The New Jersey Patient Safety Act and Reporting

New Jersey Department of Health
Patient Safety Reporting System
Objectives

- Review legislation and rules
- Review reporting requirements
- Review reporting process
- Review Root Cause Analysis requirements
- Allow time for discussion and questions
The Patient Safety Act

- C.26:2H-12.23 Enacted in April 2004
  - Enhance Patient Safety
  - Minimize Number of Adverse Events
  - Minimize Patient Harm
  - Improve System/Facility Performance
Confidentiality Protection

- Patient Safety Act encourages honest, critical self-analysis and restricts:
  - Discoverability
  - Admissibility
  - Disclosure of documents, materials and information
    - Be clear about separation between Patient Safety and Quality Improvement activities
Patient Safety in NJ

- We all want the same thing for the patients of NJ:
  - The best care that they can receive
  - Prevention of adverse events
Patient Safety in NJ

- Let’s promote a culture of safety
  - Open-minded to change and improvement
  - Blame-free environment
  - Collaboration between all levels and disciplines of staff
  - Strive for “Zero” adverse events, not just better than the national average
  - Commit resources to improvement
Patient Safety in NJ

- The NJ Patient Safety Reporting System (PSRS) tries to make patient safety:
  - Non-Punitive
    - No public reports are issued by PSRS about patient safety that list individual facilities
  - Educational
    - Encourage literature review for best practices
  - Collegial
Patient Safety
Rules and Requirements

- N.J.A.C. 8:43E Subchapter 10 requires facilities to do the following:
  - Establish Patient Safety Committee
  - Establish Patient Safety Plan
  - Report Adverse Events to DOH or DHS
  - Conduct Analyses of Adverse Events
  - Submit Analyses of Adverse Events to DOH or DHS
Facility Administrators

- PSRS requests a minimum of 2 facility administrative users (FacAdmins)
- FacAdmins must sign a User Agreement
- FacAdmins receive emails sent through the system
- FacAdmins expected to cover for days off
  - Report Readers and Writers who are not FacAdmins do not receive emails in the system
Reporting Requirements

- Event Report entered into the online Patient Safety Reporting System (PSRS) within 5 business days of discovery
  - The physician or surgeon is a member of the healthcare team.
  - If the physician or anyone associated with the ASC becomes aware of an adverse event, this is considered the date and time of discovery.
Reporting Requirements

- PSRS reviews event report in online system
  - PSRS determines whether a Root Cause Analysis (RCA) is required based on the rules and regulations and notifies the facility
- If event accepted by PSRS, RCA submitted to PSRS within 45 calendar days from initial event report
Extensions

- Extensions for events and RCAs may be granted upon request—Send request with rationale as a comment through online system for that Event/RCA

- Some extensions granted automatically if time frame for event review is lengthy
General Reporting
Recommendations for ASCs

- Surgical events (wrong site, procedure, etc.)
- Aspiration
- Pneumothorax
- Perforation of an organ
- Cardiac and/or respiratory issues
- Moderate to severe bleeding
- Infections that require intervention
- Falls with injury
General Reporting Recommendations for ASCs Cont’d

- Any patient transferred to the Emergency Department
  - Transfer from ASC directly to ED
  - Visit to ED or other health care facility (Urgent Care Center, etc.) after discharge from ASC

- Recommend reporting all adverse events
  - PSRS will determine whether event meets criteria for acceptance
Choosing a Category

- **Surgical — Intra/Post-op Coma/Death/Other**
  - Includes cases where anesthesia was administered regardless of whether the planned procedure was carried out
  - Includes cases where adverse events occur within 24 hours of the procedure

- **Surgical — Other**
  - Generally used for infections and any other surgical event that does not fit into the previous surgical event category
Choosing a Category Cont’d

- The following surgical event types have no threshold of injury:
  - Retained Foreign Object
  - Wrong Site
  - Wrong Procedure
  - Wrong Patient
Certain surgical events have a “threshold of injury” requirement in the regulations

