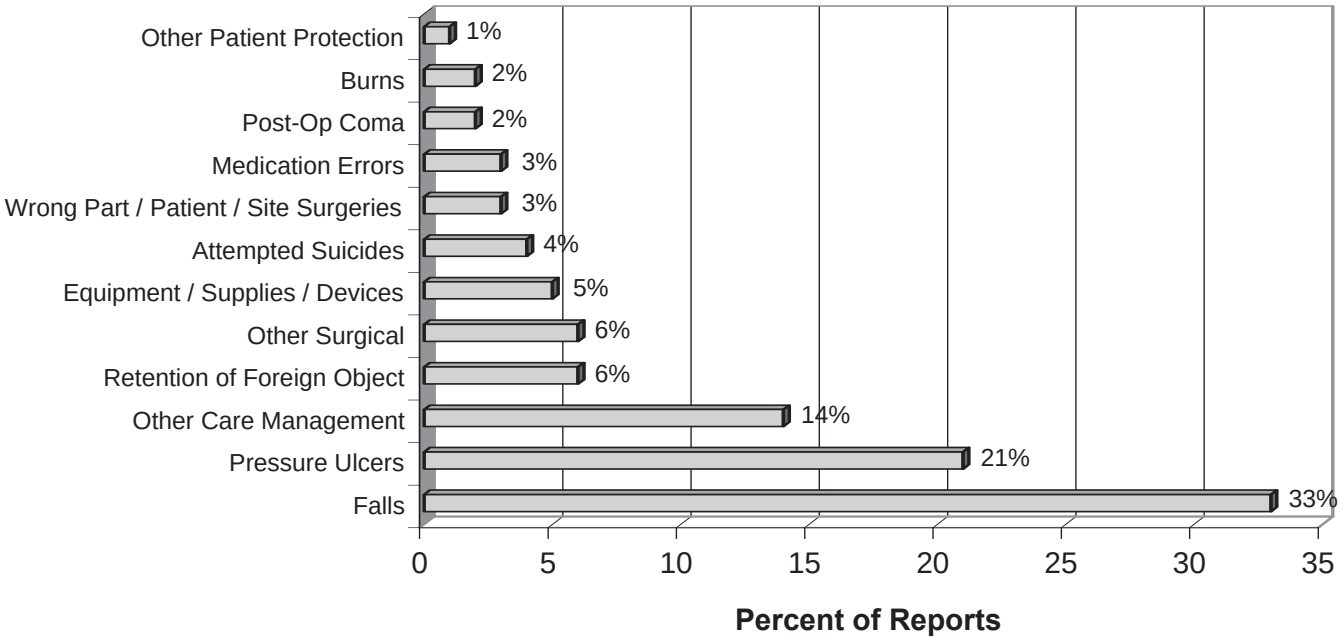
[4] American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *J Am Geriatri Soc.* 2001;49:664–672.

[5] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Intern Med.* 2001;135(8 Part 2):744-751.

[6] Kozak LJ, Lees KA, DeFrances CJ. National Hospital Discharge Survey: 2003 Annual Summary with Detailed Diagnosis and Procedure Data. Vital and Health Statistics 13 (160). Hyattsville, MD: National Center for Health Statistics; 2006.

Other major groups of reported events include "other care management" (14%; this includes, for example, errors associated with imaging studies) and four sub-categories of surgical errors (totaling 17%). Of the reported surgical errors, retention of foreign object (6%) was the most frequently reported event. Equipment failures (5%; such as broken surgical instruments), attempted suicides (4%), medication errors (3%), burns (2%) and other patient protection events (1%) comprised the remainder of the submitted event reports. Specific issues concerning falls, pressure ulcers, surgical errors, imaging studies, equipment failures, and medication errors are further explored later in this report.

