

Special Article

PATIENT SAFETY

FATIGUE AMONG CLINICIANS AND THE SAFETY OF PATIENTS

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SLEEP deprivation due to extended work hours and circadian disruption has long been a concern in medicine.¹ It has been called the Achilles' heel of the medical profession.² The levels of continuous duty and work hours for health care personnel are much greater than those allowed in the transportation and nuclear-power industries.^{3,4} The problem is most severe for residents in training but extends to experienced physicians and nurses. Clinicians who have been deprived of sleep are part of a health care system in trouble. A report from the Institute of Medicine concludes that the system fails to ensure that patients are safe or that the quality of care they receive is high.⁵ Kenneth Shine, former president of the institute, stated, "We have nurses working 12-hour sessions back to back; we have house officers working enormous hours. We would never do that if we were designing a good system in terms of quality of care."⁶

In this article, we discuss current and proposed policies concerning clinicians' work hours and fatigue.

SLEEP DEPRIVATION AMONG RESIDENTS

The work and on-call hours of residents are disturbing to them^{7,8} and to the media.⁹ Many trainees work more than 80 hours a week, and 100-to-120-hour weeks are common.^{8,10} Regularly scheduled on-call duty is often 24 to 36 hours long and is occasionally even longer. If sleep is possible during on-call duty, it is often limited and fragmented. Fatigue is a common complaint of house staff,⁸ and many trainees (41 percent) say they have made errors that they attribute to fatigue.¹¹ In addition, there is some evidence that house staff are at increased risk for motor vehicle accidents attributable to fatigue.^{12,13}

DOES FATIGUE IMPAIR PERFORMANCE?

There is a large body of laboratory data showing beyond a doubt that fatigue impairs human performance.^{14,15} In fact, the effect of sleep deprivation on a task that involves tracking has been shown to be equivalent to the effect of alcohol intoxication; in one study,

performance of such a task after 24 hours of sustained wakefulness was equivalent to the performance with a blood alcohol concentration of 0.10 percent.¹⁶ Studies of simulated driving have had similar results.¹⁷

Over the past 30 years, many studies have provided unequivocal evidence that mood is worsened by fatigue, as indicated by increased scores on measures of depression, anxiety, confusion, and anger, and that psychomotor performance is impaired in sleep-deprived residents.¹⁸⁻²⁴ Studies in sleep laboratories show that both at base line and after on-call duty, levels of daytime sleepiness in residents are similar to or higher than those in patients with narcolepsy or sleep apnea.²⁵

It has been more difficult to prove that sleep deprivation impairs clinical performance. Most, but not all, studies show impaired performance of clinically relevant, although artificial, tasks.^{18-21,23} For example, sleep deprivation affected hand-eye coordination in surgeons performing laparoscopy²⁶ but did not impair the performance of surgical residents on written board examinations.²⁷ Many of these studies have had serious methodologic flaws, including the use of unvalidated measures of clinical performance, inconsistent definitions of fatigued and rested subjects, failure to measure fatigue objectively, limited statistical power, and failure to account for circadian effects.

DOES THE SYSTEM NEED TO BE CHANGED?

Thus, despite many anecdotes about errors that were attributed to fatigue,²⁸ no study has proved that fatigue on the part of health care personnel causes errors that harm patients. Even when impaired clinical performance due to fatigue²⁹ or falling asleep³⁰ has allegedly been the cause of specific medical catastrophes, these incidents have been viewed as isolated lapses that do not prove that the safety of patients is system-

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atically jeopardized.³¹ In addition, some suggest that long hours of work and on-call duty are needed to expose residents to a sufficiently broad spectrum of cases, prepare them for long hours as practicing physicians, and provide adequate time for teaching conferences and other training activities.³² Reducing work hours, it is alleged, will inevitably result in substandard clinical training. Finally, many point to the costs and organizational difficulty of reducing clinicians' hours of work and on-call duty.

