ADVERSE EVENTS: ROOT CAUSE(S) AND LATENT FACTORS

The case was a difficult one. The patient had a large lesion in segments 7 and 8 of her liver; a hepatoma in a setting of hepatitis C induced cirrhosis. After careful evaluation, the surgeon recommended resection and the patient agreed. In retrospect, they both might have wished they hadn't.

The conduct of the case was routine-at first. The liver was mobilized; the ultrasound showed no surprises and the blood loss had been minimal. A previous cholecsytectomy made the dissection more tedious. Though the procedure went on for more than an hour longer than scheduled, the surgeon felt satisfied as she left the resident to close the patient and hurried to clinic.

Postoperatively the patient had a rough course. Fever and elevated white blood cell count prompted a CT scan on post op day 4. The surgeon felt a chill when she looked at it. There was a lap sponge in the resected bed. Immediate reoperation was proposed and consented. The sponge was densely adherent to the cut surface of the liver and there was significant blood loss. Though the patient was ultimately closed and sent to the ICU, the combination of 10 units of packed red blood cells and underlying liver disease led to a two week course of liver failure and then, death.

The hospital followed the routine proscribed by the state and the Joint Commission for the Accreditation of Health Care Organizations. The state board of medicine was notified of this "sentinel event." Two weeks later a "RCA" was convened by the risk manager. In attendance were the chief safety physician, the chief medical officer, the risk manager and the VP in charge of quality and safety. The operating room records, operative notes, and policies for instrument and surgical item counts were reviewed. Interviews had been conducted with the nurses and techs involved. The surgeon had blamed the resident for the oversight and was generally uncooperative with the investigation. The group decided that two errors had occurred: both the scrub and circulating nurse had counted incorrectly. A note was placed in each of their files. The surgeon was reminded of the importance of a thorough examination of the body cavity before closure.

Within a year the nurses involved were brought before the state nurse licensing bureau and reprimanded. Ultimately the surgeon was fined $10,000 by the sate board of medicine for her negligence. The patient's family sued the hospital but not the surgeon or nurses. A settlement was reached. As part of the settlement both parties agreed not to disclose the terms of the agreement.

A Different Approach

On December 8, 2005, a Southwest Airlines Boeing 737-700 jet landed at Midway Airport and ran off the end of runway 31C onto Central Avenue where it struck a car. A child in the car was killed, one other occupant sustained major injuries and three others received minor injuries. Eighteen of the 103 occupants of the airplane (98 passengers, three flight attendants and two pilots) received minor injuries during the evacuation.

The National Transportation Safety Board convened an investigation that included representatives from Boeing, the engine manufacturers, the avionics manufacturers, the Chicago Aviation Authority, the pilots and flight attendants' unions, the carrier, the Federal Aviation Administration and the city of Chicago, among other stakeholders. *Two years* later the NTSB released its findings.(1) The probable cause was "the pilots' failure to use available reverse thrust in a timely manner to safely slow or stop the airplane after landing, which resulted in a runway overrun." But, the board went on. "This failure occurred because the pilots' first experience and lack of familiarity with the airplane's autobrake system distracted them from thrust reverser usage during the challenging landing."

They didn't stop there. Contributing factors were determined:

1. Southwest Airlines failure to provide it pilots with clear and consistent guidance and training regarding company policies and procedures related to arrival landing distance calculations.
2. Southwest Airlines' programming and design of its on board performance computer.
3. Southwest's plan to implement new autobrake procedures without a familiarization period.
4. Southwest's failure to include a margin of safety in the arrival assessment to account for operational uncertainties.
5. The absence of an engineering materials arresting system (at the end of the runway.)

Latent Factors and Root Causes

These two scenarios, one hypothetical, one actual are emblematic of two different philosophies of root cause analysis. In the health care environment investigations of adverse events are often conducted in secret with only a few participants. The process frequently concludes that human error was at fault and often recommends remedial training for the persons involved along with some sort of punishment. As if the surgeon and the nurses had set a goal to leave a sponge behind in a critically ill patient.

