Guidance on Development of a Root Cause Analysis For Patient Safety Reporting

Patient Safety Initiative
Health Care Quality Assessment
Department of Health and Senior Services

March 2008

Contents

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A. GENERAL APPROACH TO RCAs

1. Overview of this Guidance Document

This guidance document was developed to provide specific information on Root Cause Analysis (RCA) development and is to be used in addition to the **Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities** available at http://www.nj.gov/health/ps.

Section B provides an outline of the content of any RCA. Since falls and pressure ulcers are the most frequently reported events, *Section C* gives an example of an RCA for a fall and *Section D* covers the RCA narrative elements for a pressure ulcer event.

2. Purpose of a Root Cause Analysis (RCA)

The purpose of the RCA is to uncover the factor(s) that led to and caused the serious preventable adverse event. The preventable adverse event is, very often, the tip of the iceberg. Conducting and writing an RCA is an opportunity to examine how the systems for providing care function. The more areas investigated, the greater the possibility the system(s) will become higher functioning and prevent the next event from occurring.

TIP: RCAs do not focus on individual performance but on performance improvement through a review of hospital systems. The focus is on the "how" and the "why" not on the "who":

- What happened?
- Why did it happen?
- What can be done to prevent it from happening again?

3. General Format of the Report

- Every page of the RCA must include:
  - a Heading with the name of your system and/or the facility, and
  - the NJDHSS Report Number**.**
- Report must be submitted in no less than 10 size font.
- Do not use proper names anywhere in the RCA. *Use titles only* to identify staff, and refer to patient as "the patient."
- It is not necessary to submit copies of progress notes, nurses' notes, medication sheets (MAR) or any other documents from the patient's chart.
- Be brief but complete.
- Format is flexible; e.g., using paragraphs or bullets are both acceptable.

- The Causality Statements, Action Plans, and Monitoring may be presented as a grid in three separate columns. For specific tips, refer to *Section B. RCA Content*.

- **The RCA Team**
  - The RCA multidisciplinary team must be composed of subject matter experts from all systems involved in the adverse event in addition to those not in the field.

  - List RCA team members by titles only.

TIP: Using a multidisciplinary team approach in conducting an RCA can raise the consciousness of all hospital staff about patient safety issues. From CEO to housekeeping and maintenance, conducting an RCA can help to define each person's role in preventing serious injury and death.

4. RCA Form

- Submit the two-page form with each RCA.

- Incident Information on the Adverse Event Report form must match the Incident Information on the RCA Form.

- Patient's name should be spelled correctly on both forms.

- Date and time for the event should match on Event and RCA forms.

- Billing and Medical Record numbers should match on both forms.

- Date the Adverse Event Report was faxed to NJDHSS Patient Safety Initiative must match the date we received it. The date we received it is located at the top of the page on the Facility Notification Form.

B. RCA Content

The RCA must include the four components: Facts of the Event, Causality Statements, Action Plan, and Monitoring.

1. Facts of the Event

- This narrative provides relevant information about the patient and the event. It is a summary of the relevant facts leading to the event and may include medications, lab values, and vital signs, depending on the type of event being presented.

- The Root Cause(s) should be obvious to the reviewer after reading the Facts of the Event.

- Information on the Patient: describes essential patient information and may include:
  - admitting diagnosis,
  - past medical history,
  - pertinent journey through the hospital (i.e., surgery then transfer to the ICU),
  - medications,
  - how patient was affected, and
  - any other contributing factors to the event.

- Details of the Event: provides a chronological description of the event including:
  - date and time,
  - description of the event, and
  - location.

- Include specific, relevant clinical information needed to assess possible root causes.

Example: Incorrect: Staffing was adequate.

Correct: The staffing for the night shift was adequate. Using our acuity protocol, the patient census was 30. There were 3 RNs and 2 PCAs. One PCA was a float from the Neonatal Unit. One RN was a new graduate just out of orientation.

- Include the number of similar events that have occurred in the past three years, if applicable.
  - Similar events refer to the same event or similar types of events that have occurred in your facility during the past three years. The Types of Events are listed on page 2 of the Preventable Adverse Event Report form.
  - Similar events do not refer to the same unit, floor or patient.
  - Do not list patient days or any other quality indicator.
  - List the number of times this type of event ("Falls with Serious Injury" for example) has occurred in your facility over the past three (3) years. This number should be updated with every RCA submission.
  - Following this number, describe what your facility has done to prevent future adverse events of this type.

