Chapter 12 The Need for Flexibility in the New Standards

Rosemarie Fisher, MD

Background

In 2003, the Accreditation Council for Graduate Medical Education approved accreditation standards for duty hours for all residency and fellowship programs.[1] At the time, the decision to implement common standards was based on 3 factors: (1) change in the spectrum of hospitalized patients, with higher levels of acuity and intensity of services and shorter lengths of stay; (2) the emergence of a significant body of scientific data on the effects of sleep loss on cognitive and neurobehavioral performance; and (3) a growing interest in the amount of time residents worked each week, including the length of their continuous duty period. The last was prompted by the death of Libby Zion in a New York teaching hospital in 1984 and the subsequent regulation of duty hours in New York State,[2] and a 1999 report by the Institute of Medicine, entitled ''To Err is Human.''[3] Unlike the findings of the Bell Commission that led to the establishment of New York State's duty hour regulations, the IOM report[3] did not directly implicate sleep loss in residents, but discussed the role of a host of ''human factors,'' including fatigue, as contributors to medical errors responsible for a large number of preventable deaths annually.

The 2003 standards were written to maintain a balance between the need for ACGME to ensure the high quality of education in all ACGME training programs and the need for institutions to provide high-quality round-the-clock patient care. The original duty hour standards were also designed to incorporate the rapidly enlarging body of scientific knowledge on the effects of sleep deprivation. Except for a few specialties like emergency medicine and anesthesiology, which previously had established standards more restrictive than the 2003 common duty hour requirements, and the option for programs to extend weekly duty hours by 10% under an educationally justified exception, the duty hour standards were identical across specialties, essentially espousing a notion of ''one size fits all.''

The ACGME Task Force on Quality Care and Professionalism approached the need to revise the duty hour standards from a different vantage point. It reviewed the evidence supporting a maximum weekly and continuous duty period, including data showing the effect of sleep deprivation on cognitive and neurobehavioral performance. It also considered the strongly emphasized view of the graduate medical education community that flexibility in duty hours and supervision were needed both vertically (from postgraduate year–1 [PGY-1] to higher levels of residents/fellows) and horizontally (surgical, medical, and hospital-based specialties) to allow graduated responsibility as residents progress to independent practice.

The Need for Flexibility and Graduated Responsibility

The 2008 publication of the Institute of Medicine's report on duty hours,[4] among other restrictions, recommended reduced limits on continuous duty hours for all residents and fellows. The publication of the report coincided with the ACGME's promised plan to reexamine and refine the common duty hour requirements that were implemented in 2003. Recognizing the importance of the IOM recommendations and the views of the GME community that differed from the IOM recommendations on a number of matters, the Task Force strove for a balanced view that invited the perspective of the GME community and specialties into the discussion. In June 2009, the Task Force received written position papers from more than 140 medical organizations and during 1.5 days, heard formal testimony from more than 70 national organizations representing all domains of medicine and medical education.

A recurring point in the testimony and the written positions from members of the graduate medical education community was the need for flexibility in the duty hour standards across specialties and levels of training. The American College of Physicians stated that ''rigid guidelines may unduly prohibit creativity in program design, strip residents of their ability to make the best decisions that impact them as well as their patients, and actually be counterproductive in achieving one or more of the goals. Providing flexibility in this regard is essential to allow the appropriate level of learning to occur.''[5] The American College of Surgeons (ACS) presented the results of a survey of the members of the ACS Resident and Associate Council, in which 41% of 599 respondents indicated that the current inflexible duty hour restrictions were a considerable or moderate barrier to their education.[6]

The official positions of major organizations in medicine showed a high degree of correlation between level of training and a perception that the 2003 limits had a negative effect on learning, with senior residents more likely to report that duty hours significantly impeded their education, compromising the time in the operating room necessary to increase their technical skills and the time spent to maintain continuity of patient care as they approached entering independent practice. There also was strong sentiment on the part of senior residents that they were inhibited from participating in rare and educationally valuable clinical scenarios; this may cause some graduating residents to feel less than fully prepared for independent practice. The ACS reported that this perception was supported by the fact that 77% of surgical chief residents in 2005 and 76% in 2008 chose to pursue fellowships for increased specific training, in lieu of entering general surgery practice.[7,8]