Other hazardous industries have not waited for absolute proof of risk due to operator fatigue. In the transportation industry, federal regulations limit work and duty hours.³ The current rules in the aviation industry (Table 1) stem largely from negotiations between unions and airlines in the 1930s³³; a new, more stringent set of rules based on scientific data has been proposed³⁴ but not yet adopted. Moreover, the National Transportation Safety Board considers fatigue as a possible factor when conducting investigations of accidents. If the sleep-wakefulness histories and circadian timing of crew members who have been involved in accidents suggest that fatigue was present (at levels well below those in most residents), the board formally identifies fatigue as a factor contributing to the accident.³⁵ If the same analysis were applied to accidents involving the care of patients in

teaching hospitals, fatigue on the part of clinicians would almost always be cited as a contributing factor.

REFORM OF POLICIES ON RESIDENTS' WORK HOURS

Issues related to house-staff fatigue have been raised for many years,¹ yet policy reforms have, until recently, been limited. The Libby Zion case²⁹ in 1984 triggered the formation of a commission to investigate supervision and work hours of residents in New York hospitals. On the basis of the commission's recommendations, New York State adopted regulations³⁶ that limit residents' work hours and increase their supervision.³⁷ No other states have adopted similar regulations. In the absence of regulation, the primary oversight of these issues rests with the Accreditation Council for Graduate Medical Education (ACGME), which sets standards for residency training through 27 residency-review committees. Since 1987, some of these committees have adopted standards for work hours, on-call rotations, and time off, although these standards vary widely among specialties.^{4,38} For example, there are no limits on the number of hours of work in pediatrics or obstetrics and gynecology, but there are strict limits in emergency medicine (60 hours per week in patient care).

Audits performed by both New York State^{37,39} and

TABLE 1. CURRENT AND PROPOSED RESTRICTIONS ON WORK AND ON-DUTY HOURS IN U.S. COMMERCIAL AVIATION.

CATEGORY	CURRENT REGULATIONS*	PROPOSED REGULATIONS†
Maximal hours in flight‡		
Per day	No limit (≥8 of rest required between flight periods)	10; extension to 12 allowed with restrictions; >12 allowed with relief crew and opportunities for sleep
Per week	30	4 Cumulative hours of extension (as above)
Per month	100	Insufficient data for regulation
Per year	1000	Insufficient data for regulation
Maximal hours on duty		
Per day	Not addressed	14
Per week	Not addressed	Insufficient data for regulation
Per month	Not addressed	Insufficient data for regulation
Per year	Not addressed	Insufficient data for regulation
Minimal hours of rest in preceding 24 hr		Addressed as minimal off-duty period
Scheduled flight time, <8 hr	9§	
Scheduled flight time, 8–9 hr	10§	
Scheduled flight time, ≥9 hr	11§	
Minimal hours off duty		
Per day	Addressed as minimal rest period	10 (>10 if flight period is extended)
Per week	24 (consecutive)	36 (consecutive), including 2 consecutive nights; 48 (consecutive) after flight duty in a circadian low¶
Other	Not addressed	48 after crossing multiple time zones

*Current regulations, which apply to major airlines, are set forth in the *Code of Federal Regulations* (14 CFR Part 121).

†Proposed regulations are described by Dinges et al.³⁴

‡Flight time is defined as the period when the aircraft is moving under its own power.

§Rest may be reduced by one to two hours if the next rest period is increased.

¶Persons who are awake during the circadian low (between 2 a.m. and 6 a.m.) are at increased risk for fatigue and have an increased requirement for recovery.

the ACGME⁴⁰ showed that many residency-training programs did not comply with even limited standards, although compliance has recently increased as the ACGME has become more aggressive in enforcing its policies. For example, in May 2002, the council notified the general-surgery program at Yale–New Haven Hospital in Connecticut that its accreditation will be lost if residents' work hours are not limited.⁴¹

In isolated cases, unions of residents have reduced work hours through collective bargaining. In November 1999, the National Labor Relations Board overturned a 23-year precedent by ruling that residents at private institutions can unionize and exercise collective bargaining.⁴² It was anticipated that widespread unionization would follow, resulting in sweeping changes in residents' work hours. To date, this has not occurred. Recently, a federal class-action suit was filed, alleging that the resident-matching program, the Association of American Medical Colleges, the ACGME, and other parties engaged in restraint of competition in administering the residency-training system. One allegation is that these practices have impeded efforts to reduce excessive work hours and periods of on-call duty.⁴³

