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Residency Training at a Crossroads: Duty Hour Standards 2010

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Abstract

In 2003, the Accreditation Council for Graduate Medical Education (ACMGE) implemented a single duty hour standard nationwide. The evidence to date suggests that this neither improved nor worsened patient outcomes. In June 2010, the ACGME proposed a new set of duty hour standards for implementation in July 2011. The main disadvantage of this approach is that we will not be able to determine whether different standards would have worked better to reduce resident fatigue while improving patient safety. There are many unanswered questions as to how to design duty hour standards but relatively little evidence; in addition, the same approach may not work in all specialties and all hospitals. A more flexible, dynamic policy that emphasizes ongoing testing and evaluation would be more likely to achieve improvements in clinical and educational outcomes.

In 2003, the Accreditation Council for Graduate Medical Education (ACGME) adopted duty hour standards for all specialties. Five years later, the Institute of Medicine (IOM) convened a committee on "Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety", whose report indicated that there was a paucity of data about how to optimize duty hours for physicians in training (1). Numerous studies by our research team and others evaluated the impact of the 2003 duty hour rules on patient outcomes, including deaths, readmissions, prolonged hospital stays, and complications, and found no consistent evidence of significant improvement or worsening in outcomes (2-7). However, these studies could only retrospectively evaluate the one set of duty hour standards that was implemented nationwide. These studies also could not address the

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inherent variability in training methods and implementation challenges across specialties and types of programs.

At the request of Congress in 2007, the IOM charged the Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety to "evaluate current evidence on the topic and to develop strategies to optimize work schedules... while maintaining the necessary educational experience to ensure long-term patient safety after trainees are on their own" (1). The Committee report offered a well balanced and thoughtful assessment of the status quo and suggested rapid implementation of its recommendations. Although there is strong evidence from laboratory studies linking sleep deprivation to impaired cognitive performance, as well as epidemiologic evidence linking post-call fatigue to vehicular crashes and occupational injuries (8, 9), the IOM report highlighted continuing uncertainty about how to translate these findings into health care delivery and training settings. For example, the centerpiece of the IOM Committee recommendations – that residents on extended duty overnight shifts be given a 'mandatory nap period' of 5 hours or more – has been the subject of very limited testing and has never been shown to be feasible or effective in health care settings (10, 11). The benefits of shorter shifts in terms of decreased fatigue may or may not outweigh the risks of more handoffs and cross coverage, even given recent research on how to make these handoffs safer (12, 13). Finally, reducing work hours may compromise the resident training experience, leading to less well trained physicians or to an increase in the duration of training. Ericsson has described the importance of "deliberate practice" to improve professional performance; this concept entails giving trainees tasks with well-defined goals, providing motivation to improve, offering timely feedback, and ensuring ample repetition and reinforcement (14).

In June 2010, the ACMGE proposed new duty hour standards for implementation in July 2011 (15). Although the proposed ACGME recommendations steer clear of mandating naps, intern shifts are limited to a total of 16 hours. This recommendation is largely based on evidence from a single trial that indicated that eliminating 24-hour shifts improved patient safety in an intensive care unit (16). The generalizability of these findings is uncertain, since the hazards of discontinuity of care are likely mitigated by a nurse to patient ratio of 1 to 1 or 1 to 2 in the intensive care environment, whereas the nurse to patient ratio may be as high as 1 to 8 on regular medical/surgical units. In the latter setting, the detrimental effects of hand-offs and cross-coverage (17) may outweigh the benefits of reduced fatigue among housestaff. It is also unknown whether 16 hour shifts would affect quality of care differentially across specialties, perhaps due to differences in the temporal distribution of admissions and discharges and the nature of the tasks required (i.e., cognitive versus procedural). Finally, it is noteworthy that the innovative work schedule at Brigham and Women's Hospital was deliberately discontinued when the experiment ended, so "its long-term efficacy cannot be determined."

Our purpose is not to critique the choice of 16 hour shifts for interns. While acknowledging the difficulty in defining duty hour standards for the entire profession, we are concerned that a similar ("one size fits all") approach as in 2003 is being taken, without adequate consideration of alternatives that might achieve similar objectives. If one set of duty hour standards is implemented nationwide, with no testing of alternative approaches, then five years from now we will only be able to assess whether patient outcomes changed after implementation of the new standards. Any such comparison will be confounded by contemporaneous changes in clinical practice that affect teaching hospitals. We will not know whether the new duty hour standards were better than potential alternatives at improving patient outcomes, resident training, and quality of life. As we have previously argued, not enough is known for any one alternative to be universally embraced as the 'optimal' approach to duty hour reduction in all settings (18). It is important that any

changes be critically assessed, with an emphasis on designing interventions to allow careful evaluation of their relative costs and benefits.

