May I Have the Envelope Please?

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Every year during the Oscars award ceremony, millions of people in more than 100 countries wait with charged anticipation as movie stars, clad in the grandest of tuxedos and evening gowns, utter the words "May I have the envelope please?"

In November of 2006, Dennis Quaid, one such movie star, and his spouse were jolted into our world of patient safety when their twin babies' lives hung in the balance for more than 41 hours after receiving 1000 times the intended dosage of heparin at one of our nation's leading hospitals.[1,2] When many in the patient safety movement heard the news, they immediately guessed what had happened. This was clearly a repeat event of one that led to 3 infant deaths a year earlier.[3]

One of the more than 50 films in which Dennis Quaid has appeared was *The Right Stuff*, the story of the early space program and the astronauts who were obsessed with another kind of envelope: the performance envelope of the airplanes and spacecraft that they tested—at great personal risk during the space race.[4] Originally, it was termed *flight envelope*, meaning the safe performance envelope defined by a parallelogram shape that expressed the safe zone of performance when speed and altitude are plotted on a graph.

In the film, *The Right Stuff*, the test pilots, including Gordon Cooper who was played by Dennis Quaid, would frequently refer to "pushing the outside of the envelope," often abbreviated to "pushing the envelope," meaning that they were testing and defining the outer limits of safety for the aircraft, thus helping aeronautical engineers understand how to optimize the safety and performance profile of the aircraft they were designing. The "right stuff" was the heroic combination of courage and piloting skill that allowed them to push the outside of the safety envelope, report to engineers, and to still come back alive.

This writer has had a rich span of aviation experiences. As the child of a fighter pilot and National Aeronautics and Space Administration computer scientist who worked on the Apollo program, it was exciting to experience the thrill and energy of the space program in real life. Later, after medical school, I flew many aircraft—from aerobatics in a 1929 biplane to years of piloting a business jet and an assortment of airliner simulation sessions that culminated in flying the space shuttle simulator at the Johnson Space Center under the direction of astronaut John Young. In each and every case, not a flight was undertaken without my clearly understanding performance envelope of the aircraft being flown, be it for real or in simulation.

When we consulted John Nance, patient safety expert, national news commentator, and airline captain, regarding the concept of matched performance envelopes, he responded with "Even the Wright brothers understood that an airplane will fail, stall, or crash if pushed beyond its design limits—its performance envelope—but the limitations of human pilots were never accorded the same respect. Yet incredibly, in the United States, the final key to achieving years of accident-free airline flights turned out to be nothing more than formal acceptance of the fact that people have as many performance limitations as the airplanes they fly" (oral communication, March 30, 2008).

Safe aircraft operation is accomplished when the performance envelope or capabilities of the pilot are matched with the performance envelope of the aircraft. The limits of the pilot's skill and know-how are routinely tested and taxed through simulation, to drive learning.

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ONLY WHEN WE MATCH SAFETY ENVELOPES OF CAREGIVERS AND SYSTEMS CAN WE HOPE TO BE SAFE

This paper introduces the concept of applying performance envelopes in health care. As in aviation, there are 2 envelopes that have to be considered separately and then together. We must first consider the boundaries of the safety envelope of our caregivers that are defined by their skills, knowledge, and human capabilities. The study of human factors reveals that there are indeed limits to human performance, and those limits are fluid within a range. The boundaries are not exactly fixed—they change on a daily basis as they are predictably impacted by fatigue, the work environment, and distractions. The second performance envelope we must examine is that of the system or systems that the caregiver is operating within. Only when we look at them together can we determine whether our caregivers are operating within a safe combined envelope.

We can no more defy the laws of aerodynamics and human performance in aviation than we can defy the fixed systems factors and the same human performance factors in health care. Yet we try to do so every day.