- Coma, death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge

Important for PSRS to determine if the event meets the “threshold of injury” when deciding whether the event will require an RCA
Threshold of Injury Cont’d

- Often need information from hospital about what happened once the patient was transferred or presented for treatment after surgery
- PSRS needs to determine how this event affected the patient
- Include this information in the Event Report
Suggestions for Obtaining Information from Hospitals

- Contact performance improvement or quality assurance department and ask for the person who handles patient safety
- Physicians if this is their patient and they have privileges
- If consistent with your practices, have patient sign consent for medical record release as part of routine practice (May want to check with your legal advisors)
The Online System for Reporting Adverse Events

- The two-hour window
- The 2 hour window
- The 2° window
- The 2h window
- Did I mention the two hour window?
The Online System for Reporting Adverse Events

- Choose the correct event type
- Complete the fields
  - May want to work in a word processing document (cut and paste)
  - Description of the event is unlimited field
  - PSRS was not there and we don’t know what happened
- Save your work (within the 2h window)
- Submit to PSRS
Online System Demo

- How to enter an event
- View the communication log
- View comments
- Respond to comments by editing the event
- Submit/resubmit to PSRS
- Resource Tab — Event Specific Questions
Root Cause Analysis

- A process to improve patient safety
- Emphasis on improving and redesigning systems and processes
- Emphasis **not** on individual performance
- Educational opportunity
- Nonpunitive
RCA Required Components

- A description of the event
- An analysis of why the event happened
- The corrective actions for the patient
RCA Required Components

Cont’d

- Method to identify other patients having potential to be affected by the same event and corrective action(s)
- Systemic changes to reduce likelihood of similar events
- How the corrective actions will be monitored
RCA Team

- Ad hoc under Patient Safety Committee
- Distinct from QI activities
- Multidisciplinary and diverse
  - Staff knowledgeable about processes
  - Front line staff
  - Staff involved in event?
- Commitment to RCA Process
Facts of the Event

- Detailed chronological narrative
- Who, what, when, where and how
- Clear, complete and understandable
- Provide enough detail so that a person unfamiliar with the event can understand what happened
- Document all systems/processes reviewed
Identifying a Root Cause

- Use the Facts of the Event to examine why the event occurred
- Start with a broad review of all systems/processes
  - No process is above scrutiny
  - No preconceived beliefs
  - Honest and open discussion
- Focus on prevention
Identifying a Root Cause Cont’d

- Look for Modifiable Risk Factors
- Evidence-based literature review
- Human error and violations of procedure must have a preceding system cause
- Facts of the Event should connect to the root cause
- Often more than 1 root cause
RCA Form Definitions

Patient Safety Reporting System

Mandatory Reporting Instructions, Forms & Letters

All events and RCAs must be submitted through the web based reporting system.

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These documents were created as part of the Department of Health's implementation of the "Patient Safety Act," P.L. 2004, c. 9, (N.J.S.A. 26:21-12.23-12.25) [pdf 19k] Rules (NJAC 8:42 E-10) implementing this act were published in 40 New Jersey Register 1094 (March 3, 2008). Patient Safety reporting began on February 1, 2005, for general hospitals, Psychiatric, Special and Comprehensive Rehabilitation hospitals began reporting on April 1, 2009, and Ambulatory Care Surgery Centers began reporting on October 1, 2008.

Patient Safety Memoranda

- Memo [pdf 324k] from Patient Safety Reporting System, September 7, 2010 to all licensed health care facilities currently reporting to Patient Safety regarding Uncteageable Pressure Ulcers.
- Memo from the Commissioner, April 26, 2009 to all licensed assisted living residences, comprehensive personal care homes, assisted living programs, long term care facilities, residential health care facilities attached to another facility type regarding reporting adverse patient safety events effective May 1, 2009. Form available here.
- Memo from the Commissioner, February 27, 2009 to all licensed home health care agencies, hospice care providers, and ambulatory care facilities regarding reporting adverse patient safety events effective April 10, 2009.