Figure 3
Frequency of Event Reports by Event Subcategory



C. Patient Characteristics

Table 2 presents the demographic characteristics of patients involved in the 376 reported serious preventable adverse events and comparable New Jersey patient admissions. The average patient involved in a preventable event is female, white non-Hispanic, 66 years of age, and had been admitted 17 days prior to the event. These characteristics differ somewhat from the general population of New Jersey hospital patients where the average patient is female, white non-Hispanic, 49 years of age with a total hospital stay of five days (see Table 2).

Most of the events reported to the Patient Safety Initiative involve older patients and those with long hospital stays prior to the error. State efforts in New York and Pennsylvania and national research studies have reported similar findings.[7,8,9] The New Jersey findings are related to the relatively high percentage of falls and pressure ulcers reported. Older patients are more likely to fall or to develop pressure ulcers, since their stays tend to be longer and their conditions more medically complex.[10,11]

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[7] Duthie E, Favreau B, Ruperto A, Mannion J, Flink E, Leslie R. Quantitative and qualitative analysis of medication errors: the New York experience. In: *Advances in Patient Safety: Vol. 1.* Rockville, MD: Agency for Healthcare Research and Quality; 2005;131-144.

[8] Commonwealth of Pennsylvania, Patient Safety Authority. *2005 Annual Report.* Harrisburg, PA: Commonwealth of Pennsylvania, Patient Safety Authority; 2006.

[9] Cousins DD, Kotzin DA. MEDMARX 2002 Data Report: The Quest for Quality. Available at: http://www.onlinepressroom.net/uspharm. Accessed March 16, 2006.

[10] American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopedic Surgeons Panel on Falls Prevention. 2001.

[11] Bates-Jensen. 2001.

Table 2
Demographic Characteristics of Patients from Event Reports Compared to All NJ Hospital Patients

Patient Characteristic	Event Reports[a] Mean (SD) or % of Sample	All NJ Hospital Patients[b] Mean (SD) or % of Sample
Age (years)	**65.93 (19.95)**	**49.27 (27.89)**
Newborn	2%	11%
01 – 24	3%	9%
25 – 34	3%	11%
35 – 44	6%	11%
45 – 54	9%	11%
55 – 64	15%	11%
65 – 74	20%	12%
75 – 84	27%	15%
85 – 94	14%	8%
95+	1%	1%
Days since admission[c]	16.61 (62.92)	NA
Length of stay (days)	NA	5.12 (7.47)
Gender: female	51%	58%
Race/ethnicity: white non-Hispanic	78%	70%
Inpatient	88%	NA

[a] $N = 376$.
[b] Data drawn from Uniform Billing (UB) data 2004 and include maternity patients but not same day surgery patients, $N = 1{,}548{,}691$.
[c] Inpatient only. NA = not applicable.

D. Impact of Reported Events on Patients

Based on RCAs, hospitals provide information concerning the impact of reported events for patients. Due to the 45-day time lag between the initial report to the Department and the

submission of the RCA, time extensions granted to facilities for preparation of RCAs, and required resubmissions from some facilities, information on fewer events is available for analysis. Drawing on 354 submitted RCAs, the most frequent consequences of preventable adverse events on patients are longer hospital stays, additional patient monitoring, additional laboratory and/or diagnostic tests, and major surgery (see Table 3). A moderate percentage of patients also experienced temporary to permanent physical or mental impairment.

Table 3
Impact of Preventable Adverse Events on Patients[a]

Impact/Outcome	No. of Patients	Percent of Total Events[b]
Increased length of stay	130	37%
Additional patient monitoring	129	36%
Additional laboratory and/or diagnostic testing	102	29%
Major surgery	98	28%
Physical and/or mental impairment	77	22%
Death	57	16%
Transfer to more intensive level of care	46	13%
Minor surgery	45	13%
Hospital admission	21	6%
Loss of bodily function	16	5%
System or process delay	12	3%
Other	53	15%

[a] Data are drawn from 354 submitted RCAs. Impacts/outcomes with ≤10 patients are not shown.
[b] Events do not total 100% since events generally result in more than one patient impact/outcome.

E. Identified Causes and Contributing Factors

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 five top causes of system failure reported by New Jersey hospitals can be generally grouped into communication problems and inconsistencies in staff training and performance (see Table 4).