The human performance factor envelopes of our caregivers are rarely considered by hospital leaders. The Accreditation Council for Graduate Medical Education has limited the number of work-hours to 80 hours weekly, overnight call frequency to no more than 1 overnight every third day, 30-hour maximum straight shift, and 10-hour off between shifts. Although these limits are voluntary, adherence has been mandated for the purposes of accreditation. The new requirements limiting medical interns' work to 16 consecutive hours have been found to substantially reduce serious medical errors in intensive care units.[5] Yet, despite these findings, nurses, who comprise the bulk of our workforce, are not only allowed to work excessive hours with clear risk of degraded performance and risk to patients but are even incentivized to work extra shifts.[6]

In a time-motion study of nurses in a busy hospital, during just more than 35 hours of observation, 1286 distinct communication events were identified, representing 36.5 events per person per hour. A third of the communication events (30.6%) were classified as interruptions, giving a rate of 11.15 interruptions per hour for all subjects; 10% of communication time involved 2 or more concurrent conversations.[7] Dayton and Henriksen,[8] in a separate study, found that each nurse may experience an average of 300 interruptions during an 8-hour shift. Nurses who work shifts longer than 12 hours or who work unplanned overtime at the end of a shift are as much as 3 times more likely to make errors.[9]

Ann Hendrich, MS, RN, vice president for Clinical Excellence Operations with Ascension Health, recently provided preliminary findings of a soon-to-be-published multi-institutional time/motion study of more than 2000 nursing shifts from more than 30 institutions. Nurses were found to be stationary for less than 20 seconds, pass their nursing station as many as 200 times, go to medication cabinets or storage more than 100 times, and travel between 2 and 5 miles per shift. Coupled with the frequency of interruptions during their work, previously mentioned, it is not difficult to understand why our medical error and harm rates are so high (oral communication, September 27, 2007).

Ann Rhoades, the cofounder of JetBlue and past people system leader of Southwest Airlines, who currently works with health care leaders, is amazed with our lack of attention to human performance envelopes and the absence of the use of simple checklists and tools that accommodate our predictable human performance deficits. In her words, "Simplicity and standardization drives predictable performance" (personal communication, April 1, 2008).

When catastrophic errors occur, leaders cite the fact that established policies and procedures have been violated, laying blame at the feet of the caregivers. Yet few organizations have leaders who take ownership of the reality of whether achievement by the caregivers of those policies and procedures is even possible. Few have an understanding of the limits of performance of the systems into which their caregivers are thrust every day, delegating and entrusting this responsibility to upper- and mid-level managers who typically have no clue about the embedded risk of such systems. They, in turn, entrust this responsibility to the vendors of such systems. Ultimately, no one is accountable.

In aviation, when we violate the boundaries of human and systems envelopes, we pay the price with accidents and near misses. Our pilots are the first ones at the scene of the accident.

Conversely, when we push the envelope in health care, senior leaders and many clinicians often never know about the adverse events because these events are often hidden and masked by the complexity and fragmentation of care. "When such failures are apparent," as Dennis Quaid has said, "we often maintain a conspiracy of silence that is intentionally invoked by risk management procedures and unintentionally invoked through survival instincts."[2] We automatically fall into a name-blame-shame cycle citing violated policies and ignore the laws of human performance and our responsibilities as leaders.

We have cited, in prior articles, the characteristics of leaders who fail to acknowledge the realities of patient safety. Some are ignorant of these realities and "do not know." Some are arrogant and "do not care." Some are what some consumers would say are criminal in that they "do not care that they do not know."[10]

Yet there are islands of greatness that provide a guiding light for future leaders. In a recent treasured private moment this writer had with Dr. Don Berwick, president and CEO of the Institute for Healthcare Improvement, who has been a courageous visionary of the quality movement, he shared an inspirational story of outstanding leadership. He spoke of a nursing leader and what she does after an event when a nurse is involved in harming a patient. She asks 1 question, "Did you commit this error on purpose?" When the nurse says no, she then says "Well then it is my fault….errors stem from systems flaws…I am responsible for creating safe systems."

In this 1 healing moment, she declares her ownership of the systems performance envelope and the human performance envelope (oral communication, March 17, 2008).

