CE 2.1 HOURS

Root Cause Analysis

Responding to a Sentinel Event

Brenda M. Ewen, MSN, RN, CPHRM, and
Gale Bucher, MSN, RN, COS-C

Adverse events, including sentinel events, require comprehensive review to improve patient safety and reduce healthcare errors. Root cause analysis (RCA) provides an evidence-based structure for methodical investigation and comprehensive review of an event enabling appropriate identification of opportunities for improvement. Use of RCA is described in the home care setting.

Every day, serious adverse events occur in healthcare systems across the country resulting in injury to tens of thousands of people annually (Institute of Medicine, 1999). Home care is not immune. Lack of staff supervision, communication, coordination of care, reduced ability to engage in double checks, lack of care environment control, and a heightened reliance on patient and family cooperation are situations unique to home care that contribute to serious adverse events. Some of these events will rise to the level of a sentinel event as defined by The Joint Commission.

Sentinel Event

The Joint Commission defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof" (The Joint Commission, 2012, p. 1). "Risk thereof" refers to incidents for which a recurrence would involve a significant risk of serious adverse outcome. The Joint Commission (2012) further defines reviewable sentinel events as occurrences that result in "an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition" (p. 1). Permanent loss of function may refer to sensory, motor, physiologic, or intellectual impairment requiring continued treatment or change in lifestyle not present at the start of care.

The Joint Commission's policy on sentinel events includes a subset of events that are considered reviewable regardless of death or serious injury (The Joint Commission, 2013b). In the past, these events have included occurrences involving patients or those receiving services. In July 2013, this list expanded to include certain "harm events" to staff, visitors, or vendors that occur on the healthcare organization's premises (The Joint Commission, 2012).

Root Cause Analysis

The Joint Commission designates events as sentinel because they require an immediate investigation and response. Accredited organizations are expected to respond to sentinel events with a "thorough and credible root cause analysis [RCA] and action plan" (The Joint Commission, 2013a, p. 12). RCA can be defined as "a process for identifying the basic or causal factors that underlie variation in performance (Anderson et al., 2010, p. 8). RCA is a powerful tool used to improve systems, mitigate harm, and prevent recurrence of adverse events without directing individual blame. These goals are accomplished through in-depth examination of an organization's processes and systems with the purpose of answering three questions:

1. What happened?
2. Why did it happen?
3. What can be done to prevent it from happening again?

Identifying the RCA Team

Preparation for RCA begins immediately after the event is declared sentinel. The Joint Commission allows 45 days for completion of the analysis and development of an action plan. Delays in beginning the process could result in unnecessary stress to meet the deadline. The first step in the RCA process is the identification of team members.

A multidisciplinary team, which includes staff members with knowledge of the processes and systems, allows for an effective analysis of the event. Leadership needs be involved to bring decision-making authority to the table. Individuals able to implement change are needed. The decision to involve staff directly related to the sentinel event should be made on a case-by-case basis. Individuals emotionally traumatized by an event may be further distressed through inclusion on the team.

Teams are most effective when members are chosen for their willingness to participate and cooperate. Honed listening and communication skills are key (Anderson et al., 2010). Members must be motivated with time to attend meetings and accomplish assignments. Members may attend all meetings or do so on an as needed basis.

The team needs to have a designated team leader and facilitator. Leaders with authority in the organization, knowledge of the event, and the ability to build consensus are most capable. The facilitator must be experienced with conducting RCA as well as managing groups. Small teams allow for the greatest efficiency (Croteau, 2010).

Gathering Information

Gathering appropriate information is vital to the team's ability to define the problem and determine what happened. Witness information needs to be gathered quickly before memories begin

to fade. Staff must be reassured that RCA is confidential and not used for discipline. Individual interviews can provide information that has not been influenced by others. Clinicians may feel more comfortable discussing the event in private. Group interviews can be used to increase the exchange of ideas and the development of problem-solving strategies. Open-ended questions are an effective means of encouraging staff to share, clarify, or elaborate information.

Pertinent medical records, photographs, notes, and phone logs should be gathered. Relevant policies, procedures, training or education records, time sheets, and schedules should be collected. A literature review, pertaining to the process in question, conducted early in the RCA helps to identify the root cause, strategies, and actions.