Although Task Force deliberations had considered a system of standards that would offer flexibility by specialty and level of training, the ultimate recommendations for the 2011 standards focused on flexibility by level of training, owing to the availability of scientific data supporting this approach and to reduce the danger of fragmentation and undue complexity in the new standards. There was no question about the need for maintaining the 80-hour weekly limit, which also had been supported in the recommendations of the IOM report on duty hours.[4] In contrast, there were questions of whether the 24 + up-to-6-hour limit on the continuous duty period was optimal, with the IOM report having recommended a more restrictive 16-hour limit. The positions presented to the Task Force by the academic community voiced strong support for flexibility in the continuous duty period and in the required hours of time off between scheduled duty periods. The positions also emphasized the benefits of a system that would take into account the level of training and competence of the resident, the level of supervision, the anticipated workload, and, perhaps most important, the value of graduated responsibility to prepare residents to function independently after graduation.

The need for flexibility across specialties is further emphasized by the fact that some specialties, such as dermatology, pathology, and radiology, have not been significantly affected by the 2003 duty hour standards, typically because they never reached 2003 duty hour limits even before their implementation. Others, such as surgical specialties and the inpatient experiences in many medical disciplines, needed to be revised significantly to comply with the current limits. Flexibility also is beneficial because of emergent care needs; the educational benefit of seeing rare diagnoses or treatment; the benefits to patient care of continuity, particularly in difficult or emotionally stressful circumstances; and the overlapping involvement of several specialties in the acute care setting. With the 2003 common duty hour standards, which espoused a ''one-size fits-all'' approach, residents occasionally face an ethical dilemma between their professional desire to remain beyond proscribed duty hour limits to provide the best care for their patients (in the process gaining new medical knowledge and

clinical skills) or leaving the institution in order to comply with regulations and not put their institution at risk for a citation. The Task Force felt that more flexibility in the 2011 standards would reduce the incidence and severity of these situations.

Evidence Supporting More Restrictive Limits for PGY-1 Residents

The Task Force considered 3 reviews of the relevant literature commissioned by the ACGME,[9–11] and also heard expert testimony on sleep physiology. On the basis of this information, the Task Force concluded there is physiologic data demonstrating that a statistically significant dip in performance on psychomotor vigilance tasks occurs between 16 and 24 hours of wakefulness.[12] The extent of the decline in performance varies among individuals and is most likely substantially worse for some residents.[13] The practical and clinical significance of these findings were less clear, particularly the effect on medical decision making. In addition, there was concern about the impact that added transitions of care (handoffs), under greater restrictions on the continuous duty period, may have on patient safety.

The 3 literature reviews also explored various other factors, such as resident quality of life, and the effect of sleep loss and duty hour limits on resident education and patient safety and quality of care. Most studies demonstrated an improvement in resident quality of life, but they involved only a single cohort and did not stratify by levels of training. In addition, many studies that assessed the effect of sleep loss on performance used general tasks assessing vigilance and cognitive function, or narrow task-related performance on laparoscopy-training devices, and their validity related to performance on clinical tasks may be limited. A recent systematic review of the literature[14] ranked studies that reduced the length of the continuous duty and those that reduced the frequency of overnight call of 24 to 30 hours, by using the United States Preventive Services Task Force methodology. It found that only 1 study, examining the quality of patient care after implementation of the 2003 duty hour standards, reached level I, defined as evidence obtained from at least 1 properly designed randomized trial;[15] and only 2 added studies reached a level II-1, defined as evidence obtained from well-designed controlled trials without randomization studies.[16,17] The study reaching level I had a sample size of 21 first-year residents, with a reduction in errors under a 16-hour limit on the continuous duty period.[15] Of the studies reaching level II-1, one was a prospective study that showed no difference in the number of errors per call shift.[16] The other was a retrospective controlled trial with both concurrent and historical controls that demonstrated a decrease in intensive care unit admissions and pharmacist interventions to prevent drug errors after the 2003 standards were instituted.[17] While the data showing a decline in performance after 16 hours of wakefulness is scientifically important,[12] its generalizability and practical significance is less clear, given the redundant safety and educational oversight systems of patient care in teaching hospitals in the United States. However, the limited data from high-quality studies performed within the medical environment indicated that despite the presence of these systems, PGY-1 residents made fewer errors when their continuous duty period was limited to no more than 16 hours.[15,18] The Task Force further heard evidence that PGY-1 residents work the longest hours of any resident cohort. FIGURE 1 presenting data from the ACGME Resident Survey, collected under the 2003 standards, shows this, particularly for first-year residents in specialties with a preliminary year.[19] Differences for all duty hour parameters, with the exception of home call and 1 day off in 7, are significant ($P < .0001$). The findings suggest that the current patterns of resident hours are counter to an ideal of first-year residents having more protected hours, with hours and responsibilities gradually increasing over the years of residency, and the final year beginning to emulate practice, while still under faculty supervision.

