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Root Cause Analysis in Nuclear Medicine for Sentinel Events

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Abstract:

A sentinel event is any unexpected event that results in death or serious physical or psychological injury to a patient unrelated to a patient's illness. Establishing and determining cause-and-effect relationships is key to preventing future sentinel/near-miss events. However, it can be challenging to establish a cause-and-effect relationship when a process involves multiple steps or people. Root cause analysis (RCA) is a technique that can pinpoint the causes of sentinel events for medical procedures involving numerous steps and people. This article provides a rationale for RCA and the basic steps in a nonmedical RCA investigation. The article then describes a more detailed, nine-step RCA approach for investigating sentinel events and illustrates the technique with a nuclear medicine example.

Key Words: root cause analysis, sentinel event, quality

Introduction:

A sentinel event is any unexpected event that results in death or serious physical or psychological injury to a patient unrelated to a patient's illness. *(1)* On the other hand, near-miss events are errors occurring during medical care detected and corrected before a patient is harmed. Health care providers must be aware of and scrutinize both event types critically to improve safety and quality of care.

When investigating sentinel events and near misses, the cause or why something happened and the effect of what happened must be first identified. Establishing and determining cause-and-effect relationships is key to preventing future sentinel/near-miss events.

Determining the cause-and-effect is usually straightforward for simple processes involving only one step or person. However, it's difficult to establish a cause-and-effect relationship when a process involves multiple steps or people. Root cause analysis (RCA) is a technique that can pinpoint the causes of sentinel/near-miss events for processes involving multiple steps and people.

Factors Giving Rise to the Need for RCA in Health Care

The United States' current, multifaceted healthcare system has led to increased attention on sentinel/near-miss events and the need for providers to be familiar with how to perform a systematic RCA. When the causes of events are identified, problems can be addressed and health care quality improved.

Need for Efficiency

First, the demand for scarce healthcare financial resources in the United States is at critical levels. *(2)* One reason is that life expectancy has increased from 70.1 years in 1960 to 76 in 2021. *(3,4)* Meanwhile, the percentage of gross domestic product (GDP) spent on healthcare has increased from 247 billion dollars (9.4% of US GDP) in 1980 to around 4 trillion (18% of US GDP) in 2020. *(5)* Thus, health care spending has increased considerably with only a modest increase in life expectancy. This finding points to the need for increased efficiency.

Medical Error Prevention

One strategy to increase efficiency is to decrease cost and waste. Medical errors are one of the leading causes of not only waste and increased cost but also morbidity and mortality. Original estimates in 2000 published in the Institute of Medicine's landmark report, *To Err is Human: Building a Safer Health System,* pegged annual deaths related to medical errors at 98,000. *(6)* Today that number is estimated to be over 200,000. *(7)* In response to the unacceptable number of medical errors, The Joint Commission adopted the "timeout" or "call to order" concept in 2003 to curb the rising number of medical errors.

A timeout is an immediate pause by every surgical team member before any medical intervention or procedure to verify the correct patient, procedure, and site. *(8)* The initial timeout process evolved and expanded to become a review of detailed "checklists"— a concept borrowed from the airline industry, an industry with the best safety record. The checklist model was further popularized in health care by Dr. Atul Gawande. *(9)*

Timeouts and checklists have become standard practice. However, the number of sentinel events has not significantly changed between 2005 to 2016. *(1,10)* In 2021, The Joint Commission registered 1068 self-reported and 53 non-self reported (total 1197) sentinel events. *(11)* Although timeouts and checklists play a significant role in preventing medical errors, their weakness is that they cannot address a sentinel event or medical error after it happens.

Teamwork Care Delivery Model

Another factor supporting the need for RCA is the substantial change in how health care is delivered. In the past, solo or small groups were the typical practice model. However, solo practices decreased from 41% to 17% between 1983 and 2014. *(12)* Large medical groups and hospital conglomerations are now the norm. As a result, health care has become more team-based.

To become more efficient, health care unwittingly adopted the team-based, assembly line approach of the auto industry popularized by Henry Ford in the early 1900s. *(13)* The assembly line approach subdivides processes into multiple sequential tasks involving numerous people. Many steps are simple. However, a few steps are always more complex.

