

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

Patient Safety Reporting System 2009 Summary Report



April 2011



Chris Christie, Governor
Kim Guadagno, Lt. Governor



Mary E. O'Dowd, M.P.H.
Acting Commissioner

Patient Safety Reporting System

2009 Summary Report

Office of Health Care Quality Assessment

Report Preparation Team

Cynthia M. Kirchner, MPH, Senior Policy Advisor

Emmanuel Noggoh, Director

Margaret E Lumia, PhD, MPH, Research Scientist

Patient Safety Reporting System Team

Mary Noble, MD, MPH, Clinical Director

Margaret E Lumia, PhD, MPH, Research Scientist

Sara Day, RN, BSN, CSM, Supervising Health Care Evaluator

Adan Olmeda, Administrative Support

For further information contact:

Patient Safety Reporting System

Office of Policy and Strategic Planning

Health Care Quality Assessment

New Jersey Department of Health and Senior Services

Post Office Box 360

240 West State Street

Trenton, NJ 08625-0360

Phone: (609) 633-7759

Fax: (609) 984-7707

Website: www.NJ.gov/health/ps

Table of Contents

Executive Summary..... 1

 Sharing Knowledge 2

 Enhancing the Reporting System 2

How to Use This Report 4

Reporting Patterns 7

Focusing on Specific Events 12

 Surgery-Related Events..... 12

 Wrong Site/Wrong Patient/Wrong Procedure 12

 Intra- or Post-Operative Coma or Death 16

 Product or Device Related Events..... 18

 Fall Events 19

Overall Event Reporting..... 24

 Impact of Reported Events on Patients 26

 Events Resulting in Death 27

 Root Cause Analysis 28

Specialty Hospitals 30

 Overall Reporting Patterns 30

 Types of Events Reported 30

 Impact of Reported Events on Patients 31

 Root Cause Analysis 31

Ambulatory Surgery Centers..... 33

 Overall Reporting Patterns 33

 Types of Events Reported 33

 Impact of Reported Events on Patients 33

 Root Cause Analysis 33

Conclusion..... 36

Works Cited..... 38

Division of Mental Health Services 39

 Corrective Actions:..... 39

 Overall Reporting Patterns 39

Focus on Specific Events 40

 Falls 40

 Suicide / Attempted Suicide 40

 Foreign Body Ingestion with Major Injury 41

Appendix I: Classification of Serious Reportable Adverse Events 43

Appendix II: Patient Safety Reporting System Newsletters..... 47



Table of Figures

Figure 1 Average Number of Events Reported Over Time 8
Figure 2 Event Reports per 1,000 Patient Days 9
Figure 3 Frequency of Events Reports for Each Hospital (2005-2009) 10
Figure 4 Reportable vs. Events Not Accepted..... 11
Figure 5 Wrong Site/Wrong Patient/Wrong Procedure 13
Figure 6 Location of Wrong Site/Wrong Patient/Wrong Procedure (2009)..... 14
Figure 7 Patient Impact: Wrong Site/Wrong Patient/Wrong Procedure (2009)..... 14
Figure 8 Patient Impacts 16
Figure 9 Product or Device Related Events (2005-2009) 18
Figure 10 Number of Reportable Falls Events (2005-2009)..... 19
Figure 11 Falls by Age Group (2009) 20
Figure 12 Falls by Location 21
Figure 13 Percentage of Reports by Event Category (2005-2009) 24
Figure 14 Percentage of Reports by Event Subcategory (2005-2009)..... 25
Figure 15 Deaths by Subcategory (2009) 27
Figure 16 Frequency of Reported Events by Category 31

Table of Tables

Table 1 Reporting Patterns (2005-2009) 7
Table 2 Event Reports Based on Hospital Maintained Beds (2009) 10
Table 3 Impact of Events on Patients (2009) 26
Table 4 Root Causes of Care Management “other” Events Resulting in Death (2009).... 28
Table 5 Root Causes (2009) 29
Table 6 Events Reported by Facility Type (2009)..... 30
Table 7 Impact of Events on Patients (2009) 32
Table 8 Root Causes (2009) 32
Table 9 Events Reported by Ambulatory Surgery Centers (2009) 34
Table 10 Impact of Events on Patients (2009) 34
Table 11 Root Causes (2009) 35

Executive Summary

The New Jersey Patient Safety Act (P.L. 2004, c.9), enacted in 2004, continues to foster broad policy and operational changes for patient safety in New Jersey. The Act was based on the Institute of Medicine's principles which support examining the systems for providing care in order to improve patient safety.⁽¹⁾ The entire Patient Safety Act is directed toward that goal and emphasizes the need for health care facilities to make safe care a priority through evaluating and improving their own operations.

General acute care hospitals began reporting February 1, 2005; psychiatric, special and comprehensive rehabilitation hospitals began reporting April 1, 2008; and NJ Licensed ambulatory surgery centers began reporting October 1, 2008 to the Department of Health and Senior Services (The Department), Patient Safety Reporting System (PSRS).

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

Under the New Jersey Patient Safety Act, all licensed health care facilities are required to develop a patient safety plan, including forming of a patient safety committee. The plan includes a process for a multidisciplinary team to conduct analyses of serious preventable

adverse events and near misses. Deliberations are confidential. Health care facilities must submit reports of serious preventable adverse events. These are 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 and must be reported to the Department within five (5) business days after discovery. Facilities are then required to submit a root cause analysis (RCA) for each reported event within 45 calendar days of submitting the event as described in the Department's guidelines.

Information in both the mandatory and voluntary reporting systems is not subject to discoverability in any civil, criminal or administrative action and is not considered a public record.

Under the mandatory reporting law, a total of 455 reportable events were discovered in 2009. The following list includes some of the results for the general acute care hospitals as reported in 2009:

- The total number of events decreased by 15 percent from the previous year's when 533 events were reported.
- A total of 75 patients died as a result of a serious preventable adverse event.
- Falls decreased 21 percent from 2008, but remain the biggest subcategory of reported events.



- Pressure Ulcers and Care Management “Other” continue to be the next largest subcategories after falls.
- There was an increase in the number of reportable device malfunctions, wrong patient/wrong site/wrong procedure events and suicide/attempted suicide in 2009.
- The number of retained foreign objects (RFOs) remained roughly constant from 2008 to 2009, 27 to 25 RFOs.

Since the general acute care hospitals began reporting in February 2005, a total of 2,270 reportable events have been submitted to PSRS. The number of reported events is not viewed as an absolute measure of hospital quality or the objective of the patient safety reporting system. Rather, reviewing and understanding the underlying causes of these events and then implementing and evaluating system processes and policies to prevent these occurrences and to provide a safe environment is the goal. Education and sharing experiences is also a major component of patient safety.

Sharing Knowledge

The frequent reoccurrence of certain types of events and discoveries of situations that can result in serious preventable adverse events sometimes requires immediate communication to the health care facilities through the release of newsletters, alerts, and preventative strategies. The following is a list of these publications developed and disseminated in 2009:

- A refresher on the mandatory reporting system was provided in the March 2009 newsletter: *Patient Safety Mandatory Reporting System*. This newsletter gave a brief overview of the requirements of the law and provided examples of reportable and non-reportable events (Appendix II)
- A health care facility alerted PSRS to a situation discovered during a routine medical equipment evaluation that could occur at other health care facilities. This led to the June 2009 Alert: *Automatic Endoscope Reprocessors*. This alert described a situation where an automatic endoscope reprocessor was improperly set-up by the manufacturer with the wrong disinfection time potentially affecting 500 patients (Appendix II).
- A number of reported cases of retained foreign objects that occurred during either vaginal deliveries or caesarian sections led to the release of the September 2009 newsletter: *Retained Foreign Objects During Vaginal Deliveries or Caesarian Sections*. This newsletter alerted facilities that there is a need for visual/digital inspections and counting procedures in the labor and delivery departments as well as the surgery department (Appendix II).

Enhancing the Reporting System

The development of an on-line reporting system for health care facilities to submit adverse events is almost complete. In 2010 the final development and testing of the new

system was conducted, implementation and training will begin in 2011. This new system will streamline the process, make reporting of the event detail, root causes, corrective actions and monitoring plans more consistent across facilities and will allow for the collection of more detailed information on each event via a web-based reporting system.



How to Use This Report

The Patient Safety Reporting System started collecting data from general acute care hospitals in February 2005 and continues this process to date. The compilation of this data collection from 2005-2009 is documented in the *Patient Safety Reporting System: 2009 Summary Report*. This data is used to look at trends that are occurring in the area of patient safety. This report is one component of the Department's commitment to supporting quality through collecting and analyzing information on health care quality and making this information available to the public. It is designed to provide an overview of patient safety reporting and activities. Other Department projects which focus on health care quality are listed on page 5 and available online at <http://nj.gov/health/healthcarequality/index.shtml>.

One of the difficulties in reducing serious preventable adverse events is overcoming the "culture of blame" prevalent in the health care system. The requirement to report preventable adverse events is not designed to identify and punish the involved staff. Based on the IOM strategy and the New Jersey Patient Safety Act, the objective is to assist facilities improve their systems for providing care. With the

relatively low occurrence of serious preventable adverse events, it is important to recognize that the number of reports from New Jersey facilities may differ from year to year for a variety of reasons. A higher number of reported events does not necessarily mean that a facility is less safe and a lower number does not necessarily mean the facility is safer. In some cases, the number of events may be higher at facilities that are especially vigilant about identifying and reporting events.

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

Consumers can use this report to identify situations of interest and ask their hospital or health care provider about what is being done to prevent these types of events from occurring. Consumers can also consult the New Jersey Hospital Performance Report to compare individual hospitals on their quality of care measures.

Resources for providers on the topic of patient safety include the following web sites:

- Institute for Healthcare Improvement (IHI):
<http://www.ihl.org/ihl>
- National Center for Patient Safety (NCPS):
<http://www.patientsafety.gov/tools/html>
- Agency for Healthcare Research and Quality Patient Safety Network (PSNet): <http://psnet.ahrq.gov>
- AHRQ Morbidity and Mortality Rounds on the Web:
<http://webmm.ahrq.gov/>
- Joint Commission:
<http://www.jointcommission.org/>

Resources for consumers on the topic of patient safety include the following web sites:

- New Jersey Hospital Performance Report: <http://nj.gov/health/hpr>
- Patient Safety Information for Consumers:
<http://web.doh.state.nj.us/hpr/patientsafety.shtml>
- 20 Tips to Help Prevent Medical Errors (patient fact sheet):
<http://www.ahrq.gov/consumer/20tips.htm>
- Hospital Patient Rights:
<http://web.doh.state.nj.us/hpr/patientrights.shtml>
- Consumer Information:
<http://web.doh.state.nj.us/hpr/resources.shtml>



New Jersey Health Care Quality Reporting and Assessment Initiatives

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

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

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

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

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

Bariatric Surgery: Examines trends and outcomes of bariatric surgery using hospital discharge data. Two reports released in 2005 and 2007 include basic statistics on the bariatric surgery population including gender distribution, age distribution, health insurance status, and selected outcomes. These reports are available at <http://nj.gov/health/healthcarequality/bariatric.shtml>.

Reporting Patterns

2009 was the fifth year of reporting serious preventable adverse events for New Jersey’s general acute care hospitals. Since inception, 2,270 reportable events have been collected from general acute care hospitals. In 2009, a total of 455 reportable events from general acute care hospitals were submitted to PSRS. This annual report provides an overview of the five years PSRS has been in operation. It also provides details of the 2009 reportable events and focuses on the most frequently reported event types from general acute care hospitals, specialty facilities and ambulatory surgery centers.

The following information is based on the serious preventable adverse events that occurred in general acute care hospitals, unless otherwise noted.

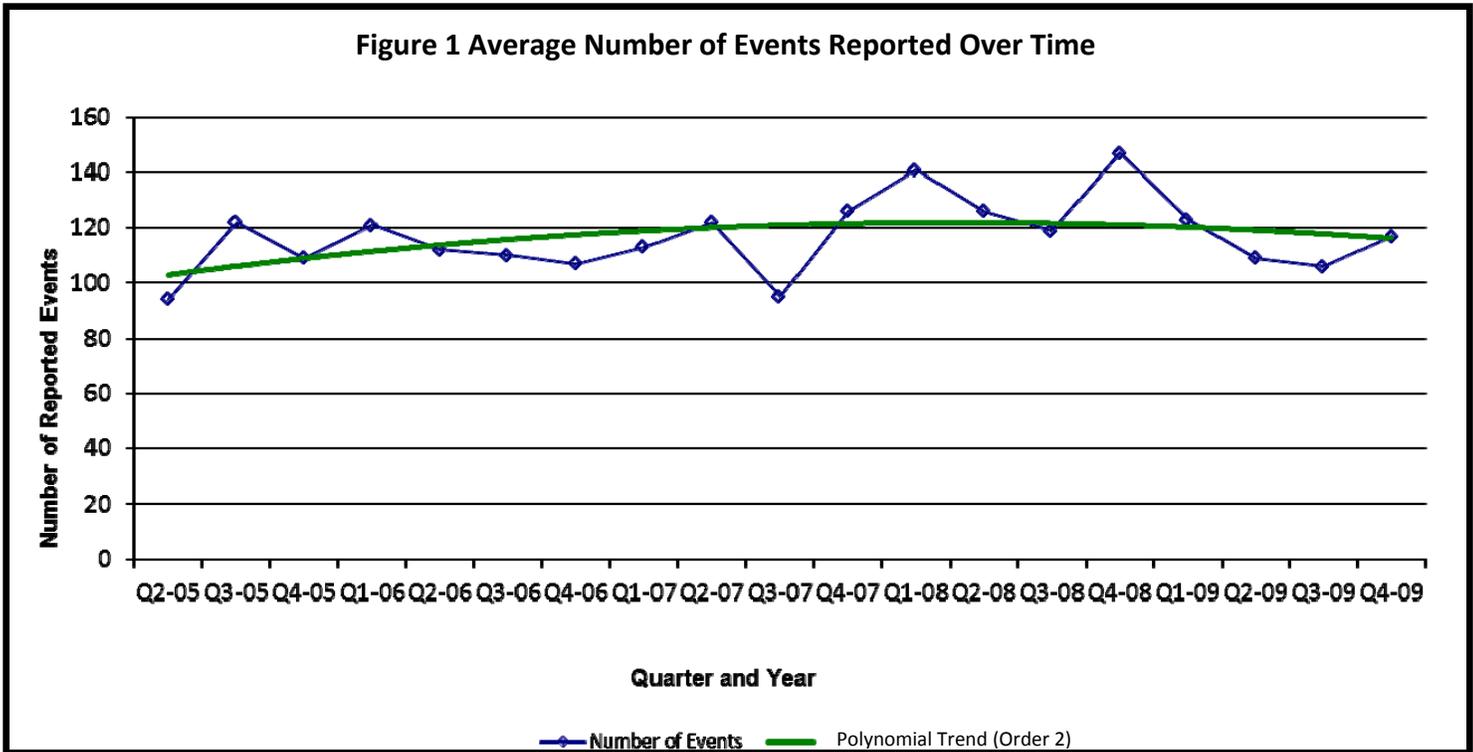
For the first time since the program began (2/2005), the number of serious preventable adverse events reported by general acute care hospitals has decreased. There was a 15 percent decrease in the number of reports in 2009 compared with 2008 (Table 1). However, four hospitals closed in 2009 and four hospitals did not report any events, which may have impacted the number of events reported.