The long hours currently worked by PGY-1 residents, linked with 2 studies showing the

negative effect of long hours (greater than 16 hours of wakefulness) on their performance, resulted in the Task Force adopting the standard that this group of residents (PGY-1s) must be limited to a maximum of 16 continuous hours on duty. The training paradigm adopted by the Task Force is predicated on better preparation and supervision of PGY-1 residents, followed by progressive liberalization of the duty hour standards as the resident demonstrates additional competency and is delegated greater degrees of conditional independence in the care of patients.

Evidence Supporting Levels of Supervision and Graduated Responsibility

The Task Force believed that data from laboratory sleep studies were only 1 factor in the design of educational standards, yet the Task Force members agreed that the clinical care environment has become much more complex, and novice residents need to be more directly and explicitly supervised to promote both patient safety and resident learning, and that supervision is likely the more important factor in preventing errors.

The concept of graduated or progressive responsibility is the cornerstone of medical training in the United States. Many participants at the 2009 Duty Hour Congress testified to the need for preparing residents for the transition from conditional independence during their years of training to independence upon graduation. In an open letter to the GME community Thomas Nasca noted that this graduated independence paradigm can be shifted in 2 ways.[20] First, the most inexperienced resident can be given a high level of authority with too little supervision (FIGURE 2), or second, too much supervision can be given throughout training (FIGURE 3), causing a lack of preparedness at the time of graduation from training, or ''falling off the cliff into practice.''[20] The ideal model is the balance of independence and supervision illustrated in FIGURE 4.[20]

The United States model of graduate medical education is different from the training paradigm in other countries, notably in Europe, where

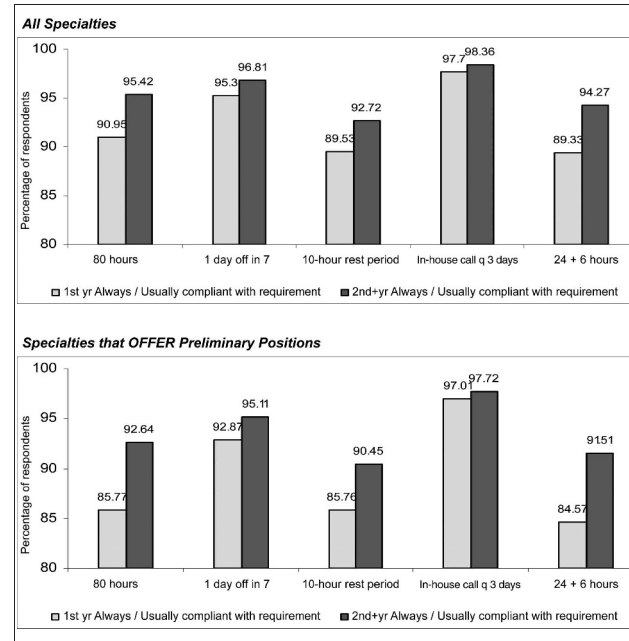

FIGURE 1 **1 Duty Hours for First-Year Residents and All Other Years**

graduates may remain in the institution where they trained under indirect supervision by their mentors as they enter practice, particularly in subspecialty areas. The training paradigm adopted by the Task Force is predicated on better preparation and supervision of PGY-1 residents during more normalized work hours,