For example, in the nuclear medicine scenario, tasks are divided into scheduling, patient preparation, scan performance, interpretation, transcription, and coding/billing. With various personnel completing each task, the physician's time is spent interpreting images and making diagnoses (complex tasks), while the other steps are distributed amongst schedulers, nurse navigators, technologists, transcriptionists, or coders (less complex tasks).

Another feature of the assembly line approach is that it matches task complexity to the skills and pay of the staff on the team. *(13)* The more complex the task, the higher the wage. With only a fraction of the tasks paid at the higher rate and the majority of tasks paid at the lower rate, overall payroll costs are reduced. However, the distribution of work into multiple steps performed by various people increases the risk of errors.

Origin of RCA and the 5 Whys

Sakichi Toyoda, a Japanese inventor and industrialist, recognized the trade-off between the distribution of labor in the assembly line approach and mistakes. He developed the "5 Whys Analysis" technique to determine and eliminate the root causes of problems in the Toyota Motors manufacturing process. *(14)*

The 5 Whys is a simple problem-solving method for quickly getting to the root of a problem. *(15)* The technique starts by identifying a problem and then asking "why?" five times sequentially to drill down and determine what caused a problem. Each time why is questioned, the answer becomes the premise for the next why question. The technique forces the investigator to dig deeper and deeper to find a problem's true cause.

To demonstrate, consider an example of the misadministration of a bone scan dose to the wrong patient:

1. Why did the patient receive the wrong radiopharmaceutical?

   Because the technologist escorted the wrong patient from the waiting room.

2. Why was it the wrong patient?

   Because two patients with the same last name were in the waiting room scheduled for different tests.

3. Why did the wrong patient come forward?

   Because the technologist only called out "Mr. Smith" in the waiting room.

4. Why didn't the technologist realize it was the wrong Mr. Smith?

   Because the technologist did not use two patient-specific forms of identification.

5. Why didn't the technologist use two forms of patient identification to identify the correct patient?

   Because the use of two patient-specific identifiers was not standard practice at the clinic.

When asking and answering the 5 Whys, obtain clear and concise answers, avoiding answers too simple or overlooking important details. The answers to the questions should be logical and backed by proof. Look for patterns and not just at the isolated event. Look for causes for which practical recommendations can be recommended.

Finally, ask why multiple times to identify the cause and not just the symptoms of a problem. Problems will usually resurface if only the symptoms are treated, and the root cause is not identified and corrected.

For example, suppose a patient with chest pain went to the doctor to get a prescription to make the chest pain go away. If the doctor merely gave the patient nitroglycerin to make the chest pain go away, the chest pain would probably return and worsen. However, suppose the doctor asked why the patient had chest pain and investigated further. In that case, the doctor could have diagnosed the patient with a coronary artery blockage and fixed the root of the problem with a stent or bypass.

Basic RCA Steps

RCA is a useful technique for pinpointing the cause of safety events. Event is used here to refer to sentinel or near-miss events. RCA discovers why, what, and how something happened to prevent similar recurrences. *(16)*

There are four primary steps in the RCA process (FIGURE 1). The first step is to collect data. Data collection is critical for obtaining complete information, understanding the event, and identifying causal factors. Diagraming, the second step, helps to organize and analyze information and to identify knowledge gaps. After the causal factors have been identified, the third step is pinpointing the root cause. Finally, step four is the generation and implementation of a solution. The solution should be achievable and aimed at preventing the event's recurrence.

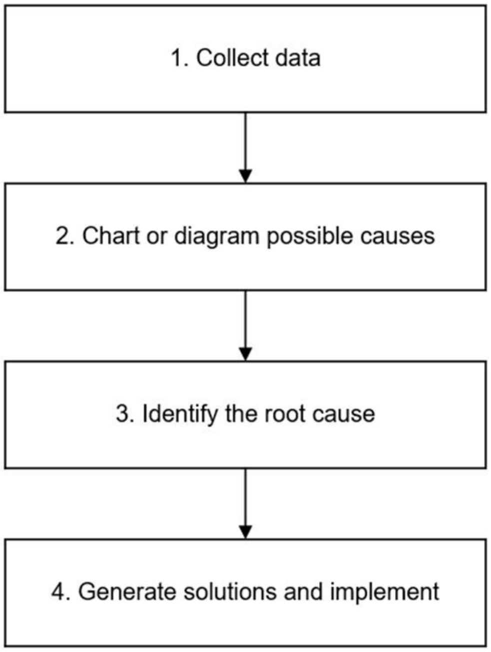

Figure 1. Basic Root Cause Analysis. At its simplest, the basic root cause analysis involves four steps.