Table 1 Reporting Patterns (2005-2009)^a

	2005 ^b	2006	2007	2008	2009
Total reported events	376	450	456	533	455
% of hospitals reporting	83%	88%	94%	95%	94%
Number of reporting hospitals	68	71	75	72	68
Reported events per 1,000 patient days	0.07	0.078	0.08	0.096	0.084
Average number of reports per hospital	4.6	5.6	5.7	7.0	6.3

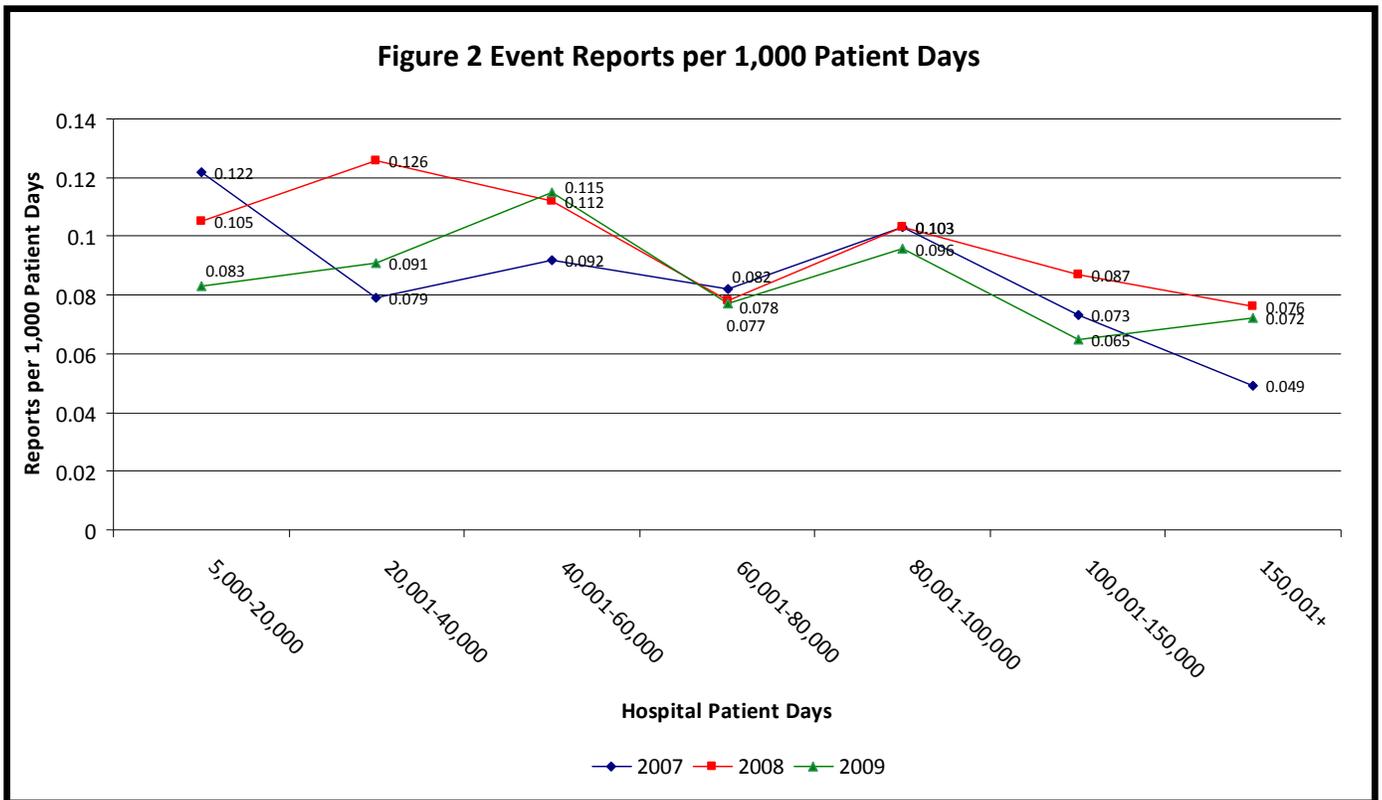
a: n=82 hospitals 2005, n=81 hospitals 2006, n=80 hospitals 2007, n=76 hospitals 2008 and n=72 hospitals 2009

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



The number of events reported per quarter varied over the last five years (Figure 1). The quarterly average of events is 114 or approximately 38 per month. The first quarter of 2005, which was the start of the program, is not included in the calculation, as it was not a complete quarter. In 2009, the month with the most reported events was January, with 49, and the lowest was February, with 28. The green trend line superimposed over the actual track of quarterly reports suggests that the volume of event reports stabilized between 2007 and 2008, but is now heading into a downward trend. This stabilization was expected. As hospitals become more aware of patient safety issues and implement measures to prevent these adverse events from occurring, the number of events reported each month should become more consistent. It will be interesting to see if the downward trend that appears

begin in 2009 continues into 2010. This new direction could be related to successful implementation of hospital policies and protocols affecting the outcome of patient care. Nonetheless, it is more likely that there is underreporting, as is evident by the four hospitals that did not submit event reports in 2009. Underreporting of serious preventable adverse events is an issue that every state with a patient safety program is experiencing. States, along with national groups such as the Agency for Healthcare Research and Quality (AHRQ) and the National Quality Forum (NQF), are working on ways to determine underreporting through developing national benchmarks. However, there are many issues and variables that make this a difficult task. The Department will continue to work with these national groups to facilitate developing national benchmarks.



During 2009, New Jersey’s general acute care hospitals had approximately 5.4 million patient days. Accounting for the volume of care provided by these general acute care hospitals, approximately 8.4 reportable events were submitted by hospitals per 100,000 total patient days. When looking at the number of reportable events submitted per 1,000 patient days, hospitals with patient volumes between 40,001 and 60,000 had the highest reporting rate. This has differed over the last three years. Previously, the lower patient volume hospitals had the highest reporting rate. The difference for 2009 could be due to the two hospitals in the lowest volume categories that did not submit any events, lowering the overall average. Consistently, the hospitals with the highest patient census have had the lowest reporting rate.

As stated in previous years, it would be expected that after adjusting for patient days there would be a similar number of events reported across all hospital sizes. However, as shown in Figure 2, the number of reportable events submitted varies by patient volume category with the largest hospitals having the lowest reporting rate.

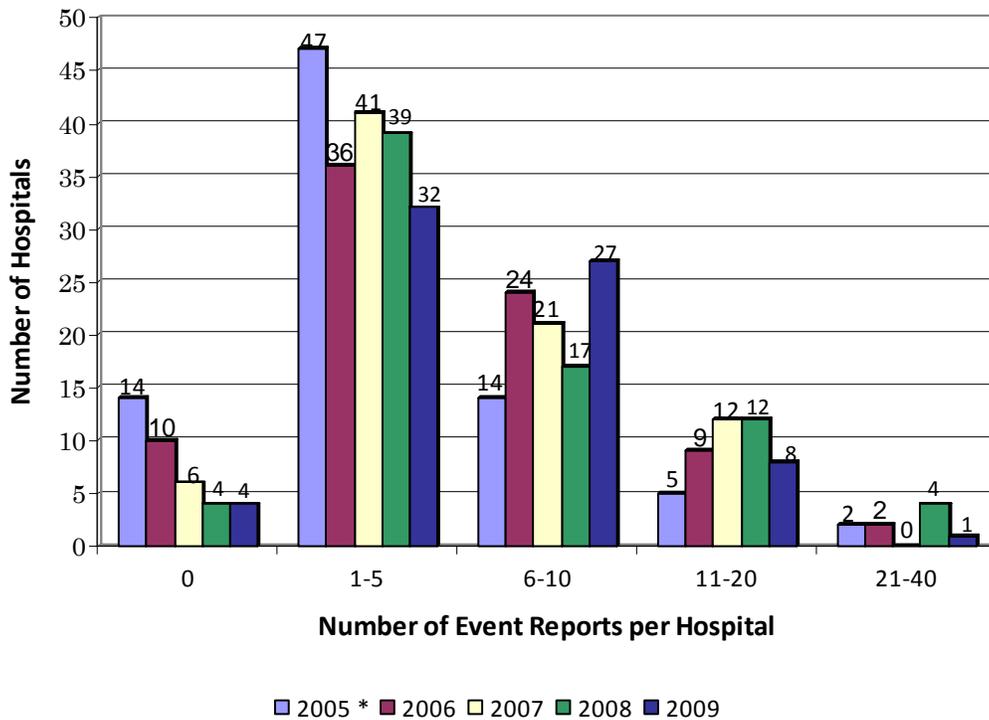
The reason for the low reporting may be related to differences in how serious preventable adverse events are identified and reported. Also, there may be a greater chance an event could ‘get lost’ in the system at a larger hospital. The Department continues to reach out to these under- and non-reporting facilities and follow-up with them to ensure an understanding of the reporting process.



Table 2 Event Reports Based on Hospital Maintained Beds (2009)

Maintained Beds	Number of Hospitals	Number of Reports	Percentage of Reports
>100	5	4	1%
101-200	20	74	16%
201-300	20	133	29%
301-400	14	98	22%
401-500	8	79	17%
501+	5	67	15%
Total	72	455	100%

Figure 3 Frequency of Events Reports for Each Hospital (2005-2009)



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

Not surprisingly, the 34 mid-sized hospitals, which include 50 percent of all hospital licensed bed capacity, accounted for 51 percent of all the reported events. The 13 large hospitals which include 33 percent of the total licensed beds had the next largest reporting percentage, 32, of all reported events (Table 2).

In 2009, 44 percent of all general acute care hospitals submitted between one and five reportable events. Thirty-eight percent submitted between six and ten events, an increase from 2008 (Figure 3).

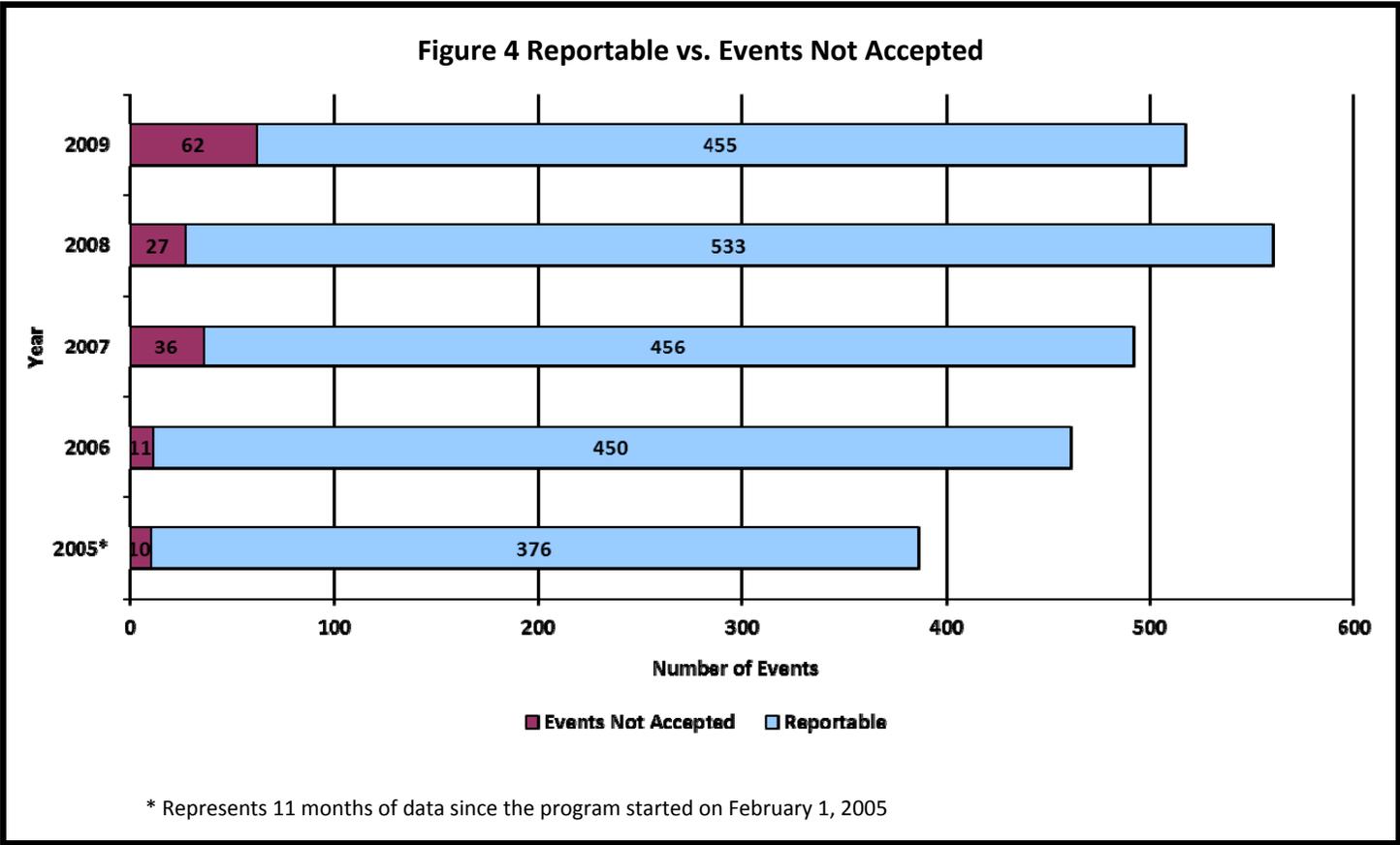


Figure 4 demonstrates the relationship between Reportable Events and Events not Accepted over the past five years. With the exception of 2009, Events Not Accepted represents less than 10 percent of the total number of events collected. There was a slight increase in Events not Accepted in 2009, but this number still only represents 12 percent of the total number of events. One of the reasons for the increase in the absolute number of Events Not Accepted is related to a change in the acceptance of less serious events as

related to falls. Previously, any injury still present after seven days or at discharge resulting from a fall was accepted as a reportable event. In 2008, to be more consistent with other states' patient safety programs and with NQF, falls resulting in long bone fractures, hip fractures, intracranial hemorrhage or injuries that severely limit basic life functions are being accepted as reportable events.



Focusing on Specific Events

Falls, pressure ulcers, care management “other” and suicides continue to be the four most commonly reported events. Previous annual summary reports and newsletters have focused on these types of events and provided recommendations on prevention.

This report will highlight the following specific event categories because of the large increase in the number of events reported in the following categories: surgery-related events, specifically wrong site/wrong patient/wrong procedure and intra- or post-operative coma or death. This report will also take a closer look at products or devices that were used or functioned other than intended and will then discuss falls, the most frequently reported event type.

