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In Conversation with…Christopher P. Landrigan, MD

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Editor's Note: *In October 2004, in what immediately became a landmark paper in patient safety, Dr. Landrigan and his colleagues reported the results of their study on sleep deprivation and medical errors among interns. The AHRQ-funded study, published in the New England Journal of Medicine, revealed 36% more serious errors and 5.6 times more serious diagnostic errors among interns working a traditional schedule of more than 24 hours in a row than among interns working shorter shifts (1). We spoke with Dr. Landrigan, an Assistant Professor of Pediatrics at Harvard Medical School, about his research and his thoughts on how the study findings might affect residency training in the future.*

Interview

Dr. Robert Wachter, Editor, AHRQ WebM&M: What led you to do this study?

Dr. Landrigan: I became interested in patient safety after noticing, when I was a resident, that sleep deprivation impaired the quality of care I felt I was delivering. Consequently, I became interested in whether sleep deprivation in general might have an impact on patient safety. It was something that had not been very thoroughly studied, so I began looking into studying interns' sleep deprivation and its effects, along with interventions to improve it.

RW: What did you expect to find before you started?

CL: Our hypothesis was that, on a schedule that limited interns' consecutive working hours from the traditional shift of 30 hours in a row down to a maximum of 16 scheduled hours, there would be fewer errors. But we were unsure about it. On the one hand, there was a wealth of sleep literature suggesting that working shifts of longer than 12 to 16 hours increases the risk of accidents and errors. However, in medicine, there has been this countervailing issue regarding handoffs—the sense that in trying to shorten shifts, we would invariably cause an increase in errors due to handoffs of care and transfer of information. So, we did not know how these issues would balance.

RW: In general in patient safety, it's tricky to figure out how to measure errors. What were your main measurement strategies?

CL: We based our measurement strategies on David Bates' work, where the major goal is to try to tabulate the frequency with which errors occur. The reason for that was simply a power-based decision. In a couple of intensive care units in a single hospital, it is pretty difficult to measure a difference in adverse events as a consequence of any intervention, unless you were willing to study the effects over years. So we started off with the goal to look at serious medical errors. In order to comprehensively capture procedural issues, diagnostic mistakes, and medication errors, we used a combination of direct observations of the interns, daily chart reviews by ICU nurse data abstractors, voluntary reports from staff, and a computerized adverse drug event detection system. But the novel measurement strategy in this study was the use of this direct observation of interns.

RW: How did you deal with the lack of blindedness on the part of the observers?

CL: That was an important concern in this study. Since it was obviously impossible to blind the observers to which schedule was being studied, we had them use a pretty broad capture of anything they thought might have been an error. But they did not make any final determinations of what actually was or was not a mistake. Instead, anything detected by direct observation or by our other study methods was presented to two reviewers who were blinded as to the study condition, and they made a final determination whether an error had taken place.

RW: One of the challenges in direct observations, especially by more senior clinicians, is they are likely to see some bad things happening, and they sometimes might have the ability to intervene. How do you prospectively think that through? What was their charge? Did they ever see a train wreck in motion and do something about it?

CL: This was a concern going into the study, but it turned out to be less of a problem than we had thought it would be. Originally, the charge for the observers was if they saw a dangerous act that would potentially cause a patient harm, then they had a choice to make. If there was an immediate risk to the patient, then they could intervene immediately with the clinical staff in the unit—even if that might disrupt our study and potentially alienate those staff. If the observer thought the issue was a little less emergent, then he or she could bring it back to the investigators to discuss and channel it through the appropriate staff in the unit.

However, it turned out that this kind of thing happened only a handful of times over the life of the study. The vast majority of the serious errors that we detected were picked up not because the observers were seeing something that was evolving but simply because they were present when clinical staff became aware of it. For example, if an intern wrote a 10-fold overdose of medication, the observer was not generally in a position to see that overdose typed into the computer. But he or she was there a few minutes later when the nurse said, "Look, you just wrote a 10-fold overdose for this medication." Most of the errors were captured that way, so there was rarely a need for the observers to intervene. When they did catch something—for example, once one of the observers noticed an x-ray hanging backwards—they pointed it out to clinical staff right away.

RW: Any particularly memorable anecdotes that came out of the study?

CL: A number of mistakes were largely due to failure to remain vigilant throughout the long shift in the intensive care unit. For example, we noticed that sleep-deprived interns would often fail to do a very

thorough history and physical examination. In most cases, we didn't particularly count that one way or another, but when a significant finding was missed, it jumped out at us. For example, one patient was admitted with complete heart block, and it was not recognized that he had Lyme disease until he'd been in the ICU for 24 hours. Why? Because nobody had rolled him over when he first came in to see the gigantic erythema migrans rash on his back. A number of those types of errors involved simply failing to check part of the exam or forgetting to follow up on a laboratory test.

RW: In the group with the longer shifts, you found 36% more serious errors. Did any outcomes surprise you particularly?

CL: We were really surprised by the magnitude of the effect. When we designed the study, we weren't sure that there would be any effect at all, and certainly not such a positive one given potential continuity of care concerns. But the effects were really striking. In particular, we found five times as many serious diagnostic errors in the sleep-deprived group, largely, I think, as a consequence of these vigilance issues. That was a shock. We didn't expect to see any kind of difference like that, particularly in that category, where transmission of information is potentially a major risk factor. We were worried that in handing off care from one intern to another in the late evening, when the day shift turned into the night shift on our intervention schedule, that follow up of tests and those types of things would be a major problem. But it turned out that those things were more of a problem in the traditional schedule when interns were more sleep deprived.

