

# CHAPTER 15 A RESEARCH AGENDA TO ASSESS THE IMPACT OF THE 2011 STANDARDS AND TO IDENTIFY OPPORTUNITIES FOR REFINEMENT

THOMAS WHALEN, MD, FACS, FAAP  
WILLIAM WALSH, MD, MPH  
ROSEMARIE FISHER, MD

After the establishment of common duty hour standards in 2003, the ACGME affirmed that future refinements should be based on scientific information on the effect of duty hour limits on patient safety, quality of care, and resident learning and well-being. Basing standards on scientific data promotes acceptance and is important in justifying revisions to members of the profession who may have concerns about the effect of duty hour limits on graduates' preparedness for independent practice. It is equally important to public stakeholders, who need assurance that patient care in teaching hospitals is safe and effective and who may be less aware of the possible negative effect of severe cuts in duty hours on resident learning and acquisition of clinical skills.

In developing the 2011 standards, the Task Force used the available scientific data, including 3 detailed reviews of the literature commissioned by the ACGME.<sup>1-3</sup> This revealed a lack of scientific data in many areas, while in others, the findings were equivocal about the benefits and drawbacks of duty hour limits. The Institute of Medicine's report entitled "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety,"<sup>4</sup> released in 2008, summarized the available evidence on the effect of duty hour limits and noted a lack of clear evidence in some key areas. This included a lack of evidence of a relationship between negative effects of sleep loss on performance with the causes of error identified in closed claims studies and root cause analyses. The report also could not answer the question of whether duty hour limits would have a negative effect on competence for independent practice. The Task Force and the literature reviews identified additional areas where empirical data are lacking. Consequently, the debate about the 2011 duty hour standards

echoed many of the concerns about the potential diminished clinical competence and professionalism of graduating cohorts as the discussions that preceded the implementation of common standards in 2003.

The review of the literature by the University of Illinois at Chicago identified additional gaps, including how to conceptualize the balance between education and service required by the ACGME standards; other gaps included the benefits and risks associated with different ways of organizing resident work periods and shifts, the cost of duty hour reductions (to programs and society), the effect on quality of life for resident and attending physicians, and the *value* society may place on trade-offs among these outcomes.<sup>1</sup> This chapter lays out a research agenda for the medical education community and the ACGME for the rigorous analysis of the 2011 standards for duty hours and related areas such as supervision, transitions of care, teamwork, and alertness management.

## Research on the Effect on Resident Competency and Professional Development

In 2003, the debate about the effect of the common standards was influenced by the number of duty hours that needed to be reduced so that residents in a given specialty could comply with the new standards. Although research on the effect of duty hour limits in different clinical specialties remains a priority, added aspects of the 2011 standards that require further investigation include the benefits and drawbacks of the new limits for first-year residents and the impact of added flexibility for senior residents.

Research into the effect of hours of practice on the acquisition of competence remains a high priority, as the lack of empirical data in this area

has made it difficult to justify, to the public and opinion leaders, that resident physicians' long hours are necessary for their clinical and professional development. Of particular interest are studies that assess the role of practice, repetition, and time in the acquisition of competence for independent practice. While there is a body of scientific evidence about the role of volume in the maintenance of competence at the institutional and individual level, scientific evidence on the role of time, volume, and repetition in the initial acquisition is lacking. As a consequence, the medical community adopted proxies from other disciplines.<sup>5</sup> These may not be the most appropriate in defining the effect of duty hour limits on the preparation of residents at graduation from training, and well-designed studies that seek to replicate the approaches used in other domains of competence clearly are needed. Research is also needed to offer added scientific evidence on the competency benefits of simulation. While accepted for its benefits to patient safety, use of simulation to facilitate the acquisition of clinical skills is still limited by the skills that lend themselves to current simulation models and by the financial and opportunity costs of its broad application in resident education.

In the nearly 10 years since the ACGME began its deliberations on common duty hour standards, several articles have commented on reduction in residents' "professionalism"—their willingness to put patients' interests above their own. However, it is difficult to separate the extent to which this may be a consequence of the limits or whether interest in the limits resulted in part from residents' desire for a balance between their personal and professional lives, as compared to prior generations of physicians. Further research is needed to explore new models that do not equate professionalism with unlimited hours but that seek to provide residents with better guidance for how to put patients' expectations first, while promoting safe and effective care and maintaining an appropriate balance between the professional and personal pursuits.