If a device or piece of equipment is involved, secure it for examination. Gather manufacturer guidelines, directions for use, and maintenance logs. It should be determined if the Safe Medical Devices Act requires reporting (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf).

Organizing Information

RCA often involves large amounts of information. It is critical to the success of the analysis that all information is well organized and easy to access. Team charters, agendas, and project plans can be used to outline objectives, set target dates, assign responsibility, and keep the team on track. A brief, factual summary of the event, written early in the process, will keep the team focused. Timelines and flow sheets improve understanding and identify disciplines.

Flow charts, affinity charts, or fishbone diagrams can be used to organize information in a visual format. Flow charts outline a process as it is designed as well as how it is commonly carried out. A comparison between a written process and the way it is implemented provides insight into process failures. Fishbone diagrams highlight contributing factors and causes. Affinity charts organize potential causes. The Joint Commission developed tools, including a RCA framework and action plan template, ensure comprehensive review of the event, and organize findings. Tools can be found at http://www.jointcommission.org/sentinel_event.aspx.

Box 1. Additional Resources

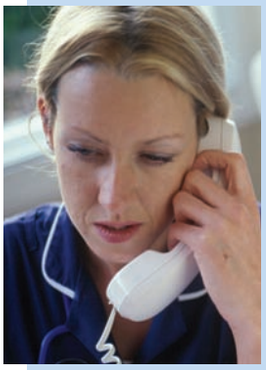
- "How Does Human Factors Engineering Apply to Healthcare?" at http://medicalhumanfactors.net/what-is-hfe/just-culture
- "'Inattentional Blindness' & Conspicuity" (Green, 2004).
- "Handoffs and Communication: The Underappreciated Roles of Situational Awareness and Inattentional Blindness (Gosbee, J., 2010).

Contributing Factors

After information is gathered and organized, the team starts to identify factors that contributed to the event. Contributing factors are system failures that produce consequences (Croteau, 2010). They are the causes of the event, although not necessarily the main cause. The key to the discovery of contributing factors is the question, "Why?"

When determining contributing factors, discussion needs to focus on outcomes and processes not on individual behavior(s). Examine processes to determine if they are inherently flawed or if a variation in the process occurred leading to the event. All possible contributing factors must be considered. Examples of possible factors include:

1. Human factors (human limitations and capabilities): Human limitations and capabilities such as fatigue, distraction, or inattentional blindness. (See Box 1.)
2. Patient assessment: Timeliness, accuracy, link to plan of care, documentation, communication.
3. Equipment: Availability, function, condition, appropriate maintenance and calibration.
4. Environmental: Lighting, accessibility, privacy, safety.
5. Information: Accessibility, accuracy, completeness.
6. Communication: Technology, documentation, timing, handoff.
7. Training/competency: Education, scope of practice, competency assessment, qualifications, effectiveness.
8. Procedural compliance: Compliance, availability of procedures and policies, barriers.
9. Care planning: Individualized, effectiveness.
10. Organizational culture: Response to risk and safety issues, communication of priorities



When determining contributing factors, discussion needs to focus on outcomes and processes not on individual behavior(s). Examine processes to determine if they are inherently flawed or if a variation in the process occurred leading to the event. All possible contributing factors must be considered.

related to safety, and prevention of adverse outcomes.

The Joint Commission offers a "Minimum Scope of Root Cause Analysis for Specific Types of sentinel events," which can aid the team in conducting a thorough review of contributing factors (The Joint Commission, n.d.). Members need to participate in conversation analyzing contributing factors. The importance of exchanging thoughts without criticizing must be emphasized. Whiteboards and flips charts are an excellent way to group ideas and ensure that all team members can visualize information. Once the team has identified all possible contributing factors, the root cause can be identified.

Identifying the Root Cause

To identify the root cause, the team will drill down the contributing factors until the root cause, or most fundamental causal factor of the event, is determined. Success depends on the team's ability to remain focused on system issues instead of human error. When a human error is involved, the cause of the error must be identified. It is the cause of the error, not the error, which must be corrected to prevent recurrence.

