The Role of Leadership in Instilling a Culture of Safety: Lessons from the Literature

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EXECUTIVE SUMMARY

The publication of To Err Is Human has highlighted concern for patient safety. Attention to date has focused primarily on micro issues such as minimizing medication errors and adverse drug reactions, improving select aspects of care, and reducing diagnostic and treatment errors. However, attention is also required to a macro issue—an organization’s culture and the level of leadership required to create a culture. This article discusses the concepts of culture and leadership and summarizes two paradigms that are useful in understanding the precursors of medical errors and developing interventions to prevent them: normal accident theory and high-reliability organization theory. It also delineates approaches to instilling a safety culture. Normal accident theory asserts that errors result from system failures. An important element of this perspective is the need for a system that collects, analyzes, and disseminates information from incidents and near misses as well as regular proactive checks on the system’s vital signs. Four subcultures are necessary to support such an environment: a reporting culture, a just culture, a flexible culture, and a learning culture.

High-reliability organization theory posits that accidents occur because individuals who operate and manage complex systems are themselves not sufficiently complex to sense and anticipate the problems generated by the system. Lessons learned from high-reliability organizations indicate that a safety culture is supported by migrated distributed decision making, management by exception or negotiation, and fostering a sense of the “big picture.” Lessons from other industries are also shared in this article.

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Concern for patient safety was raised by the Institute of Medicine report To Err Is Human (Kohn, Corrigan, and Donaldson 2000) and more recently by the events surrounding the organ transplantation procedure for Jesica Santillan, which failed because of donor-recipient blood-type incompatibility. In some circles, attention to patient safety is rapidly becoming the current mantra in healthcare. The attention given to this issue by the Joint Commission on Accreditation of Healthcare Organizations in its accreditation process (O‘Leary 1998, 2000) and by the Agency for Healthcare Research and Quality (2003) in its February 2003 launch of its online journal and forum on patient safety and healthcare quality are two manifestations of this development. By and large, patient safety has become recognized as an integral part of efforts to provide high-quality care. As stated by Berwick (1998), "the search for safety and the reduction of errors can be seen as absolutely central—an ideal starting place for the quest for improved care—not a distraction, but a threshold issue and a perfect test case for improvement of all we do."

To date, much of the attention on reducing medical errors and improving patient safety has focused on important, but micro, issues such as minimizing medication errors and adverse drug reactions (Bates 2000; Leape et al. 1995; Classen 1998), improving anesthesia care (Posner et al. 1994; Posner and Freund 1999; Gaba 2000a), and reducing diagnostic and treatment errors (Graber, Gordon, and Franklin 2002; Nolan 1999; Sleigh 2001; Vincent, Taylor-Adams, and Stahope 1998). For such efforts to succeed and spill over into other operational areas, attention is also required to a macro issue—an organization’s culture. A clear, supportive safety culture will nurture individual efforts and provide the necessary platform to extend those efforts into new areas throughout the organization.

The literature concerning the role of leadership in instilling a culture of safety is rich but diverse; the material presented here represents a synthesis of key concepts from these various streams. The goal of this article is to provide cohesive background material for practitioners and policymakers interested in understanding the elements of patient-safety culture. The sections that follow discuss the concepts of culture and leadership, review two applicable safety paradigms, and address the elements of a safety culture. Examples of safety-culture initiatives from other industries are then provided, and the article concludes with a discussion of the challenges that remain for instilling a safety culture in healthcare organizations.

CULTURE AND LEADERSHIP

The social science literature is replete with definitions of culture; for our purpose, the following statement clarifies this key term (Kilmann, Sexton, and Serpa 1985):

Culture is the invisible force behind the tangibles and observables in any organization, a social energy that moves people to act. Culture is to an organization what personality
is to the individual—a hidden, yet unifying theme that provides meaning, direction, and mobilization. Organization charts and employee manuals are simply not enough to get members to work together.

In other words, culture is a cognitive construct and relies heavily on attitudes and beliefs (Thompson and Luthans 1990).

