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In Conversation With… Lucian Leape, MD

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Editor's note: *Dr. Lucian Leape is Adjunct Professor of Health Policy at the Harvard School of Public Health, Chairman of the Lucian Leape Institute of the National Patient Safety Foundation, and a health policy innovator whose groundbreaking research has focused on patient safety and quality of care. A pioneer in patient safety, Dr. Leape's seminal article, "Error in Medicine," was published in the* Journal of the American Medical Association *in 1994. He was a member of the Institute of Medicine's Quality of Care in America Committee, which published "To Err Is Human: Building a Safer Health System" in 1999 and "Crossing the Quality Chasm" in 2001. We spoke with him about checklists and the field of patient safety.*

Dr. Robert Wachter, Editor, AHRQ WebM&M: When you read the *New England Journal of Medicine* study [which reported that a government-sponsored effort to mandate surgical checklists in Canada had no beneficial effect], what was your first reaction?

Dr. Lucian Leape: I have a very strong bias. I think that surgical checklists are one of the great things that have come along. When I first looked at it, I thought there must be something wrong with this study. So I wasn't shaken up by it, but I immediately wondered, "What have they done here that they didn't get any results?"

RW: You were asked to write an editorial for it. There are two hypotheses. One was that the early studies, the Haynes/Gawande study and others that showed how remarkably successful the checklists were, were biased—either because of the methodology or the non-generalizability we sometimes see with early clinical trials. The other is that there was something about the way that the checklists were implemented in Canada that wasn't quite right. What did you come to believe?

LL: In a sense it's a mix—I think they fell prey to the belief that checklists are a simple thing. The press talks about it: "A simple checklist saves lives." The mental image for most people for a checklist is a couple of pilots going through a checklist before they take off—Flaps neutral? Flaps neutral. Tanks fueled? Tanks fueled. So that's all there is to it. And of course that *isn't* all there is to it. The surgical checklist is that. Did the patient get the antibiotics? Yes or no. Is the blood available? Yes or no.

But the real point of the checklist is much bigger than that. It's making everyone in the room feel that safety is their personal responsibility and that they are part of a team to make things go right. This turns out to be

a very big social and cultural challenge.

RW: In reading the study from Canada, do you think the message is that you have to attend to all the other elements of implementation, the sociocultural pieces, and the buy-in? And if that is the message, how do you get that done? Because I'm sure in Canada they thought they were doing a good thing.

LL: Exactly. I think there are two things going on here. One is underestimating the difficulty of this specific kind of change—you can't just say, "We're going to do it." And the other is the bigger problem we're facing in safety and quality improvement, which is how you implement change in general.

If you look at this specific issue, the real challenge is for the surgeon to be inclusive and bring everyone in so they feel they're part of a team. So the checklist is a way to help you build a team. The surgeon does this in two different ways. One is a briefing in which he or she explains what they are going to do, makes sure everybody understands, and asks for questions, so people know what they're up to and therefore feel part of it. The second, which is a very specific element on the checklist, is having everybody introduce themselves, so it's not just surgical assistant but John Smith as surgical assistant. The objective is that everybody feels personally involved and accountable.

I was a surgeon for 25 years, and I was sure at some time I was going to operate on the wrong side [of the body]. I don't think I ever did. At least I never found out if I did. But it never occurred to me that it was anybody's responsibility but mine.

But we've learned a lot since then. We've realized that, if you really want to prevent that as well as a whole host of other problems, you have to have the whole team feel responsible. So making sure you're taking out the left kidney is the responsibility of the surgeon, the resident, the anesthesiologist, and the patient (to the extent they can be involved before they go to sleep), the scrub nurse, the surgical nurse—everybody in the room. If they feel like valued and important team members, they will then take that responsibility. What we're talking about is not ticking off the boxes, but how the surgeon and the nurses communicate. Do they project that they care about other people's opinions, respect them, and value them as members of the team?

We're asking them to do this in the most hierarchical, tradition-bound, ritualized, entrenched environment in medicine—the operating room—where everybody says the surgeon is the captain of the ship and holds him responsible for everything that happens. What we are saying is that the best way to be responsible is to start by listening to people, by making them feel responsible, too.

