

## John M. Eisenberg Patient Safety and Quality Awards

# An Interview with Lucian Leape

Interviewed by Paul M. Schyve, M.D.  
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*Lucian L. Leape, M.D.*

*Lucian L. Leape, M.D., is Adjunct Professor of Health Policy, Harvard School of Public Health, and Consultant, The RAND Corporation. A pediatric surgeon by training, Dr. Leape has devoted the last 15 years to the challenge of improving patient safety in the United States health care system. Dr. Leape has contributed a substantive body of research on medical error and has been a tireless advocate for patient safety in a variety of leadership roles—and is rightly often called “the father of patient safety.”*

*Dr. Leape’s publications on the epidemiology of medical error in the early-to-mid-1990s set the stage for current work in the field. His essential 1994 article, “Error in Medicine,” introduced the concept of systems—rather than individual-based failures as the cause of medical errors and explored the effects of errors on the individuals who made them. Dr. Leape’s work has helped enormously to disseminate the concepts of*

*human factors and systems thinking, paving the way for large-scale improvements within the health care industry. As a member of the Institute of Medicine’s Quality of Care Committee, he contributed to the landmark reports *To Err Is Human* and *Crossing the Quality Chasm*, which have provided a durable framework for improvement. Dr. Leape remains a constant motivating force for the patient safety movement.*

***Fifteen years ago, you described the problem of unnecessary surgery, which obviously represents one form of medical error. What was the medical community’s reaction to this work and related work by John Wennberg and others?***

As far as I can tell, no one noticed. I don’t recall receiving a single letter or phone call. The problem was picked up by some in public health and the health policy field, but I am not aware that it had any effect on policy. On the other hand, John Wennberg’s much more extensive work engendered considerable discussion among policy people, energized the newly developing field of quality of care research, and became a staple in quality of care education.

***Unnecessary surgery, as you pointed out then, can certainly lead to unanticipated deaths. Why do you think it did not catch the attention of the industry and the public?***

Despite recurrent reports in the media over a decade or more, overuse, which is what unnecessary surgery is, has never “grabbed” the public like medical error has. I think it is too abstract. It sometimes just sounds like a difference of opinion. If a person has an operation or any treatment and does well afterwards, they are not inclined to second guess whether they should have had it or listen to those who do. Psychologically, we always

want to believe we made the right decisions. However, if things don't go well, then the patient or his or her lawyer may conclude that it was unnecessary. Fortunately, most operations go well, so the former far outnumber the latter.

*In the Journal interview with David Bates,<sup>1</sup> David described how you, he, and David Cullen formed the Adverse Drug Event Prevention Study Group to study the epidemiology, costs, and risk factors of adverse drug events in two large hospitals and to look for systems failures. David stated that systems analysis of the preventable events suggested that improving the systems of care would have more impact than targeting high-risk individuals. Do you think this message has finally sunk in?*

Definitely. The area of health care where people have most bought into the systems concept is in medication safety. Our research helped pave the way, but two other factors were also important. The first was that pharmacists and clinical pharmacologists had been trying to get doctors and hospitals to pay more attention to the medication system for a long time. They promptly supported the new insights. Second, everyone can see that the medication system is a *system*, one that involves interactions between multiple parties, products, and equipment. In fact, that is one of the reasons we picked medications when we were looking for a system to study. In other words, the area was ripe for analysis.

*Why do you think it has taken so long for systems thinking to penetrate health care?*

There are a number of reasons why doctors in particular have trouble accepting the systems concept. I think the most important reason is that it goes against everything we are taught in medical school and residency: that if you do your lessons, know your stuff, keep up, and are careful, you won't make mistakes. It is hard to persuade people that that isn't enough, that there is much more to safety than just being careful.

The second reason is that although the numbers in the aggregate are huge—over a million serious preventable injuries annually, and, I believe, considerably more than 100,000 preventable deaths—an individual physician rarely has a preventable death, and even nonfatal injuries due to serious errors are not that common for the

individual physician. Moreover, we know that most errors are not recognized by the person making them, which further decreases the perception of a problem. This is a core challenge in safety—getting people to change their behavior, adopt a new safe practice, for something that they rarely see happen, such as operation on the wrong leg.

Finally, the shame and guilt felt by the physician following a serious injurious error can be profound. It is not surprising they don't want to talk about it or "analyze" the error.

*You were an early proponent of computerized physician order entry. What would you say to health care organizations and their leaders who are still on the fence about adopting this technology?*

This is really a tough problem. I doubt if there are many people any more who don't think computerized physician order entry (CPOE) is a good idea. Enough studies have now been done demonstrating its effectiveness in substantially reducing errors and improving the appropriateness of medication use that only the diehards are still in opposition. But, like the electronic medical record (EMR), it is very expensive. Not just in hardware and software, but in training time. Not surprisingly, adoption has been slow. A very legitimate concern is the lack of standardization and the fear that a system bought today will be outmoded within a few years.