Table 4
Identified Root Causes of Adverse Preventable Events[a]

Root Cause	No. of Patients	Percent of Total Events[b]
Communication among staff members	212	60%
Care planning process	138	39%
Physical assessment of patient	127	36%
Staff orientation and training	125	35%
Patient observation procedures	100	28%
Communication with patient/family	60	17%
Availability of information	57	16%
Equipment maintenance and management	54	15%
Physical environment	49	14%
Behavioral assessment process	29	8%
Staff competence/credentialing	29	8%
Supervision of staff	22	6%
Adequacy of technical support	13	4%
Patient identification process	11	3%
Staffing level	10	3%
Control of medications	5	1%
Security systems and processes	5	1%
Labeling of medications	4	1%
Other	69	19%

[a] Data are drawn from 354 submitted RCAs.
[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

The incidence of falls among hospitalized adults is estimated to be between 2.3 to 7 falls per 1,000 patient-days.[12] Of those who fall, 20% to 30% suffer moderate to severe injuries, such as hip fractures or head traumas that reduce mobility and limit independence.[13] Risk factors for falling include weakness, poor cognitive status, and being on medications that contribute to somnolence, confusion, and increased urination and/or bowel movements. Many falls that occur each year in hospitals are the result of patients falling while attempting to get out of bed, or while patients are ambulating without assistance, frequently to use the bathroom or bedside commode.[14] The lack of assistance for patients at high risk of falling may be due to inadequate patient screening for elevated fall potential when patients are moved among different hospital units during the course of their stay, or when their medications are changed. Also, it appears that ambulatory aids (e.g., walkers) are not consistently provided, even when a fall risk has been identified.

Falls are the most frequently reported event submitted to the Patient Safety Initiative, constituting 33% of all reported events. An analysis of falls by location indicates that the majority of falls occurred in the patient's room (81%; see Table 5). Although lower in number, 7% of falls occurred in a hallway or common area and 6% of falls occurred in the emergency department. Older patients appear to be especially prone to injury from falls (see Table 6); of the ten falls that led to patient death, all involved patients 65 years of age and older.

[12] Hitcho EB, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting. *J Gen Intern Med.* 2004;19:732-739.
[13] Ash KL, MacLeod P, Clark LA. Case control study of falls in the hospital setting. *J Gerontol Nurs.* 1998;24:7-15.
[14] Hitcho et al. 2004.

Table 5
Number and Percent of Falls by Location[a]

Location of Fall	No. of Falls	Percent of Total Falls
Patient room	101	81%
Hallway or other common area	9	7%
Emergency department	8	6%
Radiology	1	1%
In transit	1	1%
Neonatal Intensive Care Unit (NICU)	1	1%
Other	4	3%

[a] Includes both inpatient and outpatient falls. $n = 125$.

Table 6
Falls by Patient Characteristic[a]

Patient Characteristic	No. of Patients	Mean (SD) or Percent of Sample
Age (years)	-	77.10 (12.80)
Days since admission[b]	-	5.22 (6.45)
Gender: female	66	53%
Race/ethnicity: white non-Hispanic	111	89%

[a] $n = 125$.
[b] Inpatient only.

An analysis of the impact that falls have on patients reveals that, in general, increased length of stay, major surgery, physical and/or mental impairment, and additional laboratory and/or diagnostic testing were most likely to result from the injury sustained from a fall (see Table 7).

Table 7
Impact of Falls on Patients[a]

Impact/Outcome	No. of Patients	Percent of Total Falls[b]
Increased length of stay	70	59%
Major surgery	62	52%
Physical and/or mental impairment	51	43%
Additional laboratory and/or diagnostic testing	44	37%
Additional patient monitoring	28	24%
Transfer to more intensive level of care	16	13%
Death	10	8%
Minor surgery	8	7%
Loss of bodily function	6	5%
Other	20	17%

[a] Data are drawn from 119 submitted RCAs. Impacts/outcomes with ≤2 patients are not shown.
[b] Events do not total 100% since events generally result in more than one patient impact/outcome.