We fully accept the principles set forth by the ACGME's task force: (1) "patients must be safe, and receive excellent care," (2) "we must deliver outstanding education today" to ensure that our trainees are capable of providing unsupervised care in the future, and (3) "a humanistic educational environment" should "nurture professionalism and the effacement of self interest" (19). However, there are myriad ways that these principles could be translated into standards, recognizing the risks of sleep deprivation and circadian misalignment while also attending to concerns about continuity, workload, and other factors that affect safety. For example, a recent survey of 429 program directors in medicine, pediatrics, and surgery reported that 56% "strongly disagree" and 23% "moderately disagree" with the proposal to limit duty periods for interns to 16 hours, with striking differences of opinion between surgical educators and educators in medicine and pediatrics (20). Therefore, a preferred alternative to 'one size fits all' would be for the ACGME to offer a few 'acceptable' alternatives for which there is suggestive evidence. Examples of potential alternatives could include:

- 16 hour shifts for interns, which were shown to reduce errors in the medical intensive care setting but proved locally unsustainable (16);
- 5 hour mandatory naps on extended duty overnight shifts, similar to what was recommended in the IOM report (1); and
- flexibility in the number of consecutive hours of duty, based on specialty-specific and program-specific work flows (i.e., in some surgical specialties, emergency admissions are rare, teamwork is especially critical, and immediate perioperative care may extend over more than 16 hours).
- -no change from the present

Each Residency Review Committee could be given a choice of either adopting 16 hour shifts (if that is agreed upon) or encouraging residency programs in its specialty to accept randomization to one of these alternatives for the next 3 years. Non-random allocation to alternative schemes for resident work hour management could also be considered, though we would highly recommend some form of randomization. Non-random assignment would have the obvious disadvantage of producing weaker evidence on effectiveness. However, concerns about randomization should not be a barrier to providing the flexibility needed for training programs to test reasonable alternatives. The main advantage to a system that encourages the rigorous testing of alternatives would be that 5 years from now, we will have more information about which alternative was optimal in which circumstances. Medicare and all-payer data could be used to evaluate risk-adjusted patient outcomes, with all programs and/or Residency Review Committees required to collect standardized measures of case volume, educational outcomes, occupational hazards for residents, relevant patient experience, and resident quality of life.

Given the cost and very limited evidence of benefit of the work hour rules that were adopted in 2003, we suggest that the medical profession seriously consider a plan that allows for systematic testing of multiple alternatives going forward. Schedule reform, like any other therapeutic intervention, should be implemented widely only after a period of robust pilot testing that suggests that a particular plan is better than competing alternatives. There may be other approaches besides those listed above that specific residency review committees view as viable alternatives, and those approaches should be considered as well. Although the proposed ACGME standards were released in August 2010 for planned implementation in

July 2011, we are optimistic that this will be an iterative process with a robust dialogue involving all stakeholders, in which it will never be too late for good ideas to be considered. For example, the Association of American Medical Colleges has already expressed a similar interest in "rigorous, multi-institutional evaluation studies" to provide an appropriate evidence base for evolving standards (21). The American Hospital Association has emphasized the importance of "phasing in" the implementation of any new standards, to provide time for necessary planning and budgeting (22).

The proposed ACGME plan does not provide any incentives for needed innovation; indeed, we fear that its regulatory mandates will stifle innovation. The alternatives we suggest would not be any more expensive than what the ACGME has proposed, so additional incentives for accredited programs to participate would not be required, but resources would be needed to fund rigorous evaluation by third parties other than the ACGME. As the IOM recommended in 2008, "the ACGME should convene a meeting of stakeholders and potential funders to set priorities for research and evaluation... the Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, National Institutes of Health, Department of Defense, Department of Veterans Affairs, and other funders should support this work as a high priority."

Five years ago, with the specter of federal legislation looming, the ACGME implemented duty hour standards nationally without any data that the duty rules adopted would be likely to improve patient safety. The preponderance of the evidence suggests that the 2003 rules neither worsened nor improved quality of care and patient safety (2-7), even as new evidence from related disciplines has reinforced concerns about the risk of burnout and the effects of fatigue on physician performance and safety. New approaches to the problem are therefore necessary. However, implementing one approach nationally means that only one alternative can be evaluated. As a society, we will be better off five years from now if several different initiatives are tested and rigorously evaluated using the questions highlighted in the IOM report as a conceptual foundation. As in many domains of clinical practice, a more flexible, dynamic policy that emphasizes creativity, innovation, and ongoing evaluation seems like the path most likely to achieve significant improvements in clinical and educational outcomes.

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