**How Is a Culture Formed or Changed?**

In most organizations, a culture is formed early in its history and serves as the glue that holds the organization together as it matures (Schein 1985). Culture is molded by many forces such as the organization’s product, technology, competition, personnel policies, and desired position within the industry. Soon the culture is embedded within the organization and may be difficult to explicitly recognize, as it becomes deeply ingrained in everyday routines.

The organizational theory literature suggests that, to decipher corporate culture, one must look at a number of key organizational characteristics such as common understandings (e.g., attitude toward customer service and whether constructive disagreement is encouraged), the workplace environment (e.g., open or closed offices, importance of attention to detail, level of participation in meetings), everyday language (e.g., “we don’t stand on rank”), and employee attitude toward the organization (e.g., general morale and a belief that their employer cares about them and their welfare) (Allen 1985; Kono 1990; Sathe 1983).

**Who Is Responsible for Organizational Culture, and How Is It Built?**

For organizational culture development to succeed, leadership is required at many levels, but especially from the organization’s chief executive officer (CEO). Kotter (1990) lists the following six key tasks that must be performed in any organizational change:

1. Establishing direction
2. Aligning people
3. Motivating and inspiring people
4. Planning and budgeting
5. Organizing and staffing
6. Controlling and problem solving

The first three tasks, which are intended to “promote movement,” are leadership tasks, and the latter three constitute the core of modern management, “which is aimed at producing order on established dimensions and keeping an organization working efficiently” (Kotter 1990). Both leadership and management are required for an organization to prosper, yet each set of tasks requires a different mind-set and different actions. The three leadership tasks are discussed below.

To establish direction, one must develop a vision of the future to guide current activity and develop a strategy to achieve that vision. Vision development is not a solitary effort; the broader the buy-in, the greater the chances for success. Successful alignment requires good communication that encompasses ongoing rather than one-time efforts. The communication component of the alignment task entails informing and enlisting...
key individuals whose cooperation is essential to achieving the vision. In a sense, communication builds the coalitions necessary to implement the vision. *Motivation and inspiration* are the aids for overcoming barriers to successful implementation and employee inertia. Feedback and reward systems are key components of a successful motivational program. Adapting this perspective to healthcare organizations, Warden (1999) states that "leaders must be teachers, coaches and good listeners." He further notes that another important role of leadership is "having a restlessness about the status quo," a concept also noted by Schein (1992).

Culture change is a complicated proposition. Kotter (1995) enumerates eight basic errors that undermine successful efforts at change; avoiding these errors can be thought of as key to successful culture change. These errors are failing to establish a great enough sense of urgency, not building a powerful enough guiding coalition, lacking a vision, undercommunicating the vision, failing to remove obstacles to the new vision, not systematically planning for and creating short-term wins, declaring victory too soon, and not anchoring changes in the corporation’s culture. Understanding the concepts of leadership, vision, and culture are the main deterrents to committing these errors. An important warning that Kotter (1995) also conveys is that successful transformation takes a very long time, and skipping any of the steps necessary for avoiding these errors "creates only the illusion of speed and never produces a satisfying result."

**SAFETY PARADIGMS**

A safety culture must be built on an understanding of the cause of unsafe acts. Two major paradigms are found in the literature that serve as guides to improving safety and reducing errors: the normal accident theory, with its emphasis on systems, and the high-reliability organization theory, with its emphasis on flexibility and learning. Rather than viewing these paradigms as mutually exclusive, we agree with Rijpma (1997) that they complement each other and that they both provide useful insights in understanding the nature of error causation and prevention.

**Normal Accident Theory**

Safety problems can be traced to errors and accidents, and we have become acclimated to view those errors and accidents as aberrant developments. Dispelling this belief is the first step in developing a safety culture. Perrow (1984), in his book *Normal Accidents: Living with High-Risk Technologies*, rejects this belief. He notes that accidents, which result from multiple and unexpected errors, are intrinsic to most activity and even inevitable in some settings; in fact, they are "normal"—that is, they are to be expected. Unless this perspective—that errors are a consequence rather than a cause of the problem—is accepted and incorporated into an institution’s culture, progress cannot be made.