The pace of change has been accelerating. In April 2001, several lobbying organizations filed a petition with the Occupational Safety and Health Administration, alleging that excessive work hours and fatigue harm the health of residents⁴⁴; the administration has established a working group to address the issue. In October 2001, the Association of American Medical Colleges issued a policy statement⁴⁴ recommending limits on periods of on-call duty and work hours for residents but deferred implementation to the ACGME. In November 2001, a bill (H.R.3236) was introduced in the House of Representatives that would provide direct federal regulation of work hours and duty periods of house staff.⁴⁵ (A companion bill, S.2614, was introduced in the Senate in June 2002.) Although the ACGME opposed the House bill,⁴⁶ in June 2002, it announced new requirements for limited work hours that will apply to all residency programs as of July 2003 (Table 2).⁴⁷ In most cases, these requirements are more stringent than those previously imposed by the residency-review programs. The American Medical Association subsequently approved a resolution calling for limitations that are nearly identical to those announced by the ACGME.

REFORMS IN OTHER COUNTRIES

For over 10 years, the United Kingdom and other Western countries have been substantially reducing the work hours of "junior doctors."⁴⁸ A good review of the complex provisions in various countries was prepared by the Australian Medical Association.⁴⁹ In the United Kingdom, the current weekly limit for "ac-

tual work" is 56 hours (with an overall limit of 72 hours, including other in-hospital activities). Even more stringent restrictions are mandated by the European Working Time Directive, some to be implemented by 2004, and others by 2009.⁴⁸ More than 60 percent of training programs in the United Kingdom currently comply with the existing limits. These changes have not been easy to implement. A survey of different on-call and shift systems in the United Kingdom showed that rotating shifts were unpopular with trainees and sometimes interfered with educational activities or reduced contact between residents and attending physicians.⁵⁰ Ensuring that residents receive comprehensive training with shorter work shifts thus remains a challenge that will require innovations in clinical training.⁵¹ Residents' time should be assigned to activities that best promote their learning, and high-intensity approaches to training such as simulation may prove useful.⁵²

OTHER FORCES FOR CHANGE

Surprisingly, there has been little pressure from market forces to address the issue of fatigue among clinicians. Occasional exposés in the media have not generated a groundswell of public concern. Unionization of physicians has not been widespread, and work hours are only one of many issues that are dealt with in collective bargaining. Malpractice suits alleging that a clinician's fatigue caused harm have also been surprisingly rare. An increase in such allegations would provide a major incentive to change work practices.⁵³ Standards and guidelines for maximal work hours and periods of on-call duty have already been promulgated by one professional society (the American College of Emergency Physicians).

POLICY OPTIONS FOR THE UNITED STATES

The problem of fatigue-related risks in medicine will not be solved simply by limiting residents' work hours. A comprehensive strategy should include changes in organizational culture and operational safeguards,⁵⁴ as well as provisions for ensuring that the workload of clinicians is acceptable. Although residents have been the focus of the debate, the strategy should ultimately apply to experienced clinicians as well, especially since older persons are more likely than younger persons to be adversely affected by sleep deprivation.⁵⁵

Limits on Work Hours and On-Call Periods

Specific limits on work hours are the centerpiece of efforts to prevent fatigue among workers in other hazardous industries.³ Such limits are needed in health care to eliminate egregious practices that pose high risks for patients, particularly because hospitals have strong financial incentives to impose long shifts on

