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Building Physician Work Hour Regulations From First Principles and Best Evidence

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In 2003, passage of the Accreditation Council for Graduate Medical Education (ACGME) work hour standards marked the first time that work hours for physicians in training were regulated throughout the United States. Five years later, the medical profession stands at a critical juncture. At the request of Congress, the Agency for Healthcare Research and Quality has sponsored an Institute of Medicine committee to review the evidence on the relationship between residents' work hours and patient safety and to develop recommendations for improvement.[1]

There is increasing evidence that resident sleep deprivation endangers patients and residents,[2-5] but studies have not shown consistent benefit from implementation of the current ACGME standards. No changes in mortality were found in national studies of surgical patients.[6-8] Some reductions in mortality were observed for medical patients at Veterans Administration hospitals[8] and in a cohort of non−Veterans Administration hospitals,[6] although not in a larger population of medical patients covered by Medicare.[7]

The lack of consistent improvements may be due to several factors. First, there are flaws in the design of the intervention. The ACGME standards continue to allow trainees to work 30 consecutive hours, a duration repeatedly demonstrated to be hazardous both in laboratory

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studies and in studies of trainees working in hospital settings.[2-5] Second, compliance with the standards may be suboptimal.[9] Benefits from reduced fatigue might be offset by worsened continuity of patient care, particularly in hospitals in which robust systems for ensuring high-quality transitions in care have not been implemented.

In this article, we propose priorities that should guide the medical community in developing specific alternatives for physician work hour regulation, if the objectives are to maximize patient and physician safety while preserving the best possible training for physicians.

Guiding Principles

Several principles should be considered important aspects of any further modification of resident duty hours to improve patient safety. An important overriding notion is to be wary of status quo bias. Defaults often favor an inferior status quo,[10] with the lack of definitive evidence about alternatives used as a reason to retain an established approach even when it seems likely that alternatives would perform better. Current duty hour standards are strongly tied to traditional extended duty (“on-call”) shifts in academic medical centers. Emerging data on the hazards of these shifts, however, suggest it would be useful to consider entirely novel scheduling systems. “Lean production principles” from Toyota applied to medical settings intimate that the traditional approach of admitting patients to teams in boluses every third or fourth night may be less desirable than evening the workload through daily admissions. Schedule reform, like any other therapeutic intervention, should be well founded in scientific principles and use the best available scientific evidence to devise an optimal system.

Rigorously Study Alternatives for Work Hour Reduction

Not enough is known for any one alternative to be universally embraced as the “optimal” approach to duty hour reduction in all settings. It is important that any changes be critically assessed, with a premium placed on designing interventions to allow careful evaluation of their relative costs and benefits. There are myriad ways that the risks of performance decrements caused by sleep deprivation and circadian misalignment could be addressed while concurrently dealing with concerns about continuity, workload, and other factors that bear on safety. Evidence exists regarding some of these approaches, but others require further study with examination in different specialties:

1. Moving to a 16- to 18-hour shift limit. Eliminating 24-hour shifts has been found to improve patient safety in intensive care units.[2] Further evaluation across clinical settings would be informative.
2. Implementing mandatory overnight sleep programs that allow residents sufficient protected time when they are at their circadian nadirs. Studies of voluntary overnight nap programs have led to only modest sleep increases. Evaluation of the potential benefits of fully protecting sleeping interns for 6 to 8 hours would be valuable.
3. Rotating shifts in a “clockwise” manner that allows for easier circadian adjustment.

4. Scheduling shorter shifts but allowing for substantial shift overlap to minimize discontinuity of care.

5. Redesigning the flow of patients and assignment to teams to even workflow over time (eg, admitting 1-2 patients per day as opposed to “boluses” every call cycle).

Some of these approaches could be attempted concurrently, and other approaches are also possible. Randomized trials comparing the effectiveness and cost-effectiveness of any approach against the status quo would be of particular value. If further modifications are made to existing ACGME duty hour standards, randomization of training programs to different approaches for work hour reform should be considered.