Surgery-Related Events

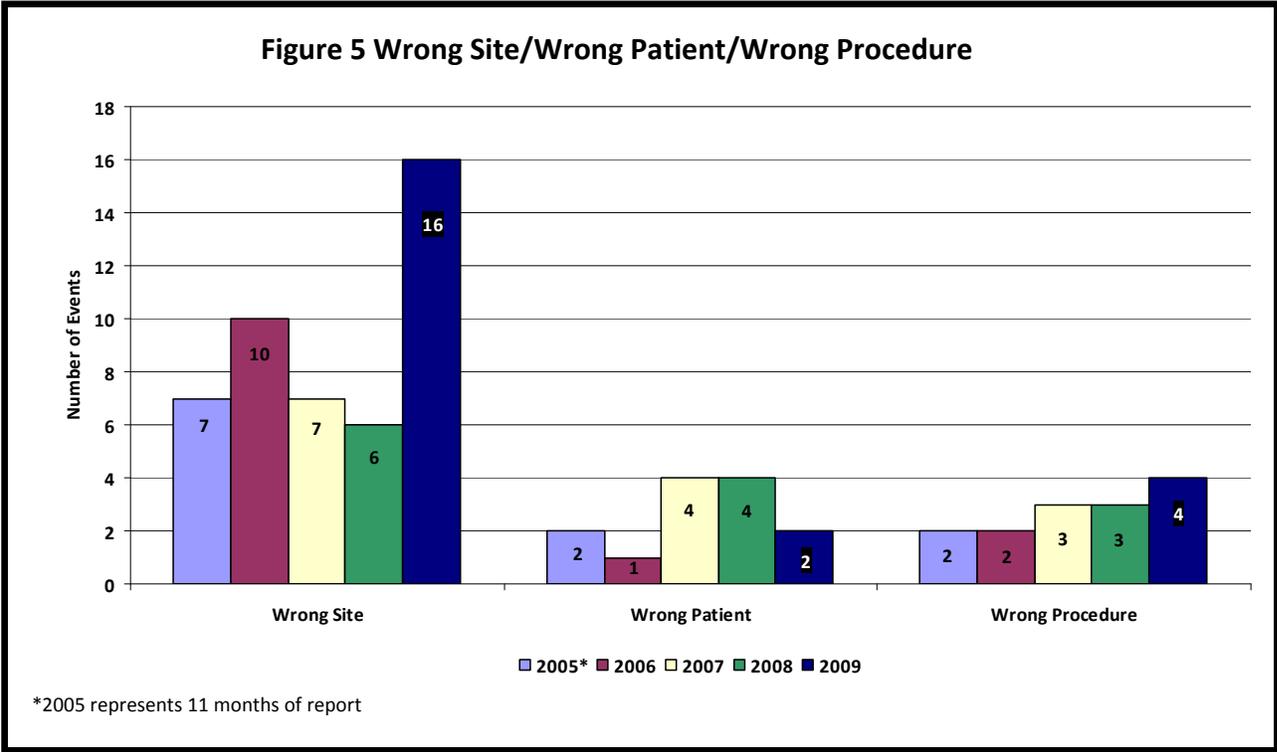
In 2009, general acute care hospitals reported an increase in the number of surgery related events, particularly intra- or post-operative coma or death

and wrong site/wrong patient/wrong procedure events. While these two subcategories individually make up less than 5% of the total reported events, there appears to be an increase in the number of incidents in these categories in 2009.

The average patient who experienced a surgery-related event in 2009 was a 54-year-old Caucasian female who had been admitted to the hospital for 3 days prior to the event.

Wrong Site/Wrong Patient/Wrong Procedure

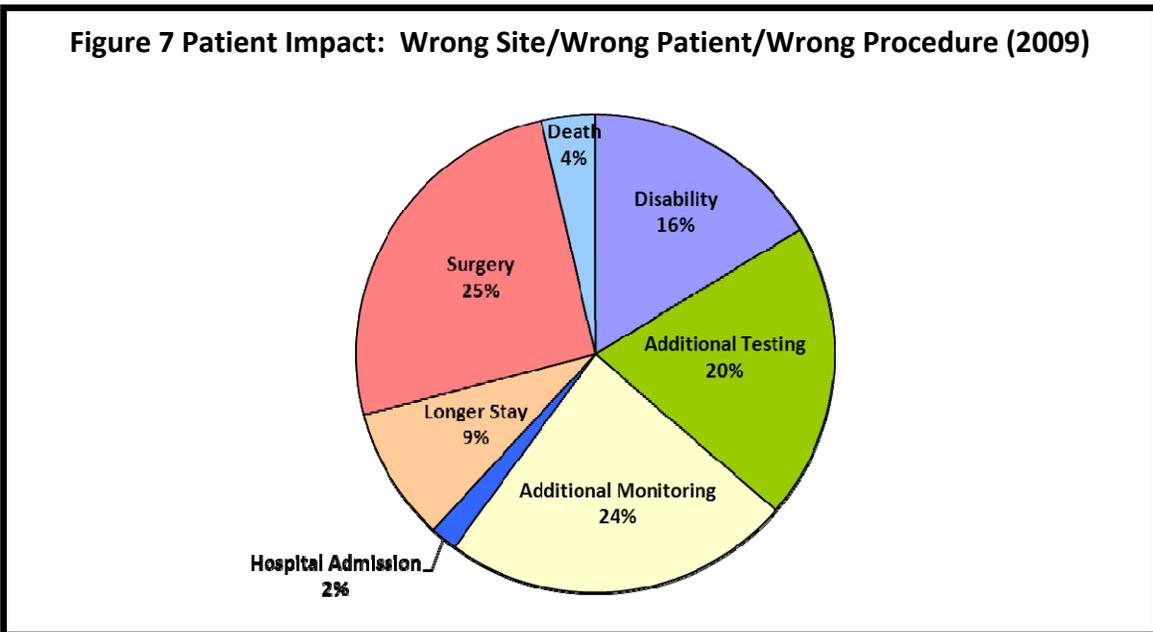
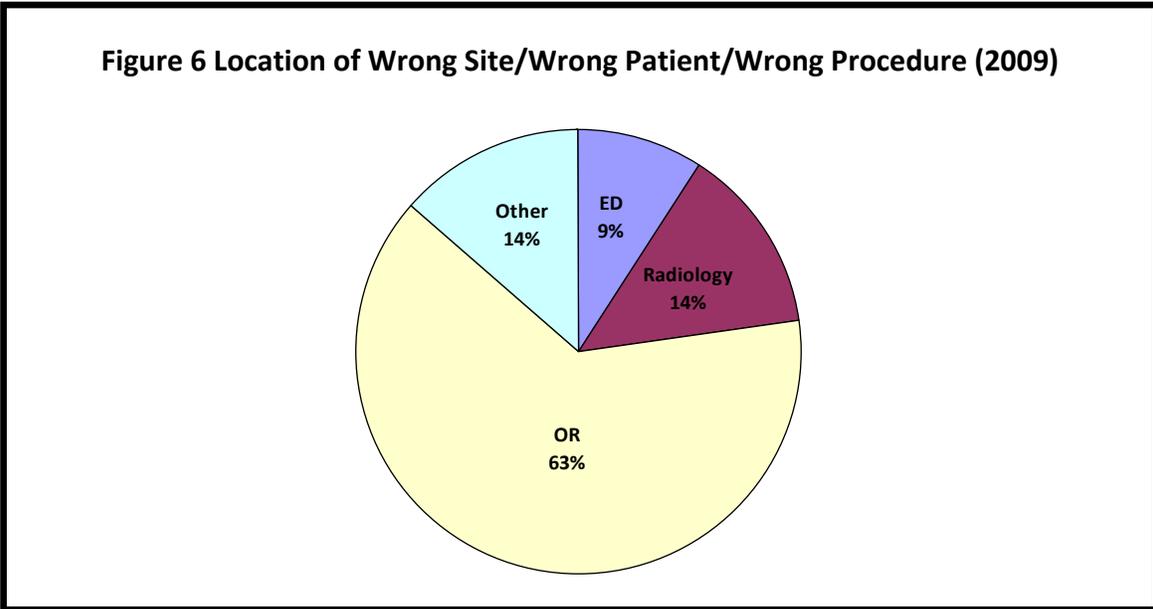
Over the past five years of the Patient Safety Reporting System, 73 reports of wrong site/wrong patient/ wrong procedure events were submitted. In 2009, 22 wrong site/ wrong patient/wrong procedure events were reported, up from 13 in the previous year, a 169% increase (Figure 5).





Over 60 percent of the wrong site/wrong patient/wrong procedure adverse events occurred in the operating room. The remainder of these events occurred in the emergency department, radiology, or other locations including critical care units and cardiac catheterization laboratories (Figure 6).

The most common impact on patients was the need for additional surgery followed by additional testing and monitoring. Sixteen percent of the patients experienced a disability. Four percent of the patients died. (Figure 7).



In 2004, the Joint Commission required all accredited organizations to comply with the *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*.⁽²⁾ The purpose of this protocol is to ensure communication between and among the surgical staff and the patient to verify the correct procedure on the correct patient and the correct site. The main components of this protocol include:⁽²⁾

- **Pre-operative verification process:** verification of patient's identity, determination that all relevant documents, studies, and images are properly labeled and available before the start of the procedure, and any required equipment or implants are available.
- **Marking the operative site:** an unambiguous mark, such as, initials or "yes", should be placed at or near the incision site in indelible ink that is visible after the patient is prepped and draped.
- **Time out immediately before the start of the procedure:** must be conducted in the location where the procedure will be done and involve the entire operative team; should be documented and include correct patient identity, correct side and site, agreement on procedure being performed, correct patient position, availability of correct implants and any special equipment.
- **Adaptation of the requirements to non-operating room settings, including bedside procedures:** must include verification, site marking, and "time out" procedures.

However, recent studies have indicated that the number of wrong site/wrong patient/ wrong procedure events has not declined since implementation of the Universal Protocols.⁽³⁾ A study published in the *Archives of Surgery* found that there continues to be a high frequency of these surgical events, especially when procedures are taking place outside of the operating room. This was observed in New Jersey where some of these events occurred in radiology and in the cardiac catheterization laboratory.

In January 2009, the Centers for Medicare and Medicaid Services stopped reimbursement for procedures performed on the wrong site or on the wrong patient. The failure is not with the Universal Protocol, but with failing to follow it for every procedure. Sometimes these checks are rushed or occur when the entire surgical team is not present.

All facilities and physicians performing invasive procedures should adopt the Universal Protocol including the Time Out Procedure to ensure the safety of their patients.⁽⁴⁾ The processes are straightforward but demand strong hospital procedures, effective communication, and constant adherence to the protocols. This is especially true for invasive procedures that occur outside the operating room where this process is not as widely accepted as routine practice.⁽⁴⁾

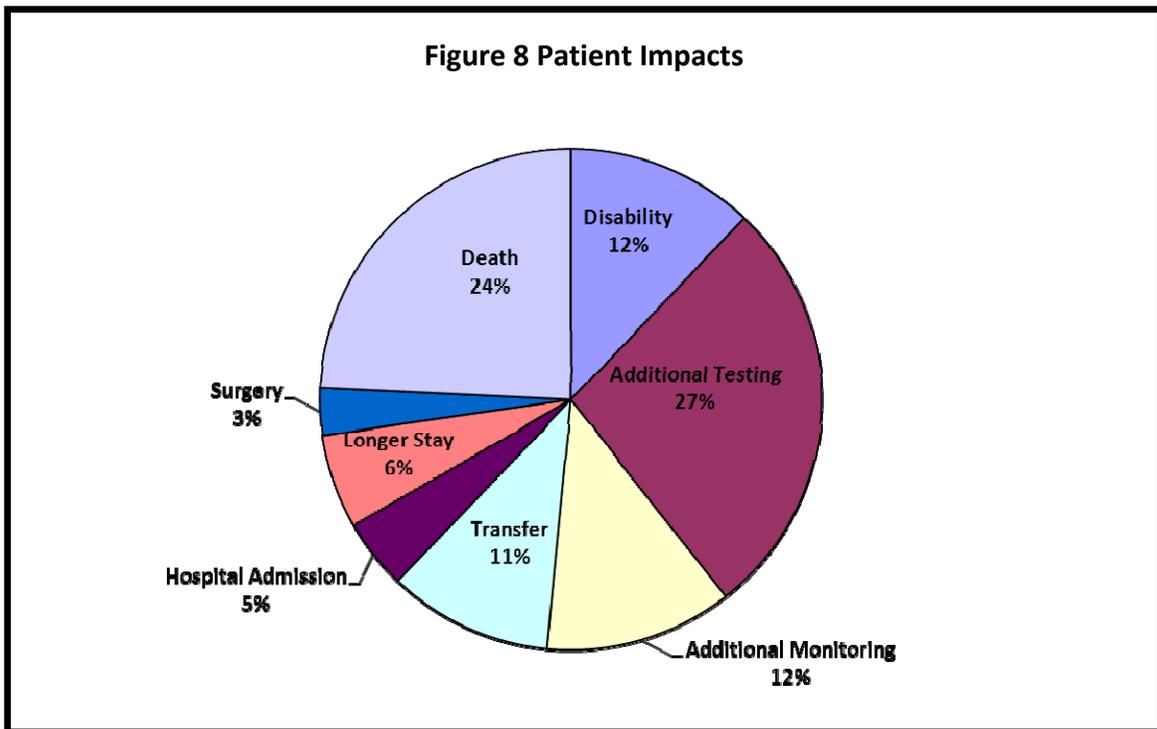


Intra- or Post-Operative Coma or Death

Reports of intra- or post-operative comas or deaths within 24 hours for any ASA Class 1 inpatient or for any ASA Class same day surgery patient or outpatient remain low, five percent of the total reported events. However, there was an increase in the number of these events in 2009. There were 23

events in this category reported in 2009, up from 11 reported in 2008. This was not a statistically significant increase.

The need for additional testing was the most frequent patient impact from an intra- or post-operative event. Sixteen (24%) of the patients died as a result of this event and eight (12%) experienced a disability (Figure 8).



According to “A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population”, a study published in *The New England Journal of Medicine*, an estimated 234 million surgeries are performed yearly. Complications associated with surgery are common and many are preventable. Data from various studies suggest that at least half of all surgical complications are preventable.⁽⁵⁾ The use of surgical checklists and protocols are associated with significantly reducing surgical-site infections or anesthesia-related adverse

events. Evidence also shows a correlation between high-function teamwork in surgery significantly reducing surgery-related adverse events.⁽⁵⁾

In 2008, the World Health Organization (WHO) published a surgical safety checklist and guidelines to reduce surgery-related adverse events and revised them in 2009. The revised guidelines and checklist can be found at http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.

Surgical Safety Checklist

World Health Organization

Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

Before skin incision

Before patient leaves operating room

(with at least nurse and anaesthetist)

(with nurse, anaesthetist and surgeon)

(with nurse, anaesthetist and surgeon)

Has the patient confirmed his/her identity, site, procedure, and consent?

 Yes

Confirm all team members have introduced themselves by name and role.

Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

 Yes
 Not applicable

Nurse Verbally Confirms:

 The name of the procedure
 Completion of instrument, sponge and needle counts
 Specimen labelling (read specimen labels aloud, including patient name)
 Whether there are any equipment problems to be addressed

Is the site marked?

 Yes
 Not applicable

Anticipated Critical Events

To Surgeon:

 What are the critical or non-routine steps?
 How long will the case take?
 What is the anticipated blood loss?

To Surgeon, Anaesthetist and Nurse:

 What are the key concerns for recovery and management of this patient?

Is the anaesthesia machine and medication check complete?

 Yes

To Anaesthetist:

 Are there any patient-specific concerns?

Is the pulse oximeter on the patient and functioning?

 Yes

To Nursing Team:

 Has sterility (including indicator results) been confirmed?
 Are there equipment issues or any concerns?

Does the patient have a:

Known allergy?

 No
 Yes

Is essential imaging displayed?

 Yes
 Not applicable

Difficult airway or aspiration risk?