TABLE 2. CURRENT AND PROPOSED STANDARDS OR REGULATIONS FOR RESIDENTS' WORK AND ON-DUTY HOURS.*

CATEGORY	CURRENT		PROPOSED			
	NEW YORK STATE ⁵⁶	ACGME (BEFORE JULY 2003) ⁵⁸	AAMC ⁵⁴	OSHA ⁴	CONGRESS (H.R.3236 ⁶⁵ AND S.2614)	ACGME (AFTER JULY 2003) ⁵⁷
Maximal hours per week	80 (averaged over 4 wk)	Imposed by some but not all RRCs (e.g., 80 for medicine; no maximum in pediatrics)	80 (not averaged)	80 (not averaged)	80 (not averaged)	80 (averaged over 4 wk)
Extensions or exemptions to weekly limit	Yes, on-call duty in surgery exempt under certain conditions	Not addressed	No	No	No	Provisions to apply for 10% extension or for total exemption
Provision for hours of work due to on-call duty from home	No	No	No	Yes, all hours at work site counted	No	Yes, all hours spent in hospital counted
Maximal hours per shift	Only for emergency medicine — 12	Only for emergency medicine — 12	24 (12 for high-intensity areas)	24	24	24 plus transition to next shift
Allowance for transition to next shift	Not addressed	Not addressed	Flexibility suggested	"In an extreme situation" (hours not specified)	Bills call for regulations to ensure quality of care during transition	6 hr
Maximal on-call frequency	Not addressed	Every third night (specified by many but not all RRCs)	Every third night (averaged over 4 wk)	Every third night (not averaged)	Every third night (not averaged)	Every third night (averaged over 4 wk)
Minimal hours off between shifts	Time off required (hours not specified)	Not addressed	8	10	10	10
Minimal consecutive hours off (per 7 days)	24	24 (required by some but not all RRCs)	24	24	24, plus one full weekend per month	24 (averaged over 4 wk)
Moonlighting	Hours included in maximal hours of work	Hours included in maximal hours of work	Hours included in maximal hours of work (no "unauthorized" moonlighting)	Not addressed	Not addressed	Hours included in maximal hours of work
Verification	Compliance plans required, audit by state	Accreditation review, provision for complaints	Defers to ACGME as accreditor	Unannounced inspections	Unannounced inspections, annual survey of residents, provision for complaints	Institutional monitoring, accreditation review, provision for complaints
Enforcement	Fines (up to \$50,000 for repeated violations)	Loss of accreditation	Defers to ACGME as accreditor	Fines	Fines (up to \$200,000 per program per year)	Loss of accreditation
Whistle-blower protection	No	No	No	Yes	Yes	No

*ACGME denotes Accreditation Council for Graduate Medical Education, AAMC Association of American Medical Colleges, OSHA Occupational Safety and Health Administration, and RRCs residency-review committees.

clinicians. What constitutes egregious practices is open to debate, but there is a growing consensus that weekly work in excess of 80 to 90 hours and periods of on-call duty that exceed 24 to 30 hours qualify. For trainees, the new ACGME requirements may be a major step forward in eradicating such practices, since failure to comply with the requirements could result in loss of accreditation. Although accreditation is voluntary, few training programs would risk its loss. However, the ACGME requirements have weaknesses. First, they are generally less stringent than other U.S. proposals (Table 2), limits imposed in other countries, or limits adopted in other industries. Second, any residency program can receive a 10 percent extension on the weekly limit by applying to the graduate medical education committee at its institution. These committees will be under great pressure to grant such requests, and it seems likely that many will do so. Residency-review committees will periodically evaluate how each institution has handled these requests, but it is uncertain how stringent these evaluations will be. Some organizations believe that the accreditation incentive is not sufficient to ensure compliance and continue to push for passage of the bills under consideration in Congress.

Managing the Consequences of Limited Work Hours

Limits on work hours will require the regular availability of well-rested clinicians to relieve those ending a shift. Improved coordination among clinicians will also be needed, since failure to coordinate care, apart from fatigue, is a recognized gap in the systems that are in place to ensure the safety of patients. Without proper procedures, transitions between clinicians can be problematic,⁵⁶ but if the transitions are managed properly, continuity of care can be ensured.⁵⁷ Furthermore, in some settings, clinicians who relieve their colleagues are more likely to discover an unrecognized problem than they are to err because of unfamiliarity with the case.⁵⁸

Both residents and experienced personnel sometimes choose to work excessive hours (including moonlighting at a second job). Incentives to moonlight are strong for residents because many have enormous educational debts. The ACGME requirements include moonlighting hours in the limit on weekly hours of work, effectively outlawing such jobs for many residents. However, this restriction will leave many trainees with unrelieved financial pressures.⁵⁹ For some experienced clinicians, the desire to maintain their income as reimbursement declines can override their desire for reasonable work hours.

