Chapter 22
The Culture of Safety

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> *"Knowledge and error flow from the same mental sources, only success can tell the one from the other."*
>
> Ernst Mach

Case Studies

Case 1

The patient was a 92-year-old male with a previous history of peptic ulcer disease requiring multiple surgeries for internal bleeding. At 8 p.m. on a Friday evening before the start of the Labor Day weekend, the surgeon was performing a procedure to insert a Jackson Pratt drain to remove excess fluids from the body. As per protocol, the staff performed the first of three sponge and instrument counts at the start of the surgery. The second count performed before the closure of the wound indicated a sponge may be missing. The staff looked in the operating room (OR) but did not find the sponge. The surgeon gingerly checked inside the patient but was unable to feel the sponge, so he called for a radiology technologist to take an X-ray. The radiologist saw a foreign object, and since the procedure called for a drain, he erroneously concluded that he was looking at a Penrose Drain when he was actually looking at the missing sponge. He wrote a brief note on the film stating, "No foreign object other than the drain." Though the team was very reluctant to close, keeping the patient under anesthesia any longer was the greater risk, so the surgeon closed the

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patient, and completed the surgery, Staff performed the final of three sponge and instrument counts and documented the missing sponge. Next day, the Chief of Surgery reviewed the X-ray and located the sponge that was the source of the confusion. A CT confirmed the location of the sponge. The patient was taken back to OR and the sponge was removed.

Case 2

A 50-year-old patient arrived in the Emergency Department (ED) via ambulance with a diagnosis of pulmonary embolism. The ED physician ordered intravenous unfractionated heparin that requires weight-based dosing. Since the patient was not ambulatory and unable to step on the scale, the ED nurse estimated the weight to be 80 kg and ordered the heparin dose accordingly. She initiated the heparin per protocol based on the estimated weight of the patient and the patient was transferred to ICU. The patient's actual weight taken in the ICU was 60 kg; however, no one made a correction in the heparin dose being administered to the patient. The lab reported the PTT result, taken 6 h after the loading dose, to be 113.3, well above the normal therapeutic range. The ICU staff recognized the error and adjusted the dose based on the actual weight of the patient. The error was classified as a Class E medication error, i.e., the error reached the patient and required treatment but did not cause permanent harm.

Introduction

The landmark report from the Institute of Medicine, *To Err is Human* [1], states that evidence-based practices are critical, but the contextual framework in which care is delivered also contributes to patient safety. By 2004, articles describing the Culture of Safety [2–4] concluded that preventing adverse incidents depends as much on cultural changes as on structural changes in healthcare organizations. Evidence-based medicine provides the rules, often in the form of policies and procedures. The culture determines how we behave when the rulebook is gone, a situation that occurs on a regular basis given the exigencies of patient care.

According to James Reason [5], much of the work performed in health care can be categorized into three types: skill-based, rule-based, and knowledge-based. Skill-based work is performed automatically and takes little conscious thought. Taking vital signs is skill-based work. Activities performed infrequently are rule-based, as are complicated processes that need a series of reminders to be sure that every step is performed as expected. On a regular basis, staff follows the rules enumerated via guidelines, protocols, and hospital policies. The protocol for dosing unfractionated heparin in the ED case study above offers an example of rule-based work and the potentially serious consequences that can ensue if the rules are not followed. Knowledge-based work is required in circumstances where the situation is unique and

rules do not apply. Professionals draw on previous experience, similar situations, other team members, or the literature in the field to devise a course of action. Case Study 1 is an example of knowledge-based work. The policy for sponge and instrument count did not anticipate a situation in which the sponge count was off and the staff could not account for it in the OR or in the patient via the radiologic image since it mistook the sponge for a drain. The policy could have dictated a response but it was assumed that if the sponge was not in the OR, it was in the patient, and that the radiologic image would be conclusive. An organization committed to patient safety offers skills training to support skills-based work; ready access to the steps in the process to support rule-based work; and a Culture of Safety to encourage staff to make good decisions when the rules no longer apply and they are required to use critical thinking skills to perform knowledge-based work.