Applying RCA to Sentinel Events

Using RCA to examine sentinel events, where a patient could be harmed or die needlessly, must be systematically and comprehensively performed. The analysis should focus on systems and processes and not just the human element of error. These steps are recommended (FIGURE 2). *(17)*

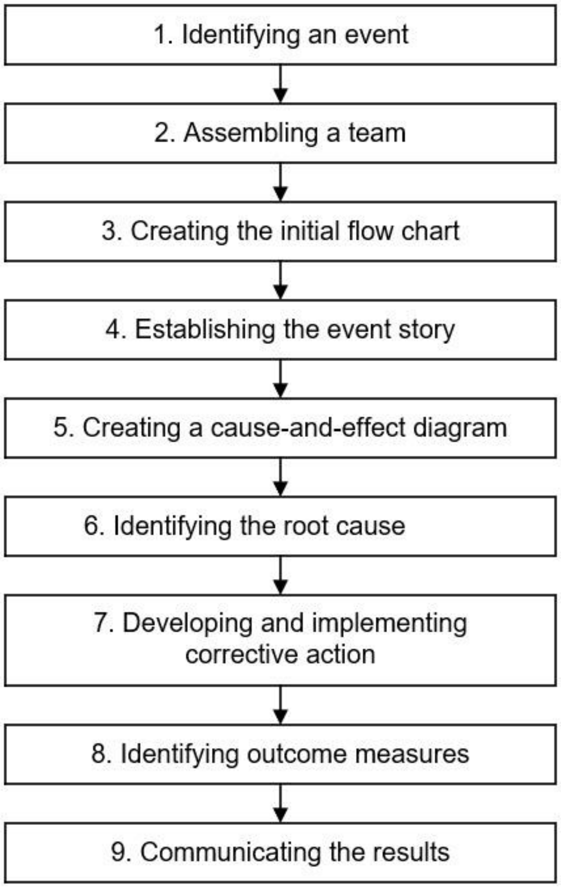

Figure 2. Root cause analysis for sentinel events. Because sentinel events happen in the healthcare setting where multiple people and steps are involved, the root cause analysis process is more involved than the basic root cause analysis process.

Step 1. Identifying an Event

The Joint Commission (TJC) clearly defines and provides a long list of what is and is not considered a sentinel event (for more information: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sentinel-event-policy/camh_24_se_all_current.pdf/). *(18)* Common examples of sentinel events include falls, unintended retention of foreign objects, suicide, wrong surgery, and treatment delay. All staff should be trained to recognize sentinel events or close-call incidents and report them within the system. Usually, a risk-based triage system or committee is used to evaluate the incident and determine the need for RCA.

A fundamental principle of RCA is honest reporting without fear of reprisal. Regrettably, fear of retaliation can be a significant barrier that inhibits staff reporting of incidents. Besides the candid reporting of events, reporting must be prompt (without delay) to ensure details are thoroughly and accurately documented. *(17)*

Step 2. Assembling a Team

Once the need for RCA is established, a small team is assembled to analyze the incident. First, the team collects preliminary data to understand what, where, when, who, and how the event happened.

Teams are usually made up of 4 to 6 individuals experienced in the field and conversant with the nuances of the process leading to the sentinel or near-miss event. Typically teams include physicians, supervisors, staff, and quality improvement experts. The team that performs RCA investigation should not consist of team members directly involved in the event to avoid bias, as bias can be an undesirable source of problems and inaccurate analysis.

Step 3. Creating an Initial Flow Chart

Flow charts are one of the best tools to describe a process or event in a graphical manner, which can usually be understood by a reader better than a description in essay form. Using the preliminary data, the team displays the processes leading to the event using a flow chart. The purpose of the flow chart is to organize the facts. (FIGURE 3).