I don't think we are going to get widespread adoption of either of these crucial technologies, EMR or CPOE—they naturally go together, of course—unless either the government or the payers are willing to pay for it. In the United Kingdom—and in the case of the U.S. Department of Veterans Affairs (VA)—the government paid. The other option, asking payers to fund them, makes even more sense. Although patients and doctors benefit in improved quality, efficiency, and safety from EMR and CPOE, the economic benefits go largely to the payers in terms of reduced payment for adverse events, reduced inappropriate use of drugs and tests, and increased billing efficiency. It seems both fair and prudent that they should make the investment.

*Resistance to altering long-held beliefs has been a continuing barrier to addressing the problem of preventable medical injury. What are some of the industry's other*

*sacred cows, and what arguments do you use in trying to persuade health care policy makers and other leaders to take the necessary actions?*

Some of the big “sacred cows” are already on the block, particularly long duty hours for residents and overtime, long shifts, and staffing ratios for nurses. I don’t know of anyone who wants to be taken care of by a doctor who has not slept in 24 hours, but figuring out how to provide 24/7 coverage, limit shifts, and still train physicians in continuity and responsibility of care is a huge challenge. There is a lot of creative and serious attention being given to this issue right now in response to the Accreditation Council for Graduate Medical Education (ACGME) requirement, which I think speaks eloquently to the dedication of our physicians. All I have to say is “God speed!” We’ll work it out.

An even tougher issue, but one that goes to the heart of creating the much vaunted culture of safety that we are striving for in health care, is the hierarchical social/organizational structure of departments and services in hospitals. Residents and nurses are still too often put down or humiliated if they question the judgment of a senior physician. This is especially true in the operating room. This needs to change. Modern health care is too complicated for any individual to always know exactly the right thing to do. We need to do a much better job of learning to work in teams.

Some have dismissed the idea of learning from aviation, but this is one place where we could learn a great deal. After several major crashes of big planes, the aviation industry recognized that the climate in the cockpit had to change so that the second officer, and everyone else, felt responsible and empowered to question or challenge the judgment of the senior pilot in potentially hazardous situations. Crew Resource Management training has changed all that, and flying is much safer as a result. The senior pilot is still in charge, but he realizes that he is part of a team. These techniques are being introduced in health care, particularly in Kaiser Permanente, the VA, and in some obstetric services; they need to be on everyone’s agenda. Simulation can be a powerful tool for teaching teamwork, and it, too, is taking off. I think we will soon have some convincing data of the effectiveness of teamwork that will help persuade the doubting Thomases.

*Early on in your work on adverse drug events, you cited human factors as an important area of study. Human factors engineering is finally starting to come in its own in the health care field. “Systems thinking” strikes some as a very abstract concept. Does “human factors” have more appeal in offering practical methods to assess and minimize risks of patient harm?*

I think it does, although once they try it, most people don’t find thinking in systems terms is that difficult. But there is a fun aspect of human factors that makes it appealing and instantly accessible. Once you read Don Norman’s *The Design of Everyday Things*<sup>2</sup> you can never again approach a door without wondering why it isn’t obvious whether to push or pull! Human factors concepts such as standardization and simplification are no-brainers—of course you will make fewer mistakes if you always do it the same way or if there are fewer steps in a process. But my favorite is the “forcing function”—a mechanism that makes it absolutely impossible for you to do the wrong thing, such as gear locks in cars and connectors that will only fit the right tubes.

But these are the easy things—the quick fixes. They are important, but they only get at a small fraction of the problem. It’s major systems changes we are after. And the key systems involve human interactions, not names, labels, and computer programs. We know a lot about what works for patient safety. The challenge is to make it happen—to make all our systems more efficient, to work better in teams to coordinate care among multiple caregivers, and to carry out safe practices 100% of the time. How do we make sure that we give perioperative antibiotics on time for 100% of patients for whom they are indicated? Disinfect our hands 100% of the time before touching a patient? Ensure that 100% of diabetic patients get a retinal examination annually? That’s the safety goal: 100%, not 80% or 90% or even 98%–100%. And the first step in getting there is to conceive that it is possible. Going to the moon started with conceiving that it was possible. Health care needs a moon shot mentality for safety.

*What, for example, do you wish they had told you about human factors when you were a surgery resident at Massachusetts General Hospital?*

That’s easy: that when you screw up it isn’t *entirely* your fault, that there are usually underlying factors that

are not under your control. Much more to the point, I wish that my attendings had realized that! Or realize it now, for that matter!