There are many tools available to assist teams. "Five Whys" is easily used to isolate a root cause (Anderson et al., 2010). The team starts with listing a contributing factor on a white board. They then ask, "Why?" The answer is listed on the white board and becomes the next factor requiring an answer to "Why?" This process continues until no new answer occurs.

For example, in the case of a wound infection, the team may start with the contributing factor of an unintended retention of a dressing.

There was a retained dressing. *Why?*
The count was not reconciled. *Why?*
Clinician A was unable to reconcile the dressing count. *Why?*
Clinician B had not documented the count. *Why?*
Clinician B forgot to document. *Why?*
Clinician B didn't have her laptop during that visit and was unable to document until later.

In this example, it takes many "Whys" before the root cause (a delay in documentation) is determined.

Identifying the root cause may be accomplished by asking three questions (Croteau, 2010):

1. Is it likely that the problem would have occurred if the cause had not been present?
2. Is the problem likely to recur due to the same causal factor if the cause is corrected?
3. Is it likely that a similar condition will recur if the cause is corrected or eliminated?

If the answer to each question is "No," then the team has identified the root cause. In the above example, it is not likely that the clinician would have forgotten to document the count if she had been able to document immediately in the home. Nor is it likely a similar problem would occur if the root cause were corrected.

It is essential that the RCA team does not prematurely stop asking "why," so that the true root cause can be identified. The team may consider whether the identified cause is actionable to prevent recurrence (Croteau, 2010). If it is, it may be acceptable to stop questioning. Teams must also recognize that more than one root cause is possible. Interactions between root causes cannot be overlooked and may be the actual precipitators of the event (The Joint Commission, 2013b). The correction of one cause does not necessarily mean the recurrence of the event will be prevented. All root causes must be corrected.

The root cause statement needs to be succinct. The Veteran's Health Administration (n.d.)

suggests considering the following guidelines while developing the statement:

1. Clearly demonstrate cause and effect.
2. Avoid negative words such as "poor" or "negligent."
3. Every human error has a preceding cause.
4. Procedure violations have a preceding cause; they are not root causes.
5. Failure to act is only a root cause if there is a preexisting duty to act.

Action Plans

After determining the root cause, the team focuses on identifying strategies to reduce the risk of recurrence. Although the goal is to implement interventions to prevent a repeat of the event, the team must understand that failures and errors do occur. Design strategies to minimize the risk a process failure will reach the patient and to mitigate the effects of the failure if it does (The Joint Commission, 2010). Strategies directed at system and process issues, not individual performance or behavior, are most effective in preventing reoccurrence.

Actions that are concrete, easily understood, and clearly linked to the root cause or a contributing factor are most valuable. To avoid work-arounds, make the safest thing to do the easiest thing to do. The plan needs to clearly define who is responsible for implementing each action and a time line for completion. Action plans may include pilot testing. Determine strategies for measuring the effectiveness of each action.

Actions can vary in effectiveness. The National Center for Patient Safety (n.d.) provides a recommended Hierarchy of Actions on their Web site. Stronger actions are thought to be the most successful. Actions are divided into three categories:

Stronger:
- Physical changes to the work environment,
- Forcing functions,
- Simplification of the process, and
- Standardization.

Intermediate:
- Increase staffing,
- Software modifications,
- educe distractions,
- Checklists/cognitive aids,
- Read back,
- Eliminate look and sound alikes,
- Enhanced documentation or communication, and
- Redundancy.

Weaker:
- Double checks,
- New procedures,
- Training, and
- Warnings.

Once proposed actions are decided, cost, resources, long-term sustainability, and barriers to implementation must be considered. Buy-in from leadership and those on the front lines who will be impacted is critical. Those assigned individual actions must take ownership.

Reporting

Sharing results of the RCA with leadership is necessary. Reports include a brief description of the event, analysis, the root cause, contributing factors, and the action plan. Share lessons learned with all staff. Transparency demonstrates that RCAs are not punitive, but a method to change processes and improve patient safety.

RCA is an excellent tool for identifying causes of sentinel events. The focus on systems and processes instead of performance brings with it a welcome change from past practices of placing blame on individuals. RCA can be used any time a home care agency has a serious adverse event. (See Figure 1.) RCA can also be used proactively to examine near misses. Instead of asking "what happened," the team asks "what might have happened?" Either way, RCA can improve systems and processes and keeps patients safer.