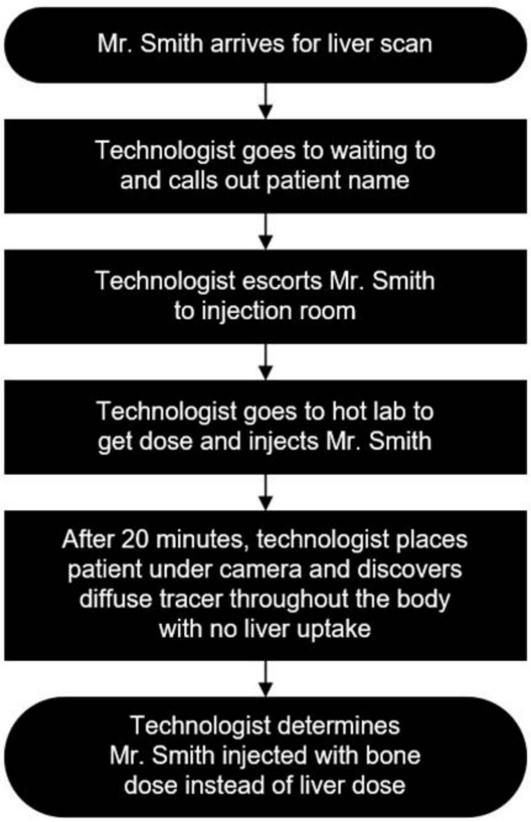

Figure 3. Misadministration initial flow chart. This chart demonstrates the initial facts surrounding the situation where the technologist administered a bone scan dose instead of a liver scan dose.

Step 4. Establishing the Event Story

The flow chart should trigger questions to guide the investigation into contributing factors. The 5 Whys technique is used at this point in the investigation. As a reminder, the goal is to not only assess the sentinel event but also to evaluate the processes leading to the event thoroughly. Therefore, fine granularity is essential in pinpointing the root cause/causes. The information gathered from the investigation adds detail to the initial flow chart for the "event story map development."

Step 5. Creating a Cause-and-Effect Diagram

Once the event story map is generated, the next step is to produce a "cause-and-effect" diagram. A cause-and-effect diagram is another visual tool to logically organize potential causes of a problem (effect). The diagram's purpose is to help the investigating team identify causal links and contributing factors to the root cause.

The components of a cause-and-effect diagram include a problem statement, potential causes (categories), and potential reasons for the causes. Using the same example of administering the wrong radiopharmaceutical to the patient (effect), there could be multiple causes related to scheduling, patient identification, pharmacy error, or patient factors (FIGURE 4 - Fishbone).

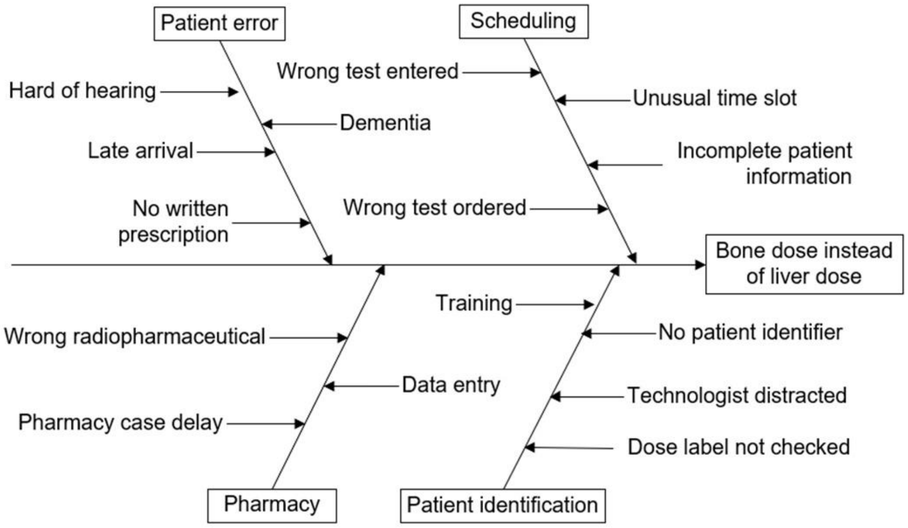

Figure 4. Misadministration Fishbone Diagram. Fishbone diagram demonstrating the effect (misadministration of a bone dose instead of a liver dose) and the potential causes. There are multiple possible reasons or contributing factors for each probable cause.

It is helpful to have the flow chart of the process and event story map side by side when identifying causes. Potential causes are then repeatedly identified until knowledge of the event is exhausted. If few causes are identified, then additional investigation is required.