Causes and Preventive Strategies for Hospital Falls

In most of the fall events analyzed, hospitals identified communication, care procedures (patient observation, care planning process), and staff orientation and training as the major causes for falls (see Table 8). The findings with respect to staff training are in line with several research studies that have demonstrated the importance of staff education in decreasing the occurrence of falls in hospitals.[15] Proper assessment of the patient upon admission, at regular intervals, and immediately following a fall have all been shown to be effective in identifying the risk factors for future falls in hospitals.[16,17]

[15] Hitcho et al. 2004.
[16] Perell KL, Nelson A, Goldman RL, Luther SL, Prieto-Lewis N, Rubinstein LZ. Fall risk assessment measures: an analytic review. *J Gerontol.* 2001;56A(12):M761-766.
[17] Rubenstein LZ, Robbins AS, Josephson KR, Schulman BL, Osterweil D. The value of assessing falls in an elderly population. A randomized clinical trial. *Ann Intern Med.* 1990;113(4):308-316.

Table 8
Identified Root Causes of Patient Falls[a]

Root Cause	No. of Patients	Percent of Total Falls[b]
Communication among staff members	63	53%
Patient observation procedures	52	44%
Care planning process	50	42%
Staff orientation and training	50	42%
Physical assessment of patient	38	32%
Communication with patient/family	35	29%
Physical environment	24	20%
Behavioral assessment process	13	11%
Staff competence/credentialing	13	11%
Availability of information	13	11%
Equipment maintenance and management	13	11%
Staffing levels	5	4%
Other	20	17%

[a] Data are drawn from 119 submitted RCAs. Causes with $\leq$2 patients are not shown.
[b] Events total more than 100% since events generally result in more than one root cause.

Hip pad protectors, environmental modifications, bed alarms, assisted toileting schedules, and increasing the availability of walkers and/or other assistive devices have all been suggested as possible preventive measures in reducing the prevalence of falls resulting in hip fractures in frail elderly and other high-risk patients.[18]

[18] Hitcho et al. 2004.

2. Pressure Ulcers

A pressure ulcer (bedsore, pressure sore, decubitus ulcer) 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.[19]

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. Future reporting criteria will exclude pressure ulcers that result from the patient's underlying vascular disease. Next to falls, pressure ulcers are the second most frequently reported serious adverse preventable event, constituting 21% of all reported events (see Figure 3).

The average patient developing a Stage III or Stage IV pressure ulcer is male, white non-Hispanic, 69 years of age, and had been admitted for 34 days prior to the event (see Table 9). This is in marked contrast to the average hospital patient who is female, white non-Hispanic, 49 years of age, and who had a total hospital stay of five days (see Table 2).

The typical risk factors for developing pressure ulcers, adapted from the Braden Scale for Predicting Pressure Sore Risk[20], 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.

[19] The Merck Manual of Diagnosis and Therapy. Available at: http://www.merck.com. Accessed March 22, 2006.
[20] Ayello EA, Braden B. How and why to do a pressure ulcer risk assessment. *Adv Skin Wound Care.* 2002;15(3):125-132.

Table 9
Pressure Ulcers by Patient Characteristic[a]

Patient Characteristic	No. of Patients	Mean (SD) or Percent of Sample
Age (years)	-	68.77 (12.36)
Days since admission	-	34.16 (29.37)
Gender: male	42	55%
Race/ethnicity: white non-Hispanic	60	78%

[a] $n = 77$. Inpatient only.

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

Table 10
Impact of Pressure Ulcers on Patients[a]

Impact/Outcome	No. of Patients	Percent of Total Pressure Ulcers[b]
Additional patient monitoring	58	79%
Increased length of stay	22	30%
Minor surgery	20	27%
Additional laboratory and/or diagnostic testing	13	18%
Physical and/or mental impairment	10	14%
Major surgery	5	7%
System or process delay	4	5%
Other	6	8%

[a] Data are drawn from 73 submitted RCAs. Impacts/outcomes with ≤ 2 patients are not shown.

