

NJ Patient Safety Reporting System:

Navigating the RCA Process



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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

Ambulatory Surgery Center (ASC) Reporting

- October 2008
 - Expansion of reporting to New Jersey licensed ASCs
- October 2008 through December 2010
 - 91 Adverse Events reported
 - Majority were Intraoperative/Postoperative Events and Surgery-Other Events
- August 2011
 - Implementation of the web based reporting system

The Patient Safety Reporting System Presents

THE TOP TEN RECOMMENDATIONS FOR
NAVIGATING THE RCA PROCESS



Recommendation #10:

Know the Law and Regulations* Slide 1

- NJ Licensed ASCs must report every serious preventable adverse event
 - Discrete, auditable and clearly defined occurrence
 - Preventable
 - Frequently unable to make this determination at time of event
 - Results in death or loss of a body part, or disability or loss of bodily function
 - Lasts 7 days or present on discharge



* See <http://nj.gov/health/ps/legislation.shtml>

Recommendation #10:

Know the Law and Regulations* Slide 2

- Develop and implement a training program for all
 - Professional staff
 - Direct patient care employees
 - Medical staff
- Program should enable participants to
 - Recognize reportable events, other events & near-misses
 - Report events & near-misses to the Patient Safety Committee



* See <http://nj.gov/health/ps/legislation.shtml>

Recommendation #10: Know the Law and Regulations* Slide 3

- Reporting Requirements are specific to the Patient Safety Act and Regulations
- Reporting Requirements for other agencies and organizations (such as NHSN, Joint Commission) are separate and not applicable to the Patient Safety Reporting System



* See <http://nj.gov/health/ps/legislation.shtml>

Recommendation #9: Know When and How to Report

- Within 5 days of discovery
 - Includes discovery by any ASC staff, surgeon, and anesthesiologist, not the Patient Safety liaison
- By electronic submission
 - Training modules available at <http://nj.gov/health/ps/workshop.shtml>
 - Assistance with registration available at adan.olmeda@doh.state.nj.us

Recommendation #8: Know What to Report Slide 1

- Wrong surgery
 - Wrong site
 - Wrong patient
 - Wrong procedure
- RFOs
- Device-related events

Recommendation #8: Know What to Report Slide 2

- Unexpected occurrences—examples include
 - Aspiration
 - Pneumothorax
 - Perforation of an organ
 - Cardiac and/or respiratory issues
 - Moderate to severe bleeding
 - Infections that require intervention
 - Falls with injury

Recommendation #8: Know What to Report Slide 3

- Any unplanned visit to the Emergency Department
 - Transfer from ASC directly to ED
 - Visit to ED after discharge from ASC
- Any unplanned hospital admission following surgery
 - Temporal relationship
- Any unplanned follow up visit with any health care provider

Recommendation #8: Know What to Report Slide 4

Do not report patients who

Are transferred to the ED and/or hospitalized with an unstable medical condition prior to the procedure and/or administration of anesthesia*

*Administration of anesthesia is considered part of the surgery/procedure (Patient Safety Regulations)

Recommendation #8:

Know What to Report Slide 5

- Do not report patients who
 - Develop an expected or common complication of surgery that is identified on the consent form and does not require hospitalization and treatment.
 - Examples include
 - Urinary retention
 - Need for more intense post-operative pain management
 - Post-operative bleeding following tonsillectomies that do not require transfusion or intervention

Recommendation #7: Provide Event Description

- What occurred
- When it occurred in relation to the surgery/procedure
- How it impacted the patient
 - Diagnoses resulting from the event
 - Required treatment after the event
 - Transfer to ED/hospital
 - Any associated follow-up health care
 - Duration of impact on the patient

Recommendation #6: Immediately begin the RCA Process

- Assemble RCA Team
 - Multidisciplinary
 - Include participation by leadership
 - Include those most closely involved in processes/systems
 - May include staff involved with the event
 - May include additional uninvolved professional staff
- Staff and physician interviews
- Generate detailed timeline for the event
- Review current evidence based literature

Recommendation #5: Provide Facts of the Event Slide 1

- Complete Medical & Surgical History
 - Pertinent social history, such as smoking
- Clinical status prior to the event
 - Provide clinical exam, relevant vital signs, pre-procedure testing results and date of tests
 - Include wound class
- Clinical status of patient after the event
 - Specific clinical findings, vital signs
 - Include wound class

Recommendation #5:

Provide Facts of the Event Slide 2

- Course in facility prior to the event
 - Prevention strategies in place at the time of the event
 - E.g., prophylactic antibiotics, checked sterilization processes, details of surgery
- Course in the facility after the event
 - Treatments and the patient's response
 - Transfers
 - Discharge care and instructions