 No
 Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

 No
 Yes, and two IVs/central access and fluids planned

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009 © WHO, 2009

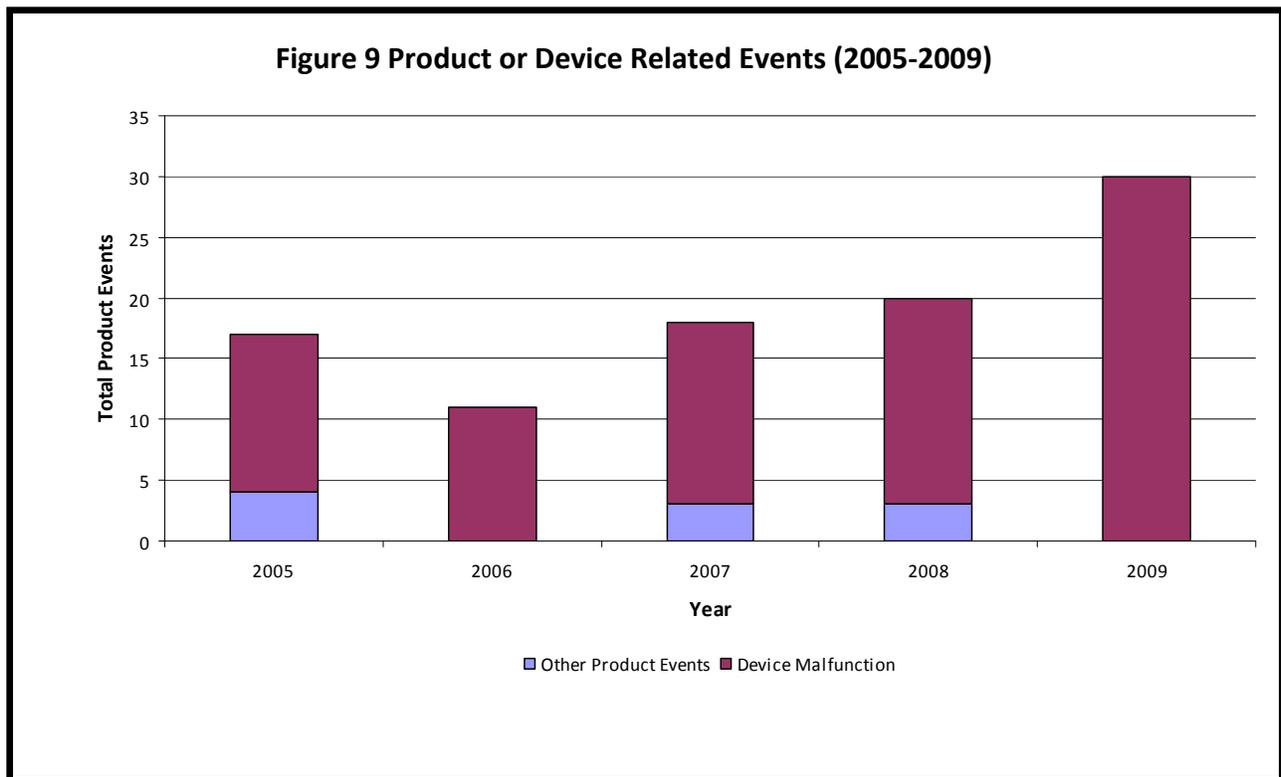


Product or Device Related Events

In 2009, there were 30 product or device related events in which the devices were used or functioned other than intended. There were no reported adverse events associated with preprocessed single-use devices. In 2008, there were 20 product or device related events, 17 of which were device malfunctions (see Figure 9).

Additional laboratory testing or diagnostic imaging was the most common impact of a device related event (32%), followed by surgery to retrieve the broken device or to minimize or repair the damage (16%).

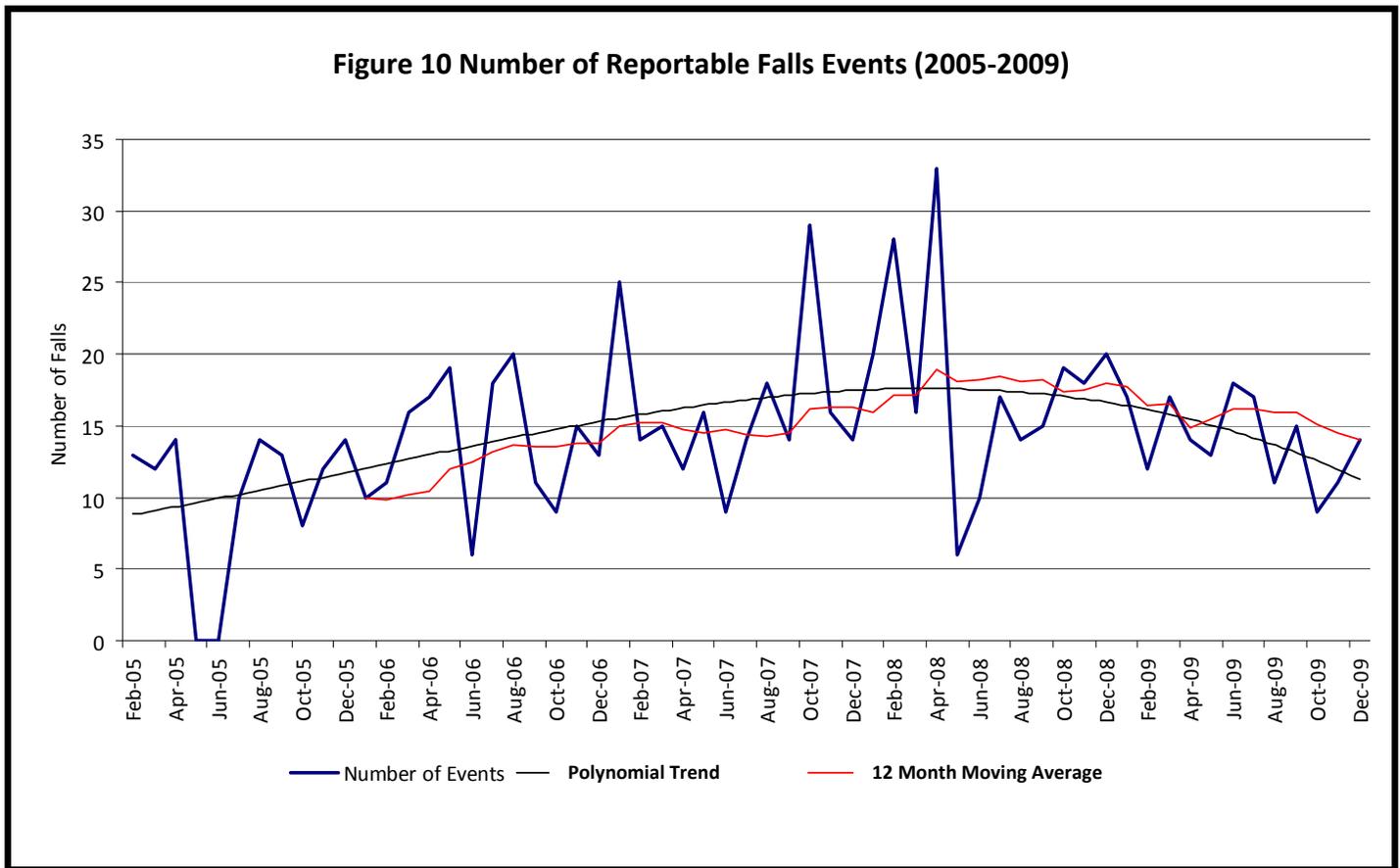
The following areas were identified by the hospitals, during the RCA, as the root causes of device-related events: poor communication among staff (48%), lack of planning (29%) and inadequate staff orientation and training (17%).



Fall Events

Falls continue to be the most frequently reported event submitted to the Patient Safety Reporting System. Until 2009, there had been a steady increase in the number of reported falls. In 2005, 33% of all events reported were falls. This

number increased to 40% in 2008. In 2009, however falls decreased slightly to 37% of all reported events. In Figure 10 below, the trend lines superimposed over the monthly falls data suggest that the volume of falls may be decreasing somewhat entering the sixth full year of reporting.



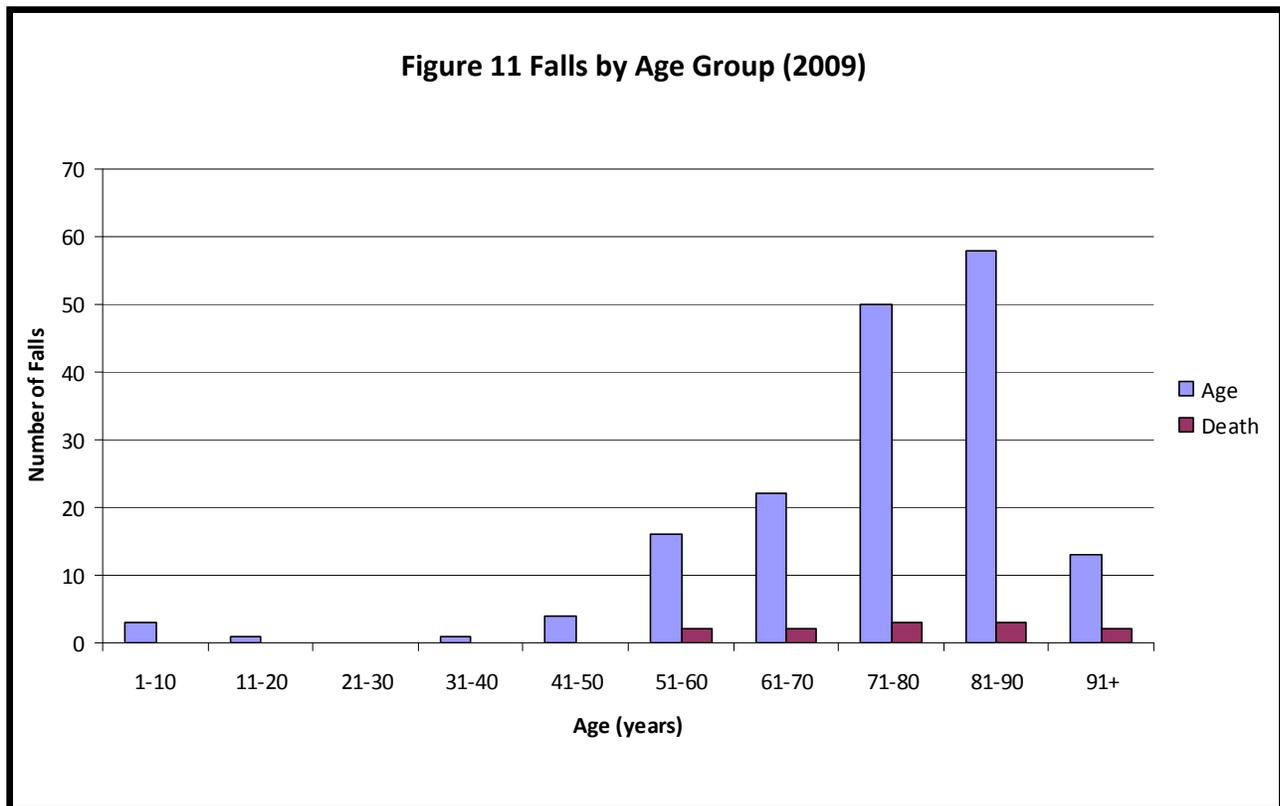


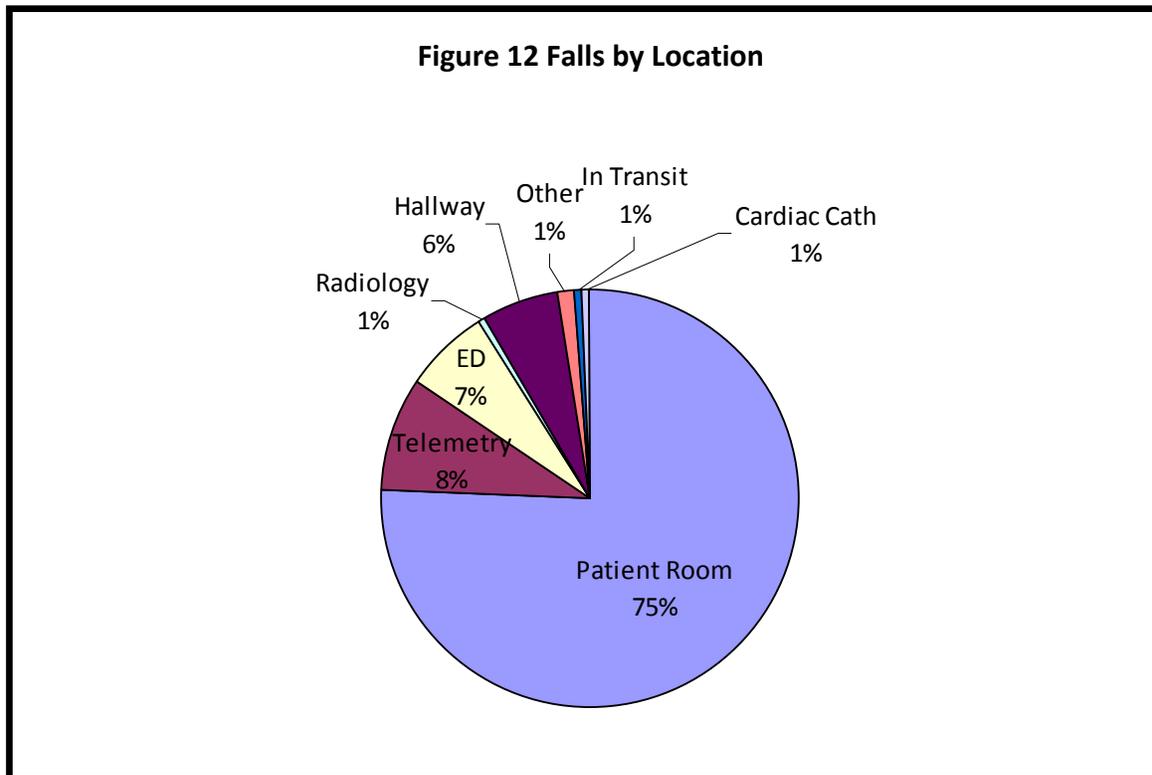
During 2009, the typical patient who sustained a fall resulting in serious injury was an older (between 81-90 years) Caucasian female patient (Figure 11). Falls become more common as patients get older, especially over age 50. The overall death rate associated with reportable falls is 7% and appears to occur with patients 50 and older. Falls have a significant risk of death and preventing falls should be a high priority at all health care facilities.

Of the 168 reported falls, the majority occurred in the patient’s room (75%), usually when the patient was attempting to go to the bathroom (Figure 12). Other locations for patient falls, although to a lesser extent, were telemetry units (8%), hallways or other

common areas (6%) and the emergency department (7%). The event usually occurred within the first 7 days following admission.

Based on the RCA reports, one of the most pervasive causes of falls in hospitals was inadequate care planning (56%) followed by poor communication among staff (42%) and inadequate patient observation (34%). In 2009, 94% of the falls resulted in additional laboratory testing or diagnostic imaging. Other common patient impacts included additional patient monitoring (78%), physical or mental impairment (69%), increased length of stay (63%), and major surgery (50%).





Since the start of the Patient Safety Reporting System (2/2005) there have been 868 reportable fall events, more than double the amount of events of the next largest category, pressure ulcers. Eight percent of these falls resulted in death. Patients that are hospitalized have an increased risk of falls due to the unfamiliar environment, illness and treatment.⁽⁶⁾

A review of the RCAs revealed an association between mental status and falls. Of the 168 reported falls in 2009 with injury, 20% of the patients had an admission diagnosis of a mental health disorder, 10% presented with an altered mental health status and 4% had substance abuse issues. These findings are supported by a study that established that falls in general acute

cares hospitals were associated with diagnosed and undiagnosed delirium. Delirium, for purposes of this study, is defined as a disturbance of consciousness, change in cognition or rapid onset and fluctuations during the course of the day.⁽⁷⁾ The study determined that 96% percent of the patients who fell showed evidence of delirium.⁽⁷⁾ The study recommends that once a patient has been identified as having delirium, standard fall-risk protocols should be implemented along with specific interventions. These specific interventions include reorientation to person, place, time and using step by step simple instructions. Hospital staff should also be cognizant of the patient's sleep cycles, nutrition, comfort and physiological care.⁽⁷⁾



Fall Prevention

A study published in the November 2010 issue of the *Journal of the American Medical Association* found that the use of a Fall Prevention Tool Kit (FPTK) using health information technology (HIT) would reduce the number of falls in an acute care hospital.⁽⁶⁾ The study results demonstrated that patients in the units used the FPTK had fewer falls than those patients in the control units. The intervention units also had significantly lower adjusted fall rates than the control units. The study also determined that the interventions were more effective and beneficial on patients 65 and older than they were on the younger patients. The study concluded that the FPTK could potentially prevent 1 fall for every 4 days, 7.5 falls each month and approximately 90 falls a year.⁽⁶⁾

A major element of the FPTK is communication.⁽⁶⁾ As seen in the RCAs submitted by New Jersey hospitals, communication among staff and communication with the patient/family were listed as root causes for 64% of the falls. The FPTK used in the study communicated fall risk alerts and preventative actions with the following methods:⁽⁶⁾

- Posters located over the bed
- Educational handouts, describing the plan of care and interventions, for the patient and family, written for a consumer
- Plan of care for staff written for the health care professional

The *JAMA* study also found that acute care hospitals commonly use fall risk screening assessments; however, the use of patient-specific assessments to help customize a prevention plan is less frequent. Fall risk assessments should be conducted on admission and entered into the admission database as soon as possible.⁽⁶⁾ Another risk assessment should be completed if there are any changes in a patient's status, such as physiological, functional or cognitive changes or whenever a fall occurs. Conducting a fall risk assessment periodically during a hospital stay or when the patient is transported (including transfers to another patient care unit) is also recommended as a good practice in preventing falls.⁽⁸⁾

Corrective Actions⁽⁹⁾

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

Preventative Actions⁽⁹⁾

- Consider peak effect for prescribed medications that affect level of

consciousness, gait and elimination when planning patient care.