RCA Case Study: Retained Foreign Object

A 75-year-old female patient was readmitted to the hospital with a wound infection post abdominal excision of a large seroma and delayed primary wound closure. Negative pressure wound therapy (NPWT) was initiated on January 5 and replaced with a wet to dry dressing prior to hospital discharge on January 8. The patient was admitted to home care and NPWT was reinitiated by Nurse 1. Information on packing count was not made available to the agency and there was no follow-up contact with the hospital staff.

Later that day, the patient complained that the NPWT system was not functioning. Nurse 1 determined the NPWT was defective, and packed wet to dry pending delivery of a new NPWT device. According to the electronic medical record, the wound was packed with six, 4 × 4 gauze pads, topped with three, 4 × 4 gauze pads (nine total) and four large abdominal gauzes pads secured with tape during the interim. The packing count removed, packing placed, and description for this dressing was documented in the clinical note.

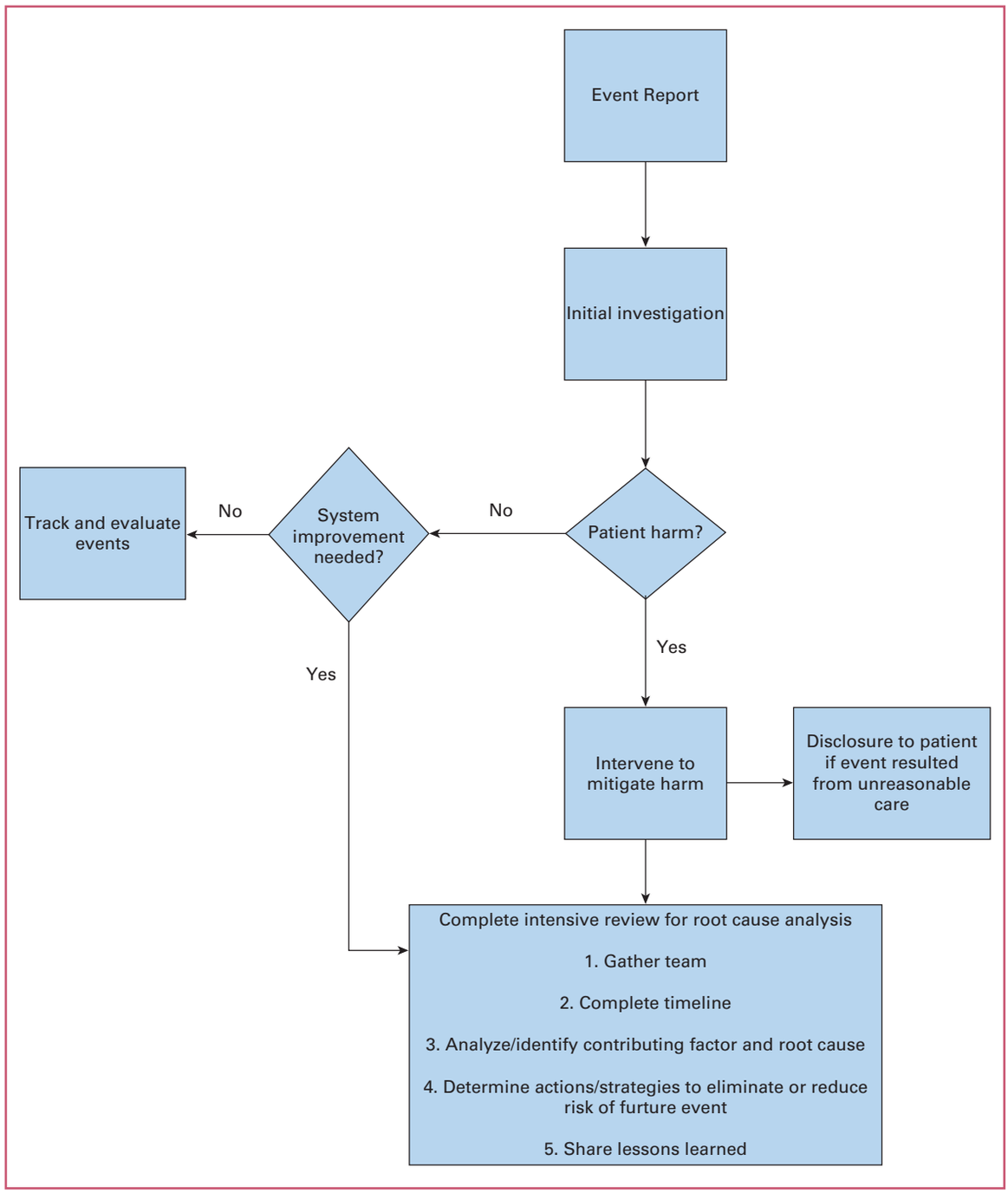


Figure 1. Process for responding to patient safety events.

On January 9, Nurse 2 removed and counted seven pieces of gauze and packed the wound with white foam, covered with black foam, and initiated the new NPWT system with no documentation of packing reconciliation. Seven pieces of gauze removed did not reconcile with the previous note, but went unnoticed. Once the NPWT was in place, the patient received home visits 3 days a week (Monday, Wednesday, and Friday) for wound assessment and dressing changes.

On January 11, Nurse 1 removed the NPWT dressing, including black and white foam as noted and one 4×4 gauze pad found in the wound bed. The nurse made a thorough exam of the wound bed using a sterile Q-tip and flashlight to visualize the deep wound bed. The patient was experiencing an increase in pain and had a temperature of 99.1°F. The nurse reported the findings immediately to the supervisor and the surgeon. The patient was accompanied by the home care nurse to the surgeon's office for further wound exploration. The patient was started on antibiotics in response to a positive wound culture.

The Joint Commission's policy on sentinel events includes retained foreign body as a reviewable event. This event warranted an immediate RCA. A timeline was created using the medical record. Inpatient records were reviewed to pinpoint when packing could have been retained. Review of inpatient and home care records indicated that it was a possibility that the gauze was retained during the inpatient stay. Because of the lack of documentation reconciliation and/or error in removing all dressings from the wound, the time of packing retention could not be pinpointed.