On top of that, a lot is known about how you make process changes. It turns out it's more than just talking that surgeon into being nice to people. There's a whole science of implementing systems changes. So we come back to: they didn't do all that in Ontario, and that's what happens when you just say, "Hey, everybody put this in." To do it right requires a tremendous amount of support, backup, training, and many other things.

RW: The sense I get is that it almost feels like a magic bullet. Like you can bypass the hard work of creating teams, changing culture, dampening down hierarchies if you just do this one thing. Whereas, your sense is that this one thing won't take unless you've already done that work and then that thing—in this

case the checklist—can support that work and remind people about some of those core principles.

LL: Exactly. Gawande made that clear upfront when he promoted checklists. The checklist is not a magic bullet. The checklist is a tool for getting you to think about how to create a safe environment in an operating room, and that turns out to be difficult and doesn't just happen. I don't have any question that the majority of hospitals that implemented it thought they were doing the right thing and tried to do the right thing. But they really didn't have the help they needed, and they didn't go through what we know is necessary to make these kind of changes.

RW: I'm going to ask you to put yourself in your mind when you were 30 years old and beginning your career as a pediatric surgeon. If someone had come to you and said you should be using a checklist in your OR, what would you have said?

LL: Well, it's kind of interesting because I had a checklist. It was my own private secret checklist. If I was doing a big operation that I didn't do frequently, like removing the lobe of a liver, the night before I would study up on it. On a little 3" x 5" card I'd write down all the steps, number them, and memorize it. Then I'd go in and try to remember it. Don Berwick once said to me, "Why don't you just post it on the wall so everybody can see it?" I said it never occurred to me to do that.

RW: Would it have been embarrassing to do that? Would it have been an admission that you weren't on top of your game?

LL: I suppose so. That was a long time ago and I don't remember, but I think there's a lot of that. Especially surgeons—literally, people's lives are in your hands and you feel the need to project competence and confidence. So it's pretty easy to look upon things like this as undermining your status. But of course we know it's the other way around, that when people show that they're open to ideas and that they don't know everything, people respect them even more.

RW: One can be sympathetic to the idea that if you're the czar of health care in the province, you have this checklist, you know it works, and so why should every place have to massage it? Why can't you just make it happen? If you're a central administrator of a province, a state, a hospital, or of Medicare—what are the lessons from this study, particularly about top-down versus bottom-up strategies for change?

LL: The great voyage we're on in patient safety, which we've been working on now for almost 20 years, is essentially about making change. When we talk about changing systems or changing process, what we're really talking about is changing the behavior of the people working those systems. All change is difficult. But process change almost always involves changing roles of various people and their relationships. What we're really saying is the way you're doing it now isn't working. And the natural reaction is well I'm doing it properly. So there is a tremendous inherent resistance, which in medicine is compounded by our traditional hierarchical system where doctor knows best and people aren't supposed to question him. But the evidence is that just doesn't work.

If I were head of a system or a state and seriously interested in how we go about accelerating the kinds of process changes we need, I would look for the successes. One awesome demonstration of process change is the Keystone Project in Michigan where Peter Pronovost was able to get 68 hospitals to totally

eliminate central line infections. You look at what he did, and boy it was anything but simple! It was not just a simple checklist. They had learned from their own experience it wasn't easy. So when these hospitals said they wanted to try this, they had very extensive requirements for participation that they had learned were necessary. The first of which is that your chief executive officer has to sign a letter saying he's committed to participate, to meet with the team on a regular basis, and to supervise it. They had to agree to have a team, which had to include a doctor, a nurse, and a hospital leader. They had to agree to collect data and submit it for analysis. They spent 5 months training people, having joint calls, doing data collection, and so forth before they actually began the intervention. They've learned over the last 10 years how to get this to happen.