The Culture of Safety is defined as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management [6]." The aviation industry has contributed important ideas to the Culture of Safety in health care because flying a plane is also considered a high-risk, complex endeavor, dependent on human factors and reliable systems. Their investigations established the significance of leadership, teamwork, situational awareness, and safety by design [7, 8]. In health care, as in the aviation, integral to systems designed for safety is the understanding that human error is inevitable, and only through systems that support safe practices will the risk of human error reaching the patient and causing harm be reduced.

Teamwork is the lynchpin of the Culture of Safety. Effective team performance requires team members to cooperate in a shared vision, i.e., patient safety and demands that there is good communication free of the authority gradient [9]. The "Time Out" process before operative and invasive procedures where all members of the team must acknowledge a common understanding of the procedure about to be performed is an example of a teamwork technique borrowed from aviation. In the case study above, the surgical team, deeply affected by the failure of their system to protect the patient from a retained foreign body, instituted a "Count Pause." Now, surgery is halted while the surgical technician performs the instrument count to minimize the risk of error. More importantly, direct physician-to-physician communication is the key. The attending surgeon must directly communicate with the radiologist to make sure they share an understanding of the indication and interpretation of the radiological image findings.

Crew Resource Management (CRM) has been the approach to teamwork in aviation. The Agency for Healthcare Research and Quality (AHRQ) used the CRM principles to develop a program called TeamSTEPPs© that focuses on the knowledge, skills, and attitudes needed for teamwork in health care. The AHRQ Web site offers a review of the literature, a patient safety culture survey, and a variety of other resources to adapt the principles of teamwork into the challenges of clinical practice (http://teamstepps.ahrq.gov/).

Other characteristics of the Culture of Safety have been identified by studying high-reliability organizations (HROs) such as nuclear power generation plants, firefighters, and hostage negotiating teams. Weick and Sutcliffe [10] found that HROs

track small failures, resist oversimplification, remain sensitive to operations, maintain capabilities for resilience, and take advantage of shifting locations of expertise. Small failures are treated as symptomatic of larger and potentially more serious problems in the system and hence a timely resolution of small failures can avert adverse safety events. In both case studies above, the patient sustained no permanent harm. However, staff treated each incident as a sentinel event because it was clear that the systems were not fail-safe. Resilience speaks to the ability to change focus and adapt to changing realities. Given the number of specialties involved and the frequently unexpected turns in the patients' conditions, the locus of expertise also often changes from one situation to the next.

James Reason [11] attributes additional characteristics to the Culture of Safety, including a "Reporting Culture" that fosters a nonpunitive environment encouraging incident reporting; a "Just Culture" that assures staff that mistakes will be handled fairly; a "Learning Culture" that encourages everyone to learn from their mistakes and adverse events; and a "Flexible Culture," where staff quickly adapt to changing circumstances.

In the Just Culture model proposed by David Marx [12], individuals have three fundamental duties: the duty to avoid causing unjustified risk or harm, the duty to produce an outcome, and the duty to follow a procedural rule. Against this background, a mistake can be classified into three categories. The first is the human error—inadvertently doing what should not have been done, also referred to as slips and lapses. The second is the at-risk behavior where risk is not recognized or mistakenly believed to be justified. The third is reckless behavior, a choice to consciously disregard a substantial and justifiable risk. The model proposes the following actions: console for human error, coach for at-risk behavior, and punish for recklessness.

Safeguards: Prevention, Mitigation, Recovery

Strategies to promote the Culture of Safety can be categorized into three phases: prevention, mitigation, and recovery. The prevention phase focuses on proactively anticipating potential risks in the system and correcting them. Mitigation occurs when there are known risks. Finally, when patient harm does occur, recovery includes a series of steps which often result in strategies that prevent or mitigate these risks in the future. Taken together these strategies support the Culture of Safety.

Prevention

Reliability is the "probability of a product performing a specified function without failure under given conditions for a specified period of time [13]." Reliability is usually reported as a defect rate, e.g., 10^{-1}, 10^{-2}, 10^{-3}, and so forth. 10^{-1} is one error in ten tries; 10^{-2} is one error in 100 tries; 10^{-3} is one error in 1,000 tries, and so on.