RW: Concerns have been raised, even by people who worry about sleep deprivation, about possibly generating a shift-work mentality among residents. Did you see any evidence of that? And if not, do you think it might be because you were doing a time-limited study? Might it change if people worked all 12-hour shifts during their training?

CL: Well, I personally don't think that a shift-work mentality has much to do with the number of hours that you work in a row. I think it has to do with a professional sense of when it would be an appropriate time to walk out the door. By no stretch of the imagination were we encouraging people, the moment that 10 PM hits, to walk out regardless of what was happening in the unit. Frequently, they would be there until midnight or one in the morning to accomplish the transfer of a critically ill patient appropriately. Our schedule was designed to allow them to sleep in the next day or to nap before coming in for their next shift. The idea that, in implementing schedule limitations, we should do it in such a rigid way that interns and residents cannot appropriately sign out is obviously wrong—but that does not mean that optimal care is provided when interns are routinely working 30 hours in a row. I think that our study would suggest that if we set that bar in a different place, but still allow the kind of flexibility that residents have enjoyed traditionally as professionals, we would be better served.

RW: What additional resources are necessary to generate a schedule for the intervention group as opposed to the traditional?

CL: It's a complicated question. In our study it didn't cost anything more, because at Brigham & Women's Hospital, the internal medicine residency program was fairly large. To make the study happen, all we needed was one additional intern for half a year, during the intervention month. So that intern was mobilized from an elective rotation without a whole lot of difficulty for the program. If you are going to

implement these types of schedules broadly, where you need four interns instead of three, then there may be substantial resource implications for hospitals. However, if you believe that these kinds of schedules actually prevent injuries due to medical errors, there are likely to be substantial savings to the system as a whole. Essentially what you are balancing is the cost of one additional resident, or other medical personnel at a similar level of training, with the cost of adverse events due to errors. If you look at the work of David Bates and others, you can see that the cost of those errors can be extremely expensive. Consequently, it is not clear to me that in the long run that this intervention would cost more. It may be, but it would need to be balanced with the potential savings generated.

RW: How has this study affected scheduling at your hospital?

CL: I think that the hospital has been rather bold in stepping up and saying that this is something that we need to address and let's see what we can do to make these kinds of changes happen. I'm not in a position to formally speak for the hospital, but my sense has been that they are very broadly supportive of this intervention and are looking for ways to try to make it widespread. One explicit goal is for interns to no longer write orders after the 18-hour mark come July 2005, and it sounds like the intention is to try to shorten it beyond that in the future, particularly in intensive care settings. We're going to have to see how this actually plays out, and what works best may vary from unit to unit.

RW: Nationally, the ACGME regulations were criticized in some quarters because of the lack of the evidence base. Your study may well be the first clinically relevant evidence base and would suggest that the ACGME work hours regulations might not be stringent enough. Do you believe that is true, and if you were the ACGME, would you limit shifts to perhaps 12, 14, 16 hours?

CL: I do believe that we should, at least in intensive care settings, and my suspicion is that the benefits will be seen in other settings. However, it is difficult to extrapolate from the data from this one study too much beyond the setting in which we conducted it. The study demonstrates that it is unsafe for interns to work more than 16-hour shifts in intensive care settings, and that?whatever new ACGME guidelines are developed?they ought to try to limit consecutive work hours in ICU settings.

RW: Previous studies have looked at comparable issues in terms of nursing hours and ratios. How did your study compare to those? If you were the hospital CEO and trying to prioritize funding, either more nurses to keep nursing shifts down or more residents or substitutes for residents to keep resident shifts down, how would you make that decision?

CL: I think that it is difficult. Our study didn't address the issue of comparing what the safety of nurses working long hours versus the safety of physicians might be. There has been pressure within the nursing community to keep shifts limited because of data, going back a decade, that suggest that nurses working longer shifts make more mistakes. If you look at other industries, the lines have usually been drawn between the 12- and 16-hour mark. In fact, a certain amount of research in industrial settings suggests that workers limited to 8-hour shifts make fewer mistakes than those doing 12-hour shifts. So the battle in the nursing community has for the most part existed at a much more stringent restriction of sleep deprivation than has been the case among physicians. My sense is that we ought to start where the problem is apparently the greatest, namely, among doctors.

RW: Why do you think nursing has addressed this more than medicine?

CL: A fundamental tenet of the American residency education system for the better part of the century has been that, in order to be well trained as a physician, you need to be at the bedside continuously (or at least continuously available), watching the progress of the illness as patients potentially go into the intensive care unit and then eventually get better. I think what has shifted over time is that the amount of activity that interns are engaged in has exploded, to the point that they have gone from sleeping 5 to 6 hours per night to 3 or 4 hours per night to, at least in many academic centers, frequently getting no sleep at all. When that happens, their ability to function is deeply impaired and, as a consequence, I think we find the kinds of results that we saw in our study.

RW: Any parting words?

CL: I wanted to point out just how many people this affects. There are currently more than 100,000 residents in the United States, and most of them work these schedules on a regular basis. While the medical community appreciates the frequency of these long work hours, the general public is mainly unaware of the extended hours that doctors work. A 2002 survey by the National Sleep Foundation found that members of the public generally feel that doctors ought to work shifts of less than 10 hours. They would be shocked that surgeries are being performed and intensive care is routinely delivered by doctors who have been working for longer than 24 hours.

Reference

1. Landrigan CP, Rothschild JM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. N Engl J Med. 2004 Oct 28;351(18):1838-1848. [go to PubMed]