Step 6. Identifying the Root Cause

The cause-and-effect diagram will show multiple causes, steps, or reasons that led to the event. It is crucial to single out the cause that led to a cascade of failed steps that led to the event. Each cause is examined and discussed along with the contributing factors until a root cause(s) is identified.

Step 7. Developing and Implementing Corrective Actions

The identified root cause is then examined again to develop corrective actions. The team should identify barriers and risk reduction strategies to ensure that the root cause does not reoccur. Multiple corrective steps may be required for each cause. The corrective action planning should include policy changes, training, and other actions to ensure and sustain compliance. In addition, the planning must provide for eliminating implementation barriers and identification of outcome measures. The corrective actions are then implemented.

Step 8. Identifying Outcome Measures

The success of any intervention/change implementation can be measured only by outcome analysis. The outcome metrics should be specific and quantifiable with the ability to be measured over time. The duration of time required for accurate outcome analysis depends on how frequently the procedure/ process in question is done. The more frequently a procedure is performed, the shorter the period of outcome analysis.

Step 9. Communicating Results

The last step is the communication of the results. The event, RCA, corrective actions, and outcome results should be reported to all staff involved and, more broadly, throughout the institution. If deemed important and not institution specific, reporting an RCA in a peer-reviewed publication can have a more significant positive impact.

Special Circumstances for RCA in Nuclear Medicine

The nuclear medicine and molecular imaging field is diverse, comprising nearly 100 diagnostic examinations and a rapidly increasing number of theranostic procedures. *(19)* Numerous procedures require several staff members or the assistance of personnel from outside of the department, such as cardiology, endocrinology, or oncology. In the setting of theranostic procedures, the opportunities for variability are multiplied with the added burden of risk for harm. This diverse number of procedures with multiple steps and various personnel involved presents many different opportunities for error (Tables 1 and 2).

Nuclear Medicine RCA Example

Let's apply the RCA process to a potential nuclear medicine sentinel event: a patient falls off the scan table to make the RCA steps more understandable and meaningful. Was the technologist just careless?

<u>Step 1. Identifying the Event</u>: On August 26, 2022, an elderly patient, Mrs.Darling, underwent whole body bone scan imaging and fell off the table while unattended. The incident happened at approximately 12:30 pm. Technologist Ray Gamma started the acquisition and left the room. About 15 minutes later, he found Mrs. Darling on the floor, moaning and complaining of hip pain. Technologist Gamma immediately reported the event to his nuclear medicine supervisor, who completed the incident form and notified the risk management department. Subsequent x-rays and examination found that Mrs. Darling had a broken right hip. The risk management director, Dr. Gaurdian, determined

the harm was not related to the patient's illness or the procedure. It was, thus, classified as a sentinel event.

<u>Step 2. Assembling the Team</u>: Dr. Gaurdian appointed a team to investigate the event. The team included Dr. Roentgen, a staff nuclear medicine physician vacationing in Florida on the day of the event; the radiology department nurse, Nurse Ivy Line; the nuclear medicine scheduler, Ms. Ida Arrangér; a nuclear medicine technologist who works at a satellite office, Mr. Pho Ton; and one of the risk managers who is an expert in RCA, Nurse Ali Waysmad.

Step 3. <u>Creating an Initial Flow Chart</u>: The team created a simple flow chart to organize the preliminary facts and began the investigation (FIGURE 5)

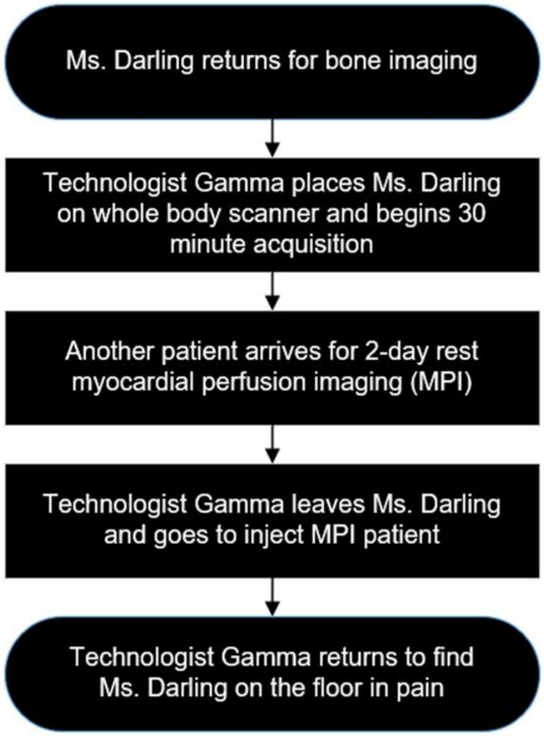

Figure 5. Initial flow chart for a patient fall sentinel event. Initial flow chart describing the facts related to a patient falling off the scan table. This table organizes the facts and will be used to stimulate questions for the investigation and to create the event story.