Amazingly, the day after Dr. Berwick shared this story, we serendipitously encountered Jeanette Ives-Erickson, RN, MS, FAAN, senior vice president for Patient Care Services and chief nurse executive of Massachusetts General Hospital, the leader to whom Dr. Berwick referred. We had the opportunity to interview her on video and asked her to describe her process when an event occurs. As she recounted her approach previously described, the video team was deeply touched and clearly aware that we were in the presence of greatness (video interview, March 18, 2008). In a few short minutes with a caregiver after an accident, this leader declares ownership of the systems envelope, and the performance envelope of her caregivers, and creates a healing constructive opportunity to prevent a repeat occurrence.

The Quaid experience of a repeat accident that never should have happened must be a call to action. This writer contacted hospitals immediately after the event and was amazed at the laissez-faire attitude that was encountered. Immediate actions to make everyone aware and to stimulate vigilance are not enough. Few organizations undertook "failure mode effects analysis" examinations of the entire medication use process from order to administration so as to prevent additional occurrences. Fewer still put together administrative rapid response teams to address similar risk scenarios.

How do we address the questions and issues highlighted by the Quaid family? When the event occurred, they struggled with the lack of immediate disclosure. When they called the hospital on the evening of the accident, prompted by intuition, they were told that all was fine. The next day, they realized "Our kids could have been dying, and we wouldn't have been able to come down to the hospital to say goodbye."[11] They struggle with the fact that the same event had occurred in another hospital with the same product labeled in the same way, causing the deaths of 3 babies. They recognized the "conspiracy of silence" that occurs after such events. They realized the responsibility of supplier companies who do not recall their products when features such as labeling contribute to adverse events. They are shocked by the seeming lack of awareness of the daunting challenges of patient safety and realize what a misplaced trust we as consumers put in our caregivers.[2]

Quoting a maxim of the Institute for Healthcare Improvement, we must ask the question "What can we do by Tuesday?" We believe that all of the key leaders in hospitals must act now—from governance leaders to servant leaders at the front line. As Dr. Gary Kaplan, CEO of Virginia Mason has said, "Leadership is not only a noun, it is a verb."[12] Position does not define leadership.

A LEADERSHIP POSITION NO MORE MAKES ONE A LEADER THAN STANDING IN A GARAGE MAKES ONE A CAR

Governance leaders must demand that they be given the basic knowledge regarding human performance factors and that these factors be considered as hospital leaders recommend staffing levels and the acquisition and implementation of new technologies. Are there policies in place that allow nursing and direct caregivers to work hours beyond what research shows are safe boundaries? If they are and financial reasons are cited, governance leaders must look at the reserves and endowments that they are so proud of maintaining and ask themselves, "How much in dark green dollars is it worth to prevent the next sentinel event causing major harm or death to patients?" If they are not briefed in detail regarding every sentinel event, they must ask why they are not. They must understand that they are personally accountable for the safety of their patients and that they cannot delegate this responsibility. Many U.S. hospitals can be extremely dangerous places, and the governance leaders have more power than anyone else to make them safe. They control the resources and are responsible for making the senior administrative team responsible for honoring the sacred trust of their patients. The National Quality Forum Safe Practice no.1, "Creating and Sustaining a Culture of Patient Safety," has direct and specific activities for governance leaders and provides a guide for the identification and mitigation of risks and hazards.[13]

The CEOs must recognize that the era of the 3 "keeps" of the CEO is over: keep the physicians happy, keep the board happy, and keep your job. The CEO is the guardian of safety of the organization. He or she must have a new command of the basics of human performance and systems performance. He must realize that hospital service reliability is 15 years behind other industries. The CEO must acknowledge that being above average means that the hospital is still unsafe and that his leadership is critical. If they do not declare that patient safety is a mission critical issue and act on this on a daily basis, then they have missed the boat. This means that they take specific issues and make them defining moments for the organization.

Officers and senior leaders must support and challenge the organization to understand the performance envelopes and profiles of their systems in pharmacy, laboratory, imaging, and nursing/direct caregiver services. Indiscriminate budget cuts and telling mid-level managers to cut budgets without providing smart and careful guidance are formulas for disaster, yet all too common.

If we use a car as the metaphor for a hospital, then governance and senior leadership would be the engine; the mid-level managers would be the transmission, translating the power to the wheels; and the wheels would be the frontline caregivers. As we fire up CEOs and senior administrators with patient safety energies, we are turbocharging the engine while the frontline wheels are encountering more and more load as if they climb the hill of treating sicker and sicker patients with less and less resources.