Aviation investigations begin with the premise that the pilots don't want to suffer bodily harm themselves. This motivates the investigation in a way that can be readily distinguished from the process in medicine. The NTSB conducts hearings in public and the findings are released to all operators of all similar airplanes. All possible "stakeholders" participate in the investigation. Several contributing factors are almost always found to be in play in most of the board's investigations.

This chapter will describe the process of root cause analysis, the theories of error that underlie the concept of systemic or latent factors that allow errors to occur or to be propagated without correction; the difference between the process in health care and those found in high reliability organizations; and will suggest some ways to augment the standard health care RCA into a more robust and helpful process.

Theories of Error

The widely acknowledged "father" of human error understanding is James Reason, a British professor of Psychology. As early as 1990 Reason was writing about the difference between human error and the systemic conditions that either lead to error or fail to catch and mitigate error. "Aviation is predicated on the assumption that people screw up. You (health care professionals) on the other hand are extensively educated to get it right and so you don't have a culture where you share readily the notion of error. So it something of a big sea change," he said in an address to the Royal College of Surgeons in 2003. (2)

Reason has categorized two approaches to human error: person and system. In the person approach, most common in health care, the focus is on the people at the sharp end, like the surgeon who leaves a sponge behind. It views unsafe acts as arising primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence and recklessness. Solutions to error are naturally enough directed at reducing variability in human behavior. Some time honored measures include posters that speak to people's sense of fear, writing additional procedures, disciplinary measures, threat of litigation, retraining, naming, blaming, and shaming. Errors are, then, essentially viewed as moral flaws. (3)

The System approach acknowledges that human beings are fallible and that errors are to be expected. Errors are seen as consequences rather than causes, "having their origins not so much in the perversity of human nature as in upstream, systemic factors. Countermeasures include system defenses to prevent or recognize and correct error. When an adverse event occurs, the important issue is not who blundered, but why the defenses failed."(3)

That healthcare has tended to employ the person approach is understandable; it is in line with a tradition of personal accountability, hard work, and diligence-all traits thought to be desirable in health care providers. Reason pointed out that it is more emotionally satisfying and more expedient to blame someone rather than target an institution, its traditions and power structure.

<u>Person Approach</u>	<u>System Approach</u>
Focus on Unsafe Act of People	Focus on Condition of Work
Unsafe Acts Cause Errors	Upstream Systemic Factors cause Error; Human fallibility is unavoidable
Error Management by reducing Unwanted variability in human Behavior	Error Management by building System Defenses
Uncouple a person's unsafe Act from Institutional responsibility	Recognize 90% of Errors are Blameless
Isolate Unsafe Acts from the System	Remove Error Provoking Properties of the System
Context-recurrent Errors (3)	

However, most human error is unintentional. For instance, in a study of aviation maintenance, 90% of quality lapses were judged blameless. (4, 5) This proportion is likely true in all facets of human performance and implies that we spend the majority of our investigative time on 10% of the problem. Though some small percentage of adverse events are due to “out of bounds” behavior, most aren’t. Thus any serious attempt at risk management must take a systems approach: why did this bad thing happen? This, then, is why a robust investigation into adverse events and near misses to determine the proximate and remote causes is so important. Yes, it is true that the Southwest jet failed to stop on the runway. The real question is why and why and why. A search for the root cause becomes a search for the root causes. In another sense, it isn’t about root; it is about the many factors that can conspire to set up a fertile environment for human error, the last domino, to tip the balance and leave the sponge behind. It is promising that some states, California for example, have begun to fine institutions for sentinel events, not the care provider. It is still a punishment model, but at least the emphasis has shifted to the environment in which the error and subsequent adverse event occurred. See below:

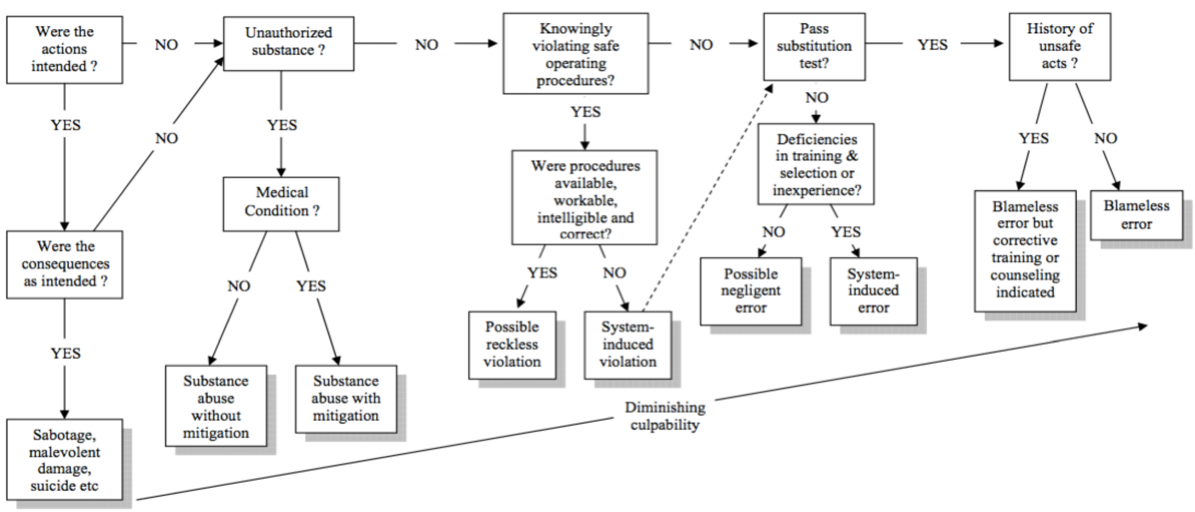


Figure 3. From Reason (1997) A decision tree for determining the culpability of unsafe acts. p209

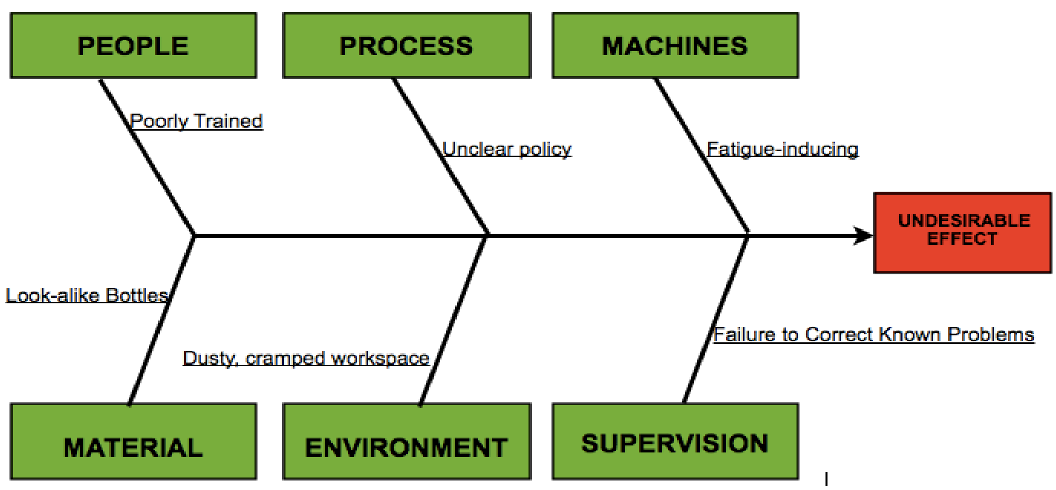
(5)

Root Cause Analysis Methods

A number of methodologies exist to assist in guiding a comprehensive, systems-based approach to events, most derived from Reason’s system approach to error mentioned above. Embracing the conceptual framework (90% of errors are blameless, system issues contribute to most errors, wide sharing of lessons, etc.) is more important than the specific tool chosen.