Table 22.1 If 99.9 % were good enough[a]

IRS lost documents	Two million per year
Major plane crashes	Three per day
Lost items in the mail	16,000 per hour
ATM errors	37,000 per hour
Pacemakers incorrectly installed	291 per year
Babies given to the wrong parents	12 per day
Erroneous medical procedures	107 per day

[a]With permission from the Massachusetts QIO

Table 22.1 provides examples of what would occur if we were content with a 10^{-3} defect rate, i.e., 99.9 % accuracy. With so much at stake, healthcare professionals hold themselves to an even higher standard; consequently, "six sigma" or 10^{-6} is the goal in many healthcare organizations.

It is estimated that unconstrained human performance guided by discretion only is generally at a reliability level between 10^{-1} and 10^{-2}. Constrained human performance with limits on discretion such as alerts built into the system or forcing functions can reach levels between 10^{-2} and 10^{-3}. Strategies likely to bring clinical practice to a level of 10^{-1} reliability include training and awareness, checklists, information/feedback mechanisms on compliance, and standardization of equipment and supplies. 10^{-2} strategies necessitate more sophisticated failure prevention such as decision aids and reminders built into the system, defaults to the desired actions, multiple layers of redundancy, habituated patterns, standardization of processes, opt-out vs. opt-in choices and forcing functions [14].

Every time another check or another signature is required, such as with the use of checklists, we are reducing the probability of human error using forced redundancy [15–17]. The use of automation improves those odds further. For example, computer-based physician ordering systems (CPOE) have built-in forcing functions to freeze the order entry screen until medication allergy information is entered and to provide warning alerts and reminders in the case of drug–drug interactions. Forcing functions essentially stop the process from moving forward to prevent a step from occurring thus improving the likelihood that evidence-based practices known to improve outcomes and reduce patient harm will be utilized.

Mitigation

In the mitigation phase, the Culture of Safety is characterized by teamwork and communication using patient safety as the organizing principle. Well-functioning teams demonstrate a common purpose of safe patient care. The roles of various team members are clear but not overly rigid so that members can easily adapt when needed. Power is decentralized and the autonomy eschewed to prevent error. The importance of teamwork is particularly acute when circumstances deviate

from the norm, when the rules are absent and the team must rely on an educated guess. This is also known as "critical thinking." Each member of the team must be free to act or contribute, because sometimes the hierarchy is unwieldy or worse, an impediment.

Good teamwork relies on good communication in order to achieve desired outcomes. Regulatory and accreditation agencies such as The Joint Commission require standardization of communication between providers to ensure that it is comprehensive and complete. SBAR, a commonly used process to standardize communication in health care is an example of a risk mitigation strategy [18].

Another initiative to mitigate risk is the team huddle where staff regularly convenes, typically at the start of the shift, to review risks associated with patient care such as wound care, surgical procedures, restraints, etc. This alerts the staff to watch for problems that may arise over the course of the shift and increases situational awareness. In the OR, a "Time Out" is required by regulation before the start of a procedure to achieve the same effect.

Recovery

In a Culture of Safety, the recovery phase after a near miss or an actual adverse event is focused on learning from the event. A full investigation that includes individual interviews with staff and a rigorous analysis of the processes associated with the failure is required for all sentinel events, but if the organization is a "fanatic for failure" [10], process analysis is used more widely for near misses as well. The Root Cause Analysis (RCA) is employed for sentinel events and an Intensive Analysis, a streamlined process investigation, is used for any case that did not go as planned even though there was no harm to the patients. An RCA is a systematic review of every structure and process associated with patient care including staffing, communication, leadership, training, information, and the environment to name a few. An intensive analysis will review some, though not all, of the issues specified in an RCA. Intensive analyses vary, but one such process relies on staff preparation of the case including a timeline and a description of the incident including time, date, and patient condition. Then staff reviews selected processes that need a drill-down, such as, the equipment, staffing, education, communication, information, environment of care, or leadership. This information is taken to a weekly risk meeting where the cases are discussed and recommendations made. These may go out to the entire organization if it is seen as a weakness. The RCA or intensive analysis process during the recovery phase provides an opportunity to learn from the potential system vulnerabilities and develop policy and protocols to effectively transition the knowledge-based work into rule-based work.