Patient Safety Instructions for Licensed Health Care Facilities

- Guidance on Development of a Root Cause Analysis for Patient Safety Reporting, March 2008 [pdf 312k]
- Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities (instructions and forms), October 27, 2008 [pdf 307k] 
- ASC Guidance, September 9, 2009 [pdf 324k] 

Consensus Definitions for the RCA Form: definitions developed to support the continual efforts to improve patient safety in your facility and to maintain consistency.

- RCA Form Definitions [pdf 26k]
### RCA Form Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Examples *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Behavioral assessment process</strong></td>
<td>Failure to evaluate any patient’s behavior or failure to act upon that assessment</td>
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<tr>
<td><strong>Patient Identification process</strong></td>
<td>Failure to identify properly a patient using at least 2 pieces of information</td>
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<tr>
<td><strong>Care planning process</strong></td>
<td>Failure to formulate or implement properly a standard plan of care from any discipline for the specific needs of the patient.</td>
</tr>
<tr>
<td><strong>Orientation and training of staff</strong></td>
<td>Failure to orient and train any staff member in his/her job requirement and facility policies.</td>
</tr>
<tr>
<td><strong>Supervision of staff</strong></td>
<td>Failure to oversee properly any facility staff member in any discipline to ensure that he/she is doing their job.</td>
</tr>
<tr>
<td><strong>Communication among staff members</strong></td>
<td>Failure to share information in an appropriate and timely manner between all levels of staff.</td>
</tr>
</tbody>
</table>

*May include nursing, PT, OT, any physician, dietary, etc.*
Care Planning Process

- Failure to formulate or implement properly a standard plan of care from any discipline for the specific needs of the patient.
- May include nursing, PT, OT, any physician, Dietary, etc.
May also include the lack of a single, comprehensive and individualized care plan that incorporates aspects of each discipline’s care plan

- Nursing
- Surgeon
- Anesthesiologist
Obstacles on the road to the Root Cause

- Motivation
- Resources
- Time
- Safe Environment
- Team Dynamics
- Commitment
Root Causes

Common Myths

- Accidental injury
- Policies and procedures in place
- Infection rate lower than national average
- The nurse/tech/physician did not...
- Patient noncompliance/characteristics
- Act of God
- No Root Cause
Actions/Prevention Strategies

- Specific, doable and measurable
- Should prevent or decrease future adverse events
- Stronger actions compared to weaker actions
- Permanent actions over temporary actions
- Each root cause may have multiple actions
Monitoring

- Describes how the effectiveness of each action will be measured and communicated.
- States what will be monitored, by whom, and for how long.
- Specific for each action
Common Pitfalls: Action Plans and Monitoring

- General and unmeasurable actions
  - What are you measuring
- Education or review of policy without observation of implementation
  - Attendance at educational sessions does not demonstrate understanding or a change in behavior
Common Pitfalls: Action Plans and Monitoring Cont’d

- Delayed Implementation of Actions
  - New events/injuries not prevented
- Insufficient timeframe for monitoring
  - Compliance wanes over time
RCA Review

- Each RCA is reviewed by one or more clinical Reviewers
- Reviewer must understand what occurred
- RCA must include required components
- RCA must be thorough and credible
RCA Review Cont’d

- RCA may be closed on initial review with comments
- RCA may be returned for additional information
- RCA must be returned for modification if it does not contain the required components of an RCA
Training on the Patient Safety Reporting System

- Familiarity with the system associated with frequency of use
- Staff wear many hats
- Multiple reporting requirements
  - e.g., NHSN
- Staff turnover inevitable
Training Cont’d

Patient Safety Reporting System

In 2004, the New Jersey Patient Safety Act (P.L. 2004, c.9) was signed into law. The statute was designed to improve patient safety in hospitals and other health care facilities by establishing a medical error reporting system.

Rather than seeking to place blame, the system promotes comprehensive reporting of adverse patient events, systematic analysis of their causes, and the creation of solutions that will improve health care quality and save lives.