Step 4. Establishing the Event Story: Using the 5 Whys, the RCA team asked questions and interviewed other staff, such as the receptionist, lead technologist, and other technologists. The team asked questions such as why did Technologist Gamma leave the patient unattended? Why didn't another staff member inject the rest myocardial perfusion patient? Could Technologist Gamma maintain visual surveillance of the patient? What was the patient's mental acuity? Did Technologist Gamma tell Ms. Darling he was leaving the room? Why did Ms. Darling fall off the table?

During the investigation, the RCA team discovered several contributing factors. First, between the bone scan injection and image acquisition, Ms. Darling was told to drink 64 ounces of water. Second, Mrs. Darling did not empty her bladder right before the scan began because the restroom located outside of the department was occupied. Third, Ms. Darling had mild dementia and was hard of hearing. Fourth, half of the technologists were at lunch when the rest myocardial perfusion imaging patient was scheduled for injection. There were no other technologists available to inject the patient. Fifth, the velcro on the table straps was worn and would not fasten well. Finally, Mrs. Darling was uncomfortable and had to use the restroom. As you can see, these factors and several others contributed to the patient's fall (FIGURE 6).

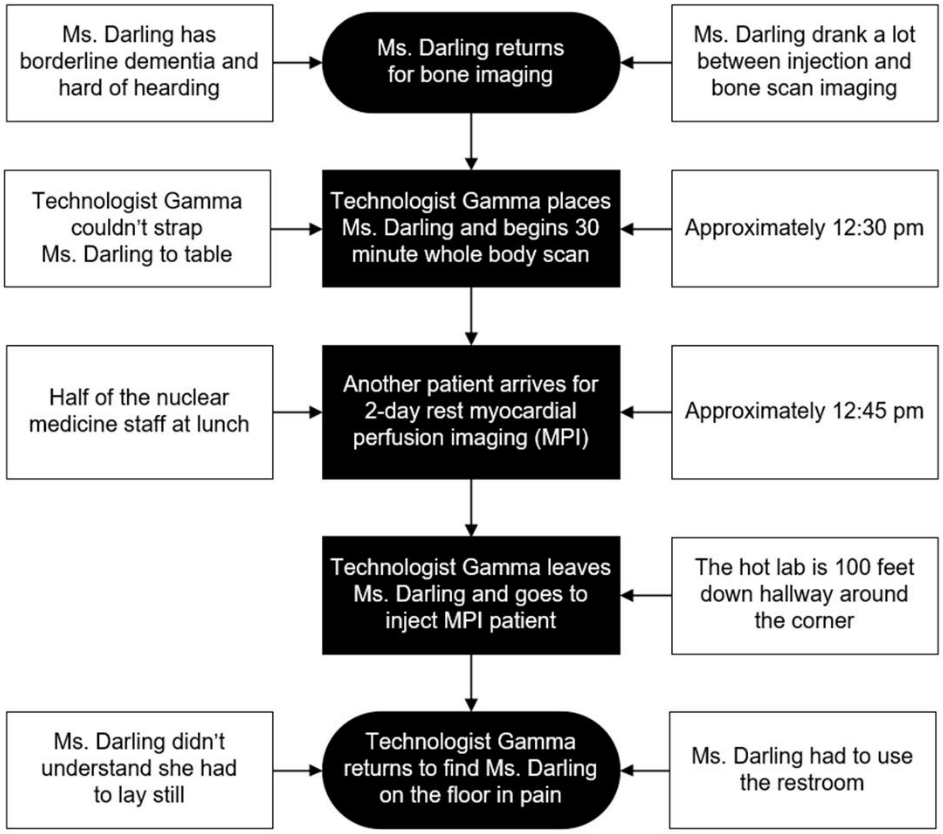

Figure 6. Event story. This chart adds contributing factors determined during the root cause analysis for a patient fall sentinel event.