Each method presses the participants to think broadly and non-linearly about the many contributing causes to an error. Only by exploring a comprehensive list of causes can a full list of contributing causes and responsive solutions be developed. A brief recap:

A. *Fishbone*: Ishikawa diagrams (also called fishbone diagrams) graphically connect causes with their various effects. (6) Each cause is an opportunity for incremental reduction in the likelihood of the adverse outcome occurring. Causes can be categorized by type such as staff, supervision, material, procedures, communication, environment, or equipment. Categorization brings value in analyzing an aggregation of like events but is less useful in the analysis of an individual event. It might, for instance, be useful to know that of the 9 wrong site operations in the last 5 years at the same hospital as the retained sponge case, 60% have been partially caused by team distraction during the timeout. Here is an example of fishbone analysis:



B. *The 5 Whys*: Attributed to the Toyota corporation, "5 whys" urges the analysts to dig deep.

> "A relentless barrage of "why's" is the best way to prepare your mind to pierce the clouded veil of thinking caused by the status quo. Use it often."
> – Shigeo Shingo

Benjamin Franklin's 5-Why Analysis:
For want of a nail a shoe was lost,
for want of a shoe a horse was lost,
for want of a horse a rider was lost,
for want of a rider an army was lost,
for want of an army a battle was lost,
for want of a battle the war was lost,
for want of the war the kingdom was lost,
and all for the want of a little horseshoe nail. (7)

Consider this example. A surgical item was retained. The nurse miscounted. Why? Because he was distracted. Why was he distracted? Because the surgeon was still closing and was asking for more sutures. Why was the count being done before the surgeon was done closing? And so on. The 5 Whys might lead to analyses such as these:

or...

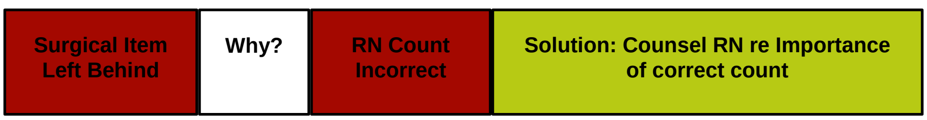
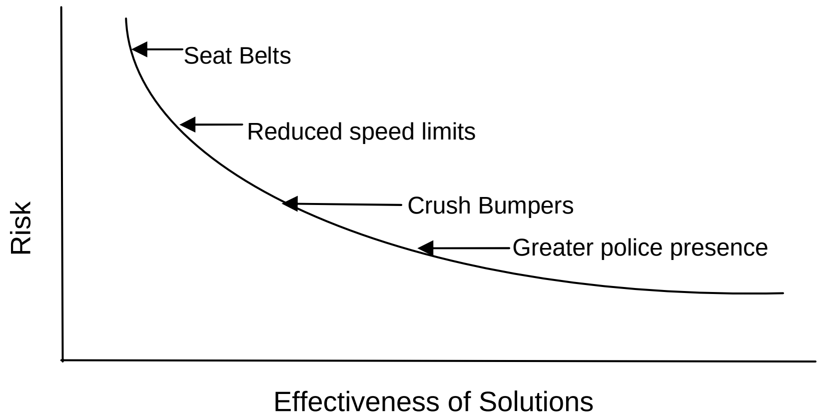


