NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

# PATIENT SAFETY REPORTING INITIATIVE

Updates - November 2005

2005: Issue 1

## Patient Safety Act Update

In April 2004, the New Jersey Patient Safety Act (P.L. 2004, C.9) was enacted. This major patient safety law applies to all licensed health care facilities in New Jersey and requires development of patient safety plans and patient safety committees. The law also requires mandatory reporting of serious preventable adverse events and allows for anonymous, voluntary reporting of less serious events and near misses. Draft rules to implement the law have been reviewed with stakeholders and will be formally proposed within the next several months.

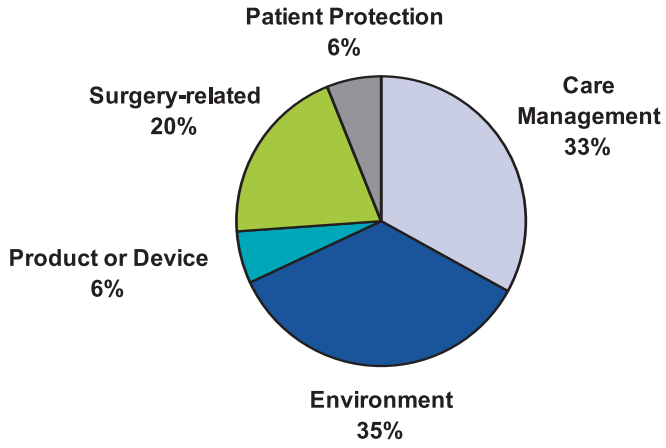
The statute is consistent with the Institute of Medicine's approach, which examines preventable adverse events in terms of systems or processes of providing care and looks for ways to improve the safety of those processes. The primary goal of the legislation is to make health care in New Jersey safer. Facilities have the major responsibility for examining how health care is provided, looking for weakness in their processes and implementing changes.

### Implementation of the Reporting System

The interim mandatory reporting system for general acute care hospitals was implemented on February 1, 2005. Under the interim system, hospitals submit event reports and root cause analyses (RCAs) following the instructions outlined in the **Interim Mandatory Patient Safety Reporting Requirements for General Hospitals.** Event reports are due to the Department of Health and Senior Services (Department) within five (5) business days of when the facility knew about the event or should have known about the event. Those events are reviewed and RCAs are due 45 calendar days after the event report. RCAs are then reviewed for acceptability by the Department.

In the first eight months of operation, more than 270 adverse events were reported. When submitting an event report, facilities are required to classify the event under one of five general categories as defined by the National Quality Forum: Care Management Events, Environmental Events, Product or Device Failure Events, Surgery-related Events, and Patient Protection Events. The relative frequency of reported serious preventable adverse events for the first eight months is illustrated in Figure 1. The majority of reported events were classified as either Care Management (primarily pressure ulcers) or Environmental (primarily falls). These two general categories account for 68% of all submitted reports.

***Figure 1:*** Percentage of Reported Events by Event Category

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# Patient Safety Act Update (cont.)

Hospitals have had no major problems with the implementation of the reporting system since it builds on previous reporting requirements. The **Second Looks** section below gives an overview of several reported events that hospitals should evaluate in terms of their own operations. The review of reportable events on page three gives an overview of events which should be reported to the Department.

## Accomplishments and Next Steps

Additional accomplishments of the Patient Safety Reporting Initiative are:

- **Workshops on reporting requirements and developing RCAs attended by more than 180 hospital staff;**
- **Four additional reporting workshops at hospitals trained approximately 150 staff;**
- **A patient safety web site that keeps facilities up to date on patient safety reporting in New Jersey and national resources;**
- **A database template that allows facilities to monitor their own events and create tracking reports;**
- **A workshop on fall prevention scheduled for November 2005.**

The Department is also in the early stages of developing a web-enabled reporting system for both the mandatory and voluntary reporting systems.

# Second Looks: Review of Events and RCAs

Since the February 1, 2005 implementation of the interim reporting system for acute care general hospitals, the Department of Health and Senior Services has received reports of serious preventable adverse events and related root cause analyses. In the interest of sharing this information and decreasing the probability of similar events happening at your facility, we invite you to take a second look at your facility with these events in mind.

## SPECIFIC EVENTS

*A non-fatal burn in the OR was caused by a laser misfiring while the wand was resting on the patient's abdomen. This hospital changed the device packs to include safety holsters, placed single holsters in all ORs and now requires that all such instruments be placed in the holster when not in use. The power unit was removed and new units purchased.*

**COMMENT:** There is a natural tendency while performing surgery to keep the frequently used instruments within easy reach and not return them to their proper locations such as safety holsters or the scrub tech's stand. This event is an example of why returning the instruments to their protective areas is important.

*A fatal dose of medication delivered via IV infusion pump after the "Stop" button on the pump failed to engage, or keep engaged, the free-flow protection device. A very small sticker on the side of the pump warns that a roller clamp should be used when removing the line from the pump.*

**COMMENT:** The manufacturer's placement of the warning sticker on a part of the pump out of the user's field of vision may have increased the likelihood that it would not be seen and that the necessary second safety device, the roller clamp, would not be used. This facility found that staff with more recent training was more likely to rely on technology, such as the digital read-out STOP, than staff that had been trained with older equipment, such as the roller-clamp.