The truly incredible thing is that residents don't make many more mistakes than they do, considering they are typically sleep-deprived, anxious, overburdened, hurried, and continuously interrupted—all conditions that we know greatly increase the chance of making an error. What safety we do have results in great measure from their dedication and constant efforts to not fall into the many error traps our systems set for them.

### *What would you like to see changed in today's professional education?*

Changing how we educate medical students and train residents should be a top priority for those concerned with patient safety. One of the major shortcomings of contemporary medical education is that it focuses too much on information management and not enough on people management, which is the only way in which our biomedical expertise can be delivered to patients. We concentrate too much on what students know and not enough on what they are. Even worse, too many, probably most, medical schools continue to perpetuate the patterns of dysfunctional behavior that lie at the heart of our nonsafe health care culture. Students need tools for safety just as they do for clinical practice—the knowledge, skills, and attitudes associated with safe patient care.

Students need to acquire knowledge about why people make mistakes, the concepts of latent errors and systems failures, human factors, and systems analysis. These are not hard to teach nor do they require large blocks of time. Students also need to develop an understanding of how patients feel when they are injured and to understand their own feelings of guilt and shame when they are the vectors of those injuries.

We also need to teach them the basic skills of conducting a systems analysis, working in teams, and how to deal with their own and their patients' feelings after a serious mishap. It's more than just "communication." I think there is a big role for simulation in teaching these skills.

Finally, we need to inculcate in students the attitudes needed in a safe culture: valuing and respecting colleagues, always placing patients' interests first, personal responsibility to model safe behavior, and a sense of

collective responsibility, that is, to value teamwork. Attitudes, of course, are not taught, they are learned from examples, from their faculty models. The challenge is to provide the right models.

### *In a Journal interview last year, Jeff Cooper cited slow progress in the establishment of nonpunitive cultures.<sup>3</sup> Do you think the pace of cultural change at the organizational level has picked up since then?*

The move toward a nonpunitive culture continues to accelerate. Most hospitals now at least give it lip service. But it is a tough slog—going against what we have always been taught, as I indicated. Some have confused the admonition to be nonpunitive toward those who make or report errors with the way in which we should respond to misconduct. Willful violation of safe practices cannot be countenanced. Blame is appropriate, and some form of sanction is necessary in these situations. As James Reason says, we seek a "just" culture, not a blame-free culture.

Culture change in terms of our interpersonal relations, working to break down hierarchical demeaning behavior and learning to work in teams, is also occurring, but still very slowly and sporadically.

### *What can be done?*

The secret of culture change is, I believe, quite simple: leadership and champions. Putting it in the negative, culture change cannot happen without strong leadership from the top and active leaders, physician champions, at the front line. Leaders must articulate the goals, demonstrate their commitment in everyday life, and persuade others to make the changes needed. In those institutions and systems where the leaders have truly made safety the top priority, dramatic changes have occurred. The challenge is how to get more of them aboard.

### *In a 2002 paper, "Reporting of Adverse Events," you argued that it was doubtful that a national voluntary system for the reporting of all medical errors and adverse events could be implemented in the United States.<sup>4</sup> How are the prospects now, especially with the Senate's passage on July 22 of the "Patient Safety and Quality Improvement Act," which calls for legal protection of voluntarily reported information?*

If the bill emerges without the “poison” clause that excludes protection whenever a judge believes it is necessary to require disclosure, it can facilitate increased reporting, particularly to the Joint Commission and other national bodies. If the clause remains, I believe it will have a very modest effect.

Fortunately, a number of voluntary systemwide or specialty-oriented reporting systems are developing even in the absence of this protection. They are providing the sharing of lessons learned that is the major objective of reporting systems.

An even more encouraging development, I believe, is the exciting move to expand the highly successful National Surgical Quality Improvement Project (NSQIP) system from the VA to surgical services in all hospitals. In effect, this replaces reporting with detailed and thorough data collection that enables the identification of systems failures and also provides feedback to the reporting institution as to how it compares with peer institutions across the country. If this system can be expanded to include systems analysis of the failures, we will have the best of all worlds. My own belief and hope is that this type of sophisticated data collection and analysis will ultimately render “reporting” as we know it obsolete.

*What do you see as the role of the physician in improving patient safety in his or her own practice? In the institutions in which he or she works?*

We will never reach the dramatic reduction in preventable injuries that many of us believe is achievable until physicians make safety an overriding priority. It cannot be done by nurses, pharmacists, risk managers, and administrators without physician involvement. Despite all the changes in the organization of health care delivery that have occurred and are yet to come, physicians will continue to be the leaders or key players in all teams, for the simple reason that they play the central role in determining how and whether patients are cared for. Thus, their leadership is crucial for developing and implementing the many systems changes that are needed. This is every bit as true in office practice as in hospitals, where most of the attention has been given. Prescribing errors, lost lab tests, wrong diagnoses, misidentification of patients, etc., are systems problems that can be virtually eliminated if physicians will focus their intellect and

energy on dealing with them. And in this era of complicated, multidisciplinary, high-technology care of patients with multisystem disease, the need for more effective teamwork both within the hospital and in the community could hardly be more obvious.

