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Learning From Mistakes: Toward Error-Free Medicine

Lucian L. Leape, M.D.

INVESTIGATOR AWARDS IN
Health Policy
Research

In 1999, when Lucian L. Leape, M.D., heard then-President Bill Clinton affirm that bad systems — not bad people — cause hundreds of thousands of preventable medical errors every year, the Harvard professor knew he'd done his job.

"He got it!" Leape said.

Clinton was responding to a landmark report by the Institute of Medicine (IOM) showing that medical errors contribute to more than 1 million injuries and up to 98,000 hospital deaths a year. The release of that report, *To Err is Human*, shattered widely held perceptions about the safety of health care in the United States and set a new agenda for protecting patients from medical errors.

For Leape, who was a driving force behind the IOM report, Clinton's statement — together with immediate responses from Congress, the news media, regulators, professional groups, and the general public — signaled that patient safety had finally captured national attention as a major public health issue.

"Everybody now knows we have a problem. Nobody can pretend it's not serious," says Leape, whose research helped lay the groundwork for *To Err is Human*. He also served on the committee that developed the report for the IOM.

Key to the success of *To Err is Human*, Leape believes, is the fact that the IOM offered a persuasive solution to the medical errors problem.

"The transforming concept here is that errors are due to faulty systems, not faulty people," says Leape. "We must stop blaming and punishing individuals and begin identifying and correcting systems failures that lead people to make errors."

Under his Robert Wood Johnson Foundation Investigator Award in Health Policy Research, Leape has taken that message to a wide array of audiences, including the general public, health care workers and managers, regulators, payers, and policymakers. Originally, he planned to do that by writing and publishing a series of essays on patient safety. (To date, one of those essays has been published in the *New England Journal of Medicine.)*

But the overwhelming response to *To Err is Human* forced him to change tactics. As a member of the IOM committee and a major contributor to the report, Leape became its lead spokesperson. "The heightened awareness and pressure for change suddenly provided an unprecedented opportunity to influence public policy," he says. "It was clear that leadership and advocacy, speaking and convening, were called for, not the scholarly research and writing that were planned."

Advocating for Policy Change

In particular, Leape has strived to influence public policy by communicating the messages of patient safety in every possible venue. That included:

- giving more than 200 public speeches and presentations;
- testifying on four occasions before Congress;
- co-chairing a National Quality Forum steering committee on serious, preventable adverse events;

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- editing a special issue of the *British Medical Journal* on patient safety;
- co-chairing a Salzburg Seminar on patient safety;
- working with the *New England Journal of Medicine* to identify authors for, commission, and publish a series of articles on key issues in patient safety; and
- consulting and working with professional organizations — including the American Association of Medical Colleges, the American Board of Medical Specialties, the Federation of State Medical Boards, the Joint Commission on Accreditation of Healthcare Organizations, the American Hospital Association, the American Nurses Association, the American Health Lawyers Association, and others — to determine how they could contribute to improving patient safety.

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"My goal was to motivate policymakers to create incentives" for correcting the system, Leape says. "I focused mostly on the health care establishment to get them to understand what was wrong." But *To Err is Human* raised the debate to a new — and much more public — level. "The IOM report brought the public in and increased the pressure on the establishment. Once the public and news media were involved, it greatly increased awareness and accelerated the pressure."

Within days of the report's release, Congress scheduled hearings and President Clinton directed the Quality Interagency Coordination Task Force to analyze the report. Two months later, at the task force's recommendation, the President called on all federal health agencies to implement the IOM's recommendations.

Since then, the Joint Commission on Accreditation of Healthcare Organizations has identified and incorporated 11 new "safe practices" into its inspections. Even more significantly, as of 2006, all of the Joint Commission's hospital inspections will be unannounced.

The Agency for Healthcare Research and Quality has, as envisioned by the IOM, become a national focus for safety. Congress appropriated $50 million a year for patient safety research, which has greatly increased work in the field and attracted and provided support for an emerging research infrastructure of young investigators.

"Still, $50 million does not reflect a real national commitment to reducing medical errors," Leape remarks. "We need 100 to 500 times that. We lose more lives each year from medical errors than NIH's scientific and technological advances save. We should spend as much trying to do something about it." He believes that $25 billion to $30 billion a year would be a more appropriate level of support.

Discarding a Culture of Blame

Just as important as funding new research is changing the culture of medicine. And Leape believes there's still a long way to go on that front.

"We have a blaming culture, so that when someone gets hurt, the response is emotional, punitive in most cases," he says. More often than not, that translates into a single belief: Someone has to pay.

"We're trying to get people to understand that that's the wrong approach," Leape says. "The answer is not to blame and punish people, but to try to understand what happened and fix it. We've learned from other industries that when people make mistakes, it's because the system is hindering them in some way from doing what they're supposed to do. Quality improvement is essentially about redesigning systems, and that's what safety is about, too."

One big problem, though, is that most physicians don't buy this argument. Leape sees two reasons for this. First, physicians are seldom involved in safety breaches that result in serious patient injury or death, so errors tend not to be a pressing concern. "Ninety-eight thousand hospital deaths a year sounds like a lot, but the frequency for individual physicians isn't very high at all," Leape says. "You might recognize one of those deaths yourself just once every 10 or 12 years."