During the RCA of case study 2, one manager recommended counseling action against the employees who ordered and administered the heparin without getting a weight on the patient. Hearing that there are no gurneys in the ED that have built-in

scales, the team recommended the purchase of new equipment. Upon further consideration, this solution, too, was rejected as impractical. There is no guarantee that this gurney would be available when a patient needing to be weighed arrived in the ED which may be why this is not the community standard. The solution devised by the team, therefore, was that heparin dosed in the ED with an estimated weight will include an alert in the system for the unit staff indicating that heparin was dosed with estimated weights. The patient then needs to be weighed immediately upon arrival in the unit and heparin dose must be adjusted accordingly. The policy now includes a procedure in which the pharmacist will adjust the dosing if the estimated weight is more than ten pounds off in either direction.

Thus, the recovery phase often leads to additional steps for prevention and mitigation of risks, completing the cycle. None of this would be possible without a staff willing to report the error in an environment promoting transparency. To foster transparency, institutional leadership must ensure that those reporting adverse events are safe from unfair retribution, that the process for reporting is easy and well understood, and that the process analysis is just. In addition, staff must be confident that the purpose of the discussion is to learn from the experience and not to unjustifiably prosecute those that were involved [11].

Storytelling is also becoming an important part of patient safety armamentarium in the recovery phase. Dennis Quaid [19], Sorrel King [20], Linda Kenney [21], and others have had a national impact telling their stories to large audiences of healthcare workers. At the local level, hospitals across the country are using stories to facilitate the implementation of new patient safety policies and procedures; sometimes patients are also included in the discussions so that they can provide staff with firsthand accounts. The quality reports to the Board that include "Lessons Learned" or "Stories from the Field" provides Board members with a deeper understanding of the complexities associated with delivering safe patient care. One of the six recommendations from the Institute for Healthcare Improvement (IHI) on engaging boards in improving quality and safety includes storytelling [22]. Specifically, they recommend, "Select and review progress toward safer care as the first agenda item at every board meeting, grounded in transparency, and putting a 'human face' on harm data."

Measuring the Culture of Safety

The truism, "you manage what you measure," prompted AHRQ to sponsor the development of a Culture of Safety survey; the Joint Commission and other regulatory agencies also require that the organizations administer such a survey on a regular basis. The dimensions on the AHRQ survey that can be found on its Web site [23] include leadership, the learning environment, willingness to report, teamwork, and communication to enumerate a few critical ones. The purpose of the survey is to raise staff awareness, assess the current situation of the organization, and support the improvement efforts.

Barriers to the Culture of Safety

Competing priorities, fragmentation of work among different disciplines, and hierarchical structures are a few of the long-standing challenges for organizations that are striving to create a Culture of Safety. Steep authority gradient is still common in hospital operations that must give way to shared responsibility needed for patient safety. The constant production pressures may lead to greater efficiency but can also create obstacles to the checks and double-checks on high-risk operations by an increasingly busier staff. Finally, the redesign of processes is a costly endeavor and is often undertaken after an adverse event rather than proactively in an effort to design safe systems.

In a Culture of Safety, autonomy and trust in an individual professional is not enough; it must be supplemented by fail-safe processes designed to prevent errors. A double-check when transfusing blood products or administering high-risk medications is not an inefficiency but a precaution that serves to protect patients from harm due to healthcare error.

Other traditional viewpoints have had to change as we have become more sensitized to patient safety. When guidelines and protocols were introduced, they were disparagingly called "cookbook medicine" and were seen as a threat to the autonomy of the clinicians. Now we understand them as important tools to facilitate the implementation of best practices. The acknowledgement of human fallibility still remains problematic in health care. Transparency has had an uphill battle for acceptance. Physicians and staff are well aware of the threat of litigation, and it may seem that to admit wrongdoing is to put themselves and the hospital in financial jeopardy if the patient sues. And, the courts continue to search for someone to blame. It seems counterintuitive to many that disclosure may actually reduce the overall risk of patient dissatisfaction and litigious behavior.