Measure Outcomes Related to Resident Education

Insufficient data exist on how duty hour reform affects training. Although residents’ case volume experience might be diminished in some settings with reduction of work hours, better-rested residents might also learn more efficiently because sleep-deprived individuals have impaired consolidation of memory.[11] Systematic assessment is needed of the effects of different work hour reduction strategies on long-term educational outcomes.

Improve “Sign-Out” Procedures

The days of haphazard sign-outs scribbled on pieces of paper should long be over, but they are not. Errors caused by handoffs between clinicians are a major concern with duty hour regulation and a potential barrier to use of shorter shifts. Pilot studies have suggested these risks can be significantly reduced through the use of structured computerized sign-out tools.[12] Significant efforts in this area could substantially improve the safety of the health care system regardless of which approach to duty hour reform is taken.

Eliminate or Minimize Situations in Which Residents Work 24 to 30 Continuous Hours

Strong and consistent relationships between sleep deprivation and impaired performance have been well documented. After 24 hours of continuous wakefulness, impairments in performance are similar to those induced by a blood alcohol level of 0.10%.[13] In one study, residents working 24-hour shifts made 36% more serious medical errors and 460% more serious diagnostic errors than those working 16-hour or shorter shifts.[2] Twenty-four-hour shifts were also associated with a 61% increase in the odds of sustaining a needle stick or other sharp injury[5] and a doubling in the risk of motor vehicle crashes while driving home from work.[4] In a meta-analysis of 60 studies of sleep deprivation and performance, residents’ clinical performance after 24 hours awake decreased 1.5 SDs to approximately the seventh percentile of their mean rested performance.[3] Compared with interns working no 24-hour shifts in a month, interns working 5 or more such shifts reported making 7 times as many fatigue-related medical errors that harm patients and 4 times as many fatigue-related medical errors that result in death.[14]

These statistics raise serious concerns about the safety of 24- to 30-hour continuous shifts for both patients and residents.

Improve Monitoring of Standards

There is no central repository for information on compliance with the ACGME duty hour standards besides the ACGME, and there are reasons to question whether residents voluntarily report noncompliance to a regulatory agency. A third-party mechanism for monitoring and enforcement with adequate whistle-blower protection such as that provided by the Federal Aviation Administration for aviation safety reports would greatly enhance the ability to ascertain compliance and effectiveness of future work hour improvement efforts.

Increase Flexibility for Implementation and Enforcement

The ACGME Committee on Innovation has been working to change the accreditation process from a blunt “stick based” approve/disapprove approach, in which the only means of enforcing standards is to threaten removal of accreditation (a step unlikely to be taken with any regularity), to one in which there is more flexibility to offer gradated rewards to programs achieving excellence on a variety of dimensions. Such efforts by the ACGME or other regulatory bodies to increase the flexibility of enforcement methods are important and should be accelerated.

Recognize the Importance of Supervision and Work Intensity

The Bell Commission reports on the Libby Zion laws emphasized that supervision is an essential element for improving quality of care among patients receiving care by physicians in training. In addition, if inadequate staffing is in place, reduction in resident work hours will lead to a reduction in the number of clinicians available in the hospital at any given time, overburdening those residents who remain on duty unless fewer patients are assigned to residents. With inadequate supervision or insufficient addition of support staff and physician extenders, conscientious residents will try to fit more work into less time. Recognizing the importance of these 2 elements and properly designing new staffing plans and supervision patterns that address these issues and acknowledge the effect of different systems on attending physicians and fellows will be important to optimize the ability of any proposed duty hour schedule to lead to better patient outcomes.

