



Published in final edited form as:

N Engl J Med. 2019 June 13; 380(24): 2379–2380. doi:10.1056/NEJMc1905064.

Patient Safety under Flexible and Standard Duty-Hour Rules

Christopher P. Landrigan, M.D., M.P.H.,

Boston Children's Hospital, Boston, MA

Charles A. Czeisler, Ph.D., M.D.

Brigham and Women's Hospital, Boston, MA

To the Editor:

In the iCOMPARE (Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education) trial, Silber et al. (March 7 issue)¹ prespecified an unreasonable noninferiority threshold based on an increase in 30-day mortality from 12.5% to 13.5%. Even the highest estimates would project that fewer than a quarter of deaths (and probably far fewer) in hospitals are due to medical errors.^{2,3} An absolute increase of 1 percentage point in error-related mortality (i.e., from approximately 3% to approximately 4%) would therefore represent an increase of more than 30% in error-related mortality. It was unreasonable to set such a high threshold for noninferiority, since this is not an acceptably small degree of harm. First-year resident physicians make up only a small fraction of the providers of direct patient care in teaching hospitals, and although fatigue is an important root cause of error, it is but one of many. The authors' data revealed a 15% higher rate of death related to medical errors among patients who received care in hospitals that were allowed to schedule first-year resident physicians to work extended-duration (>24-hour) shifts than among those who received care in hospitals where first-year resident physicians were not allowed to work more than 16 consecutive hours. This was a degree of difference for which the authors had insufficient power to assess significance. The authors' conclusion that allowing physicians to work extended-duration shifts was noninferior was thus based on unreasonable criteria. Moreover, this conclusion is contrary to extensive data showing that extended-duration shifts endanger resident physicians and their patients.^{4,5} Large as it was, the iCOMPARE trial was underpowered by an order of magnitude to determine the effects of work-hour limits on in-hospital mortality.

Acknowledgments

Drs. Landrigan and Czeisler report being principal investigators of the Randomized Order Safety Trial Evaluating Resident-Physician Schedules (ROSTERS), which is supported by grants (U01-HL-111478 and U01-HL-111691) from the National Heart, Lung, and Blood Institute; Dr. Czeisler, receiving grants from Cephalon, Jazz Pharmaceuticals, Philips Respironics, and Teva Pharmaceutical Industries; receiving consulting fees from Teva Pharma Australia, Vanda Pharmaceuticals, and the Washington State Board of Pilotage Commissioners; holding a number of process patents in the field of sleep and circadian rhythms (e.g., photic resetting of the human circadian pacemaker) and an equity interest in Vanda Pharmaceuticals; being the incumbent of an endowed professorship provided to Harvard University by Cephalon; receiving fees for serving as an expert on various legal and technical cases related to sleep or circadian rhythms; and receiving royalties from Philips Respironics for the Actiwatch 2 and Actiwatch Spectrum devices (Dr. Czeisler's interests were reviewed and managed by Brigham and Women's

Hospital and Partners HealthCare in accordance with their conflict of interest policies); and Dr. Landrigan, receiving grants from Patient-Centered Outcomes Research Institute, consulting fees and equity from the I-PASS Patient Safety Institute, and consulting fees from Virgin Pulse. No other potential conflict of interest relevant to this letter was reported.

References

1. Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med* 2019; 380: 905–14. [PubMed: 30855740]
2. Makary MA, Daniel M. Medical error – the third leading cause of death in the US. *BMJ* 2016; 353: i2139. [PubMed: 27143499]
3. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000; 284: 93–5. [PubMed: 10872021]
4. Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med* 2005; 352: 125–34. [PubMed: 15647575]
5. 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; 351: 1838–48. DOI: 10.1056/NEJMc1905064 [PubMed: 15509817]