It's taken a lot of us by surprise. We didn't really think it was that complicated. We knew it wasn't just a matter of ticking off a checklist, but to see how much has to be done is rather daunting. That's why in the editorial I called for major support for collaboratives in which teams from different hospitals come together, learn together, and learn from each other, which seems to be the best way to do this. It's not easy. It takes resources. It takes time. It takes expertise. It takes data. It takes a lot of hard work. But when you do that you can get results. That's what we need to do with surgical checklists. If I were the czar in a state that wanted to do it, I would go to the legislature and say, "I want $10 million to implement this one practice." And they'd look at me like I was crazy. And I'd say, "You'll get it back."

RW: It's now 15 years since the IOM report, 20 years after your initial clarion call for a new approach to patient safety and medical mistakes in hospitals. The general narrative is that it has not gone as well as one would have hoped. Is that your take on it, and if so are there other reasons that you think it has not moved along as quickly as one might have hoped?

LL: Absolutely. It hasn't gone as well as we had hoped. That was because we were naÏve about what it takes to implement a single process change—10 or 15 years ago none of us realized it was that complicated. There are two other things going on. One sad thing about patient safety is the consequences are borne almost entirely by the patient. We don't pay much of a price for our mistakes. Very different from aviation where the pilot goes down with the plane; the airline loses business if their planes crash. We don't have that kind of incentive. Instead, it's our moral sense that we shouldn't be hurting people, we don't want to hurt people, and we have a great desire not to. That's what compels people to work on it. But there's not much of a penalty if you don't do it. And there's not much of an obvious reward when you do, other than seeing that your rates go down and taking satisfaction in that. So we have that problem right up front.

The second is that we don't really understand how complicated it is and what all needs to be done. We have not as a society at any level—at the federal level, at the state level, or even really in major systems level—invested the resources it's going to take. It will be more costly than we thought because of the kinds of changes that are needed. I said rather flippantly, "You'll get it back." I really think that's true because the cost of medical errors is much greater than reported. The cost to a patient is far more than just their hospital bills. Lost wages is a huge amount, seldom noted. There needs to be a substantial upfront investment. We've recently invested $30 billion in getting computerized patient records in doctors' offices and hospitals. What I'm talking about is more than two or three times that. I don't see anybody willing to put up that kind of money. It's tragic because I think we do know enough now about how to do it. It just is not

simple.

RW: At this stage now in the safety field, what do you see that gives you hope?

LL: I'm one of those people that really thinks the Affordable Care Act was a good thing. It has within it a lot of elements to further this including some financial support. The Patient-Centered Outcomes Research Institute has substantial money for funding research in terms of practices and measures, etc. If we move away from the fee-for-service system into more bundled payments and capitated care, if we really do develop accountable care organizations, it will become very much in their interest to make care safer and more efficient. It's one of those win-win-win things. So many of us are hopeful that as we change the financing, which seems to be moving ahead rather rapidly, we'll begin to line up the incentives for safety and get more interest in doing some of the things that need to be done.

RW: Has the politics surprised you? You're a very savvy person. You probably anticipated some of the sources of pushback. And there probably are some things that have happened along the way that you might not have anticipated. How do you feel about the way it's played out in terms of what institutions have done and political actors in this?

LL: Well thank you for the compliment. I don't think I am very politically savvy, but I've been impressed that the real progress in change has been at systems levels. When you see Kaiser Permanente or other big systems take it on, or smaller systems that are really committed like Virginia Mason Medical Center or Cincinnati Children's, it's really inspiring. This change is all voluntary. It's done because people think it's the right thing to do. They certainly wouldn't continue doing it if it was putting their bottom line in the red. So we have pretty good inferential evidence that it pays off. That part has been heartening. What's disappointing is that the great majority of physicians and the great majority of health care is not given in places like that, and most hospitals really haven't changed a whole lot. I don't know what the politics is there, other than changing the method of payment. That's why we're putting a lot of hope in that.

RW: One thing I'm sure you're hearing is people who are believers in this, who want to make care better, want to change processes, are burning out. They feel like they're being asked to do so much, with new initiatives all the time, and the EMR is adding a whole new set of workflow issues. What do you say to the young person who comes up to you at a conference and says, "I really believe in this stuff, but I'm not sure how much longer I can do it"?