Step 5: Creating a Cause-and-Effect Diagram: The RCA team organized all the discovered factors to create the cause-and-effect diagram in FIGURE 7. The problem (effect) was that the patient fell off the scan table. The major causal factors were related to the patient, department operation, equipment, and technologist. There were also multiple underlying reasons for each of the major causal factors.

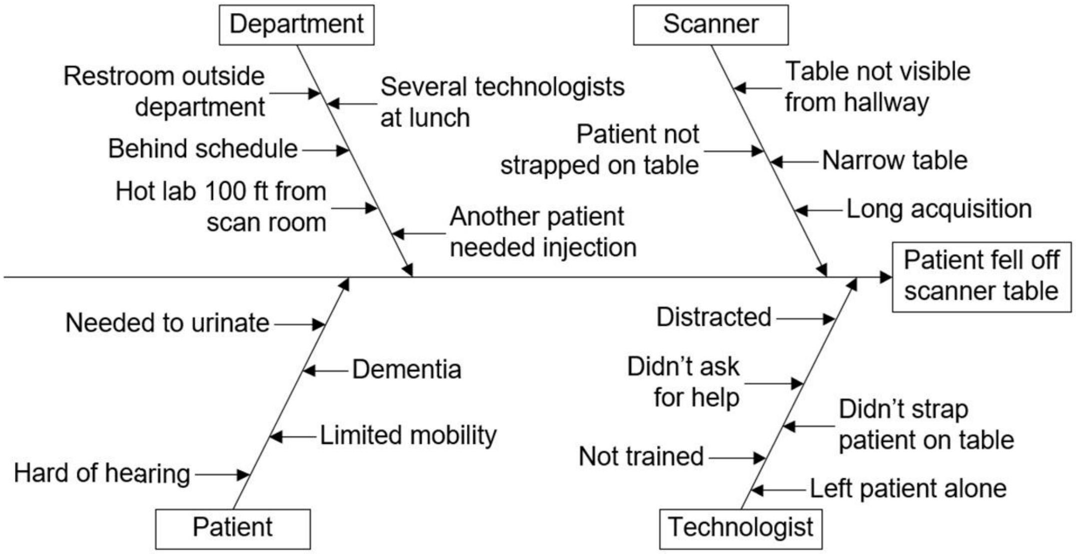

Figure 7. Fishbone diagram of a patient fall sentinel event. The fishbone diagram demonstrates the effect (the patient fell off the scanner table), the potential causes, and contributing factors.

Step 6. Identifying the Root Cause: The RCA team evaluated the fishbone diagram related to Mrs. Darling's fall and identified the root cause. The department was short-staffed during lunch, but patients were routinely scheduled during that time resulting in technologists caring for multiple patients simultaneously. Technologist Gamma believed he had no choice but to leave Mrs. Darling and inject the myocardial perfusion imaging patient because no other technologists were available, and the department was running behind schedule. Contributing factors were the nature of bone scan hydration requirements, lack of an available restroom near the nuclear medicine department, malfunctioning table straps, and the patient's need for continuous monitoring. Although Technologist Gamma could have made other choices, there was more to the story than he was simply careless.

Step 7. Developing and Implementing Corrective Actions: The RCA team, the nuclear medicine supervisor, and other staff reviewed the cause-and-effect diagram and discussed the root cause. They implemented these changes. First, lunches were staggered over a more extended period, so fewer technologists were simultaneously absent from the department. Second, the schedule was adjusted so technologists would not be responsible for more than one patient at a time. For example, a technologist would not have to inject one patient while scanning another. Finally, the velcro patient safety straps were replaced as a minor corrective action.

Step 8. Identifying Outcome Measures. To assess the effectiveness of the intervention, the RCA team and nuclear medicine department monitored the number of times technologists had to care for more than one patient at a time. As numerous procedures were performed daily, the team collected data for one month and then evaluated and made changes as necessary.

Step 9. Communicating Results. To ensure the corrective actions were implemented and sustained, the nuclear medicine supervisor created a new scheduling grid and instructions that were shared with the scheduling department. The supervisor also made a lunch schedule that she posted on the lounge wall and shared during a staff meeting. Finally, the entire nuclear medicine department attended training on caring for patients with varying needs.