TIP: Using a bullet style helps the reviewers to understand the efforts your facility has made toward prevention of similar types of events.

Example of Similar Event:
Adverse Event Type: Surgery performed on the wrong body part:
There have been 3 wrong site surgeries at our facility over the past three years. In response, the facility has instituted the following interventions:

- Designated a Patient Safety Coordinator for the operating suite.
- Implemented a standardized mark, as recommended by the American College of Surgeons, to designate the operative site.
- VP of Surgery and Director of the Surgical Suite empowered all staff to monitor time-outs for compliance and accuracy.
- Education on "Eliminating Preventable Adverse Events in the OR Suite - Patient Safety a Priority for Everyone" was given to all staff including nurses, OR techs, housekeeping, anesthesia personnel, and physicians.

TIP: The reason Similar Events are required is to provide the clinical reviewers with a broader sense of what has already been implemented to prevent this type of event from re-occurring.

2. Causality Statement(s)

- The Causality Statement connects the various factors with the event/adverse outcome. Restate the root cause as a connection with the various factors.
- Use the **Facts of the Event** to examine and identify ***why*** the event occurred.
- Refer to Rules of Causation Guidelines in the Appendix of the **Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities** for investigating potential root causes.
- Many facilities find that using a grid helps to focus and track casual statements, actions and monitoring components. We suggest including three columns with the following labels:

Causality Statement	Actions/Strategies/Interventions	Monitoring

TIP: Do not use negative descriptions/judgments in the causality statements.

TIP: It is helpful to write a Causality Statements as follows: "A lack of xxx (insert factor(s)) related to (insert the reason it happened/the root cause) may have caused the (insert name of the adverse event type)."

3. Action Plan

- Consists of interventions, actions/prevention strategies that will be used to address the causality statement in the first column.
- The action(s) must be specific, have been implemented within 45 days from the date of the adverse event, or are currently being implemented.
- If using a grid, list action(s) in the column next to the Causality Statement.
- Specify the time frame for implementation of each action.
- Each action must be specific and quantifiable.
- Include the title only of the person responsible for carrying out the action.

TIP: The action of submitting information to a committee for further discussion is usually not acceptable.

TIP: We suggest that you use the Rapid Cycle Improvement model endorsed by the Institute for Healthcare Improvement (IHI) when implementing actions. Find it at http://www.ihi.org.

4. **Monitoring**
   - Describes how the effectiveness of each specific action will be measured and communicated.
   - Clearly states what will be monitored, by whom, and for how long.
   - Must be specific for each action.
   - If reviewing charts as part of monitoring, include the number or percentage of charts to be reviewed within the specified time frame.

TIP: Monthly or quarterly tracking is not sufficient for RCA monitoring because such tracking does not give feedback on whether or not an intervention occurred. RCAs are designed to prevent the next adverse event from happening; the monitoring should measure whether the specific action was implemented accurately and completely.

Example: The Nurse Managers on each unit will review 100% of the charts for any Agency Nurse working on their unit for compliance with Fall Risk Assessments and Prevention Protocol every week for one month. Staff not in compliance, for whatever reason, will be given gentle feedback immediately following the discovery of an error to prevent future confusion, misunderstandings or lack of compliance.

TIP: Determining what a patient has learned immediately after receiving the training (as opposed to observing the patient as he/she is being educated) ensures that the patient understands the instructions and is able to implement them correctly and safely. This principle of "return demonstration" means to observe a patient as they independently perform the procedure the nurse taught them. This same principle is used for RCA monitoring.

TIP: Monitoring should answer the questions: How do you know that the interventions are, in fact, being implemented correctly? Was the education understood as it was intended? Is the staff accurate and complete in implementing the action/policy/program?

C. EXAMPLE OF A FALL RCA

TIP: <u>What Makes Facts of the Event for Falls Different</u>?
The **Facts of the Event** (the Narrative) tracks a particular patient's condition through the course of the patient's hospital stay. The ultimate goal is to discover the system failures that caused or contributed to the fall within a chronological and clinically coherent presentation. When the event is a Fall, it becomes necessary to understand more of the clinical aspects and thus requires more clinical evidence.