Changing the Behavior of Clinicians and the Culture of Health Care Organizations

Limiting work hours is only the first step. Additional measures should be part of the work environment.

Preparing for work by getting sufficient sleep and making sure one is alert should become recognized responsibilities of clinicians. Health care organizations, for their part, should assume responsibility for reforming work practices and for changing attitudes toward work so that exhaustion is considered as posing an unacceptable risk rather than as a sign of dedication. In theory, tests of alertness can be used to determine whether a clinician is excessively fatigued, but there is no consensus on the appropriate tests or on thresholds for establishing fitness for duty. Some express concern that adopting a "shift work mentality" may interfere with the physician-patient relationship and destroy medical professionalism.³² In all likelihood, a larger problem is that fatigue-related depression and anger^{1,18-21} result in detachment and a lack of compassion for patients.^{60,61}

Even with limits imposed on overall work hours, periods of duty should be scheduled to account for the known effects of sleep physiology.^{3,62} For example, because of circadian effects, clockwise shift rotation (i.e., from days to evenings to nights) is preferable to counterclockwise rotation.^{3,62}

Although fragmented sleep is not as restorative as uninterrupted sleep, any short period of sleep (a nap) is better than none. To avoid drowsiness on awakening ("sleep inertia"), the nap should last for at least 40 minutes if a substantially longer period is unlikely.⁶³ In a study of airline pilots, those who napped in their seats for 40 minutes were more alert and performed better than those who did not nap.⁶³ Work practices could be changed to guarantee nap periods for clinicians during night shifts or long periods of duty. Also, a nap taken before a clinician drives home may reduce the risk of an automobile accident related to fatigue.

The use of potent medications such as amphetamines to maintain alertness is not sanctioned for clinicians because of the associated risks. However, many people use caffeine to stay awake. They rarely use it strategically, reducing its efficacy when they need it and impeding their ability to nap when they should. Modafinil, a nonamphetamine drug approved for the treatment of narcolepsy, is being evaluated for its efficacy in maintaining alertness in military personnel and shift workers.⁶⁴ However, the long-term use of drugs (including caffeine) to guarantee alertness during long periods of duty may pose occupational health risks and is no substitute for reasonable work practices and adequate sleep.

COSTS AND BENEFITS OF POLICY OPTIONS

Analyses of the costs, benefits, and side effects of policy options designed to prevent fatigue among clinicians are extremely complicated, requiring detailed

models of clinical tasks and workforce characteristics, and are beyond the scope of this article. Such analyses are needed to shape future policies. Since residents provide cheap labor, nearly all options for reducing their work hours are expensive — an estimated \$1.4 billion to \$1.8 billion per year nationwide (in 1994 dollars), depending on who performs the work.⁶⁵ The ACGME recognizes that compliance with its new standards will increase costs.⁴⁷

Reducing work hours and periods of on-call duty will require a substantial restructuring of clinical work. High-intensity activities currently performed at night should be relegated to daytime hours whenever possible.⁶⁶ Some work performed by residents can be transferred to attending physicians, to clinicians other than physicians, or to nonclinicians.⁶⁵ However, solving the problem of sleep deprivation among residents by shifting it to others would be shortsighted.

If work hours of experienced clinicians are modified, patients may need to adjust their expectations about the provision of care. For example, a patient might have to accept a last-minute postponement of planned surgery if the attending surgeon had been up all night — a practice rarely followed today. Alternatively, if the patient had a relationship with a team of physicians, another surgeon might perform the operation.

CONCLUSIONS

In the United States, medical professionals, especially residents, are working far beyond the limits that society deems acceptable in other sectors. This practice is incompatible with a safe, high-quality health care system. An integrated program of measures to prevent excessive hours of work and sleep deprivation should be adopted. Substantial reform is possible within the current system of medical care. The steps recently taken by the ACGME are promising but may not be sufficient, since they contain various loopholes, do not go as far as they could, and apply only to residents. The ACGME requirements are more lenient than those imposed in other Western countries and in other hazardous U.S. industries. If the medical profession does not implement meaningful changes for trainees and, eventually, for experienced clinicians, they may ultimately be forced on us.³⁷

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