Adverse Events: Root Causes and Latent Factors

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KEYWORDS
- Root cause analysis
- Theories of error
- Systemic factors
- 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 had not.

The conduct of the case was routine at first. The liver was mobilized; ultrasonography showed no surprises and the blood loss had been minimal. A previous cholecystectomy made the dissection more tedious. Although the procedure took 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 increased white blood cell count prompted a computed tomography scan on postoperative 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. Although the patient was ultimately closed and sent to the intensive care unit, the combination of 10 units of packed red blood cells and underlying liver disease led to a 2-week course of liver failure and then death.

The hospital followed the routine prescribed 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 root cause analysis (RCA) was convened by the risk manager. In attendance were the chief safety physician, the chief medical officer, the risk manager, and the vice president 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 technicians involved. The surgeon had blamed the resident for the oversight and was generally uncooperative with the investigation. The group decided that 2 errors had occurred: both the scrub and circulating nurse had counted incorrectly. A note was placed in each of their files. The

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surgery 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. The surgeon was fined $10,000 by the state 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 occupant sustained major injuries, and 3 others received minor injuries. Eighteen of the 103 occupants of the airplane (98 passengers, 3 flight attendants, and 2 pilots) received minor injuries during the evacuation.

The National Transportation Safety Board (NTSB) 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. 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 did not stop there. Contributing factors were determined:

1. Southwest Airlines’ failure to provide its 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 Airlines’ plan to implement new autobrake procedures without a familiarization period
4. Southwest Airlines’ 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 2 scenarios (1 hypothetical, 1 actual) are emblematic of 2 different philosophies of RCA. 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. It is 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 do not want to suffer bodily harm themselves. This premise 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 article describes the process of RCA, 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 suggests 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 is something of a big sea change,” he said in an address to the Royal College of Surgeons in 2003.

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 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.

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.”

That health care has tended to use the person approach is understandable; it is in line with a tradition of personal accountability, hard work, and diligence: all traits believed 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 (Table 1).

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<tr>
<th>Table 1</th>
<th>Reason’s person versus system approach</th>
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<td><strong>Person Approach</strong></td>
<td><strong>System Approach</strong></td>
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<tr>
<td>Focus on unsafe act of people</td>
<td>Focus on condition of work</td>
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<td>Unsafe acts cause error</td>
<td>Upstream systemic factors cause error; human fallibility is unavoidable</td>
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<td>Error management by reducing unwanted variability in human behavior</td>
<td>Error management by building system defenses</td>
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<td>Uncouple a person’s unsafe act from institutional responsibility</td>
<td>Recognize 90% of errors are blameless</td>
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<td>Isolate unsafe acts from the system</td>
<td>Remove error-provoking properties of the system</td>
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<td>Context-recurrent errors</td>
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Data from Reason J. Human error: models and management. BMJ 2000;320.
However, most human error is unintentional. For instance, in a study of aviation maintenance, 90% of quality lapses were judged blameless.\textsuperscript{4,5} This proportion is likely true in all facets of human performance and implies that we spend most of our investigative time on 10% of the problem. Although some small percentage of adverse events are caused by out-of-bounds behavior, most are not. Thus any serious attempt at risk management must take a systems approach: why did this bad thing happen? For this reason, then, a robust investigation into adverse events and near misses to determine the proximate and remote causes is important. Yes, it is true that the Southwest Airlines jet failed to stop on the runway. The real question is why. A search for the root cause becomes a search for the root causes. In another sense, it is not 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 (Fig. 1).

**RCA METHODS**

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

Each method presses the participants to think broadly and nonlinearly about the many contributing causes to an error. Only by exploring a comprehensive list of contributing causes can a full list of responsive solutions be developed.

**Fishbone**

Ishikawa diagrams (also called fishbone diagrams) graphically connect causes with their various effects.\textsuperscript{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. For instance, it might 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 time-out. Fig. 2 is an example of fishbone analysis.

**The 5 Whys**

Attributed to the Toyota Corporation, the 5 whys urge the analysts to dig deep. \textit{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\textsuperscript{7}

\begin{quote}
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,
\end{quote}
Fig. 1. A decision tree for determining the culpability of unsafe acts. (From Reason J. Managing the risks of organizational accidents. Aldershot: Ashgate; 1997. p. 209; with permission.)
for want of the war the kingdom was lost, and all for the want of a little horseshoe nail.  

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 had finished closing? And so on. The 5 whys might lead to analyses such as those shown in Fig. 3.

These analyses of the miscount are linear. The risk is that they can lead to 1 solution or 1 culprit: the surgeon erred or the nurse erred. One could conclude that there is a magic bullet at the terminus of each example: 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. For instance, take the issue of traffic fatalities. Each solution in Fig. 4 arises from a different cause. Each reduces the likelihood of traffic fatalities. No one solution 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. The cost of each intervention can be evaluated in relationship to the cost of human lives.