<u>Facts of the Event</u>
An 81 year old male was brought to the ED from an assisted living facility via ambulance on 3/2/08 at 11p.m. with non-radiating chest pain, diaphoresis, and SOB x 4 hours. EKG showed possible changes consistent with an AMI.

ED Treatment: He was given Nitro SL x 2 and 2 mg. Morphine IV for chest pain with good relief. Lasix IV was given for bilateral rales and a chest x-ray that indicated CHF. Lab values indicated a potassium of 3.2 for which the patient received KCL 20 meq. IV x 2 over one hour each. Patient was stabilized and transferred to the cardiac ICU on 3/3 at 6 a.m. with a diagnosis of AMI and an order for a Cardiology consult.

Past Medical History (PMH): Non-insulin Dependent DM, MI one year ago, cardiac disease including CHF and irregular heart beat, arthritis of both knees

Past Surgical History (PSH): CABG x 4 10 years ago, appendectomy 30 years ago

Social History: This patient lives alone in an assisted living facility and is independent with ADLs. His wife of 47 years died a year ago. He has four children in the area who visit him weekly. The nurses at the assisted living facility monitor his BP.

TIP: The patient's social history can be a predictor of hospital behavior with regard to compliance with assistance orders such as "OOB with assistance only." It can also provide the clinical staff with clues for possible depression, family support for 1:1 implementation if needed, and a baseline for degree of forgetfulness or confusion.

Medications taken at home: Glimepiride, Ecotrin, Digoxin, Lasix, KCL, Coumadin, Nexium, Advil, multivitamin.

Medications given in the hospital: Glimepiride, regular insulin, aspirin, Digoxin, Lasix, KCL, Prilosec, NTG, Morphine.

Chronology of Hospital Course:
VS on admission to the ICU were 140/80, 75, 24, 98.2. Pulse Ox was 85% with 2L O2 via NC. After a second dose of IV Lasix given at 7 a.m. the pulse ox was 97% with O2.
Glucose remained between 210-145 with regular insulin.
The EKG rhythm was controlled A-Fib. Bilateral rales were present in both bases – some SOB and DOE were noted.
Chest pain was a 3 on scale of 1-10. Nitroglycerin SL was given x 1at 6:30 a.m. with relief.
Activity order was OOB to BSC.
Pt. had IV of 0.45% NS at 30cc/hr

The Fall Risk Assessment:
The Fall Risk Assessment was completed using the Morse II Scale. Patient was determined to be a high fall risk, and appropriate Fall Prevention strategies were implemented: Universal level (bed in low position, call bell and personal articles within reach, nonskid slippers, etc) plus Level Three high risk precautions (patient instructed to ask for assistance for any patient activity, hourly rounding for toileting, pain, and position needs, evaluation of medications by Pharmacist for poly-pharmacy and medications that increase fall risk, etc).

TIP: If Fall Prevention Program has been implemented in the ED, provide the Fall Risk severity (high, medium, low) in the ED as well as during the hospital course.

TIP: Fall Prevention strategies can be listed in the narrative or a copy of your Fall Prevention Program can be submitted with the RCA.

Event Specifics:
The patient was instructed to call the nurse for assistance if he wanted to use the bathroom. He was wearing non-skid slippers per protocol. He was alert and oriented x 3.

The patient's transfer occurred near the change of shift and the commode was not yet at his bedside. About 7:30 a.m. the patient, having recently received more Lasix IV, attempted to get up by himself to use the urinal.

Although a PCA was out on the floor during morning report, she was a float from the Neuro ICU and unfamiliar with the patient's current history and the ICU's hourly rounding protocol for high risk fall patients.

She heard a loud cry and thud from the patient's room and found him on the floor beside the bed. Patient stated, "I stood up and got dizzy and fell down."

TIP: An exact statement from the patient can give the RCA Team clues as to what might have happened. For example, if a patient that uses the phrase "I think" or "I'm not sure," it may indicate that the patient did not slip or trip. This might indicate a clinical event such as anemia, dehydration, a cardiac arrhythmia or a new HTN medication causing lightheadedness.

He was bleeding from his forehead and c/o pain in left hip area. Three staff members assisted the patient back to bed. The IV of 0.45% NS infiltrated and was restarted by the RN.