- Educate staff to increase awareness of high risk patients.
 - Use the standardized color code system to identify a high fall risk patient.
 - Educate the patient and their family about the risk of falling and the patient's limited mobility.
 - Include the patient's family in the development of an individualized safety plan.
 - Instruct patients to rise slowly and take their time to make sure they are stable.
 - Orient the patient to his/her bed area, location of the bathroom and how to request assistance.
 - Instruct the patient or resident to request assistance as needed.



Overall Event Reporting

There are five main categories of events: care management, environment, product or device, surgery related and patient protection. The percentage of event reports for each of the five event categories for 2005 through 2009 is presented in Figure 13. As in previous

years, the majority of events are in the care management and environment categories. These two categories accounted for 67% of the reports in 2009.

Figure 13 Percentage of Reports by Event Category (2005-2009)

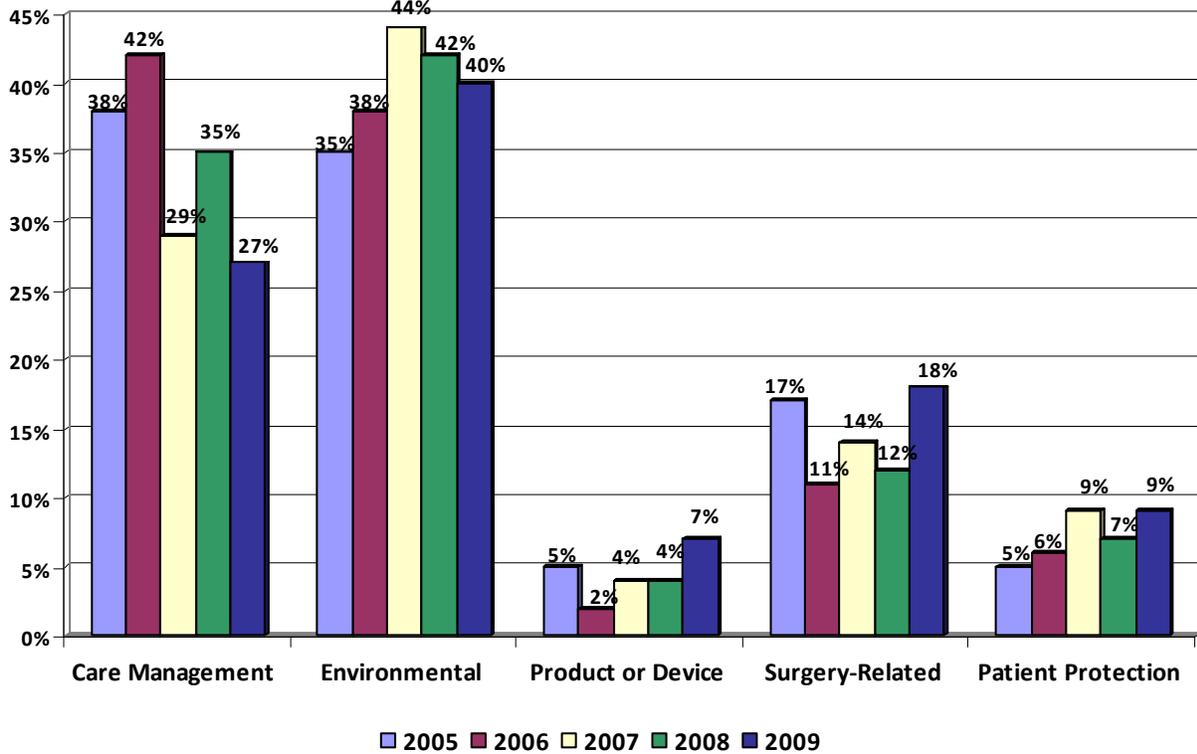
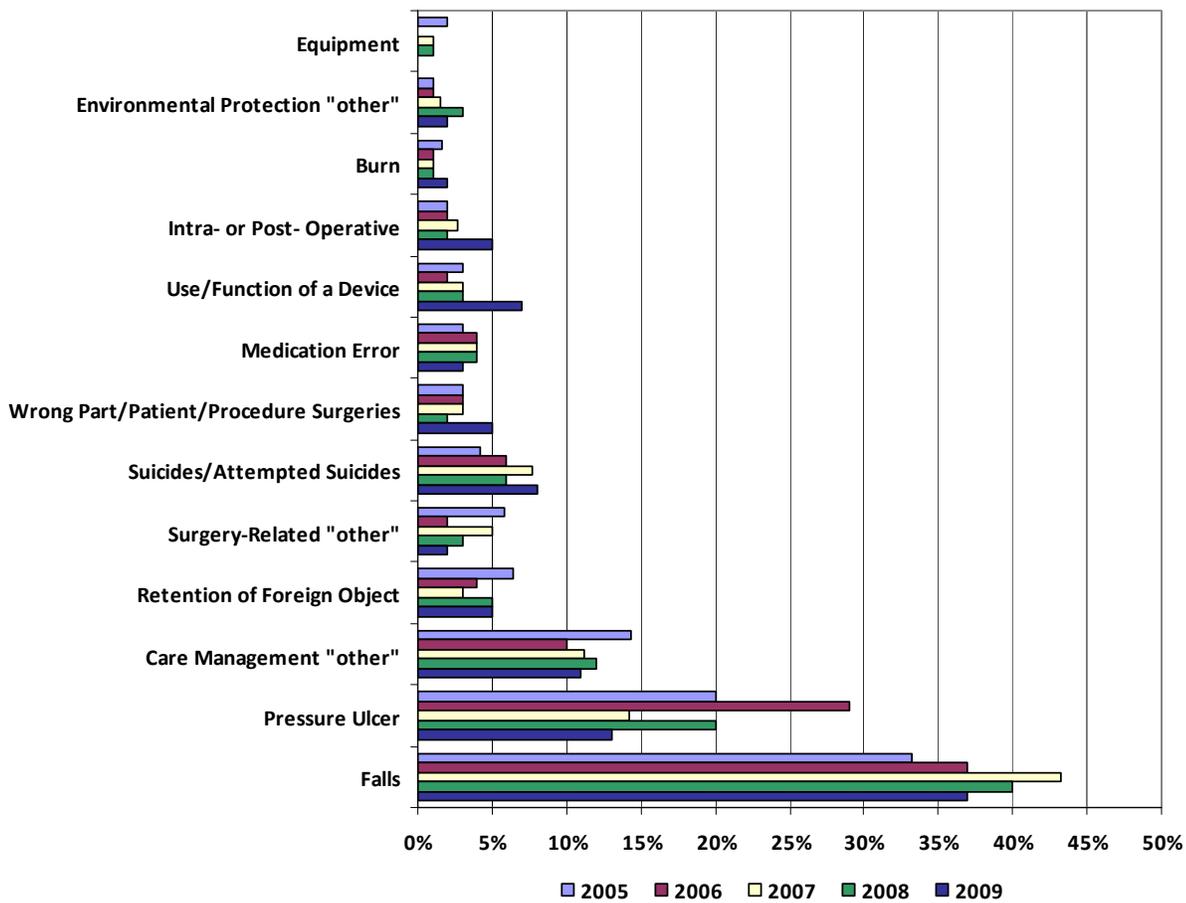


Figure 14 Percentage of Reports by Event Subcategory (2005-2009)



The distributions of reporting for specific types of subcategories in each event type for 2005 through 2009 are presented in Figure 14. Falls and pressure ulcers continue to be the most frequently reported events. In 2009, there was an increase in the percentage of suicides/attempted suicides, wrong patient/wrong site/wrong procedure, use/function of a device, intra- or post-operative coma or death and burn events. However, there was a decrease in the percentage of falls, pressure ulcers, care management “other” events, medication errors and surgery related “other” events. When compared to previous years, 2009 had

the lowest percentage of pressure ulcers.

As in previous years, the care management “other” subcategory represents the third largest percentage of overall reporting event types. This subcategory includes events that relate directly to general patient care events that are not included in other categories, e.g., timely follow-up of laboratory and imaging studies, delay in treatment, etc.



Impact of Reported Events on Patients

A review of the 455 events and corresponding RCA reports submitted for 2009 revealed that the most frequent consequences of serious preventable adverse events on patients

included additional patient monitoring or diagnostic imaging (69%) and additional laboratory testing (65%). A moderate percentage of patients also experienced physical disability or mental impairment (45%) or an increase in their length of stay (33%) as shown in Table 3.

Table 3 Impact of Events on Patients (2009)^a

Impact/Outcome	Number of Patients	Percentage of Patients^b
Additional patient monitoring or diagnostic imaging	313	68.8%
Additional laboratory testing	295	64.8%
Physical disability or mental impairment	203	44.6%
Increased length of stay	152	33.4%
Major surgery	121	26.6%
Transfer to higher level of care	98	21.5%
Death	74	16.3%
Other additional testing	57	12.5%
Minor surgery	50	11.0%
Hospital admission	38	8.4%
System/process delay	34	7.5%
Visit to Emergency Department	25	5.5%
To be determined	24	5.3%
Loss of bodily function	20	4.4%
Loss of sensory function	7	1.5%
Other	4	0.9%
Loss of Digits	2	0.4%
Loss of Body Part	1	0.2%

^a Data drawn from 455 RCAs submitted for 2009 events

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

Events Resulting in Death

The most serious outcome of a preventable adverse event for a patient is death. There were 75 deaths in 2009 related to serious preventable adverse events. Similar to 2007 and 2008, in 2009 the majority of the deaths (n=25; 33%) were attributed to the care management “other” event subcategory

followed by intra- or post-operative (n=16; 21%) events and fall events (n=12; 16%) (Figure 15). When looking at the root causes of the 25 care management “other” events that resulted in death, one of the most common causes is poor communication among staff (64%) followed by inadequate physical assessment (52%) (Table 4).

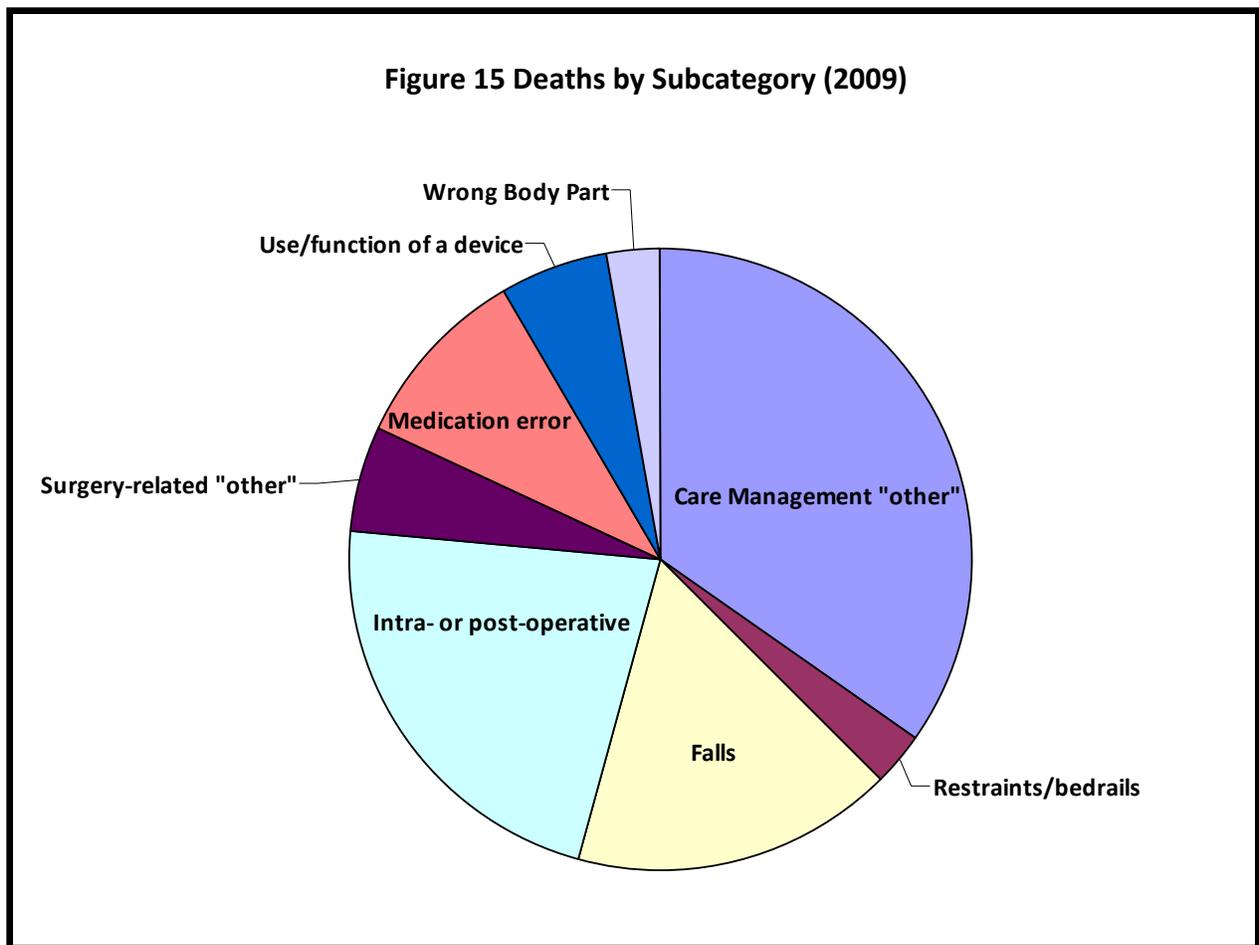




Table 4 Root Causes of Care Management “other” Events Resulting in Death (2009)

Root Cause	Number of Events	Percentage of Events ^b
Communication among staff	16	64%
Physical assessment	13	52%
Orientation	10	40%
Planning	10	40%
Availability of information	9	36%
Observation	8	32%
Supervision	5	20%
Competency	4	16%
Equipment maintenance	3	12%
Communication with patient/family	3	12%
Physical environment	3	12%
Other	2	8%
Adequacy of technical support	2	8%

^a Data drawn from 25 care management other events with death RCAs submitted for 2009 events

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

Root Cause Analysis

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

Each RCA must include the following four components:

- *The facts of the event.* A detailed account of the event including the date/time/location. There must be a clear description of how the event occurred which is the basis for further analysis to determine causality.
- *The causality statements* which identify root causes and address the underlying vulnerabilities in systems for providing care.
- *Action plans* (risk reduction strategies) which include stated actions or strategies to prevent or reduce the probability of future events, or reduce the harm caused by such events. The risk reduction strategies should specifically address each identified root cause and be feasible to implement. The implementation time frame and the person responsible should be specified.
- *Monitoring plans* that include defined time frames and the responsible person. There should be a monitoring plan for each risk reduction strategy.