THE WEAKEST LINK IN THE CHAIN OF COMMAND IS MID-LEVEL MANAGEMENT

It is as if the transmission of mid-level managers were made of balsa wood. They are ill-prepared without the skills or knowledge to deal with the stresses, and we are, in effect, stripping the gears. It is not their fault. Governance leaders and CEOs must make sure that we equip them with the know-how to keep the caregivers and systems functioning within safe envelopes.

Chief medical and chief nursing officers have the clinical backgrounds that lend themselves to be the communicators of human performance factor issues; however, if they do not keep up on the latest evidence, they can easily endorse unsafe operation plans through their silence. The many national collaborative efforts linking such clinical leaders together provide rich opportunities for rapid learning and, more importantly, opportunities to learn from like organizations.[14,15]

Patient safety officers are the lifelines for patients and life jackets for CEOs.[16] They now have clear direction provided through the National Quality Forum Safe practices that will only be more important over time as the practices are updated. The new leadership requirements defined by the Joint Commission[17] will continue to drive the responsibilities of leaders and continue to be communicated to the national community. As presented by Peter Angood, MD, vice president, The Joint Commission; chief patient safety officer, Joint Commission International Center for Patient Safety, at the March 26, 2008, High Performer Workshop, "leadership is one of the more common root causes for sentinel events" (oral presentation, March 26, 2008).[18]

Risk management and legal leaders need to become familiar with the emerging trend of rapid disclosure and the terrific benefits that come from early remediation and what Richard Boothman, chief risk officer, University of Michigan Health System coined the value of "extreme honesty," which means taking a principle-based approach to dealing with medical errors causing harm. Another national leader in disclosure and patient safety is Dr. Tim McDonald, professor of Anesthesiology and Pediatrics, and associate chief medical officer for Safety, Risk Management and Quality at the University of Illinois Medical Center. Dr. McDonald believes that "Disclosure is the Trojan horse of cultural change" and that such behavior brings an organization back to the values that make health care great (oral communication, March 10, 2008).

Frontline caregivers must recognize and communicate the risks they see every day on the frontline and have the courage to "stop the line" when they know they are putting their patients at risk. Clearly, this is very difficult and, in some cases, almost impossible without leadership support.

Many celebrities have been involved in medical errors that serve to generate awareness such as Julie Andrews, Dana Garvey, Rod Steiger, Maurice Gibb of the Bee Gees, and astronaut, Pete Conrad, the third man to walk on the moon. Their episodes and the Quaid incident keep the issue in the news and help keep up the demand for answers. Consumers think "if it happened to them, it could happen to me."

This writer had the amazing experience of walking through an air and space museum, the only interloper with 6 of those original astronauts, including the recently deceased Gordon Cooper, as they looked at pictures of themselves and mementos of the space race. Although, now mature men in their 60s, it was as if they had been teleported back to those days of youthful exuberance. It was clear that they knew they had been involved in something greater than themselves and that their opportunity had been to serve an exciting and common good. This is something we need to recapture through our leaders in health care.

The major message of this paper is that the magic ingredient to success in patient safety is leadership. We need leaders at every level to have the "right stuff" which, in the case of health care, means to have the courage to define and stay within our safety envelopes and to develop the skills to drive patient safety practices. Those with the right stuff will own the systems issues and understand human performance factors. They will take the responsibility for systems failures and not wrap themselves in a cloak of malpractice avoidance-speak, unfairly leaving their caregivers to hang alone.

SUCCESS BEGINS WITH LEADERSHIP, ENDS WITH LEADERSHIP, AND IS ALL ABOUT LEADERSHIP

In the future, the best hospitals will be led by really great leaders who will make performance envelopes a priority. When they consider implementing a new technology, or envision launching a new procedure, they will own the responsibility for safety envelopes of their systems and caregiver performance envelopes. They will want to look at them together, and the first question they may ask regarding new technologies or safety of a department or unit will be…"May I have the envelope, please?"

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