Figure 2

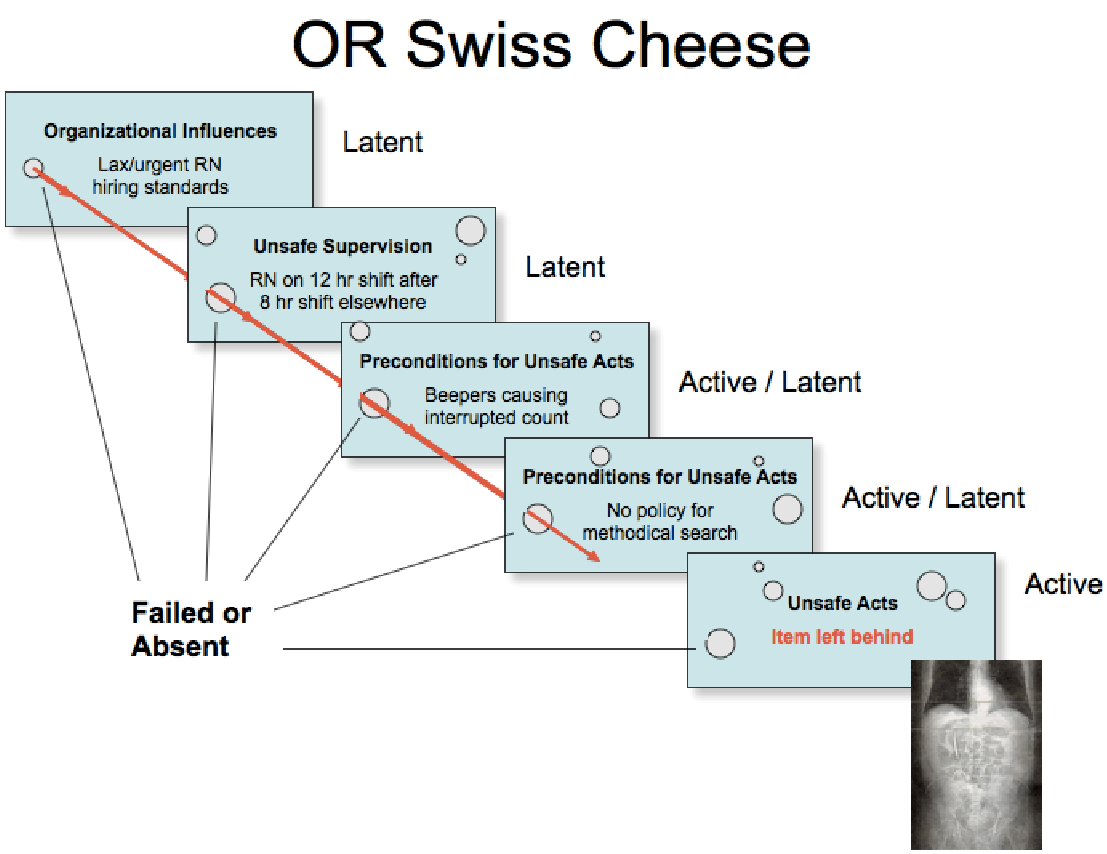
These analyses of the miscount are linear. The risk is they can lead to one solution or one culprit - the surgeon erred or the nurse erred. One could conclude that there is a magic bullet at each example’s terminus: if that cause were fixed, the offending error would not recur. Be cautious of linear cause maps.

All error derives from complex, at times imperfect, systems. Take for instance the issue of traffic fatalities. Each solution in the graph below arises from a different cause. (8) Each reduces the likelihood of traffic fatalities. No one solely eliminates traffic deaths. Given the inevitability of human error, the risk is never reduced to zero. Highly safe systems layer on error-avoiding and error-trapping processes to reach their acceptable level of risk.

The more defenses, the lower the risk of error occurring and not being caught. Note that each solution reduces the risk of traffic deaths. The cost of each intervention can be evaluated in relationship to potential cost of human lives.