Limitations of RCA

The limitations of applying the RCA methods used in the auto manufacturing industry to medicine have been well documented. *(20)* While RCA may be well suited for automobile manufacturing, where the parts and final product are standardized in the form of model, year, and make of the vehicle, medicine deals with humans without the same model, year, and make. The diverse composition of the patient population and their individual needs, including emotional and psychological, create a situation far more complex than an auto manufacturing assembly line. Consequently, RCA in healthcare must be more detailed and involved, as described in the nine steps for RCA in sentinel event investigation.

Another limitation of RCA is that it must be supported by the administration downwards to improve safety and induce cultural changes. *(21)* There must be a blame-free environment so that individuals feel safe and persuaded to talk openly about events. Effective sentinel event communication is key to institutional learning and preventing future events. *(20)*

Finally, RCA can be time-consuming and requires adequately trained personnel. In and of itself, RCA is a complex, multistep process that is operator-dependent. It is often not properly performed, which affects the tool's utility. As a result, there is limited published research demonstrating the effectiveness of RCA in reducing sentinel events and near misses. Thus to be effective, nuclear medicine personnel, including technologists, must be knowledgable and skilled in the technique.

Conclusion

The reliability and accuracy of nuclear medicine procedures are highly dependent on the competency of the nuclear medicine technologist. Despite a technologist's training and skill, the complexity of nuclear medicine procedures increases the likelihood of sentinel events and near misses. Therefore, technologists play a pivotal role in RCA performance and the subsequent prevention of future events.

The team members not only need to know their assigned job but also should know the jobs of the team members who work in the earlier and later steps of the multistep procedure. This knowledge can help to identify and correct errors before a small error snowballs into a catastrophic avalanche.

The technologist team player should not only understand and follow protocols but also understand the principle behind a protocol. Due to the diversity of procedures and diversity of human anatomy and physiology, along with the need for patient-centered care, nuclear medicine technologists must be able to modify protocols without affecting the outcome. The utilization of RCA in nuclear medicine is an invaluable tool to address many challenges encountered in the field.

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Table 1. Diagnostic Nuclear Medicine Error Opportunities

Procedure Stage	Examples Where Medical Error(s) May Occur	Staff Involved
Scheduling	Single vs. multiple-day procedures, procedures with a delay between injection to imaging	Scheduler / Referring Physician
Screening	Scan appropriateness, medication interference, pregnancy/breast-feeding	NM Physician
Patient Preparation	Medications (prescribed and over the counter), NPO status, hydration, caffeine avoidance, oral contrast (barium), IV (iodinated contrast)	Scheduler / Technologist
Radiopharmaceutical Administration	Correct radiopharmaceutical, amount, route, and timing	Technologist
Special Techniques	Stress testing, injections in other departments (e.g., surgery)	Technologist / Stress Test Personnel / Other Physician
Image Acquisition	Collimator, energy window, matrix size, acquisition type (e.g., static vs. dynamic), planar vs. SPECT, SPECT/CT, PET/CT, positioning, technical quality	Technologist
Image Processing and Display	ROI placement, image summation, filtering, normal database comparison, archiving	Technologist
Interpretation and Reporting	Misdiagnoses, missed pathology, incomplete reporting, report timeliness	NM Physician

NM = Nuclear Medicine

Table 2. Nuclear Medicine Therapy Error Opportunities

Procedure Stage	Examples Where Medical Error(s) May Occur	Staff Involved
Scheduling	Single vs. multiple-day therapies, radioisotope availability	Scheduler / Referring Physician /NM Physician
Screening	Therapy appropriateness, medication interference, pregnancy/breast-feeding	Referring Physician / NM Physician / Physicist
Consult	Pre-treatment history, laboratory and other diagnostic testing results, patient factors (e.g., breast-feeding, incontinence, inability to swallow), and home environment	Patient / Family / NM Physician
Patient Preparation	Preparation length (e.g., few days to weeks), Medications (prescribed and over the counter), NPO status, hydration, oral contrast (barium), IV (iodinated contrast)	Scheduler / Technologist / Nurse/ NM Physician
"Timeout" / Radioisotope Administration	Correct patient, therapy, radioisotope, amount, route, timing, complete dose administration	Technologist / Authorized User / NM Physician
Post-therapy	Imaging and timing, medical and radiation safety instructions	Technologist / NM Physician

NM = Nuclear Medicine