Reason’s Swiss cheese diagram (Fig. 5) shows several levels of defenses against inevitable human error. Fig. 5 is an example of Reason’s multilayered approach to error as adapted to the surgical environment.
MULTIPLE CAUSES ANALYSIS

Let’s rethink the earlier retained surgical item (RSI) scenario. 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 had not 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 multipronged 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. An example is given in Fig. 6.

This way of thinking leads to a distinction between the term root cause (singular,) connoting one, primary, dominate cause, and an alternate approach that analyzes many possible causes (plural). Although 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, cost of implementation, and effectiveness. The multicause approach supports

Fig. 4. Risk versus effectiveness of solutions. (*Courtesy of M. Galley.*)

Fig. 5. Operating room Swiss cheese model. RN, registered nurse. (*Data from* Reason J. Human error: models and management. Br Med J 2000; 320.)
Reason’s system versus person approach to error and recognizes the latent conditions that lead to, support, and may create error.

Continuing with the RSI example, a multipronged cause analysis would arrive at several solutions, each of which would reduce (but not eliminate) the risk of RSI. Some possibilities include:

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 radiographs in cases in which the count is unreconciled.

Each of these solutions can be evaluated and prioritized based on 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.

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 1 cause--or a “root cause.”

A further advantage of the multicause approach to analysis and resolution is that the chosen corrections flow directly from the causes. Solutions imposed on the organization that obviously bear little relationship to what the staff know 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 an 8-month-old child. She was fired by the hospital and investigated by the state’s nursing commission. In April 2011, she killed herself. This terrible consequence shows the price we pay as a profession for the secrecy and judgmental approach to medical error. In medication errors, root cause analyses frequently find several systemic causes, like the similarity in appearance of bottles with different dosages; arithmetical errors in situations in which no double-check system is in place; fatigue; and inadequate hand-off policies.

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. The sense of responsibility for and chagrin about a mistake weighs heavily on our fellow caregivers.

SECRECY, MALPRACTICE, AND ERROR

Some risk managers in US hospitals may 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 situation is in direct contradiction of the principle 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 elsewhere in this issue.

DO RCAs WORK?

Recently concern has been voiced about the usefulness of RCAs in health care. Why is it that a tool used so effectively by the NTSB has not become commonplace and useful in medicine? Wu and colleagues noted that many medical RCAs were conducted incompletely or incorrectly. These investigators found that many placed inappropriate emphasis on finding the single most common reason. Furthermore, implementing actions in response to RCA findings, even modest ones, was difficult. Politics, resources, and lack of understanding of the RCA process were attributed causes for several instances in which the hospital had repeated adverse events of the same nature even after several obvious causes had been uncovered in RCA. This finding leads some administrators to discount the process as unhelpful. Adding to that concern is the worry that RCA content is discoverable during malpractice litigation further reinforces the blame, secrecy, and self-protective political environment that may make another event occur.

A UK study by Nicolini and colleagues 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. These investigators 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 NTSB, RCAs carried out in one hospital, no matter how excellent and telling, are not likely to be of use in neighboring institutions.
SCENARIO 1: ULTIMATE RESOLUTION

In the case of the liver resection described at the beginning of this article, a new physician safety officer was appointed and charged with revisiting the RSI. This time the RCA was carried out to 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 officer of the hospital, the chief financial officer, the chairwoman of the surgery department, the chair of anesthesiology, and 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 revealing. 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. The resident was new; he had never worked with this surgeon before and had assumed that the surgeon had performed an extensive body cavity search for RSIs. The hospital did not 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 computer 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 goal of no retained items. 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 that he could 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 surgical item, the patient had said, “I knew something was bad wrong.”

In the end, the RCA group concluded their work with a report not dissimilar to the NTSB report cited earlier. They found that the probable cause of the retained sponge, reoperation, and subsequent death was 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, or 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 operative and postoperative 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 chief executive officer (CEO) of the hospital received the report and posted it on internal and external Web sites. 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 repetitive outlying behavior by any member of 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 inpatient and outpatient 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 performing the work. The new way of doing things was believed to be home grown, not enforced from the top.

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 PERFORM CAUSE ANALYSIS

Are cause analyses performed only 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, nonjeopardy near-miss reporting system to gather those imperfections. Cause analyses should be performed on aggregated events because sentinel events occur infrequently. Cause analysis can be performed for any process error even if it did not produce an unfavorable outcome. Only when health care develops a serious system for tracking and acting on near misses will patient safety improve.

REFERENCES