*How could you respond to the kind of argument that we often hear from physicians: “Safety is something that we, as physicians, have built into our practice. Everything we do and think about is designed to minimize the risk of treatment and provide treatments with risks only when the potential benefit justifies that risk.”*

This is true, but it refers to the unavoidable risks inherent in much of what we do. Safety is not about that, it is about the avoidable risks, about preventing the preventable—the mishaps that occur because our treatment did not go as planned. For example, some side effects of medications are unpredictable and, thus, unavoidable. But many, perhaps most, complications of drugs occur because of errors in prescribing, dispensing, or administering the medication, and these are things we can do a great deal about. Will we ever eliminate risk? Of course not. But we can reduce iatrogenic risk by 90%—and then by 90% again.

*Physicians also often offer this kind of comment: “There is a spectrum of risk-benefit that is far more difficult to manage than something as straightforward as the simple act of flying a plane—load of people in and out of a busy airport. Compared to the aviation industry, the delivery of health care is exponentially more complex and thus not as amenable to the simple solutions of that industry. The aviation model has its merits that may apply to hospital delivery of health care but does not apply as easily to the practice of clinical medicine by physicians.”*

There is no question that practicing medicine is far more complicated than flying an airplane, particularly a highly automated modern airliner. Every patient is different, and every patient has a “defect,” that is, they are sick. But we are finding that many techniques used in aviation to reduce mistakes work in our practices as well: standardization, simplification, use of forcing functions, checklists, protocols, and, as mentioned, working more effectively in teams, to mention a few. These human factor concepts are already finding widespread application

in doctors offices as well as hospitals. Forget what aviation does that doesn't apply in medicine; use what does.

*Recently, there has been increasing discussion about what and how to communicate to patients when serious errors or injuries occur. The Joint Commission requires hospitals to have a policy about disclosure but leaves it up to them to work out the details. Some have advocated "full disclosure," including apology, but others fear that doing so increases the likelihood of being sued. What should doctors do?*

I may be wrong, but I think that full disclosure is an idea whose time has come. No one questions that it is the right thing to do—the patient has a right to know what has happened when things go wrong. It is also the human thing to do—to be honest and to apologize. Although full disclosure is difficult when you have been the one who made the mistake, being what I call the “vector” of the failed system, I think the major barrier to physicians being honest with their patients is fear of malpractice litigation. It inhibits their ability to discuss their mistakes and to admit them to their patients. They are afraid that doing so will lead the patient to sue them and that the admission will be used against them in court.

Fortunately, evidence is accumulating that shows this is a myth. It is just the other way around: it is the failure to be straightforward in telling patients what happened when things go wrong, and to apologize, that increases the risk of being sued. One of the major reasons people sue—some lawyers tell me, the *major* reason—is that they are angry because the doctor withheld information and did not take responsibility or apologize for the mishap. We need to change this. We need to treat patients the way we would like to be treated ourselves.

A related myth is that providing financial compensation for the costs of mishaps increases the risk of suit. That, too, is unfounded. I have long believed we should institute no-fault compensation for all medical injuries, but even in its absence, hospitals would be well advised to pay up front for patients' added expenses. There is no

evidence that it increases the risk of suit. What little evidence we have shows the opposite, and also that total costs are reduced.

*Are there any other patient safety issues that we haven't talked about that you think are important for health care to consider?*

One area that we have to begin to talk about is “problem doctors,” physicians whose performance is substandard and a threat to patient safety. Although Don Berwick and I have repeatedly made the point that it isn't bad people, it's bad systems that cause most of our safety problems, *some* errors and injuries are caused by physicians who are not practicing at an acceptable level, and we don't deal with them very well.

In addition to problems with drug and alcohol abuse, which are generally well-handled by state medical society programs, as many as 10–15% of physicians have psychiatric problems, others have slipping competency, and still others engage in disruptive or antisocial behavior toward patients or colleagues that impairs safe practice. When you put all causes together, it looks as if a third or more of physicians will, at one time or another in their career, experience a problem that constitutes a threat to patient welfare.

While there are some programs to help these physicians, the number is clearly insufficient, and the resources for assessment and retraining or other treatment are inadequate. In addition, most hospitals lack effective systems for early identification of doctors who need help, before they injure patients, and for taking prompt action to help them. I think we need to develop much more rigorous, and objective, methods for identifying our colleagues who need help and for making it available to them. The answer isn't to “get rid of them,” it is to enable them to practice safe and competent care. We can do much better.

*Thank you so much, Lucian, for sharing your perspectives and congratulations on winning the award. ■*

## References

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