LL: Well, I think the answer is to say, "That's the challenge." Maybe we need to focus less on specifics of safety practices and much more on changing the workplace and the culture. One thing that quality improvement has been guilty of from day one is that most of the things we recommend people do requires some extra effort. They certainly require the extra effort to change the system, but sometimes it requires them to do extra things. Clearly from the beginning, we should have said one of the criteria for any safety or quality improvement exercise is that it reduces the work burden. The classic and terrible example of that is the electronic health record. I think we all believed that once we got it working right, it would be better and safer. But we sure haven't figured out how to make it more efficient so that doctors find that using electronic records saves them time rather than costs them time. There are horrible stories of physicians working 10 or 12 hours a day and then going home and spending 2 or 3 hours bringing their computerized records up to

date. This is madness, and it has to stop. If I were czar, I would launch a major program financed at the federal level to figure out how to dramatically reduce all of the busy work that physicians and nurses have to do. We have to change the environment and get people back to taking care of patients, not taking care of the computer.

RW: I asked you the hard mental act of putting yourself back to the point where you were a practicing surgeon and thinking about how you would have responded to the checklist; fast forward that some years to the point where you were helping to put together the IOM report. Knowing what you knew at the time, not what you know now, is there anything that you wish you had done differently in launching this field?

LL: The biggest mistake we made was assuming that everybody would be excited about it and immediately grab on to it like we did. That it was self-evidently a good thing. How can anybody not want to get rid of mistakes? We quit blaming the individual clinician. We're going to get away from all that malpractice stuff, shaming, and so forth, and we're going to push this by changing systems. Come onboard, let's go. And we were pretty naÏve in thinking that (a) they would believe us, and (b) that they could make those kinds of changes when the forces against it were much stronger than we realized. So we were remiss in not recognizing the changes we were talking about were much more profound than we realized, and in not paying much more attention to what's needed to do that. There is of course a vast literature on change. But it's like the literature on human factors 20 years ago. We were blissfully ignorant of that, and we still have a long way to go on the other. If we'd have been a little smarter about thinking about what the culture changes would be and what would be necessary, it may have been better. But the way we finance health care in America works very strongly against all of this. That's what has to change.

RW: It's also possible if you were more realistic about what was needed, you might not have done it. It was the blind optimism that carried you through.

LL: I think there's a point to that, yes. You have to have somebody aspire to the ideal, even if it's not accomplished.

RW: Do you see a next trend in the patient safety field? You can chart out the checklist era was really since Peter Pronovost's study in the *New England Journal of Medicine*. That seemed to dominate many safety conversations for the last 5 or 6 years. What do you think the next 5 to 7 years will hold in terms of the megatrends?

LL: Well, I'm not very good with the crystal ball. Mine's pretty cloudy. If we do get financial incentives better aligned, that will make it easier for people to do what they want to do. We have trained up a large cadre of patient safety people who have learned how to make change, who are aware of what we're talking about, and there are literally thousands of people involved now. Given the right environment, they could really go gangbusters. Even though we haven't found the magic bullet to make it happen or pulled the right lever, I'm hopeful that we have the infrastructure in terms of knowledge. We have a lot of safe practices to implement. I like to say I think we know what to do and we're learning more about how to do it; so my hope is that we will see increasing support for that. As people have more success, it will be reinforcing. At the present time, I'm afraid that's just a hope.

As to megatrends, I think we will finally wrestle the computer demon to the ground and begin to see the electronic health record work much better for the doctors and nurses and also begin to realize its potential for improving quality and safety by facilitating data collection, analysis, and feedback. Second, I think the pressure will build to make the workplace more humane. We have to stop the busywork—data collection, etc.—so doctors and nurses have the time to do what they and we all want them to do: take care of patients. Part of making that happen is a third trend of moving to true team care, which is a triple win: improving quality of care; giving the doctor more time to spend with patients by taking away tasks that others can do; and improving the joy and meaning of work for nurses, physician assistants, and others as they expand their scope of work. Increasing patient engagement in all aspects of their care is also inevitable. As we learn to invite them in, we will all benefit. Finally, I think the culture change we seek will happen faster than we expect. The new generation won't put up with the old disrespectful ways. They will force health care organizations to create supportive, meaningful, and enjoyable workplaces, and we and our patients will all benefit.