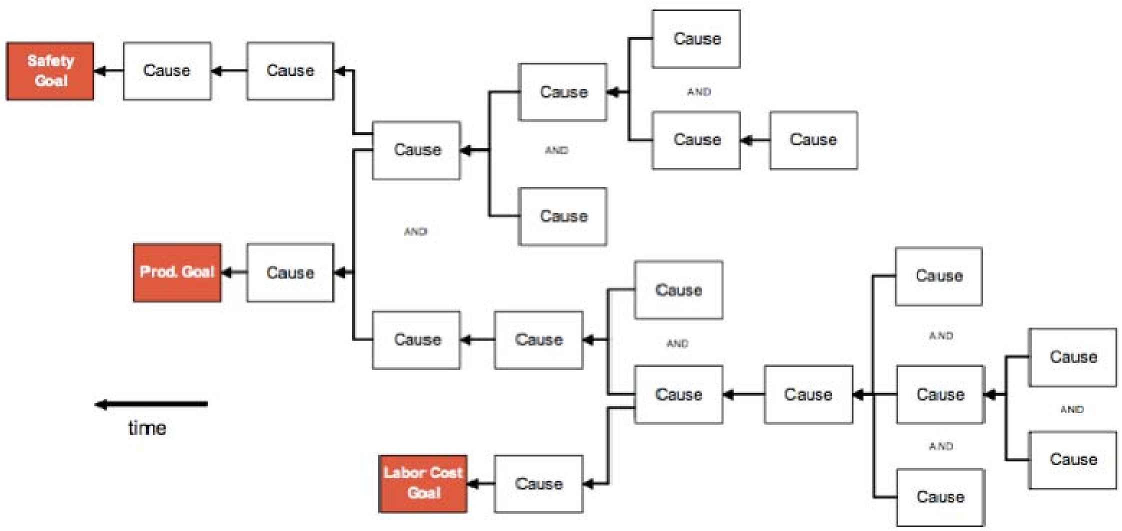
Reason's Swiss cheese diagram shows several levels of defenses against inevitable human error. This is an example of Reason's multi-layered approach to error as adapted to the surgical environment.



Figure

Multiple Causes Analysis: Let's rethink the retained item scenario above.
The nurse miscounted. Why? Because he was distracted and the odds of a count of 100 items being in error is +/-10%. Why was he distracted? Because the music was loud, the beepers were going off, the surgeon hadn't closed and was asking for more sutures during the count, and there was mental pressure to get the next case started.

If we built a graph of this cause analysis it would be multi-pronged and complex. It would represent the many system issues that bear on the outcome. Each cause would have its own effects and its own possible solutions - a more robust and fruitful analysis. Here is an example:



(9)

This way of thinking leads to a distinction between the term root cause (singular,) connoting one, primary, dominate cause and an alternate approach which analyzes many possible causeS (plural). While the NTSB does conclude with one "probable" cause, it also goes on to list many "contributing" causes for each accident.

An alternate approach dispenses with prioritization of causes. Causes have corresponding solutions so the objective is to discover all causes and the resultant array of solutions. In this approach the solutions, not the causes, are prioritized as to their ease and cost of implementation, and their effectiveness. This approach supports Reason's system vs. person approach to error and it recognizes the latent conditions that lead to, support and may create error.

Continuing with the retained surgical item (RSI) example. A multi-pronged cause analysis would arrive at a number of solutions each of which would reduce (but not eliminate) the risk of RSI. Some possibilities:

1. Assertive reduction and management of the environmental distractions such as pagers, music and door openings.

2. A required search of the body cavity by both the Attending and the Resident.

3. Clarity that ensuring the extant case goes well outweighs any institutional pressure to start the next case (along with a change in the policies that might provide the pressure.)

4. A high tech wand detection system to perform a final check for RSIs.

5. Mandatory X-rays in cases in which the count is unreconciled.

6. …and so forth

Each of these solutions can be evaluated and prioritized based upon their ability to reduce the risk of RSI and their total cost. Considering Reason's Swiss cheese model, several of the possible error-reducing or error-catching tools may be layered into the process, depending on the level of risk the hospital is willing to take. (9)

"Many people think of cause and effect as a linear relationship, where an effect has a cause. In fact, cause-and-effect relationships connect based on the principle of a system. A system has parts just like an effect has causes...Most organizations mistakenly believe that an investigation is about finding the one cause-or a "root cause." (9) An alternate approach dispenses with prioritization of causes. Causes have corresponding solutions so the objective is to discover all causes and therefore an array of solutions. In this approach the solutions, not the causes, are prioritized as to their ease and cost of implementation and their effectiveness. A further advantage of this approach to analysis and resolution is that the chosen corrections flow directly from the actual causes. Solutions imposed on the organization that obviously bear little relationship to what the staff knows to be the issues, lead to disparagement of the RCA process. Worse yet, a barrage of solutions unrelated to the underlying causes is thrown at the organization, potentially further deteriorating the work environment with extra steps and procedures not related to the discovered causes

The Consequences of the Person Approach to Medical Error.