As one can see from the documentation, the investigation and "what-ifs" can be complex. If the reader is counting, one gauze pad is still unaccounted. The first opportunity missed was communication of packing from the hospital. The second missed opportunity occurred on January 9 when the nurse did not document that the count of packing removed was reconciled with the documentation from January 8. The gauze pads could have been retained at any point where there was no communication and/or reconciliation. A gauze pad could have been saturated in a large wound and gone unnoticed. Do staff count and reconcile cover dressings? How thoroughly are staff checking the wound bed to ensure there are no retained dressings?

The team consisted of the agency's chief nursing officer as leader, medical advisor as champion, risk manager as facilitator, wound ostomy continence nurse, supervisor, and staff nurse representatives. Members were selected to provide expert opinions and offer solutions. The chief nursing officer was essential for decision making and implementation of change. The team began the investigation by finding out what happened from interviews and documentation review. An immediate action was to send an alert to staff regarding the importance of adhering to procedures on packing reconciliation and documentation. It is imperative that staff are notified to reduce likelihood of recurrence even during investigation. The team developed an affinity chart to identify possible cause(s) and contributing factors. (See Figure 2.)

Contributing factors were as follows:

- Process for documenting wound packing and cover dressings was not standardized.
- Lack of available Kerlix for single length packing of wounds.
- Risk of retained packing increases with use of multiple dressings.
- Variation in wound assessment; wounds are inconsistently probed and examined with high-quality lighting.
- Large wound with copious drainage made it more likely that dressings would become saturated and invisible in the wound bed.
- Reconciling counts was inconsistent among staff. This was a new process and nurses were still integrating it into practice.

The team learned that secondary cover and packed dressing materials can saturate and stick together, making it difficult to differentiate from cover and packed materials. The root cause determined by the team: *Gauze used to cover wounds are not included in the count and reconciliation process; this practice increases the potential for the cover dressing to be counted as wound packing in large wounds with copious drainage resulting in a retained foreign body.* This shows that the cause-and-effect relationship, if controlled or eliminated, will prevent or minimize future events. The root cause statement includes a specific description for the preceding cause, not human error or procedure violation.