[b] Events do not total 100% since events generally result in more than one patient impact/outcome.

Causes of Hospital-Acquired Pressure Ulcers

Similar to the causes of patient falls, care procedures (i.e., care planning process, patient assessment and observation), staff communication, and staff orientation and training were the most frequently identified causes of the deterioration of skin integrity to a Stage III or Stage IV pressure ulcer (see Table 11). The use of air or gel mattresses, reducing bed elevation to prevent shearing forces, use of 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 the prevalence of hospital-acquired pressure ulcers.[21]

Table 11
Identified Root Causes of Pressure Ulcers[a]

Root Cause	No. of Patients	Percent of Total Pressure Ulcers[b]
Care planning process	55	75%
Communication among staff members	55	75%
Physical assessment of patient	48	66%
Staff orientation and training	28	38%
Patient observation procedures	19	26%
Availability of information	9	12%
Equipment maintenance and management	8	11%
Communication with patient/family	7	10%
Supervision of staff	7	10%
Physical environment	3	4%
Other	9	12%

[a] Data are drawn from 73 submitted RCAs. Causes with ≤2 patients are not shown.

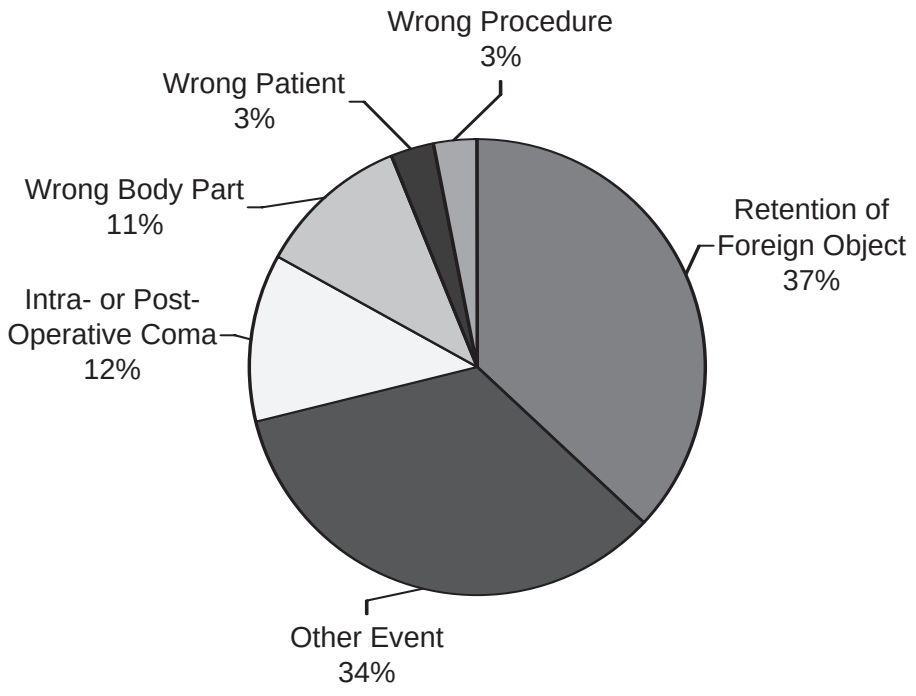
[b] Events do not total 100% since events generally have more than one root cause.

[21] 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.

3. Surgical Events

The most commonly reported surgical events were retention of a foreign object (37%), other event (34%) and intra- or post-operative coma (12%; see Figure 4). The prevalence of retained foreign objects is particularly noteworthy, as it has been identified by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as a target patient safety indicator for all JCAHO-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.