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*A cardiac alarm not heard in an ICU led to an unrecognized fatal arrhythmia and patient death. The facility had recently purchased new monitors and analysis of this event revealed that the new monitors had pleasant, almost musical, sounding alarms, accessible volume controls and did not produce a paper run, as the old ones did, when a lethal arrhythmia was detected.*

**COMMENT:** The facility concluded in its root cause analysis that the use of a pleasant sounding tone made it less likely that the staff would identify the sound as an alarm and react to the emergency. The staff was also accustomed to the visual cue of a paper run when the monitor detected a lethal arrhythmia and its elimination increased the likelihood that the staff would not recognize the emergency.

## GENERAL TOPICS

*Wrong site, wrong procedure and wrong patient, surgeries have been reported to the Department. Analysis of the events by the reporting hospitals revealed that in all cases the "Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery, including Time-Outs," was not performed according to the JCAHO protocol and there was no monitoring of whether the Protocol was followed and the Time-Out performed.*

**This protocol may be found at:**
***http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/universal_protocol.pdf***

**COMMENT:** These cases illustrate the importance of monitoring both the process, the Universal Protocol with the Time-Out, and the outcome, decreasing wrong-site/procedure/person surgery, in sustaining the change initiated by new policies and procedures.

*Attempted suicides using drawstrings have been reported.*

**COMMENT:** When a patient is an identified suicide risk, it is common procedure to remove articles of clothing, such as belts, ties and shoelaces, which may be used to inflict self-harm. Today, however, patients are just as likely to be admitted wearing sweatpants as a tie. The drawstrings of sweatpants, hoods, jackets and shorts, which also may be worn as underwear, may escape detection unless specifically looked for.

## Examples of Reportable and Non-reportable Events

These examples give an indication of how a hospital should report specific events. Refer to **Interim Mandatory Patient Safety Reporting Requirements for General Hospitals** for Chapter references. Please call the Patient Safety Reporting Initiative at (609) 530-7473 if you have questions about specific events.

**EVENT 1:** A 55 year-old patient presents to the ED complaining of shortness of breath (SOB). A right pneumothorax is noted on the chest x-ray. A left chest tube is inserted by the physician.

***Reportable Event – See Surgery-Related Events (Chapter II, Section 5.D).***

**EVENT 2:** A 74 year-old patient climbs out of bed, slips and falls onto the floor. Subsequent x-rays reveal a fracture of the right hip.

***Reportable Event – See Environmental Events (Chapter II, Section 5.B).***

**EVENT 3:** A 44 year-old patient develops a Stage II pressure ulcer (decubitus) following a prolonged ICU admission after bariatric surgery.

***Non-reportable Event – See Care Management Events (Chapter II, Section 5.A). Only Stage III and IV decubitus ulcers are reportable.***

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**EVENT 4:** An 80 year-old patient who was transferred from another facility to your hospital is admitted with electrolyte imbalance. Upon admission it is noted that she has a Stage I pressure ulcer. Two weeks later a skin evaluation indicates that the ulcer has progressed to a Stage III.

***Reportable Event – See Care Management Events (Chapter II, Section 5.A).***

**EVENT 5:** A 38 year-old patient comes to your hospital with abdominal pain. X-rays reveal a retained sponge from a previous surgery performed at another hospital. The patient has surgery at your hospital for removal of the sponge.

***Reportable Event for you but RCA not required by your hospital – See Surgery-Related Events (Chapter II, Section 5.D).***

**EVENT 6:** A 50 year-old patient presents with abdominal pain. In the recent past she had surgery for abdominal adhesions at your hospital. X-rays reveal a retained surgical instrument in the abdominal cavity. She has surgery to have it removed at your hospital.

***Reportable Event - See Surgery-Related Events (Chapter II, Section 5.D). Your hospital is required to do the Adverse Event Report and the RCA.***

**EVENT 7:** A 25 year-old patient attempts to hang himself with his belt in his hospital room. There is only minimal bruising about the neck with no lasting damage or injury.

***Reportable Event – See Patient Protection Events (Chapter II, Section 5.E).***

**EVENT 8:** Patient is admitted with a diagnosis of deep vein thrombosis (DVT). He is already anticoagulated for another illness. The patient receives two extra doses of Heparin. The patient develops GI bleeding and a possible subarachnoid hemorrhage.

***Reportable Event – See Care Management Events (Chapter II, Section 5.A).***

**EVENT 9:** A 33 year-old patient in Labor and Delivery on oxytocin via a continuous infusion pump is given a massive dose of the drug due to a malfunction of the pump. Her uterus ruptures and an emergency C-section and hysterectomy result.

***Reportable Event – See Care Management Events (Chapter II, Section 5.A).***

**EVENT 10:** A water main breaks and the fire department has to shut off the water at the main valve in order to repair the problem. Your hospital will be without water for the next eight hours.

***This event is not reportable to the Patient Safety Reporting Initiative. Report to Department of Health and Senior Services, Acute Care Survey Unit at (800) 792-9770.***

**EVENT 11:** A 21 year-old patient in the ED with a stab wound of the abdomen is shot in the chest by a visitor.

***This event is not reportable to the Patient Safety Reporting Initiative. Alleged Criminal Activity - Report to Department of Health and Senior Services, Acute Care Survey Unit at (800) 792-9770.***

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

***For more information or comments on this report please contact:***

Patient Safety Initiative Tel: **(609) 530-7473**

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

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