Align Incentives for Payment With Desired Objectives

In 2004, Medicare spent about $2.7 billion on direct medical education and $5.7 billion on indirect medical education, or about $110 000 per resident in the United States.[15] However, the ACGME duty hour standards have been experienced by teaching hospitals as an unfunded mandate. Properly addressing duty hour reform by reducing the workload of residents and assigning some of the workload to other clinicians requires resources. Support for this should be considered. In addition, the ideal duty hour standard would include financial incentives for payers that would support and sustain duty hour standards or related objectives as part of pay for performance. Tying some portion of ongoing reimbursement for direct medical education and indirect medical education to performance on clinical or educational outcomes or metrics such as resident safety and compliance with duty hour standards would likely effect change and encourage significant innovation among residency programs and health systems nationally. A system of positive and negative incentives that uses existing pools of money could be designed to reward programs that performed well on

these measures. An incentive-based approach, in contrast to a regulatory approach, would also encourage programs to be innovative in determining ways to outperform current standards as opposed to simply striving to meet existing standards for performance.

CONCLUSION

There is opportunity to improve the safety of teaching hospitals through modification of resident work hours. As in 2003, the Institute of Medicine committee, ACGME, and others are again coming under increasing pressure to move forward. A major barrier to informed decision making is that there is insufficient evidence on the effectiveness and cost-effectiveness of different alternatives. However, the absence of conclusive data on the perfect solution should not stymie further reform efforts, because the hazards of the status quo have become apparent. Keeping the 8 principles described above in mind, duty hour regulation can move forward, even in the absence of perfect data, in ways that will be more likely to help than to harm patients.

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REFERENCES

1. Institute of Medicine. Optimizing graduate medical trainee (resident) hours and work schedules to improve patient safety. http://www.iom.edu/CMS/3809/48553.aspx
2. 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(18):1838–1848. Medline:15509817. [PubMed: 15509817]
3. Philibert I. Sleep loss and performance in residents and nonphysicians: a meta-analytic examination. Sleep. 2005; 28(11):1392–1402. Medline:16335329. [PubMed: 16335329]
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(2):125–134. Medline:15647575. [PubMed: 15647575]
5. Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. JAMA. 2006; 296(9):1055–1062. Medline:16954484. [PubMed: 16954484]
6. Shetty KD, Bhattacharya J. Changes in hospital mortality associated with residency work-hour regulations. Ann Intern Med. 2007; 147(2):73–80. Medline:17548403. [PubMed: 17548403]
7. Volpp KG, Rosen AK, Rosenbaum PR, et al. Mortality among hospitalized Medicare beneficiaries in the first 2 years following ACGME resident duty hour reform. JAMA. 2007; 298(9):975–983. Medline:17785642. [PubMed: 17785642]
8. Volpp KG, Rosen AK, Rosenbaum PR, et al. Mortality among patients in VA hospitals in the first 2 years following ACGME resident duty hour reform. JAMA. 2007; 298(9):984–992. Medline: 17785643. [PubMed: 17785643]
9. Landrigan CP, Barger LK, Cade BE, Ayas NT, Czeisler CA. Interns' compliance with accreditation council for graduate medical education work-hour limits. JAMA. 2006; 296(9):1063–1070. Medline:16954485. [PubMed: 16954485]
10. Halpern SD, Ubel PA, Asch DA. Harnessing the power of default options to improve health care. N Engl J Med. 2007; 357(13):1340–1344. Medline:17898105. [PubMed: 17898105]

11. Stickgold R. Sleep-dependent memory consolidation. Nature. 2005; 437(7063):1272–1278. Medline:16251952. [PubMed: 16251952]

12. Petersen LA, Orav EJ, Teich JM, O'Neil AC. Using a computerized sign-out program to improve continuity of inpatient care and prevent adverse events. Jt Comm J Qual Improv. 1998; 24(2):77–87. Medline:9547682. [PubMed: 9547682]

13. Dawson D, Reid K. Fatigue, alcohol and performance impairment. Nature. 1997; 388(6639):235. Medline:9230429. [PubMed: 9230429]

14. Barger LK, Ayas NT, Cade BE, et al. Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. PLoS Med. 2006; 3(12):e487. Medline:17194188. [PubMed: 17194188]

15. Projected Expenditures on Direct and Indirect Medical Expenditures—FY. CMS Office of the Actuary; 2008.