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

inadequate policies and procedures.^[17] In 2009, the major causes of events reported to the Patient Safety Reporting System were care planning process, communication among staff, staff orientation and training, and physical assessment of the patient as shown in Table 5.

Table 5 Root Causes (2009)^a

Root Cause	Number of Events	Percentage of Events ^b
Communication among staff	208	45.7%
Care planning	202	44.4%
Staff orientation/training	131	28.8%
Physical assessment	117	25.7%
Patient observation	116	25.5%
Equipment maintenance	66	14.5%
Availability of information	63	13.8%
Communication with family	60	13.2%
Supervision of staff	49	10.8%
Physical environment	49	10.8%
Behavioral assessment	43	9.5%
Other	40	8.8%
Staff competence	21	4.6%
Patient identification	14	3.1%
Staffing	9	2.0%
Adequacy of technical support	9	2.0%
Security systems	6	1.3%
Control of medication	6	1.3%
Labeling of medication	6	1.3%

a Data drawn from 455 RCAs submitted for 2009 events

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



Specialty Hospitals

Comprehensive Rehabilitation, Psychiatric and Special Hospitals

Mandatory reporting for the comprehensive rehabilitation, psychiatric and special hospitals began April 1, 2008. Therefore, 2009 was the first full year of reporting for these hospitals. Only eight months of data was collected in 2008 which does not allow for true comparisons of the events and RCAs between these two years. It is also difficult with the limited data to really draw any conclusions or determine trends. Additional years of data will be needed to determine patient safety event trends in the specialty hospitals.

Overall Reporting Patterns

There were 54 reportable events submitted from specialty hospitals in 2009. The number of reported events varied by month and by specialty type.

Comprehensive rehabilitation hospitals submitted the most events, averaging two event reports per month.

Special hospitals were the lowest reporters, only reporting seven events for the year (Table 6). Special hospitals have consistently been low reporters of serious preventable adverse events. Variation in reporting may relate to the size and patient population of the facility.

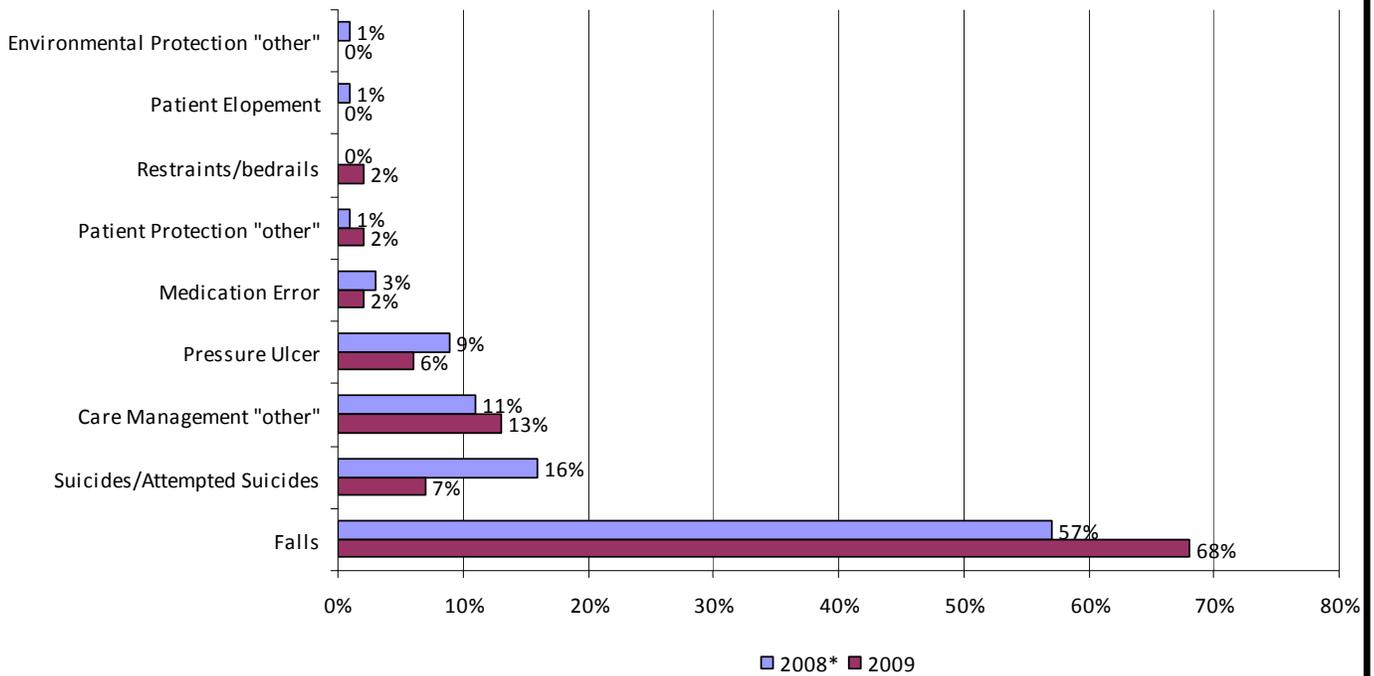
Types of Events Reported

The breakdown of reported events by event type for 2008 and 2009 is illustrated in Figure 16. The majority of the events for 2009 were falls (68%), followed by care management “other” (13%) and suicide/attempted suicide (7%). These percentages are similar to some of the most commonly reported event types seen by the general acute care hospitals.

Table 6 Events Reported by Facility Type (2009)

Facility Type	Number of Hospitals	Percentage of Hospitals Reporting	Number of Reports	Percentage of Reports
Comprehensive Rehabilitation	15	53%	27	50%
Psychiatric	10	60%	20	37%
Special	13	30%	7	13%
Total	38	NA	54	100%

Figure 16 Frequency of Reported Events by Category



*2008 represents 8 months of reporting

Impact of Reported Events on Patients

Based on the 54 events and corresponding RCA reports submitted for 2009, the most frequent consequences of preventable adverse events for patients were physical disability or mental impairment (81%). Many patients also needed additional laboratory testing (80%) and additional patient monitoring (72%). Sixty-five percent of the patients required hospital admission and approximately half (52%) of patients underwent major surgery (Table 7).

Root Cause Analysis

A review of the 54 RCA reports revealed that the most common cause of all events in the specialty hospitals was inadequate care planning (77%). This was followed by poor communication among staff (41%), deficient patient observation (30%) and insufficient staff orientation or training (24%) (Table 8).



Table 7 Impact of Events on Patients (2009)^a

Impact/Outcome	Number of Patients	Percentage of Patients^b
Physical disability or mental impairment	44	81%
Additional laboratory testing	43	80%
Additional patient monitoring	39	72%
Hospital admission	35	65%
Major surgery	28	52%
Transfer to higher level of care	22	41%
Increased length of stay	21	39%
Loss of Bodily Function	6	11%
Other additional testing	6	11%
Minor surgery	4	7%
Death	2	4%

a Data drawn from 54 RCAs submitted for 2009 events

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

Table 8 Root Causes (2009)^a

Root Cause	Number of Events	Percentage of Events^b
Care planning	32	59%
Communication among staff	22	41%
Patient observation	16	30%
Staff orientation/training	13	24%
Physical assessment	12	22%
Behavioral assessment	10	19%
Communication with family	9	17%
Supervision of staff	9	17%
Physical environment	6	11%
Availability of information	6	11%
Staff competence	3	6%
Equipment maintenance	5	9%
Staffing	2	4%
Patient identification	1	2%

a Data drawn from 54 RCAs submitted for 2009 events

b Percentages do not total 100% since events generally have more than one root cause

Ambulatory Surgery Centers

On October 1, 2008, in accordance with the New Jersey Patient Safety Act (P.L. 2004, c.9) phase-in approach, licensed ambulatory surgery centers began reporting serious preventable adverse events. The first year of reporting for the ambulatory surgery centers consisted of three months. 2009 was the first full year of reporting. The event and RCA report summary information for 2009 is provided in the following tables and figures.

Overall Reporting Patterns

Since reporting began for ambulatory surgery centers, 56 facilities have reported at least one event. In 2009, 28 facilities reported 48 events.

Types of Events Reported

The majority of the reported events were surgery-related “other” (28), followed by intra-operative or post-operative coma or death (8), as shown in Table 9. Different types of events that may be categorized as a surgery-related “other” include, but are not limited to the following: perforation of an organ, cardiac and/or respiratory related problems, moderate to severe bleeding, serious infections, prolonged decrease in oxygenation and/or blood pressure, all of which required intervention.

Impact of reported events on patients

Based on the 48 events and corresponding RCA reports submitted for 2009, the most frequent consequences of preventable adverse events for patients were additional laboratory testing (74%), hospital admission (72%), and additional patient monitoring (63%), followed by minor surgery (24%) as shown in Table 10.

Root Cause Analysis

The 48 RCA reports showed that one of the more frequent causes of all the events reported by ambulatory surgery centers was poor communication among staff members (20%) followed by inadequate staff supervision (17%) (Table 11).



Table 9 Events Reported by Ambulatory Surgery Centers (2009)

Event Category	Number of Events	Percentage of Total Events
Medication Error	1	2%
Retention of a Foreign Object	1	2%
Device Malfunction	5	10%
Wrong Site Surgery	5	10%
Intra or post-operative coma or death	8	17%
Surgery-related "other"	28	58%

Table 10 Impact of Events on Patients (2009)^a

Impact/Outcome	Number of Patients	Percentage of Patients^b
Additional laboratory testing	34	74%
Hospital admission	33	72%
Additional patient monitoring	29	63%
Minor surgery	11	24%
Physical disability or mental impairment	10	22%
Major surgery	5	11%
Increased length of stay	5	11%
Transfer to higher level of care	4	9%
Loss of sensory function	4	9%
Loss of bodily function	3	7%
Other additional testing	3	7%

^a Data drawn from 48 RCAs submitted for 2009 events

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

Table 11 Root Causes (2009)^a

Root Cause	Number of Events	Percentage of Events^b
Communication among staff	9	20%
Supervision of staff	8	17%
Communication with family	7	15%
Equipment maintenance	6	13%
Availability of information	6	13%
Staff orientation/training	6	13%
Physical environment	6	13%
Care planning	5	11%
Staff competence	4	9%
Control of medications	3	7%
Patient identification	3	7%
Physical environment	2	4%
Patient observation	2	4%
Other	17	37%

a Data drawn from 48 RCAs submitted for 2009 events

b Percentages do not total 100% since events generally have more than one root cause



Conclusion

The release of the Fifth Annual Summary of serious preventable adverse events reported under New Jersey's Patient Safety Act shows that progress has been made in reducing patient safety adverse events. However, there is still a need to continue improving patient safety in New Jersey's health care facilities.

2009 was the fifth year of the Patient Safety Reporting System. Under the mandatory reporting law, a total of 455 reportable events were discovered in 2009. The total number of reportable events decreased by 15 percent from the total number of reportable events submitted in 2008. In 2009, 75 patients died as a result of a serious preventable adverse event.

The reporting results remain similar to previous years. There is still inconsistent reporting across hospitals by patient-volume. Except for 2009, the smallest patient-volume hospitals are the largest reporters of events.

Falls decreased 21 percent from 2008, but remain the biggest subcategory of reported events. After plotting the number of fall events per quarter from the second quarter of 2005 through the fourth quarter in 2009, a trend line was superimposed over the data. The trend that was calculated suggests that the volume of falls may be decreasing somewhat entering the sixth full year of reporting. Another interesting trend revealed, after reviewing the RCA

submitted for falls, is an association between mental status and falls.

Pressure Ulcers and Care Management "Other" continue to be the next largest subcategories after falls.

In 2009, general acute care hospitals reported an increase in the number of surgery related events, particularly intra- or post-operative coma or death and wrong site/wrong patient/wrong procedures. In 2009, 22 wrong site/wrong patient/wrong procedure events were reported, up from 13 in 2008, a 169% increase. Forty percent of the wrong site/ wrong patient/wrong procedure events in 2009 occurred outside the operating room, such as in the emergency department, radiology, or other locations including critical care units and cardiac catheterization laboratories. This is consistent with national trends.

All clinicians performing invasive procedures should adopt the Universal Protocol including the "time out" procedure. The continual occurrence of wrong site/ wrong patient/wrong procedure events is not a failure of the Universal Protocol, but with a failure to follow it for every procedure.

For the specialty hospitals and the ambulatory surgery centers, 2009 was the first full year of reporting. However, due to the limited amount of data, it is difficult to draw any conclusions or determine any trends.

The specialty hospitals submitted 54 reportable events in 2009. The majority of these events were falls (68%) followed by care management “other” (13%) and suicide/attempted suicide (7%). The ambulatory surgery centers submitted 48 events in 2009. The majority of these events were surgery-related “other” followed by intra- or post-operative coma or death events.

In August 2008, State Psychiatric Hospitals began reporting serious preventable adverse events to the Department of Human Services, Division of Mental Health Services. The analysis of the 2009 events and RCAs are found in the next section of this report.

The Department’s Patient Safety staff continues to develop an understanding of each facility’s unique culture and organizational structure. These facilities also continue to expand their understanding of the requirements for RCAs and increase the complexity of

their analysis and preventive actions. This results in better collaboration and a more productive relationship between the facilities and the Department’s Patient Safety staff.

Future development for the Patient Safety Reporting System involves addressing the following issues:

- Implementation of a web-based reporting system allowing for more detailed event/RCA reporting and additional analytical capacity for both health care facilities and the Department.
- Initiation of additional cooperative projects with health care facilities that support the growth of patient safety and use of the information collected through the reporting system.
- Continued work with health care facilities to ensure consistent reporting.



Works Cited

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. **The Joint Commission.** Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery. *The Joint Commission*. [Online] 2003. http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf.
3. **O'Reilly, Kevin.** Wrong-patient procedures persist despite safety protocols. *American Medical News*. [Online] November 15, 2010. <http://www.ama-assn.org/amednews/2010/11/01/prl21101.htm>.
4. *A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.* **Haynes, Alex, Weiser, Thomas et al.** : New England Journal of Medicine, 2009, Vol. 360 No.5.
5. *Wrong-Site Surgery and Wrong-Patient Procedures in the Universal Protocol Era.* **Stahel, Philip, Sabel, Allison et al.:** Archives of Surgery, 2010, Vol. 10 N. 145.
6. *Fall Prevention in Acute Care Hospitals.* **Dykes. Patricia, Carroll, Diane et al.:** JAMA, 2010, Vol. 304 No.17.
7. *Falls in the General Hospital: Association with Delirium, Advanced Age, and Specific Surgical Procedures.* **Lakotos, Barbara, Capasso, Virginia et al.:** Psychosomatics; Academy of Psychosomatic Medicine, 2009, Vol. 50 No.3.
8. **University of Texas Health Science Center.** Policies and Procedures for Fall Prevention/Interventions Strategies. *Primier HealthCare Alliance*. [Online] 2003. <http://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/downloads/S-09-uthsc-pol-procedures.doc>.
9. **Primier HealthCare Alliance.** Fall Prevention. *Primier HealthCare Alliance*. [Online] 2007. <http://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/>.