Figure 4
Frequency of Surgical Events by Subcategory (*n* = 65)



The average person who experienced a surgical event was female, white non-Hispanic, 59 years of age and had been admitted to the hospital for 16 days prior to the event (see 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 testing, increased length of stay, minor surgery, additional monitoring and hospital admission (see Table 13). Of note is the greater length of stay in the hospital prior to the surgical event (16 days) and the incidence of patient death (15% of cases). Surgical deaths were due, in several cases, to failures in the pre-operative clearance process or lapses in the intra- or post-operative monitoring processes; for example, an unrecognized post-operative hemorrhage. In response, some hospitals have initiated changes in their surgical clearance and monitoring processes.

Table 12
Surgical Events by Patient Characteristic[a]

Patient Characteristic	No. of Patients	Mean (SD) or Percent of Sample
Age (years)	-	58.85 (17.67)
Days since admission	-	16.26 (43.64)
Gender: female	33	51%
Race/ethnicity: white non-Hispanic	41	63%

[a] $n = 65$.

Table 13
Impact of Surgical Events on Patients[a]

Impact/Outcome	No. of Patients	Percent of Total Surgical Events[b]
Major surgery	22	37%
Additional laboratory and/or diagnostic testing	21	35%
Increased length of stay	19	32%
Minor surgery	15	25%
Additional patient monitoring	14	23%
Hospital admission	13	22%
Death	9	15%
Transfer to more intensive level of care	9	15%
Physical or mental impairment	7	12%
Loss of bodily function	4	7%
Loss of sensory function	4	7%
Other	9	15%

[a] Data are drawn from 60 submitted RCAs.
[b] Events do not total 100% since events generally result in more than one patient impact/outcome.

Causes of Surgical Events

Communication among staff, the availability of information (from the medical record, patient, or family member), physical assessment of the patient and equipment maintenance and management were the most frequently reported causes of surgical errors identified by hospitals (see Table 14).

Table 14
Identified Root Causes of Surgical Events[a]

Root Cause	No. of Patients	Percent of Total Surgical Events[b]
Communication among staff members	34	57%
Availability of information	16	27%
Physical assessment of patient	16	27%
Equipment maintenance and management	13	22%
Staff orientation and training	10	17%
Care planning process	7	12%
Adequacy of technical support	5	8%
Communication with patient/family	4	7%
Patient identification process	3	5%
Supervision of staff	3	5%
Other	20	33%

[a] Data are drawn from 60 submitted RCAs. Causes with ≤2 patients are not shown.
[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.

Diagnostic Imaging

Of the 54 reported preventable adverse events under the category of "other care management event," 11% (n = 6) are attributable to diagnostic imaging errors. Most of these events involved patients whose disease or condition was not identified on the initial reading of an imaging study. For example, patient death occurred in two cases due to the failure to identify free air under the diaphragm. In both cases, the imaging study was misread by a non-radiologist.

Other errors occurred when diagnostic studies were ordered, but either no study or the wrong study was performed or the results were not communicated quickly to the treating physician. As a corrective measure, some hospitals have instituted policies that require a radiologist or senior radiology resident to interpret imaging studies and for the critical results to be directly communicated to the treating physician.

Equipment Failures

Equipment/device failures were identified in 5% of all reported serious preventable adverse events. These events include items that broke during surgical procedures (e.g., trochars and fiber optic laser tips), the misfiring of a laser wand while resting on a patient's abdomen, and the failure of alert/monitoring devices and IV pumps. Corrective measures used by hospitals include replacement of the defective laser power unit and the purchase of laser wand safety holsters, removal of the volume controls on telemetry monitors, and the use of a roller-clamp to ensure that medication delivered via digital IV infusion pumps was halted after the "stop" button was engaged.

Medication Errors

Few pharmacological errors (3%; 12 events) have been reported to the Patient Safety Initiative. Some studies have estimated medication error rates as high as one medication error per hospital patient per day.[22] The difference is likely due to the vast majority of medication errors being either near misses or resulting in minimal patient impact. These error events do not meet the New Jersey standard for mandatory reporting of serious preventable adverse events. Of the medication errors reported to the Patient Safety Initiative, the majority (58%) involved administering the wrong dose to a patient.