The greatest dilemma facing the Culture of Safety has been the need to balance accountability while promoting a nonpunitive environment that encourages reporting and transparency [24]. Hospital administrators have sought to strike a balance using James Reason's types of work (skills-, rule-, and knowledge-based) in conjunction with Just Culture algorithms to determine appropriateness and type of staff counseling and disciplinary action. Table 22.2 displays one method to determine accountability for human error is by first determining the type of work performed and asking relevant questions. If all questions can be answered in the positive, then the staff is believed to have acted in a responsible manner. If any are answered in the negative, then it is reasonable to hold the staff accountable and offer solutions such as counseling, coaching, or other disciplinary actions.

Building and Improving the Culture of Safety

Despite these challenges, changes have occurred, some voluntarily and others under duress. The Leapfrog Group [25], IHI's "100,000 Lives Campaign" [26], and the "5 million Lives Campaign" [27] are voluntary initiatives that have affected sweeping

Table 22.2 Determining accountability for medical error. To determine whether staff should be counseled, review the criteria for each type of work. If all can be answered in the affirmative, staff is not held accountable. If any of the questions is negative, staff is accountable for the error

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Type of work: Skill-based

Questions for skill-based work

1. Did staff assigned to the task have the appropriate skill?
2. Was the skill something that could be expected for this job category?
3. Did the hospital adequately train staff to ensure competencies are present?
4. Was the activity known to carry risk?
5. Were safeguards performed properly?

Example: Staff held accountable

The Case: A nurse was dosing insulin for a diabetic patient. Hospital policy requires a second signature because insulin is considered a high-risk medication. However, the unit was very busy and the nurse was a seasoned professional so she handed the chart to the second nurse who cosigned without checking.

Analysis:

1. Did staff assigned to the task have the appropriate skill? Yes.
2. Was the skill something that could be expected for this job category? Yes.
3. Did the hospital adequately train staff to ensure competencies are present? Yes.
4. Was the activity known to carry risk? Yes.
5. Were safeguards performed properly? No.

Result: Both nurses were counseled.

Discussion: "Busy" cannot be an excuse for unsafe care.

Example: Staff not held accountable

The Case: A patient with blood type AB needed fresh frozen plasma (FFP) at 2 a.m., but the Blood Bank did not have the AB type. The blood bank technician (BBT) removed the informational chart from the wall and erroneously noted that Type A FFP was a clinically appropriate substitution. After discussing with the supervisor, he released the FFP to the clinical area where an astute nurse caught the error and prevented patient harm. The analysis revealed that the BBT had mistakenly read the informational chart for packed cells where Type A is an appropriate substitution.

Analysis—BBT:

1. Did staff assigned to the task have the appropriate skill? Yes.
2. Was the skill something that could be expected for this job category? Yes.
3. Did the hospital adequately train staff to ensure competencies are present? Yes.
4. Was the activity known to carry risk? Yes.
5. Were safeguards performed properly? Yes.

Result: The technical was appraised of the mistake but was not counseled. However, the supervisor was counseled as he failed to double-check the work of the technician.

Discussion: The technician committed a slip, but slips are a part of the human condition. Hospital processes include double, triple, and quadruple checks to accommodate this reality.

Type of work: Rule-based

Questions for rule-based work

1. Did staff know the rules?
2. Should staff have known them?
3. Were the rules available for review if needed?
4. Was it reasonable to make an exception in this circumstance?

Table 22.2 (continued)

Type of work: Rule-based

Example: Staff held accountable

The Case: The surgical checklist includes verifying the presence of a valid history and physical (H&P) performed within 30 days. The nurses were responsible for assuring the completeness of the surgical checklist. The H & P on the chart was 35 days old and the physician had little tolerance for rules he thought were foolish; so, the nurse let the patient go through.

Analysis:
1. Did staff know the rules? Yes.
2. Should staff have known them? Yes.
3. Were the rules available for review if needed? Yes.
4. Was it reasonable to make an exception in this circumstance? No.

Result: The nurse was counseled and this was included in the physician's Ongoing Professional Practice Evaluation (OPPE).

Discussion: Staff knew the rules and the extenuating circumstances were not sufficient for ignoring them. A current H & P is a patient safety concern. If the nurse was uncomfortable, she should have spoken to her supervisor.