Many errors arise from system failures (Leape 1997). In the case of Jesica Santillian’s failed organ transplantation, not enough safeguards were in place to ensure that donor-recipient blood types matched. The challenge when any...
error occurs is learning from it (rather than identifying the person to blame) and learning how to better design systems to minimize future errors and accidents. Minimization rather than absolute avoidance is the goal because we cannot anticipate everything that can go wrong in delivering a product as complex as healthcare.

A key to minimizing errors and improving safety is a better understanding of their precursors. Numerous causation models have been advanced in the literature (e.g., Cox and Cox 1996); the model proposed by Reason (1997) has gained widespread attention by those studying medical errors within healthcare. He notes that accidents occur when organizational, human, and technical defenses are inadequate or lacking. Those defenses are governed by two processes common to all organizations: production and protection. Productive operations expose people and assets to danger, and all organizations require various forms of protection to intervene between hazards and their possible victims.

To understand how these defenses can fail, Reason proposed a paradigm that he calls “the Swiss cheese model of defenses.” Some defenses are engineered (i.e., are structural), others rely on people, and yet others depend on procedures and administrative controls. Although most defenses function as designed, weaknesses can still be found within. In an ideal world, each defensive layer would be intact. In reality, however, according to Reason (1997),

they are more like slices of Swiss cheese, having many holes—though unlike the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one “slice” does not normally cause a bad outcome. Usually, this can only happen when holes in many layers momentarily line up to permit a trajectory of accident opportunity—bringing hazards into damaging contact with victims.

Reason (1997) further disaggregates “holes in defenses” into two categories: active failures and latent conditions. Active failures are the unsafe acts committed by people who are in direct contact with the patient or system (i.e., at the “sharp end” of production—the human-system interface) and are “slips, lapses, fumbles, mistakes, and procedural violations.” He likens latent conditions to “resident pathogens” within the system. They arise from decisions made by designers and builders or by management, or they are inherent in current procedures and may lie dormant for many years before they combine with active failures to create an accident opportunity. A key point Reason makes is that most often the system rather than the person is to blame for accidents. Reason notes that “the best people can make the worst errors as a result of latent conditions.”

Followers of the aberrant-behavior approach to errors and accidents often look no further for the cause of an error once they identify the active failure. However, virtually all such acts have a causal history that extends back in time and up through the levels of the system. Understanding the interplay between active failures and latent conditions should lead to both a proactive
rather than a reactive risk-management program and a more comprehensive program aimed at several different targets: the person, the team, the task, the workplace, and the institution as a whole.

High-Reliability Organization Theory
The high-reliability organization theory was developed primarily by a group of social scientists at the University of California at Berkeley based on their field studies of high-risk organizations—aircraft carrier flight decks, nuclear power plants, and the Federal Aviation Administration’s (FAA) air traffic control system—that appear to have achieved very low accident and error rates (LaPorte and Consolini 1991, 1998; Weick, Sutcliffe, and Obstfeld 1999). This viewpoint is based on the belief that “humans who operate and manage complex systems are themselves not sufficiently complex to sense and anticipate the problems generated by the system” (Weick 1987). However, proper organizations of people, process, and technology can handle complex and hazardous activities (Gaba 2000b). The following characteristics were identified in these reliability-enhancing organizations (Roberts 1993):

- People must be helpful to and supportive of one another.
- People must trust one another.
- People must have friendly, open relationships emphasizing credibility and attentiveness.
- The work environment should be resilient and emphasize creativity and goal achievement, and it should provide strong feelings of credibility and personal trust.

These values were attained through constant bargaining and negotiation and emphasized peak daily performance within the recognition of the organization’s long-term goals. Each of these individual characteristics can be described as elements of a high-reliability organization culture.

BUILDING A SAFETY CULTURE
Roberts (1993) identified three managerial processes that support the creation of the cultural attributes found in high-reliability organizations: migrated distributed decision making, management by exception or negotiation, and fostering a sense of the “big picture.” Decision migration allows for almost instantaneous movement from centralized to local control (the point at which the event is occurring) and the reverse. Management by exception permits the quick identification of a problem and is built on continuous training and an environment in which senior-level staff do not have to make all decisions by themselves but can also function as checks and balances on less-senior staff. This flow of control enhances overall training efforts and builds in an element of redundancy that promotes long-range functioning. The big picture acts as an umbrella for the organization’s overall activities.