Division of Mental Health Services

Department of Human Services

Each hospital's risk management department has the responsibility for coding incidents in the Unusual Incident Reporting Management System. If the incident is a patient safety act event then a box indicating such must be checked. In addition, to ensure adherence, members of the Division of Mental Health Services' Patient Safety Act Event oversight committee monitors incident reports from all five state psychiatric hospitals to ascertain if the event should be categorized as a Patient Safety Act Event and that a root cause analysis is conducted. This committee is tasked with assessing the root cause analyses for thoroughness and credibility using The Joint Commission criteria as well as the requirements of the Patient Safety Act. This committee also evaluates system-wide or hospital-specific patient safety issues and makes additional recommendations to reduce the risk to patients. A log is maintained and timeliness of completion and review of the root cause analysis is tracked.

Several of the root cause analyses were considered insufficient by the oversight committee and required revisions. In some cases, the findings and preventive actions were not able to be incorporated into this report. As a result, much of the year was spent on re-educating Risk Managers, Chief Executive Officers, Directors of Quality Management and Medical Directors. In addition, this committee sought clarification regarding reportability on some fall events from Department of Health and Senior Services.

Corrective Actions:

Revise Division-wide processes for hospitals to increase accountability to increase timeliness, thoroughness and credibility of future root cause analyses.

Overall Reporting Patterns

From January 1, 2009 through December 31, 2009, eighteen (18) events were reported by 4 of the 5 hospitals of which eleven (11) met the definition of a Patient Safety Act event. The events were analyzed with the following results.

The majority of the events (seven out of eleven, 64%) were falls with major injury.



Focus on Specific Events

Falls

Of the seven falls, 2 patients fell twice. Four of the five patients were male with an average age of 74.75; one was Hispanic and the other three were Caucasian with two of the patients having 2 falls each, with all four falls occurring between 9 pm and 12:55 am. It is interesting to note that all four male patients did not have a prior psychiatric history and three of the four fell within 2-4 weeks after admission. All of these falls occurred during the summer months within weeks of each other. The Division of Mental Health Services oversight committee noted that these four patients had vascular dementia and were receiving antipsychotic medications which have a black box warning.

Prevention Strategies:

- Patients at high risk for falls need to have the risk for fall included in their individual treatment plan along with appropriate interventions.
- Use technological devices to alert care givers when a patient is exiting a bed or chair and other devices to reduce the injury from falls.
- Sponsor Division-wide training for physicians and nurses on using a risk-benefit approach prior to prescribing antipsychotic drugs for elderly individuals with dementia and behavioral disorders.

- Include patients' risk for falls at handoff communication points.
- Enhance assessment and reassessment processes with regards to timeliness of completion and fall prevention triggers for interventions.

Suicide / Attempted Suicide

There was one suicide by a Caucasian female, 67 years of age with a diagnosis of Bipolar Disorder, Depressed with psychotic features. Availability of Information, Environment of Care and Patient Observations Procedures were identified as problematic. The two attempted suicides were by non-geriatric adult Caucasian females with borderline personality disorder.

Corrective Actions:

- Exposed piping in bathrooms covered with hard plastic. Revise environmental suicide risk assessment tool to enable risk to be more clearly prioritized.
- Only thoroughly trained individuals permitted to complete suicide risk assessment.
- Assignment sheets and documentation requirements of persons on special observation were more clearly defined.

Prevention Actions:

- Revise the state-wide policy on contraband.

- Provide state-wide training on Suicide Prevention through Skilled Assessment.
- Continue to evaluate the development and implementation of a standardized suicide risk assessment tool.
- Prior to allowing patients to go on day passes or briefs visits, Treatment Teams to assess whether or not isolated contact with the person responsible for the patient's supervision would be medically or therapeutically contraindicated.
- Require that all affiliation agreements with screening agencies and short term care facilities to include the need for all progress notes at the time of transfer.

Foreign Body Ingestion with Major Injury

One case of foreign body ingestion with major injury was reported. Patient was an African American female in her 20s admitted for the 1st time to a state psychiatric hospital. The root cause analysis team was unable to determine if

she had swallowed the objects prior or after her admission as she was a poor historian. Prior to her admission she had a lodged key removed from her esophagus at a local hospital. Upon her admission she was found hoarding several items such as screws.

Preventive Actions:

Process put in place that flat plate x-ray of the abdomen would be obtained for patients with poor cognition, limited prior

medical history and who are suspected of foreign-body ingestion behavior. While this action won't prevent a patient from ingesting a foreign object, this action would enable the clinicians to intervene more rapidly.



**Department of Human Services
Division of Mental Health Services**

Report Preparation Team

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

Alberto Regalado
Quality Assurance Coordinator
Office of State Hospital Management

Robert Eilers, M.D.
Medical Director

John Whitenack
Acting Assistant Director
Office of State Hospital Management

Appendix I: Classification of Serious Reportable Adverse Events¹

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

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

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



function lasting more than seven days or still present at the time of discharge not included within the definitions above.

- B. Environmental events include, but are not limited to:
1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with any shock while being cared for in a health care facility. Excludes events involving planned treatments, such as electric counter shock (heart stimulation).
 2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances and results in patient/resident death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge.
 3. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a burn incurred from any source while in a health care facility.
 4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a fall while in a health care facility.
 5. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with the use of restraints or bedrails while in a health care facility.
 6. Other environmentally-related adverse preventable events resulting in patient/resident death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- C. Product or device-related events include, but are not limited to:
1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product.
 2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use or function of a device in patient/resident care in which the device is used or functions other than as intended, including but not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
 3. Intravascular air embolism that occurs while the patient/resident is in the facility. However, this does not include deaths or disability associated with

neurosurgical procedures known to present a high risk of intravascular air embolism.

4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with use of a new single-use device or a reprocessed single-use device in which the device is used or functions other than as intended. All events related to single-use devices should be reported in this category. Indicate whether the device was new or had been reprocessed.
 5. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- D. Surgery-related events (i.e., any invasive manual or operative methods including endoscopies, colonoscopies, cardiac catheterizations, and other invasive procedures) include but are not limited to:
1. Surgery initiated (whether or not completed) on the wrong body part.
 2. A surgical procedure (whether or not completed) intended for a different patient of the facility.
 3. A wrong surgical procedure initiated (whether or not completed) on a patient.
 4. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
 5. Intraoperative or postoperative (i.e., within twenty-four hours) coma, death or other serious preventable adverse event for an ASA Class I inpatient or for any ASA Class same day surgery patient or outpatient. Includes all patient deaths, comas or other serious preventable adverse events in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
 6. Other surgery-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.



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

Appendix II: Patient Safety Reporting System Newsletters

- June October 2010: *Sharing Experiences and Preventative Measures*
- September 2009: *Retained Foreign Objects During Vaginal Deliveries and Caesarian Sections*
- February 2010 Alert: *Potential Errors Associated with Radiation Therapy*



Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE

Updates - March 2009



Heather Howard
Commissioner

2009: Issue 7

Patient Safety Initiative Update

- The third annual report, Patient Safety Initiative: 2007 Summary Report was released in December 2008 covering reporting and Patient Safety Initiative activities. Overall, reporting has increased both in terms of the number of reports and the number of hospitals submitting reports. Falls and pressure ulcers continue to be the most frequently reported events.
- On October 1, 2008 mandatory reporting of adverse patient safety events took effect for ambulatory surgery centers. On November 6th and 12th 2008, the NJ Association of Ambulatory Surgery Centers in cooperation with the Department of Health and Senior Services Patient Safety Initiative conducted special training sessions for these newly reporting facilities on event reporting and RCA development. In attendance were a total of 163 staff representatives from ambulatory surgery centers from around the state.

(N.J.A.C. 8:43E-10), which implemented the NJ Patient Safety Act, were approved on January 31, 2008 and published in the *New Jersey Register* on March 3, 2008.

All health care facilities are required to develop a patient safety plan, including the formation of a multidisciplinary patient safety committee to conduct analyses of serious preventable adverse events and near misses. Deliberations and reports are confidential.

Implementation of the Reporting System

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

The mandatory reporting system is based on the National Quality Forum's (NQF) list of "never events."³ Events are defined as an occurrence that results in death, loss of a body part, disability or loss of bodily function lasting more than seven days or present at discharge. Some events (e.g. suicide attempts and surgery-related wrong site, wrong person and wrong procedure) do not need to meet a threshold of injury to be reported. New Jersey's system uses five of the general categories: care management, environment, product or device failure, surgery-related and patient protection. Changes from the NQF categories and definitions include:

- An "other" category was added to each of the five categories 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.

Overview: Patient Safety Mandatory Reporting System

Patient safety continues to be one of the nation's most challenging health care issues. It has been ten years since the landmark studies *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century* were published by the Institute of Medicine (IOM).^{1,2} Since these publications, there has been a major increase in patient safety awareness among health care providers, state and federal governments, and the general public.

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

- The NQF list, published in 2002, included only falls resulting in death. In 2007 NQF changed this requirement to include falls resulting in serious injury which is consistent with the New Jersey statute.
- In January 2007, the product/device failure category was modified to distinguish between single-use and reusable devices which do not function as intended.
- Certain criminal events are included in the NQF list but are not covered by the NJ Patient Safety Act. These events must be reported to the Department's Office of Health Facilities Assessment and Survey.
- Reporting for pressure ulcers does not include skin ulcers that develop as a result of an underlying vascular etiology or that develop as a result of an underlying neuropathy. This is different from the CMS reporting requirements.
- Surgery reporting should include post-operative coma, death or any other event that occurs within **twenty-four hours** instead of the previous requirement of **twelve hours**.

Health care facilities must submit reports of serious preventable adverse events within **five (5) business days** after learning of the event to the New Jersey Patient Safety Initiative. They are also required to submit a Root Cause Analysis (RCA) for each reported event within **forty-five (45) calendar days** of submitting the event.

- RCAs must include:
 - a. *Facts of the events*: a clear, brief narrative description of how the event occurred including the date/time/location, contributing medications, conditions, and procedures.
 - b. *Causality statements* (root causes): the underlying vulnerabilities in a process or a system for providing care that were responsible for the event occurring.
 - c. *Action plans* (risk reduction strategies): actions or strategies that would likely prevent or reduce the probability of future events, or reduce the harm caused by such events.
 - d. *Monitoring plans* (measures of effectiveness): a monitoring plan for each risk reduction strategy that includes defined time frames for

completion and the person responsible for implementation.

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

Second Looks: Review of Types of Events to Report

From February 1, 2005, the implementation of the New Jersey Patient Safety Initiative, to December 31, 2008 the Department of Health and Senior Services has received almost 2,000 patient safety events from the reporting health care facilities.

Examples of Reportable and Non-reportable Events

All events are to be reported to the New Jersey Patient Safety Initiative. The New Jersey Patient Safety Initiative team carefully reviews every submitted event to determine if it meets the statutory definition of a reportable event and requires an RCA. The following are examples of events that were submitted and the decisions reached by the Patient Safety Initiative team on whether or not they were reportable and the reasoning behind each decision.

1. *A female patient complained of a sharp pain in her left hip when her foot got caught on a sheet during a transfer with a Rehabilitation Assistant from her bed to her wheel chair. The patient was examined by her physician and an x-ray was taken, revealing a periprosthetic fracture of the left hip.*

Reportable: This is an "other care management" event. The fracture was caused during the transfer from her bed to her wheel chair and resulted in the patient experiencing loss of bodily function for more than seven days.

2. *A female patient was found on the floor on her left side. An x-ray identified a left femoral neck fracture with slight impaction.*

Reportable: The patient sustained a fracture that required surgery and an increase in length of stay.

3. *A male patient was admitted to an acute care hospital with a past medical history of hypertension, diabetes mellitus, severe retinopathy, neuropathy, peripheral vascular disease, and end stage renal disease. The patient developed Stage II decubiti during his hospitalization which progressed to Stage III.*

Non-Reportable: After careful review it was determined by the Patient Safety Initiative team that this pressure ulcer event did not meet the statutory definition of a reportable event. Reporting for pressure ulcers does not include skin ulcers that develop as a result of an underlying vascular etiology or that develop as a result of an underlying neuropathy.

4. *A female patient had a procedure for severe nasal obstruction secondary to septal deviation performed at an ambulatory surgery center. After extubation in the OR, she experienced laryngospasms resulting in a drop in her oxygen saturation with cyanosis and hypoxic bradycardia. Once the patient was stabilized, she was transferred to an acute care hospital by ambulance. The patient was admitted for observation and after three days was discharged home with no permanent impairment or loss in bodily function.*

Reportable: This is a surgery-related “other” event. This event was considered reportable because the patient was admitted to an acute care hospital.

5. *A female patient was scheduled for a left lumbar 5 sacral transforaminal epidural steroid injection. The site was marked with the physician’s initials and a “time out” was completed. Lidocaine was injected on the right side. The physician realized the error, prepped the left side and completed the procedure.*

Reportable: This is a wrong site surgery event.

6. *A male patient, admitted to an inpatient psychiatric unit, attempted to strangle himself with his hands four different times.*

Reportable: This is considered an attempted suicide event; all suicide attempts are considered reportable.

7. *A male patient was found on the floor and stated “I think I hit my head.” A CT scan revealed a tiny left tentorial subdural hematoma and no evidence of a fracture.*

Reportable: The patient sustained a subdural hematoma which required a transfer to a more intensive level of care and a longer length of stay.

8. *A female patient arrived in emergency department complaining of neck pain and an inability to move her upper extremities. An MRI was ordered in the morning but was not completed due to patient movements. The incomplete MRI was not reported to the emergency department physician or nurse. In the late afternoon an MRI was attempted a second time and completed with a diagnosis of epidural abscess and spinal cord compression. The patient was taken to surgery later that same evening. The patient remains on a ventilator and unable to move her extremities.*

Reportable: This is an “other care management” event. There was miscommunication and a delay in treatment that likely contributed to the patient experiencing loss of bodily functions for more than seven days.

9. *A female patient was found with a pillow case on her head. The patient stated that she attempted to kill herself because she felt rejected by other patients on the floor.*

Reportable: This is considered an attempted suicide event; all suicide attempts are considered reportable.

10. *A female patient was found on the floor. She stated that she had gotten out of bed to use the bathroom and blacked out. The patient received fractures of both nasal bones and the anterior aspect of the nasal septum.*

Non-reportable: After careful review it was determined by the Patient Safety Initiative team that this fall event did not meet the statutory definition of a reportable event.

11. A female patient had a vaginal delivery, a normal postpartum course and was discharged. Three days later the patient returned to ED with complaints of fever, abdominal pain and foul smelling vaginal discharge. Upon examination a retained sponge (gauze) was discovered in the vagina. The gauze was removed and the patient was admitted for treatment with antibiotics and analgesics.

Reportable: This is a surgery-related-retained object event.

12. A male patient was found on the floor at the foot of the bed, with a lacerated wound noted behind his ear on right side.

Non-reportable: After careful review it was determined by the Patient Safety Initiative team that this fall event did not meet the statutory definition of a reportable event.

Resources on Types of Events to Report

NJ Patient Safety Initiative available at:
<http://nj.gov/health/ps/>

Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities available at:
http://nj.gov/health/ps/documents/final_directions_oct08.pdf

Frequently Asked Questions available at:
<http://nj.gov/health/ps/faq.shtml>

Contact the NJ Patient Safety Initiative at:
<http://nj.gov/health/ps/contact.shtml>

References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human – Building a Safer Health System. Washington, DC: National Academy of Science Press; 2000.
2. Committee on Quality of Health Care in America, Institute of Medicine, Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
3. National Quality Forum. Serious Reportable Events in Healthcare: A Consensus Report. Washington, DC: National Quality Forum; 2002.



Heather Howard
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) 633-7759

Patient Safety Web Site: www.NJ.gov/health/ps

2009.02.21



Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE

Alert - June 2009



Heather Howard
Commissioner

2009

Automatic Endoscope Reprocessors

The New Jersey Department of Health and Senior Services' (DHSS) Patient Safety Initiative has received a report of a potentially Serious Adverse Event, a "Near Miss" involving automatic endoscope reprocessors that had the incorrect disinfection time set and no temperature gauge.