In September 2010 Kimberly Hiatt, a critical care nurse in Seattle Children's Hospital, made a medication error that contributed to the death of a 8 month old child. She was fired by the hospital and investigated by the state's nursing commission. In April 2011, she killed herself. (10)This terrible consequence illustrates the price we pay as a profession for the secrecy and judgmental approach to medical error. In medication error incidents, root cause analyses frequently find several systemic causes like the similarity in appearance of bottles with different dosages; arithmetic errors in situations where no double check system is in place; fatigue; inadequate handoff policies, etc.

It is estimated that 250 doctors commit suicide yearly; a rate about twice that of the general population. For those involved in medical error, the rate of contemplating suicide is three times higher than other physicians. Obviously, the sense of responsibility and chagrin about a mistake weigh heavily on our fellow caregivers. (10)

Secrecy, Malpractice and Error

Most risk managers in US hospitals will tell you that their job is to keep the institution out of trouble and out of the newspapers. Fear of litigation and public exposure is a cultural hallmark of medicine. This fact is in direct contradiction of the principal of "widely shared error," open exploration of the causes of adverse events and a "just culture.' These barriers to cause analysis are described in detail in chapter III.

Do RCAs Work?

Recently concern has been voiced about the usefulness of RCA's in healthcare. Why is IT that a tool used so effectively by the NTSB has not become commonplace and useful in medicine? Wu et al (11) noted that many medical RCAs were conducted incompletely or incorrectly. They found that many placed inappropriate emphasis on finding the single "most common reason." Furthermore, formulating actions in response to RCA findings, even modest ones, were difficult to implement. Politics, resources and lack of understanding of the RCA process were attributed causes for several instances where the hospital had repeated adverse events of the same nature even after several obvious causes had been uncovered in RCA. This leads some administrators to discount the process as unhelpful. Add to that concern the worry that RCA content is discoverable during mal-practice litigation. This further reinforces the blame, secrecy, self protective political environment that sees to it, surely, that another event will occur.
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Wu et al also found little literature to support RCA's abilities to reduce risk or improve safety. There were also no studies in the peer reviewed literature to suggest that implementation of RCA findings could be cost effective.

A paper from the UK by Nicolini et al (12)suggests that RCAs are prone to inconsistent application and misuse. Management can use the process to increase governance hegemony and those on the investigation side of the process have many clever ways to subvert the intent of the RCA, especially when their expertise, motivation or sincerity is called into question. They conclude that a "failure to understand the inner contradictions, together with unreflective policy interventions, may produce counterintuitive negative effects which hamper, instead of further, the cause of patient safety"

It seems obvious that without a national overseeing body such as the Federal Aviation Administration and the National Transportation Safety Board, that RCAs done in one hospital, no matter how excellent and telling, will likely not be found to be of use in neighboring institutions.

Scenario 1- Ultimate Resolution
In the case of the liver resection described at the beginning of this chapter, a new physician safety officer was appointed and charged with revisiting the retained surgical item. This time the RCA was done with an attempt to find the underlying causes and contributing factors leading to the adverse event.

The RCA was convened at noon on a Wednesday. The Chief Operating Office of the hospital, the Chief Financial Officer, the Chairwoman of the Surgery Department, the Chair of anesthesiology, the nursing director of the operating room were all present. In addition, the hospital had invited a representative of the patient's family to participate. The nurses, technicians, surgeons and residents involved in the case were all present. The timing, the location and the attendees all signaled interest in this process at the highest levels of the organization.