Geller (1994) suggests other ways to instill a safety culture. He notes that the organization’s beliefs should drive the safety process rather than external
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regulatory dictates, as this increases ownership, commitment, and proactive behaviors. Furthermore, behavior-based and person-based factors determine success; that is, behavior should be dictated by pleasant consequences—success rather than failure—and the focus should emphasize the work process, which is more amenable to change than is the final outcome. (He uses the sports metaphor of keeping your eye on the ball rather than the score). Communicating, coaching, and recognizing—observation and feedback—now become key elements in changing work behavior, and fostering self-esteem and a feeling of belonging become powerful positive motivators. Geller also urges shifting safety from "a priority to a value," as priorities are more subject to change than deep-seated beliefs (i.e., values)—a tenet emphasized by the high-reliability organization paradigm.

Reason (2000) delineates another important component of a safety culture: an information system that collects, analyses, and disseminates information from incidents and near misses as well as regular proactive checks on the system's vital signs. These activities make up an "informed culture"—one in which those who manage have current knowledge about the human, technical, organizational, and environmental factors that determine the safety of the system as a whole.

To create an informed culture, Reason (2000) states, four subcultures must be established. First, it is important to engineer a reporting culture—an organizational climate in which people are prepared to report accidents and near misses. An effective reporting culture depends in turn on how an organization handles blame and punishment. Thus, a just culture is needed. A just culture features an atmosphere of trust in which people are encouraged to provide, and even rewarded, for providing essential safety-related information but also in which they are clear about where the line must be drawn between acceptable and unacceptable behavior. Next, flexibility is key, particularly the ability to reconfigure in the face of high-tempo operations or certain kinds of danger. A flexible culture takes a number of forms, but in many cases it involves shifting from the conventional hierarchical mode to a flatter professional structure in which control passes to task experts on the spot and then reverts back to the traditional bureaucratic mode once the emergency has passed. Such adaptability depends crucially on respect. Respect must be earned, and this requires a major training investment on the part of the organization. Finally, an organization must possess a learning culture, which is characterized by "the willingness and the competence to draw the right conclusions from its safety information system and the will to implement major reforms when their need is indicated."

Another point made by Reason (2000) is especially instructive. "If you are convinced that your organization has a good safety culture, you are certainly mistaken. Like a state of grace, a safety culture is something that is striven for but rarely obtained. As in religion, the process is more important than the product."
EXAMPLES OF SAFETY-CULTURE INITIATIVES FROM OTHER INDUSTRIES

Former U.S. Secretary of the Treasury Paul O'Neill made safety his overriding concern. When he became Alcoa's CEO, O'Neill not only conveyed this concern to his senior managers, he also helped make it the company's concern. As detailed in a case study written by Varley (1992) for teaching purposes at Harvard University's John F. Kennedy School of Government, O'Neill made safety his signature issue, and this effort in turn fostered a new corporate culture. Safety was the first item O'Neill focused on when meeting with company executives; he used every opportunity to consistently emphasize it. Fairly quickly, people realized that to engage his interest in their concern they had to begin by addressing his concern.

The "Six Sigma Challenge" is one way to jump-start a safety program, and Chassin (1998) has suggested it as a possible model for healthcare. This strategy, developed by the General Electric Company and Motorola, draws its name from statistical measures of variation and entails adopting tolerance limits for "defective" products or services that are outside 6 standard deviations of the mean, which translates into less than 3.4 defects per million opportunities.

The reporting approach used by the FAA for air traffic incidents is also instructive and suggests an approach that merits consideration in healthcare. The FAA reporting system, which is based on the National Aeronautics and Space Administration's Aviation Safety Reporting System, is nonpunitive, confidential, independent of any authority with the power to punish, timely, and systems oriented. It is also responsive—it yield results—and is built on analyses performed by experts who understand the operational circumstances. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998) recommended it as a model, as did Leape (2002). The Veterans Health Administration has recently initiated a safety-oriented program that embodies many of these elements (Weeks and Bagian 2000).