During a medical equipment evaluation of the automatic endoscope reprocessors in an endoscopy department, it was discovered that a reprocessor's disinfection cycle was set for one minute instead of the manufacturer's recommended five minutes. The computer printout revealed that while the total disinfection process was more than five minutes, the actual time the equipment was in contact with the disinfectant was only one minute. Upon review of the log books containing the computer printouts, it was discovered that the reprocessor had been set at the one minute disinfection time for almost a year, potentially affecting almost 500 patients.

Further investigation of the automatic endoscope reprocessors also showed another potential issue; it was observed that a red light would turn on when the disinfectant liquid reached the effective temperature and would turn off when the temperature decreased. There was no temperature gauge provided with the machine to allow for a second check to determine that the disinfectant remained at the optimal temperature. The concern is that the reliance on a light only, with no visual temperature gauge, may cause facilities to assume the safe cleaning of their equipment even when the light on the processor may not be working properly.

A break down of the evaluation findings revealed several pertinent issues:

- Improper initial set-up of the equipment by the manufacturer.
- Lack of adequate staff training on interpreting and understanding the computer printouts.
- No instruction manual available for the equipment users.
- No visual temperature gauge.

DHSS Patient Safety Initiative recommendations:

- The facility's engineering and biomed should work with the manufacturer to ensure that the equipment is installed properly and all cycle times are at the right setting.*
- Staff should be adequately trained on all aspects of equipment including reading and understanding computer printouts.*
- A copy of the instruction manual must be kept with the equipment and available to the end-users.*
- Facilities should purchase equipment that has a visual temperature gauge. If a temperature gauge is not an option, facilities should purchase a thermometer that can be placed in the automatic reprocessor to confirm the temperature.

* Service Solutions: Equipment Failure is not an Option. 24x7 Technology and Service Solutions for Biomed. April 2004. Available at www.24x7mag.com/issues/articles/2004-04_01.asp



Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE NEWSLETTER

September 2009



Heather Howard
Commissioner

2009: Issue 8

Overview: Retained Foreign Objects During Vaginal Deliveries and Caesarian Sections

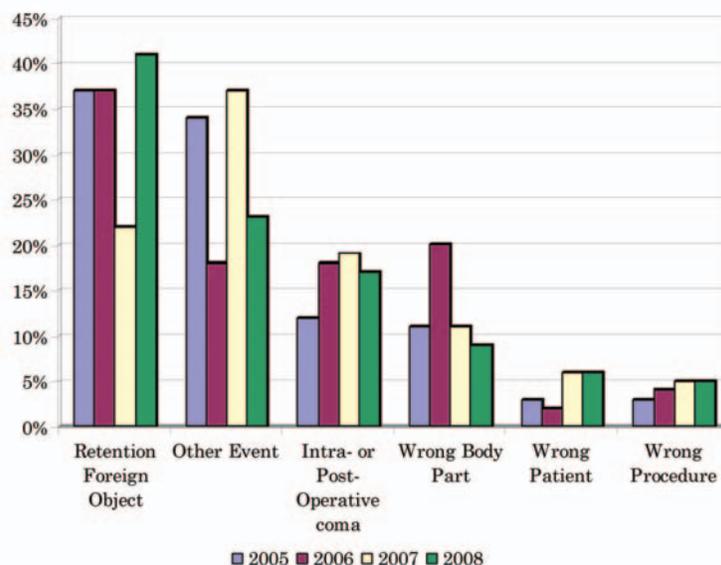
Retention of foreign objects, such as, sponges and instruments is considered by the National Quality Forum and other national organizations to be a preventable adverse event that should never happen. The Centers for Medicare and Medicaid Services includes the retention of foreign objects in its list of non-reimbursed hospital-acquired conditions. In 2005, The Joint Commission added retained foreign objects to its list of sentinel events. Nationally, it is the seventh most frequently reported sentinel event and the fourth most frequently reported event in 2008.¹

A retained foreign object can result in post procedure infections, bowel perforations, abscess, undue pain, return to surgery and even death.¹ A retrospective case-control study was conducted on patients with retained instruments or sponges following a procedure. Sixty cases were identified with 54 of these cases confirmed to have a retained object. Sixty-nine percent of these cases identified the retained objects as sponges. Over half of these objects were retained in the abdomen or pelvis and 22% were retained in the vagina.²

In the four years that the New Jersey Department of Health and Senior Services (NJ DHSS) has been collecting serious preventable adverse events, retention of foreign objects has been the most frequently reported surgery-related event type. Since 2005, there have been 111 retained foreign object events, 64 (58%) of them occurring in female patients. Of these 64 events, 36% were related to obstetrical procedures, generally caesarian sections and vaginal deliveries.

Many facilities do implement counting protocols for surgical procedures that occur in the operating room. However, after review of the root cause analyses (RCAs) for the retained object events reported to NJ DHSS following a vaginal delivery or caesarian section, 50% of the events did not include a count of the sponges, pads, or gauze for these types of procedures. Upon review of the RCAs another trend emerged. Frequently visual inspection of the vagina or a gauze count after a repair of the vaginal area is not required. Thirty-one percent of the RCAs did report a documented correct count, however it later turned out that these counts were incorrect. In some facilities (13% of the events) the count was conducted as the surgeon was closing the incision. In one case, the surgeon was made aware of the missing instrument and decided to close anyway. Most of these retained objects were discovered within two weeks of the event. However, one retained object was not discovered for three years and was calcified.

Surgery-Related Events



Dependability of Counts

There have been several studies conducted on the reliability of surgical counts. Generally, the labor and delivery team rely on discrepancies in the count to screen for the possibility of retained objects.³ However, many studies have found this practice to be unreliable or insufficient. One study on retained objects discovered that the majority of the retained objects were associated with a count that was erroneously thought to be correct, which is consistent with NJ DHSS's findings.² The incorrect counts were due to limitations in the counting procedures, such as, additions, incorrect documentation, or miscounting. These studies concluded that manual counts are not reliable enough to be used without concurrent manual visual checks. Any count discrepancy should prompt a thorough search and reconciliation and should never be ignored.⁴

There is technology available to help assist in the detection and prevention of retained objects. To augment the manual count, radio-frequency (RF), radio-frequency identification (RFID) and bar coded detectable sponges, gauze, and laparotomy pads are available.³ Use of this technology will help with early detection of retained objects, prevention of additional surgery to retrieve the objects, and the need for x-rays to locate retained objects.

Human and Environmental Factors

Many different human and environmental risk factors can result in retained objects. These include communication failures, distractions from the various competing interests and lack of staff.³ According to The Joint Commission, the number one causal reason identified in all the root cause analyses was miscommunication or lack of communication.⁵ The Joint Commission has designated communication as one of its national patient safety goals.

There is a hierarchical structure in many facilities that contribute to communication failures: cross-cultural (physician to nurse), gender-related (male to female), captain-crew (surgeon to OR team) and structural (medical staff to hospital staff).⁶ Other cultural aspects include levels of education, training, and experience. Those with less education or training may feel intimidated by those with more and may not feel comfortable speaking up about issues such as a discrepancy in the counts. Another

factor in miscommunication is the different styles of communication; closed or harsh communication can limit the exchange of information. Many facilities have implemented Situation, Background, Assessment, and Recommendations (SBAR) as one way of improving communication.

Environmental factors also contribute to retained objects.⁵ Noise in the procedure room (i.e. music, conversations, and equipment noise) traffic in and out of the room and interruptions can all cause distractions during the counting process.⁶ Noise can and should be controlled. Traffic and interruptions should be at a minimum, especially while counting, to avoid errors in the process.

Other causes of retained objects include abbreviated or omitted counts during emergency situations, additional unexpected surgical procedures, transvaginal surgery or vaginal emergencies.⁶ A patient's higher body mass is another risk factor that can make it difficult to visually determine if an object is still in the patient. Sponges sticking together and the use of a poor counting system are additional risk factors.

Second Look: Review of Events and RCAs

1. An emergency caesarian section was performed. A sponge count was done and documented as correct following the surgery by the circulating nurse. During one of the counts a lap sponge fell to the floor and when it was found it was not certain if it was placed with the other soiled sponges. This sponge was included in the count and may have been counted twice, resulting in the count being correct. Post operatively, the patient experienced abdominal pain and x-rays were taken. The x-rays detected a lap sponge in the abdomen.

Response: As a result of the RCA process, the facility has revised its protocols to have both the scrub and circulating nurse count the instruments and sponges. The circulating nurse will stretch out all of the lap sponges on a blue pad in the room for visualization, count all the items aloud, confirm the number with the scrub nurse and document the number on the count

sheet. This will be repeated at set intervals during the procedure and at the end of the procedure. Both nurses will sign off on the count sheet when the counts are correct.

- A female patient presented to the emergency department with complaints of abdominal and pelvic pain. Two weeks earlier the patient had a vaginal delivery of a healthy infant with no complications. Upon examination, surgical gauze was found and removed from the vagina.*

Response: Although the patient suffered no lasting physical harm, the facility revised its vaginal delivery checklist to include post delivery digital vaginal inspection and a sponge count. Documentation that this inspection was completed is now required and will be completed by both a physician and a nurse. Also, a sponge count will now be conducted on **all** labor and delivery cases.

- A patient underwent a caesarian section for a pre-term delivery. During surgery a large ovarian mass was removed. At the end of the lengthy procedure the instrument and sponge count was incorrect. An x-ray was performed and a nurse was informed by radiology that it appeared that something was on the film, probably drains. The nurse asked the anesthesiologist and another nurse if the patient had drains, to which they replied yes. It was then assumed that this was what was showing up on the x-ray. The attending surgeon did not speak to the radiologist and accepted the information given by the nurse that the x-ray was negative. The missing lap pad was never accounted for. Approximately one month after the surgery the patient returned for follow-up and x-rays were taken, which revealed the lap pad. The patient underwent exploratory surgery and the pad was removed.*

Response: A break down in communication was the primary cause of the retained object. To improve communication, a new process was developed. When there is an incorrect count, the nurse will document the incorrect count in the chart and complete an OR x-ray request form. The x-ray technologist will sign off on the form and complete the x-ray. The form is then scanned to radiology and the times of the order, when the x-ray was completed, when the radiologist was notified and the time that the radiologist spoke to

the surgeon will be entered on the form, similar to a chain of custody form. Also, the ability to remotely read the x-ray on the labor and delivery unit will allow interactive communication between the radiologist and the surgeon.

Effective Corrective Actions/ Recommendations

There are several issues involved in preventing retained objects, especially during vaginal deliveries or caesarian sections. The first issue is making sure that there are policies and protocols in place for counting sponges/soft goods during these procedures. Other issues include ensuring the reliability of surgical counts, recognizing, evaluating, and controlling the human and environmental factors during the counting process.

Counting Procedures and Protocols

- The Institute for Clinical Systems Improvement (ICSI) believes that active support from administrative and medical leadership for counting sponges/soft goods during vaginal deliveries and caesarian sections is crucial.
- ICSI recommends 3 rules that should be included in the protocol:
 - All sponges and sharps will be counted for **every** vaginal delivery
 - Only radiopaque sponges/soft goods will be present on the labor and delivery trays or enter the delivery field
 - If the count can not be reconciled imaging must be done
- The count process should be performed at the following times:
 - Immediately before the delivery pack is used
 - At the end of the delivery
 - Any time a member of the labor and delivery team is concerned about the accuracy of the count
 - Whenever there is a permanent change of the labor and delivery nurse
- Other recommendations for counting protocols include:^{5,7}
 - Use of audible and visual aids such as, having a count worksheet or a white board in labor and delivery to keep track of baseline and final counts

- A dedicated receptacle for all used sponges/soft goods. This should be in a location where staff can retrieve and count these items and not be mixed with the waste bucket
- Allow sufficient time for the count
- Counting process should include a registered nurse and another person trained in the counting process
- Unless absolutely necessary, avoid disturbing the nurse during the count
- Inform the labor and delivery team about additional items added to the count
- Actively ask if the count procedures have been conducted at the end of the procedure
- Verify the final count before any items are removed from the labor and delivery area
- Countable items that accompany the infant out of the labor and delivery area will be communicated to the labor and delivery nurse and documented
- After all the counts have been reconciled, all the items should be removed from the labor and delivery area
- Have a policy in place for when the count does not reconcile, including accountability for initiating this policy

Minnesota's SAFE COUNT

In 2008 the Minnesota Hospital Association (MHA) started its "Safe Count" campaign to eliminate retained sponges in labor and delivery. Since this campaign started the number of these cases has almost been eliminated.⁸ In 2009, Buffalo Hospital Birth Center was recognized by MHA for putting the "Safe Count" into action and reducing the number of retained sponges following vaginal births to zero for 2008 and into the present.⁹

Safe Count ⁷

- S** Safe Count Teams
- A** Access to information
- F** Facility expectations
- E** Educate staff
- C** Count sponges, sharps, and miscellaneous items
- O** Obtain post-delivery imaging
- U** Use of white board/other visual documentation
- N** Never use anything but radiopaque
- T** Time-out "pause for gauze"

Resources on Prevention of Retained Objects

Minnesota Hospital Association "Safe Count" available at

<http://www.mnhospitals.org/index/tools-app/tool.385?view=detail>

ICSI "Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries" available at:

<http://www.icsi.org/forms/feedback.aspx?catID=12818&itemID=12847>

References

1. Joint Commission. Joint Commission Sentinel Event Trends [online] 2008; available at: http://www.jointcommission.org/NR/rdonlyres/67297896-4E16-4BB7-BF0F-5DA4A87B02F2/0/se_stats_trends_year.pdf
2. Gawande AA, Studdert DM, Orav EJ, et al. Risk Factors for Retained Instruments and Sponges after Surgery. *N Eng J Med* 2003 Jan 16; 348(3):229-235
3. Beyond the Count: Preventing Retention of Foreign Objects. PA PSRS Patient Saf Advis [online] 2009 June; 6(2): 39-45 available at: https://www.ecri.org/Documents/PA_PSRS/2009.06_Advisory.pdf
4. Egorova NN, Moskowitz A, Gelijns A, et al. Managing the Prevention of Retained Surgical Instruments. What is the Value of Counting? *Ann Surg* 2008 Jan; 247(1): 13-8
5. Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries. 2nd Ed. Institute for Clinical Systems Improvement [online] 2008 Sept; available at: http://www.icsi.org/retained_foreign_objects_during_vaginal_deliveries/retained_foreign_objects_during_vaginal_deliveries_prevention_of_untentionally_protocol.html

6. Prevention of Retained Sponges and Towels Following Surgery. Educational Review Systems, Inc [online] 2008; available at: <http://www.cardinalhealth.com/education/ce/>
7. Road Map to Preventing Retained Objects in Vaginal Deliveries. Minnesota Hospital Association [online] available at: <http://www.mnhospitals.org/inc/data/tools/SafeCount-Toolkit/Roadmap.pdf>
8. Spotlight on Patient Safety. MN Department of Health [online] 2009 April; available at: http://www.health.state.mn.us/patientsafety/publications/newsletter0409_rfo.pdf
9. Buffalo Hospital Birth Center recognized for excellence. Allina Hospitals & Clinics [online] 2009 April 15; available at: http://www.allina.com/ahs/news.nsf/newspage/Bufalo_MHA_Safety_Award



For more information or comments on this issue or past issues of the *Patient Safety Initiative Newsletter* please contact:

Patient Safety Initiative Tel: (609) 633-7759

Patient Safety Web Site: www.NJ.gov/health/ps

C1482

Patient Safety Reporting System 2009 Summary Report