The House Physician was notified by phone at 7:45 a.m. The doctor examined the patient at the bedside at about 8:30 a.m. Bleeding was controlled with just pressure so a Stat CT of the head and X-rays of the left hip could be done. The patient was taken to Radiology at 9:15 a.m. with a RN escorting him. Patient returned from radiology at 10:45 a.m.

CT of the head was negative for active bleeding. Hip x-rays showed a fracture of the hip. Upon his return the head laceration was cleaned with NACL and Betadine and four sutures were used to close the wound.

TIP: Using the exact times and dates for examinations, consults, and diagnostic testing can provide a window into the effective functioning of systems like radiology, the laboratory, and the communication mechanisms used to contact physicians and transmit critical results of lab values, x-rays, etc.

Post-Fall Assessment:

- Vital signs before the fall 150/75, 72, 22, 98.4 at 6 a.m.
- Vital signs immediately after the fall 170/85, 104, 28, 98.4 at 7:35 a.m.
- Accucheck immediately after the fall 130
- Pulse OX with oxygen immediately after the fall 98%
- Telemetry strips reviewed immediately after the fall: rapid A-fib, no other arthyminas noted

Medications 0-6 hours before the fall included:

- Routine – None
- PRN – Lasix IV at 7 a.m., Nitro SL at 6:30 a.m.

Patient was stabilized and cleared by Cardiology for ORIF on 3/5/08.

TIP: A well-developed Post-Fall Assessment form that contains most of the information needed for the RCA can reduce the number of hours involved in reviewing the patient's chart. Facilities can expand their Incident Report form or create an entirely new form. It is suggested that the form be completed by the RN caring for the patient at the time of the event.

RCA Team:

VP of Medicine, VP of Nursing, Clinical Pharmacist, ICU Nurse Manager, ICU Falls Champion RN, Risk Manager, and Nursing PI Chair of Falls Committee.

Causality Statement	Action Plan/Prevention Strategies	Monitoring
1. The lack of proper implementation of the Falls Prevention Protocol for high risk fall patients was related to the lack of a cross training program for float staff and may have led to the fall event.	Float personnel have been designated and were cross trained to work only on specific units that are within their expertise.	All Nurse Managers (NM) will review daily staffing patterns to ensure that float personnel have appropriate training for one month. Issues related to staff expertise that arise on the off shifts will be reported to the NM by phone/beeper 24-7 for one month. These reviews and issues will be reported weekly to the VP of Nursing. Once staff skill levels have been determined to be in compliance, reporting will be monthly.
	Retired RNs and PCAs who have worked for the hospital have been recruited to act as on call staff to ensure that staff have appropriate skill levels.	VP of Nursing will monitor the effectiveness of this group through monthly staffing reports.
2. The lack of knowledge about the patient's current condition by the PCA and the lack of the BSC related to the change of shift transfer may have led to the fall event.	A new policy was developed that eliminates all transfers of patients at change of shift.	NM will review time of day for all admissions and discharges daily for one month and then monthly.

TIP: Check the Veterans Administration web site for information on fall prevention. http://www.va.gov/ncps/SafetyTopics/fallstoolkit/index.html.

D. PRESSURE ULCER RCA ELEMENTS

In addition to including the patient's hospital course, as outlined in *Section B. RCA Content*, the following elements should be considered when developing the **Facts of the Event** for a pressure ulcer RCA:

Skin Assessment:

- Use of a validated assessment tool like the Braden.
- Skin evaluation done within 8 hours of admission.
- Routine, accurate skin assessments completed and communicated to other staff during end of shift reports and transfers to other units.
- Consultation with the wound care nurse or team. Specify who or what triggered the consult.
- Frequency of patient assessment by the wound care nurse; the norm is one week.

Nutrition:

- Date and time of the request for nutrition consult. Specify who or what triggered the consult.
- Frequency of patient evaluation by the nutritionist.
- Frequency of blood albumin levels.
- Description of dietary orders that were implemented.

Pain Management:

- Description of adequate pain management.

Resource Equipment:

- Availability of appropriate equipment, e.g., specialty beds, mattresses, wound care products.
- Chronological list of dates and resources used to prevent further skin breakdown.