The findings were interesting. The surgeon, pressured to be in clinic after the operation, had left a resident to close. There were metrics in place to dissuade the surgeon from being late to clinic; and there was no mechanism by which a surgeon could have a valid priority reason to be tardy, regardless of the reason. The resident was new; he had never worked with this surgeon before and had assumed that the surgeon had done an extensive body cavity search for retained surgical items. The hospital did not at the time have any policy regarding responsibility of the surgical team for cavity searches. For that matter the hospital had never specified who was responsible for closing any surgical patient's wound.

Interviews with the nursing staff were also illuminating. During the closing "first count," the circulating nurse was relieved for lunch in the middle of the count. The new nurse did not restart the count, but picked up where the previous nurse had left. Examination of the operating room computing system found that the first and second counts were marked as correct by the relieving circulator. A literature search concluded that the chance of a counting error was 10 in 100; making reliance on counting procedures alone unlikely to achieve the go of no item left behind. The resident testified that he felt hurried; the attending expected him in clinic as soon as possible. He acknowledged that he directed that the radio be turned up loud so as to hear some rock and roll.

Interviews with the patient's family were troublesome. The patient complained of an unusual, and new, back pain immediately after surgery. The family was puzzled also by her complaint of right shoulder pain. The family expressed frustration that these complaints were met with a patronizing attitude by both nurses and physicians attending the patient. When finally told of the retained foreign object, the patient had said, "I knew something was bad wrong."

In the end, the RCA group concluded their finding with a report not dissimilar to the NTSB report cited above. They found that the probable cause of the retained sponge, reoperation and subsequent death to be due to distraction of the operating room personnel at the time the sponges were counted. Contributing factors were:

1. Failure to perform a careful body cavity search.
2. No clear hospital policy regarding cavity search requirements by the operative team.
3. No policy for distracting music, beepers, phone calls in surgical suites.
4. No guidelines for the responsibility of the attending surgeon to be present for the entire operation.
5. Unworkable attendance requirements for clinic attendance that had the effect of distracting caregivers in other parts of the hospital.
6. Lack of consistent application of existing policies already in place regarding time outs, pre and post operative briefings, which led to inconsistent conduct of these tools
7. Lack of policy prohibiting team member relief during high stress portions of the procedure; the team noted that the peak stress period was different for the nursing team, anesthesia team and the surgical team.

The new CEO of the hospital received the report and posted it on internal and external websites. She directed the chairs of Surgery and Anesthesia and the director of nursing to convene a group of in house experts to develop workable policies that would address the issues discovered. Policies for relief, time outs, briefings, counts and distractions were developed. The hospital CEO directed that outlying behavior by any member of the staff be directed to her exclusively. Additional staff was hired to manage beepers and phone calls during surgery. A team of physicians without operative responsibilities was appointed to deal with in and out patient issues while the operative team was in the operating room. All solutions flowed logically and directly from the causes identified in and disclosed from the RCA so that they made operational sense to the individuals doing the work. The new way of doing things was thought to be home grown, not enforced from the C suite.

When queried by a reporter at an event honoring the hospital as the safest in the nation, the CEO said, “I had no idea as to the chaotic environment in which we used to ask our hard working, altruistic people to work. I didn’t accomplish this, they did. They did an analysis of each problem that was robust, non-linear, thoughtful and not judgmental. Then they came to our administrative team and proposed changes. Since many of the administrators, including me, had been at the RCA and heard the patient’s family speak, they had no trouble convincing us to apply the resources and the support, both administratively and emotionally, for a safe environment. It is the people on the front lines that know what needs to be done.”

When to do Causes Analysis

Are cause analyses only done for major sentinel events? Commercial aviation found its major events occurring so infrequently that to continue to improve it had to focus on daily system imperfections. It developed a robust, non-jeopardy near miss reporting system to gather those imperfections. Cause analyses should be performed on aggregated events since sentinel events occur infrequently. Cause analysis can be done for any process error even if it did not produce an unfavorable outcome. It is only when health care gets to a serious system for tracking and acting on near misses, will the issue of patient safety finally see some improvement.

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