The site is designed to help health care facilities develop strong patient safety programs and fulfill the law’s mandatory reporting requirements.

Information for Patients and/or Caregivers

Helpful Links for Consumers about Patient Safety:
- Patient Safety Information for Consumer
- Tips for Safer Surgery
- Hospital Performance Report
- Filing Hospital Complaints in New Jersey about care that you or a family member received

Now and Noteworthy

The new reporting web-based system is now available to General Acute Care Hospitals, Comprehensive Rehabilitation Hospitals, Psychiatric Hospitals, Specialty Hospitals and Ambulatory Surgery Centers. All events and RCAAs must be submitted through the web-based reporting system at: www.nj.gov/health/hps/report/

The 2010 Summary Report is now available. This summary report presents the findings from serious preventable adverse events reported to the Department’s Office of Health Care Quality Assessment (HCQA), Patient Safety Reporting System (PSRS). This report also includes the findings of reportable events from Division of Mental Health and Addiction Services (DHMAS). Click here to download the PDF.

On November 15, 2012, the Patient Safety Reporting System presented to the Surgery Center Coalition a comprehensive PowerPoint presentation on Navigating the RCA (Root Cause Analysis) Process. The PowerPoint breaks down the process into 10 easy to follow recommendations that should assist facilities on completing a thorough and concise RCA. To download the PDF, please click here.

The web-based reporting system training presentation is now posted on the Training Materials page.

Prevention Strategies

Event: Patients have sustained severe burns following the application of a hot compress that had been heated in a microwave.

Facility Strategy: Prevention strategies included discontinuing the use of microwaves to prepare hot compresses. Signs were placed near all microwave ovens to remind staff not to use microwave ovens to heat compresses. Education was provided to all clinical staff regarding the proper procedure for preparation of hot compresses. The facility is monitoring the procedure for application of hot compresses with observation.

Previous Prevention Strategies
Patient Safety Reporting System

Training Materials

Information and guidance covering the Department of Health (DOH) requirements for Patient Safety & Root Cause Analysis (RCA). RCA reports are based on the Veterans Administration (VA) model.

New Online Reporting System Training

The four modules are available in Powerpoint slides, Adobe PDF and Flash Audio/Video.

- Module 1: Covers an overview of the system and system access including registering for the myNJ network
- Module 2: Covers how to add a new event into the system
- Module 3: Covers how to enter an RCA with an emphasis on Root Cause and Action Plan
- Module 4: Covers help resources available in the system and ad-hoc reporting

Consensus Definitions for the RCA Form: definitions developed to support the continual efforts to improve patient safety in your facility and to maintain consistency.

- RCA Form Definitions [pdf 26k]

Training Information for Psychiatric, Specialty, and Rehabilitation Hospitals

- PowerPoint Presentation [pdf 420k]
- RCA Guidelines [pdf 13k]
- VA Triangle Questions [pdf 109k]

Training Information for General Acute Care Hospitals

- PowerPoint presentation [ppt 2013]
- Nursing Sites Surgery Case Example [pdf 13k]

Guidance Information for Ambulatory Surgery Centers

- November 2012 Presentation to the Surgery Center Coalition
- June 2011 Presentation to the NJ ASC [pdf 109k]
Resources

- NJ Patient Safety Website

- VA National Center for Patient Safety (NCPS)
  - http://www.patientsafety.va.gov/

- AHRQ Patient Safety Network (PSNet)
  - http://psnet.ahrq.gov/

- National Quality Forum
  - http://www.qualityforum.org
PSRS Contact Information

- PSRS Telephone: 609-633-7759
- PSRS Website http://nj.gov/health/ps

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The significant problems we face cannot be solved at the same level of thinking we were at when we created them

–Albert Einstein (attributed)
US (German-born) physicist (1879 - 1955)
Insanity

Doing the same thing over and over again
And expecting different results.

–Albert Einstein (attributed)
US (German-born) physicist (1879 - 1955)
Discussion and Questions