Second, most physicians have been trained to rely on their own knowledge, skills, and practices in taking care of patients. "When something does go wrong, physicians tend to focus on individual actions and responsibility," Leape says. Often, they do not fully understand or see the need for a systems approach and are put off by concerns about professional autonomy and malpractice liability.

A Vision for Safety

So what would a "safe" medical culture look like?

In Leape's model health care system, physicians, nurses, and other health care professionals would work together in multi-disciplinary teams and assume personal responsibility for ensuring safe practice and identifying hazards. "Indeed, they would have almost an obsession about safety," Leape says. "They would respond to mistakes in a non-punitive way. Instead of pointing a finger of blame, they would seek to determine what went wrong with the system and how to fix it."

Hospitals and other health care organizations would focus on learning from mistakes as well. They would place explicit value on collaboration, teamwork, and safety, and search aggressively for safety hazards out of a desire to correct them. When mistakes did occur, the response would be one of accountability, responsibility, and correction — not denial and blame.

"Quality improvement is essentially about redesigning systems, and that's what safety is about, too."

As a result, patients would see a difference in their care. They would notice that all health care personnel were taking obvious pains not to make mistakes. They would see visible signs of safe practices — warnings, check lists, double-checks, and repetitive communication to ensure against medication allergies and other potential problems. In addition, they would be informed in writing — through brochures, admission instructions, and other documents — that safety was the hospital's primary concern and part of its mission.

"Very importantly, patients would be intimately, extensively, and constantly involved as partners in their own health care," Leape says. "And finally, they would have complete confidence that everyone was treating them openly and honestly and keeping them completely informed. They would trust us."

But, according to Leape, that's only happening "slowly, in fits and starts, and in some places."

Looking Ahead

Making a quantum leap in patient safety will require addressing the "fundamental deficiencies and dysfunctions of our health care system," Leape says. Many things, he believes, need to happen:

- Efforts to computerize patient records and order entry — which have the potential to prevent hundreds of thousands of errors a year — should be expedited.
- Working conditions at hospitals must be improved so that nurse-staffing ratios are appropriate, physician workloads are reasonable, and limits on working hours are enforced.
- Full disclosure policies should be implemented to inform patients promptly and compassionately when errors are made in the course of their care.

About the Investigator

Lucian L. Leape, M.D., is an adjunct professor at the Harvard School of Public Health and a health policy analyst whose research has focused on error prevention and appropriateness of care. Prior to joining Harvard, he was professor of surgery at Tufts University School of Medicine and chief of pediatric surgery at the New England Medical Center.

He has been a leading advocate of a non-punitive, systems-based approach to preventing medical errors and has led several studies of adverse drug events and their underlying systems failures. In addition, he has directed research into overuse and underuse of cardiovascular procedures.

Dr. Leape is a member of the Board of Directors of the National Patient Safety Foundation and the Institute of Medicine Quality of Care in America Committee that produced the report *To Err is Human*. He has also served on the Agency for Healthcare Research and Quality Health Services Research Review Committee and the Physician Payment Review Commission Access Advisory Committee.

In 1999, he received the Donabedian Award from the Medical Care Section of the American Public Health Association and in 2003, the duPont Award for Excellence in Children's Health Care. Dr. Leape is a graduate of Cornell University and Harvard Medical School. He is the author of more than 200 medical articles, book chapters, and monographs.

- A system of no-fault, enterprise responsibility should provide compensation for medical injuries, regardless of whether they are caused by errors.
- A Federal Health Safety Agency — sort of a Federal Aviation Authority for health care — should be created to set and enforce national standards for patient safety.

A tall order? Leape believes that, under the right leadership, it can happen. And he remains optimistic that one day, it will. After all, everyone wants to be safe. Inattention to patient safety "hurts people — even kills them," Leape notes. "No one wants to be hurt, and no one wants to hurt people."

Publications

Dr. Leape discusses patient safety issues in a variety of publications, including the following:

- Leape LL. Robert E. Gross Lecture. Making health care safe: are we up to it? *Journal of Pediatric Surgery*, March 2004; 39(3):258-66.
- Leape LL. Is it defensible to use volume standards for purchasing care? *Annals of Surgery*, August 2003; 238(2):168-9.
- Leape, LL. Problem doctors. *Law and Bioethics Report*, 2003; 3:2-3.
- Leape, LL. Human factors meet health care: the ultimate challenge. *Journal of Medical Licensure and Discipline*, 2003; 4:179-85.
- Leape LL. Reporting of adverse events. *New England Journal of Medicine*, November 14, 2002; 347(20):1633-8.
- Leape L, Epstein AM, Hamel MB. A series on patient safety. *New England Journal of Medicine*, October 17, 2002; 347(16):1272-4.
- Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. *Journal of the American Medical Association*, July 24-31, 2002; 288(4):501-7.
- Leape LL. Foreword: preventing medical accidents: is "systems analysis" the answer? *American Journal of Law & Medicine*, 2001; 27(2-3):145-8.
- Leape LL, Berwick DM. Safe health care: are we up to it? *British Medical Journal*, March 18, 2000; 320(7327):725-6.
- Leape, LL. IOM medical error figures are not exaggerated. *Journal of the American Medical Association*, July 5, 2000; 284(1):95-97.
- Leape, LL. Reporting of medical errors: time for a reality check. *Quality in Health Care*, September 2000; 9(3):144-5.

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