Risk reduction strategies/actions were identified to eliminate or reduce the chance that the event would recur. There should be an action for

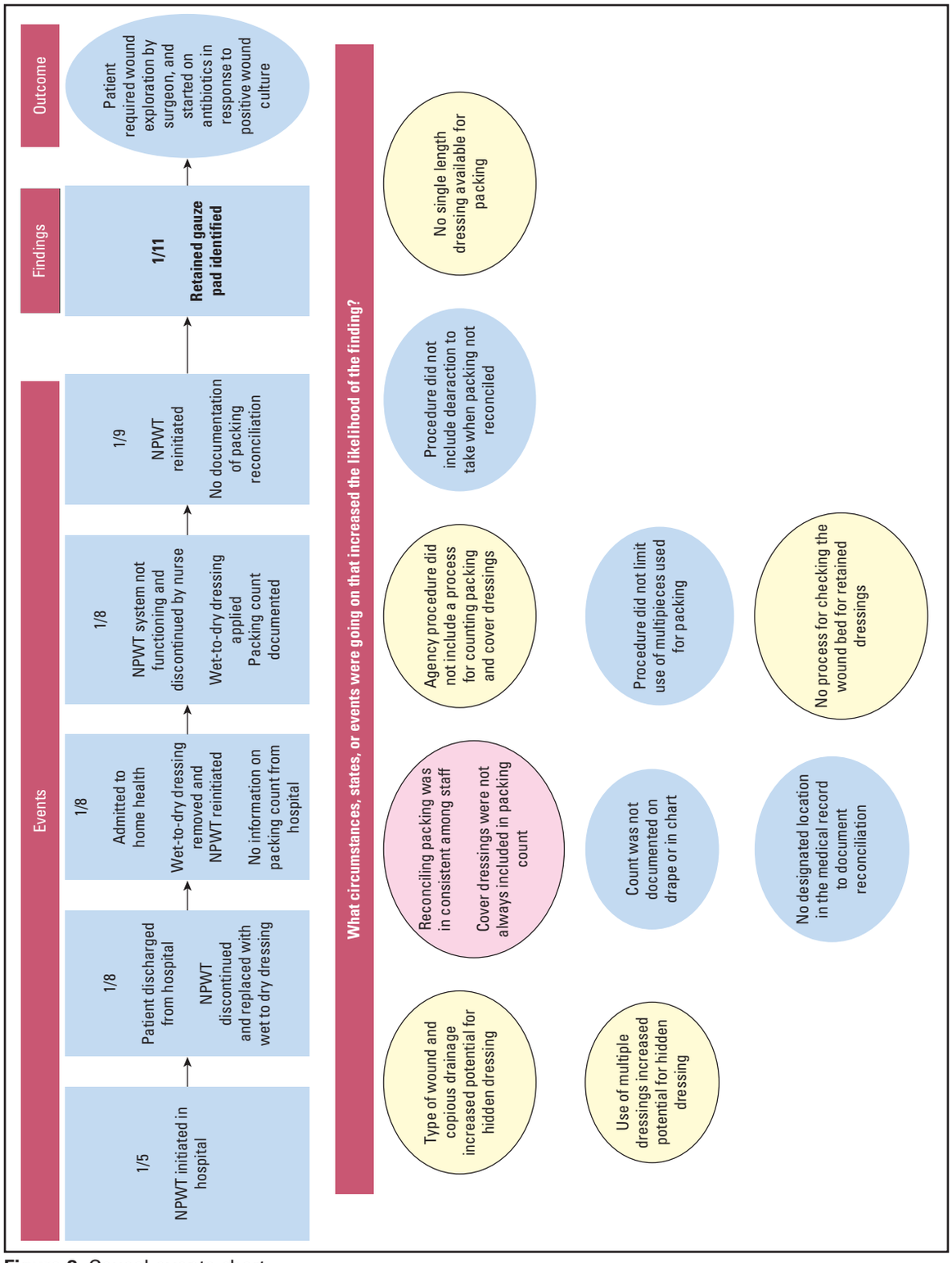


Figure 2. Causal events chart.