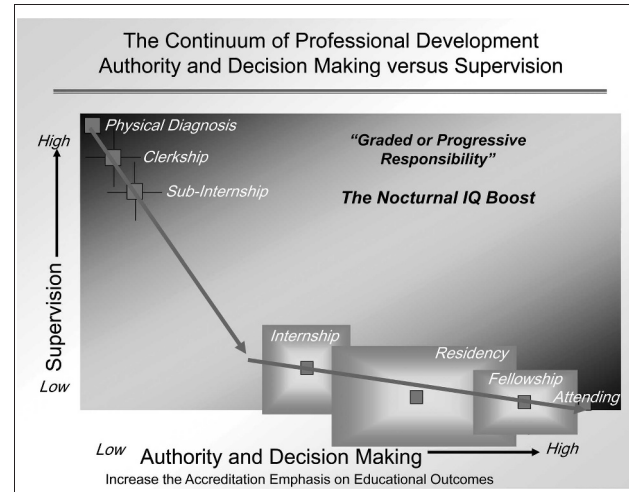

FIGURE 2 **Inadequate Supervision of Junior Residents for the Level of Authority and Decision-Making Responsibility**

Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.

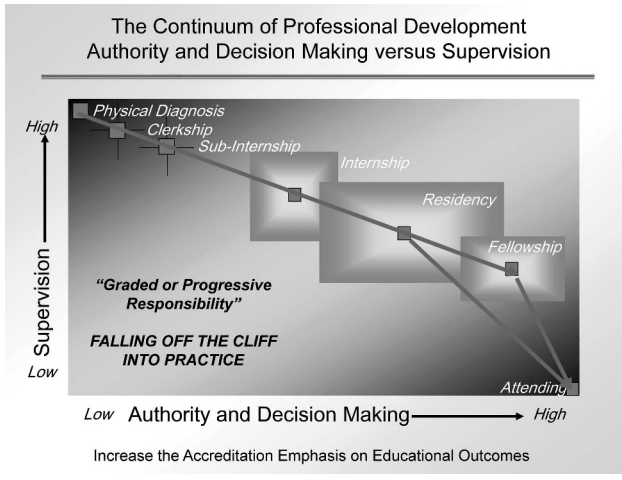

FIGURE 3 **Over-supervision at All Stages With Relatively Little Authority to Make Decisions**

Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.

followed by progressive liberalization of the duty hour standards as the resident demonstrates competencies that can be used as the basis for granting them greater conditional independence in the care of patients. This progression of responsibility to unsupervised independence is primarily based on the level of training in the new standards, but the ACGME Review Committees will have some latitude in modifying the standards to meet more specific specialty needs. It will be aided significantly by the development of the educational ''milestones,'' which is already underway in internal medicine,[21] pediatrics,[22,23] general surgery, urology, and obstetrics-gynecology, and will be initiated in the remaining specialties during the next few years. The milestones will provide a more solid and individualized basis for charting residents' road to independent practice.

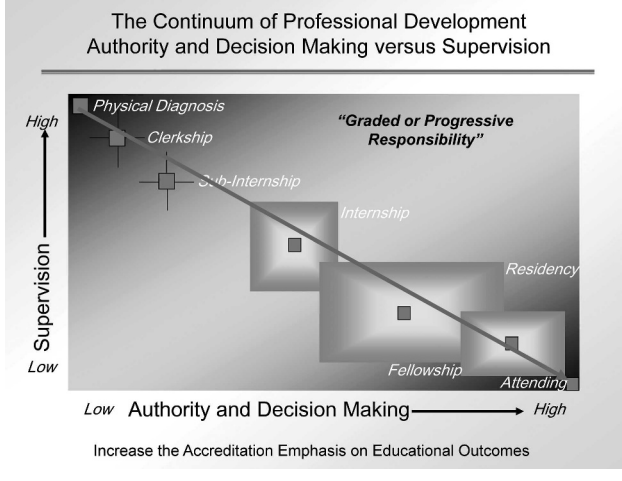

FIGURE 4 **The Training Paradigm of Graduated Responsibility**

Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.

Conclusion

The Task Force developed the new standards in the context of an expanded awareness and emphasis on professionalism, a long recognized need for more defined supervision of residents, and a widely expressed desire for greater flexibility in duty hours to facilitate the education of residents who must be prepared to enter the unsupervised practice of medicine at the completion of training.

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