Recommendation #5: Provide Facts of the Event Slide 3

- Medication at facility
 - Dosages & times administered
- Other factors
 - Specific staffing numbers, ratios, staff training and experience
 - Pertinent labs, other studies
- Additional information
 - All relevant information not addressed in previous sections

Recommendation #5:

Provide Facts of the Event Slide 4

- Document all processes reviewed
- Document which processes were not involved and how this was determined
- Should include enough detail so that a person not familiar with the event can understand what happened
- Should describe the direct cause of the event
- Should include potential causes of the event

The information in the Facts of the Event should lead to the Root Cause and Causality Statement

Recommendation #4: Identify Root Cause(s) Slide 1

- Use the Facts of the Event to examine WHY something happened
 - Address the direct cause
 - Identify potential underlying procedural or systemic causes
 - Continue to ask “WHY” until you identify the underlying root cause(s)
 - Which processes were not involved and how was this determined?

Recommendation #4: Identify Root Cause(s) Slide 2

- Remove barriers
 - There are no sacred cows (i.e., policies, procedures)
 - “This is the way we always did it”
- Don’t make assumptions
 - “I think I know what happened”
- Don’t blame the patient for the event
 - “Patient characteristics”
- Don’t dismiss the event as a complication
 - Many complications can be prevented
 - Focus on modifiable risk factors

Recommendation #4: Identify Root Cause(s) Slide 3

- The Causality Statement should connect the Root Causes with the event.
- There must be documentation to support the finding of each root cause
- Document which processes were not involved and how this was determined

Recommendation #4: Identify Root Cause(s) Slide 4

- The Five Rules of Causation
 - Clearly show the cause and effect relationship.
 - Use specific and accurate descriptors for what occurred, rather than negative and vague.
 - Identify the preceding cause(s), not the human error.
 - Identify the preceding cause(s) of procedural violations.
 - Failure to act is only causal when there is a pre-existing duty to act.

Recommendation #3:

Develop and Implement Action Plan

- Describe the new corrective actions the facility will implement to prevent a similar event
 - Corrective Actions should be specific and address each Root Cause
 - Someone who is not a member should be able to understand what to do next
 - Actions must be auditable
 - There can be more than one Action for each Root Cause
 - There can be (and usually are) more than one root cause

Recommendation #2:

Develop and Implement Monitoring

- Describe how each corrective action's effectiveness will be measured
- How will the facility know whether each Action was implemented?
 - Observation
 - Provides more immediate information
 - Verifies documentation
 - Audits
 - May be time delayed
- Describe how each corrective action's effectiveness will be monitored over time

RCA Process Case Example

Facts of the Event (in brief)

- The 38 year old male patient had a history of a knee injury with meniscus tear
- The patient underwent arthroscopic surgery for repair
- There were no intraoperative complications
- The wound was clean
- The patient was discharged home with instructions to follow-up with surgeon
- Six days postoperatively, the patient presented to the ED with a possible surgical site infection

RCA Process Case Example

Root Cause Analysis:

- Identify what factors can contribute to this type of infection
- Check (examples)
 - Pre procedure assessment
 - Sterilization and disinfection logs
 - Sterilization and disinfection practices
 - Scrub practices
 - OR air exchange
 - Aseptic technique
 - Patient's understanding of discharge instructions

RCA Process Case Example

- Root Cause 1: Care Planning Process
 - Failure to identify or implement properly a standard plan of care from any discipline for the specific needs of the facility
- Causality Statement: The sterilization logs were incomplete at the time of the surgery which may have led to the event. (“If it was not documented, it wasn’t done”.)

RCA Process Case Example

- Actions:
 - Designated staff will review and complete the sterilization and disinfection logs
 - Logs will be reviewed and completed twice daily

RCA Process Case Example

- Monitoring:
 - The OR Supervisor will monitor the action
 - Direct, random observation
 - At least 5 cases per week
 - Review of sterilization and disinfection logs for 100% compliance for 6 months and longer, if necessary, until 100% compliance is achieved.

RCA Process Case Example

- Root Cause 2: Physical Assessment Process
 - Failure by any caregiver to evaluate any patient in an appropriate and timely manner. The evaluation must be consistent with standards of care of the respective discipline
- Causality Statement: Potential modifiable risk factors were not addressed which may have led to the event, such as smoking, diabetes.

Recommendation #1: Make a Commitment to the Process

- Dedicate time to the process
- Dedicate manpower to the process
- Dedicate resources to the process
- Believe this is an opportunity to make a significant difference in patient health care and safety

Resources

- NJ Patient Safety web site:
<http://nj.gov/health/ps/>
- Institute for HealthCare Improvement (IHI)
<http://www.ihl.org/ihl>
- National Center for Patient Safety (NCPS)
www.patientsafety.gov/tools/html
- AHRQ Patient Safety Network (PSNet)
<http://psnet.ahrq.gov/>

PSRS Contact Information

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