Jon S. Corzine
Governor

PATIENT SAFETY INITIATIVE
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Heather Howard
Commissioner

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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 at total of 163 staff representatives from ambulatory surgery centers from around the state.

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 (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.

- 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 laryngiospasms 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.

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

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**

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