### **Research on “Work Intensity” and “Work Compression”**

There are many indications that resident work has not diminished proportionately to the reductions in hours and that work intensity has increased in the past decade. This is not solely due to the duty hour standards, and one reason for the institution of common duty hour limits in 2003 was growing acuity and intensity of service in the inpatient setting. However, since the implementation of duty hour limits in 2003, financial pressures have forced many hospitals to preserve residents' significant role in the care of patients in teaching hospitals.<sup>6</sup> At present, few studies have sought to quantify the degree of work intensity that residents experience in their shortened hours, though some exploratory studies suggest that added reductions result in compression of activities. This may hamper learning by contributing work and cognitive overload, particularly for junior learners.

### **Research on the Effect on Patient Safety and Quality of Care**

One reason for the public demand for duty hour limits in the United States was to reduce excessive duty hours and fatigue as potential performance-shaping factors and contributing causes in health care errors. Yet the literature on the effect of duty hour reductions on quality and safety has not produced unequivocal findings. Despite large sample sizes and the power to detect minute differences, studies of the effect of the common duty hour limits found little change in patient mortality during the early years after the implementation of the 2003 standards.<sup>7-10</sup> Minor gains in patient safety and quality indicators were not associated with teaching status, suggesting that other factors accounted for these improvements and that the duty hour limits did not have a positive or negative effect.

These observations suggest the need for further research to analyze the patient safety benefits associated with the larger changes under the 2011 standards, including the enhanced standards for supervision, resident professionalism, transitions of care, and alertness management. Supervision of resident physicians is an important area that,

except for a few recent high-quality studies, is underdescribed in the literature. An important area requiring additional work is that of resident attitudes toward supervision and behaviors (on the part of learners and supervisors) that impede learning or negatively affect patient safety. Another important area for research is assessing the effectiveness of supervision and exploring the educational needs of faculty and resident physicians entrusted with supervisory responsibilities.<sup>1</sup>

Other aspects of the duty hour limits that have not been fully researched include differences among specialties and among different years of training, the effects of replacing residents with other providers, and whether there may be trade-offs under which duty hour limits reduce errors related to fatigue, but increase errors attributed to problems with transitions and continuity of care.

Residents' role as learners and their lack of familiarity with clinical settings may make them vulnerable to errors. Duty hour limits fit among other systems approaches that seek to reduce sources of errors by addressing sleep loss, which may add to residents' vulnerability. At the same time, research in the determinants of patient safety suggests that safety results require broader attention at the system level, including multiprofessional engagement and communication, routine monitoring of care processes, and the ability to evaluate the impact of changes in work systems.<sup>11</sup> How these efforts interact in a given clinical setting with residents' limited hours and relatively short tenure is an important area for future investigative work.

### **Research in Alertness Management and Predicting the Effects of Sleep Loss**

To date, few trials of alertness management strategies have been undertaken with resident physicians in real-life clinical settings. The military and the transportation industry have designed fatigue management studies that could be adapted for residents in clinical settings. The results gleaned from such studies could foster a better understanding of the proper use and

benefits of short nap periods, physical activity, and the judicious use of caffeine as fatigue management strategies in the clinical environment. Research is also needed to explore how the more controlled learning environment during residency will affect performance in situations of fatigue and stress in practice, to assess whether experiencing these situations in training is vital to the development of coping skills for handling demanding situations. Finally, the Task Force has reviewed early, yet promising research into predictive models of alertness and performance. This is an area where further study would significantly benefit residents and practicing physicians.

### **Innovative Approaches to Learning and Clinical Care**

A significant body of research and several commentaries have focused on the added clinical pressures on faculty under reduced resident hours and concurrent expectations for clinical productivity. These pressures may contribute to less time for resident teaching at the bedside, in the clinic, and in the operating room, where opportunity to observe and assist in procedures before performing them under supervision may be becoming the exception rather than the norm. Research is needed on approaches that decouple educational goals and patient service demands, including expedited learning through use of standardized patients, objective skills-based clinical examinations, and simulation with extensive debriefing and feedback. Concurrent research needs to explore how to free up faculty physicians for teaching and reward them for their teaching role. Some promising programs and institutional initiatives have been found, but added study is needed to evaluate these practices before dissemination for adoption or adaptation in other settings. Knowledge about how institutions and programs create a better learning environment will allow others to learn from these models.