Some medication errors were related to the use of computerized physician order entry (CPOE) systems that are intended to reduce such errors. In several cases, the hospital found that their CPOE system allowed staff to work around the programmed safeguards and order medication

[22] Kohn et al. 2000.

using a non-approved administration route. In response, some hospitals have implemented changes in their CPOE system software to generate alerts for medications exceeding standard dosages and to restrict the administration route for certain high-risk medications (e.g., Vistaril).

The February 2006 edition of the *Patient Safety Initiative Updates* newsletter provided facilities with strategies to reduce medication errors drawn from the action plans of submitted serious preventable adverse event reports (www.state.nj.us/health/hcqo/ps/newsletter.shtml). The New Jersey reporting system, consistent with other research findings,[23] found that medication errors typically occurred at the point of administration as well as during the process of prescribing, transcription, dispensing and monitoring.

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. For example, communication among staff members was selected as the most frequent cause for total events, falls, pressure ulcers and surgical errors; security systems and processes were selected only for total events and surgical errors. Although the selections and rankings are similar among the specific event types, there is enough variation to detect selection patterns. For example, preventable falls were most frequently the result of failures in communication among staff members, patient observation procedures, the care planning process, and staff orientation and training, while surgical errors were most frequently the result of failures in the behavioral assessment process, communication among staff members and "other," such as the patient's medical condition.

[23] 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.

Table 15
Ranking of Root Causes by Frequency for Total Events, Falls, Pressure Ulcers and Surgical Events

Root Cause	Rank[a]			
	Total Events[b]	Falls[c]	Pressure Ulcers[d]	Surgical Events[e]
Behavioral assessment process	11.5	10.5	13	
Patient identification process	15	16	13	10.5
Care planning process	2	3.5	1.5	7
Staff orientation and training	4	3.5	4	6
Supervision of staff	13	14	9.5	10.5
Communication among staff members	1	1	1.5	1
Adequacy of technical support	14	15	15	8
Physical environment	10	7	11	12.5
Control of medications	17.5			
Physical assessment process	3	5	3	3.5
Patient observation procedures	5	2	5	12.5
Staffing levels	16	13		14.5
Staff competence/credentialing	11.5	10.5	13	
Communication with patient/family	7	6	9.5	9
Availability of information	8	10.5	6.5	3.5
Equipment maintenance/management	9	10.5	8	5
Security systems and processes	17.5			14.5
Labeling of medications	19			
Other	6	8	6.5	2

[a] A mean rank is assigned if two or more data values are equal.
[b] Data are drawn from 354 submitted RCAs.
[c] $n = 119$.
[d] $n = 73$.
[e] $n = 60$.

IV. Conclusion

This report describes the results of the New Jersey Patient Safety Serious Preventable Adverse Event Reporting System during its first year of operation. As such, the data trends and their interpretation may vary over time as additional data are received and analyzed throughout the life of the project. The analyses and their associated inferences contained herein are thus preliminary and reflect the experiences over the initial eleven months of system operation.

Due to the combination of human factors, high-tech equipment and sophisticated, often dangerous medications and procedures, hospital patients are at risk of preventable harm ranging from minor, temporary harm to death. Although it is impossible to eliminate all unanticipated adverse events, by examining the process by which health care is delivered and developing protocols that account for vulnerabilities in the various care processes, the likelihood of future adverse events can be reduced. Increased awareness of these system vulnerabilities so that corrective actions can be taken is the fundamental goal of the Patient Safety Act. The Department encourages this process by reviewing individual RCAs to assure that hospitals are striving to find the underlying as well as the proximate causes of errors. Additionally, through training collaboratives, newsletters, and more comprehensive reports like this one, the Department shares with the whole hospital industry, without naming names, information on events reported and effective strategies to prevent reoccurrence.

Appendix

Classification of Serious Reportable Adverse Events[1]

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. Excludes progression from Stage II to Stage III if Stage II was recognized upon admission;
7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility;
8. Other patient 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.

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

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 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.

Patient Safety Initiative
2005 Summary Report

C0951