Example: Staff not held accountable

Case: Nurses were asked to provide gentle reminders to physicians to sign their telephone orders within 48 h. One physician did not take kindly to these and let the nurses know it, but the Joint Commission had recently cited the hospital for this offense. When the physician came on the floor, the staff nurse looked for her supervisor but she was not available. So she let him go through.

Analysis:
1. Did staff know the rules? Yes.
2. Should staff have known them? Yes.
3. Were the rules available for review if needed? Yes.
4. Was it reasonable to make an exception in this circumstance? Yes.

Result: The nurse was not counseled.

Discussion: The hospital took the position that it has a responsibility to protect its staff from disruptive physicians. She discussed the situation with the nurse, and the supervisor approached the physician in an alternative venue.

Type of work: Knowledge-based

Questions for knowledge-based work

Given the choices this person made, did s/he show good judgment?

Example: Staff held accountable

The Case: An ICU nurse floating to the ED had an order for intravenous methylprednisolone. Methylprednisolone was in the ICU smart pump library, but not in the ED library. Hence, she delivered the medication free-flow. The error was discovered when the patient received an overdose.

Analysis:
Given the choices this person made, did s/he show good judgment? No.

Result: The nurse was counseled.

Discussion: Given the risks of the medication, the nurse did not show good judgment protecting the patient from harm because no attempt was made to contact a physician or the supervisor. She was floating from another unit and could be expected to encounter slightly different circumstances which she had the responsibility to check.

Example: Staff not held accountable

The Case: See Case Study 1. The sponge was inside the patient but they closed anyway.

Analysis:
Given the choices this person made, did s/he show good judgment? Yes.

Result: Staff was not counseled.

Discussion: Staff followed the policy and acted in the best interest of the patient under the circumstances. The risk of prolonged anesthesia was greater than the risk of the sponge. A CT performed the next day provided the location of the retained sponge.

changes. For example, The Leapfrog Group was among the first to recommend the implementation of computerized physician order entry (CPOE) to reducing medication errors. Federal funding is now available for CPOE implementation through incentive payments for the use of certified electronic health records. Rapid Response Teams (RRTs), a voluntary initiative in the 100,000 Lives Campaign, was considered so valuable that it is now incorporated in the Joint Commission's regulations requiring that hospitals recognize and respond to a patient's change in condition using RRTs (Hospital Accreditation Standards, PC.02.01.19).

Regulation has played an important part in promoting a Culture of Safety. The Joint Commission requires a staff climate survey that includes questions on willingness to report errors and other dimensions associated with the Culture of Safety and the leadership standards for accreditation require hospital administration to provide the resources needed for a patient safety program. A number of states have laws that require hospitals to report their serious adverse events and publish their findings on the Web. In 2005, the federal government authorized the creation of Patient Safety Organizations (PSOs) to encourage reporting of adverse events by hospitals without the fear of reprisals. The goal of the PSOs is to improve quality and safety through the collection and analysis of data on adverse events [28].

Leadership engagement has taken a number of forms; one example includes the implementation of executive walkabouts where members of the executive team walk around the units to directly hear patient safety concerns from the staff [29]. Many have embraced transparency and a balanced view of the responsibility of the organization and the individual.

Conclusion and Lessons Learned

The following are key considerations in building and sustaining an organizational culture that promotes safety:

Patient Safety as an Organizing Principle: Given that there are inherent risks in patient care are the processes designed to keep patients free from harm due to medical mistakes? Does staff hold patient safety as an inviolable principle?

Leadership: Does the organization commit the resources need to address safety concerns? Do the leaders encourage transparency?

Teamwork and Communication: When faced with a problem, does everyone within and between departments step forward to help regardless of the roles and hierarchy? Is everyone free to speak to alert the team about threats to patient safety?

Transparency: Is your team willing to report errors without fear of reprisals?

A Learning Environment: When an error occurs, does the team come together to understand what happened and how this can be prevented in the future? Can the organization adapt to the changes needed when a risk to patient safety is uncovered?

If your organization has a Culture of Safety, you are likely to find a team willing to work together, to see good communication within and between departments, and to have a robust process for analyzing process; in short, you will have patient safety as an organizing principle pervasive throughout the organization.

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