CHALLENGES TO IMPLEMENTING A SAFETY CULTURE

In attempting to instill a culture of safety, it is crucial to recognize conflicting incentives. Chief among them is the current national concern for containing the rising cost of healthcare. Developing the information systems and reporting requirements that are necessary to support a safety culture will be expensive. Although in the long run reducing errors should be cost saving, in the short term it will require an infusion of new funds to support the necessary interventions. The industries that formed the study setting for the high-reliability organization theory had abundant resources, enabling them to invest in reliability-enhancing activities (LaPorte and Consolini 1991). Payers, who together with patients will ultimately reap the benefit of this effort, must be willing to reimburse these costs. Researchers and purchasers must
make the business case for safety improvement (Fernandopulle et al. 2003). A “Hill-Burton” type program aimed at improving information technology may be required.

A second challenge is recognizing and accepting that perfection really is unattainable, although such a goal is laudable. Sustaining an informed culture, which is built on a safety information system, can only occur after both a reporting culture and a just culture have been established. To do this, one must first change the belief (ingrained by the existing educational system) that medicine should be an error-free practice (Classen and Kilbridge 2002; Leape 1997). Until providers of care and the public at large accept that perfection cannot be achieved and the legitimate fears engendered by the current liability system are removed, the type of reporting required to sustain both an informed culture and a learning culture will be difficult to develop and sustain. A willingness to acknowledge errors and deal with the psychological impact they have on patients and their families as well as those providing care (Gallagher et al. 2003; Goode et al. 2002; Robinson et al. 2002; Vincent 2003; Wu 2000) is a key step in achieving a safety culture.

The current structure of the mortality and morbidity conference (which is held weekly, biweekly, or monthly in all teaching hospitals but less frequently in nonteaching hospitals) illustrates this challenge. A major step forward would be to reengineer it to become a learning experience rather than a setting for apportioning blame (Bate 2000; Orlander, Barber, and Fincke 2002). Senior physicians should lead the way by candidly discussing their own current or past errors. Furthermore, the scope of this conference should be enlarged to encompass the nonphysicians involved in providing care, and the discussion should be conducted emphasizing teamwork, collegiality, and respect for everyone’s role (Brennan 2002).

A final challenge is the fact that neither patients nor physicians currently believe that addressing medical errors is not an urgent matter (Blendon et al. 2002). Furthermore, little if any market pressure is applied to any aspects of quality of care (Berwick, James, and Coye 2003). This situation must be forcefully addressed and corrected. Only then can leadership begin to foster the desired culture and environment for safety.

CONCLUDING OBSERVATIONS
Despite these challenges, some good work is currently being done toward enhancing patient safety and instilling a safety culture in healthcare. Two groups active in developing and disseminating ways to reduce errors and improve safety are the Institute for Healthcare Improvement and the American Medical Association’s National Patient Safety Foundation. Finally, external leadership in this effort is being provided by the Leapfrog Group—a coalition of more than 100 public and private organizations that provide healthcare benefits—that was formed to save lives and reduce preventable medical mistakes by mobilizing employer purchasing power to initiate breakthrough improvements in the
safety of healthcare (Milstein et al. 2000).

A useful checklist called Strategies for Leadership delineates what hospital executives can do to begin to instill a safety culture that embodies many of the elements discussed in this article (Conway 2001). This checklist, along with much of the medical errors literature, has focused on hospital care, but it is important to expand the scope of current efforts to span the entire continuum of care, including outpatient activity (Forster et al. 2003; Gandhi et al. 2003) and nursing home or other subacute facilities.

As healthcare providers strive to define themselves in today's turbulent healthcare market, making the creation of a safety culture a signature issue is an excellent strategic decision.

References


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**PRACTITIONER APPLICATION**

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Leadership is one of the most important elements of healthcare. An environment fostering patient safety is also paramount, but how do we get there from here? Because of increases in reporting requirements and societal litigiousness as well as reductions in reimbursement and concomitant capital restraints, tracking and trending patient safety data is difficult at best and hazardous at worst. But