Notes: NPWT = negative pressure wound therapy. Root cause (highest-level causes) indicated with pink; contributing factors (first-level causes) indicated by yellow.
Source: Data from Buys, J. R., & Clark, J. L. (1995). *Events and Casual Factors Analysis.* Idaho Palls, ID: Technical Research and Analysis Center, SCIENTECH, Inc.

each cause and contributing factor. The following actions were implemented:

- *Policy*: Referrals involving packed wounds must include packing count for reconciliation.
- *Procedure*: Revision of wound packing process included a process for counting packing and cover dressings, limiting use of multipieces used for packing and documenting dressings materials on the outside of the dressing. The nurse will immediately notify the supervisor when packing is not reconciled.
- *Availability of equipment*: Supply a dressing kit including single length Kerlix for use on all NPWT cases in the event that NPWT is interrupted. Upgrade quality of flashlights for wound exploration.
- *Communication*: Develop a log for patients and family members who change or reinforce dressings. Standardize clinical documentation and evaluate potential for customizing documentation software to include alerts. Adherence is evaluated during record review and shared with supervisors and staff.
- *Training/competency*: Instruct staff on the rationale for accounting for all dressing materials. Simulation training was utilized for demonstration of NPWT dressings and new documentation requirements.

The actions listed include stronger actions such as simplification (use of single length of packing material) and forcing function (software alerts). Although routine staff training is considered a weaker action, use of simulation is considered highly effective. Each action was assigned to an individual who was accountable.

Equally important was sharing lessons learned with the organization. Home healthcare agencies that are part of a healthcare system may have a structure that requires broader sharing results of the RCA. The committee may include members from other care settings and community experts. In our example, new handoff procedures from one level of care to another can result in increased patient safety.

The use and understanding of RCA is essential to healthcare risk management. Healthcare professionals who master RCAs offer valuable expertise to the organization. Experts drive direct care staff to identify best strategies for patient safety. ☗

***Brenda M. Ewen, MSN, RN, CPHRM**, is a Risk Manager at the Christiana Care Visiting Nurse Association, New Castle, Delaware.*

***Gale Bucher, MSN, RN, COS-C**, is the Director of Quality/Risk Management at the Christiana Care Visiting Nurse Association, New Castle, Delaware.*

The authors wish to acknowledge Gale Faraone and Michelle Campbell for their support and guidance.

The authors declare no conflicts of interest.

Address for correspondence: Brenda M. Ewen, MSN, RN, CPHRM, Christiana Care Visiting Nurse Association, 1 Read's Way, Suite 100, New Castle, DE 19720 (bewen@christianacare.org).

DOI:10.1097/NHH.0b013e3182a1dc32

REFERENCES

Anderson, B., Fagerhaug, T., & Beltz, M. (2010). *Root Cause Analysis and Improvement in the Healthcare Sector.* Milwaukee, WI: ASQ Quality Press.

Croteau, R. J. (Ed.). (2010). *Root Cause Analysis in Health Care: Tools and Technique.* Oakbrook Terrace, IL: Joint Commission Resources.

Department of Veterans Affairs National Center for Patient Safety (NCPS). (n.d). *Root cause analysis tools.* Retrieved April 5, 2013, from http://www.patientsafety.gov/CogAIds/RCA/index.html

Gosbee, J. (2010). Handoffs and communication: The underappreciated roles of situational Awareness and inattentional blindness. *Clinical Obstetrics and Gynecology, 53*(3), 545-558.

Green, M. (2004). "Inattentional blindness" and conspicuity. Retrieved from http://www.visualexpert.com/Resources/inattentionalblindness.html

Institute of Medicine. (1999). *To Err is Human: Building a Safer Health System.* Retrieved April 3, 2013, from http://www.nap.edu/openbook.php?isbn=0309068371

Sentinel event policy expanded beyond patients. *Joint Commission Perspectives, 32*(12), 1-3.

The Joint Commission. (2013a). *Comprehensive Accreditation Manual for Home Care.* Oakbrook Terrace, IL: Joint Commission Resources.

The Joint Commission. (2013b). Responding to sentinel events conducting an effective root cause analysis. *The Source, 32*(12), 12-14.

The Joint Commission. (n.d.). *Sentinel events.* Retrieved April 3, 2013, from http://www.jointcommission.org/assets/1/6/2011_CAMLTC_SE_(2).pdf