### **Local Implementation**

A challenging aspect of research on the effect of the new standards on patient care and resident

learning is that the duty hour and related standards, while significant, are one set of inputs in a system with multiple other inputs. Studies of the effect of the 2003 standards have shown that it is difficult to separate the effect of the limits from other factors in the learning environment, and that it may be equally difficult to isolate their effect on resident competence.

Research on other large-scale changes has highlighted differences in implementation among settings due to variation in context and organizational preparedness, suggesting it is influenced by local factors. Study designs must be sensitive to complex variation by using multiple qualitative and quantitative measures, collecting data over time to understand change, and capturing interactions between national standards and the local contexts under which they are implemented.<sup>12</sup>

### Conclusion

As the ACGME Task Force was formulating the new duty hour standards in 2009 and early 2010, the body of knowledge to assess the effect of the common duty hour limits on patient care and resident learning was still emerging. Some surgical specialties with longer training periods had graduated just 1 or 2 resident cohorts educated entirely under duty hour limits. As a result, some of the knowledge about the educational and patient effects of the resident duty hour limits is just emerging and other areas have not been studied. The areas discussed above are a starting point for a research agenda to assess the effect of the 2011 standards and to provide the scientific undergirding for future refinements.

---

### References

- 1 Schwartz A, Pappas C, Bashook P, et al. *Conceptual Frameworks in the Study of Duty Hour Changes in Graduate Medical Education: An Integrative Review*. Chicago, IL: University of Illinois at Chicago Departments of Medical Education, Department of Obstetrics and Gynecology, and Library of Health Sciences; September 2009.
- 2 Caruso JW, Veloski J, Grasberger M, et al. *Systematic Review of the Literature on the Impact Variation in Residents' Duty Hour Schedules on Patient Safety*. Philadelphia, PA: Jefferson Medical College; September 2009.
- 3 Fletcher K, Reed D, Arora V. *Systematic Review of Literature: Resident Duty Hours and Related Topics*. Milwaukee, WI: Department of Medicine, Milwaukee VAMC/ Medical College of Wisconsin; Rochester, MN: Department of Medicine, Mayo Clinic College of Medicine; Chicago, IL: Department of Medicine, University of Chicago, Pritzker School of Medicine; September 2009.
- 4 Ulmer C, Wolman D, Johns M, eds; Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety, Institute of Medicine. *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. Washington, DC: National Academies Press; 2008.
- 5 Charness N, Krampe R, Mayr U. The role of practice and coaching in entrepreneurial skill domains: an international comparison of life-span chess skill acquisition. In: Ericsson KA, ed. *The Road to Excellence: The Acquisition of Expert Performance in the Arts and Sciences, Sports, and Games*. Mahwah, NJ: Erlbaum; 1996:51–80.
- 6 Weinstein DF. Duty hours for resident physicians: tough choices for teaching hospitals. *New Engl J Med*. 2002;347(16):1275–1278.
- 7 Volpp KG, Rosen AK, Rosenbaum PR, Romano PS, 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.
- 8 Volpp KG, Rosen AK, Rosenbaum PR, Romano PS, et al. Mortality among hospitalized Medicare beneficiaries in the first 2 years following ACGME resident duty hour reform. *JAMA*. 2007;298(9):975–983.
- 9 Prasad M, Iwashyna TJ, Christie JD, et al. Effect of work-hours regulations on intensive care unit mortality in United States teaching hospitals. *Crit Care Med*. 2009;37(9):2564–2569.
- 10 Volpp KG, Rosen AK, Rosenbaum PR, et al. Did duty hour reform lead to better outcomes among the highest risk patients? *J Gen Intern Med*. 2009;24(10):1149–1155.
- 11 Benn J, Burnett S, Parand A, Pinto A, Iskander S, Vincent C. Perceptions of the impact of a large-scale collaborative improvement programme: experience in the UK Safer Patients Initiative. *J Eval Clin Pract*. 2009;15(3):524–540.
- 12 Benn J, Burnett S, Parand A, Pinto A, Iskander S, Vincent C. Studying large-scale programmes to improve patient safety in whole care systems: challenges for research. *Soc Sci Med*. 2009;69(12):1767–1776.