David C. Warltier, M.D., Ph.D., Editor

Anesthesiology 2002; 97:1281-94

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Fatigue in Anesthesia

Implications and Strategies for Patient and Provider Safety Steven K. Howard, M.D.,* Mark R. Rosekind, Ph.D.,† Jonathan D. Katz, M.D.,‡ Arnold J. Berry, M.D., M.P.H.§

HEALTHCARE delivery takes place 24 h a day, 7 days a week, and is colloquially termed a "24/7" operation. Anesthesia providers are required to deliver critical around-the-clock care to a variety of patients. This parallels the situation in many other domains that provide such services, *e.g.*, transportation, law enforcement, communications, fire fighting, technology, manufacturing, and the military. Even "convenience" industries (*e.g.*, gas stations and grocery stores) now provide uninterrupted access. These continuous operational demands present unique physiologic challenges to the hu-

This article is accompanied by an Editorial View. Please see: Lydic R: Fact and fantasy about sleep and anesthesiology. ANESTHESIOLOGY 2002; 97:1050-1.

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Submitted for publication March 25, 2002. Accepted for publication June 21, 2002. Supported by Patient Safety Center of Inquiry Program, Department of Veterans Affairs, Washington, DC (Dr. Howard).

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||QuIC report to the President on Medical Errors available at: http://www. quic.gov/report. Accessed July 1, 2002.

#In this manuscript, the word *fatigue* is used as the summary or synthesis descriptor for the varied effects and labels used to describe the cognitive, behavioral, and physiologic outcomes of sleep loss and circadian disruption. The term *sleepiness* as used in this manuscript describes the changes in physiologic alertness measured by standardized, objective sleep laboratory methodology.

**Jha AK, Duncan BW, Bates DW: Chapter 46. Fatigue, sleepiness and medical errors, Making Health Care Safer: A critical analysis of patient safety practices. Edited by Shojania KG, Duncan BW, McDonald KM, Wachter RM. Agency for Healthcare Research and Quality Evidence Report/Technology Assessment, No 43. Available at: http://www.ahrq.gov/clinic/ptsafety/chap46a.htm. Accessed July 1, 2002.

††ACGME Work Group on Resident Duty Hours. Proposed common requirements for resident duty hours. Available at: http://www.acgme.org/index2.htm. Accessed July 1, 2002.

mans who are called on to provide safe operations within these systems. Human physiologic design dictates circadian patterns of alertness and performance and includes a vital need for sleep. Human requirements for sleep and a stable circadian clock can be, and often are, in direct opposition to the societal demand for continuous operations.

Recently, patient safety has taken center stage in health care. The Institute of Medicine's report "To Err Is Human: Building a Safer Health System," revealed that medical errors contribute to many hospital deaths and serious adverse events.¹ The response to this report was widespread and included the Quality Interagency Coordination Task Force's response to the President of the United States, "Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact." $\|^2$ This report listed more than 100 action items to be undertaken by federal agencies to improve quality and reduce medical errors. One action promised by the Agency for Healthcare Research and Quality was "the development and dissemination of evidence-based, best safety practices to provider organizations." In addition to the multiple recommendations to improve patient safety, the report from the Agency for Healthcare Research and Quality included a review chapter on sleep, fatigue,# and medical errors.**

There is evidence that the issue of fatigue in health care is coming to prominence on a national level. In April 2001, Public Citizen (a consumer and health advocacy group) and a consortium of interested parties petitioned the Occupational Safety and Health Administration to implement new regulations on resident work hours (table 1). The primary intent of the regulations is to provide more humane working conditions, which the petitioners declare will result in a better standard of care for all patients. Also, the Patient and Physician Safety and Protection Act of 2001, which would limit resident physician work hours, was introduced in Congress. Recently, the Accreditation Council on Graduate Medical Education, the accrediting organization for residency training programs in the United States, has approved common program requirements for resident duty and rest hours that will take effect in July 2003.^{††}

Table 1. Public Citizen's Proposed Work Hours Regulations

A limit of 80 h of work per week
Limit of 24 consecutive hours worked in one shift
A limit of on-call shifts to every third night
A minimum of 10 h off between shifts
At least one 24-h period off-duty time per week
A limit of 12 consecutive hours on duty per day for emergency
medicine residents working in hospitals receiving more than
15,000 unscheduled patient visits per year
"Moonlighting" is not mentioned

Data from Public Citizen Web site. Petition to the Occupational Health and Safety Administration requesting that limits be placed on hours worked by medical residents (HRG Publication #1570). Available at: http://www.citizen.org/publications/release.cfm?ID=6771. Accessed 7/1/02.

The potential impact of sleep loss and fatigue, specifically among anesthesiologists, has received only sporadic attention.^{3,4} The cognitive demands of intraoperative patient care requires an iteration of data collection, evaluation of its relevance to patient status, development and implementation of plans to maintain the desired patient status, and monitoring the outcome of interventions. These complex tasks require sustained attention or "vigilance" and are particularly vulnerable to the effects of fatigue.⁵⁻⁸ The purpose of this article is to review the physiology of prolonged work cycles and fatigue, to relate this to the work milieu of the practice of anesthesiology, and suggest economically feasible recommendations to mitigate the effects of fatigue.

The Risks: Safety, Performance, and Health

Sleep loss and disruption of circadian rhythm that result from arduous work schedules can lead to reduced safety, performance, and health. While some of these outcomes are well documented, much remains to be learned about the short- and long-term effects of sleep and circadian disruption. The following nonmedical examples of the safety, performance, and health risks associated with around-the-clock operations illustrate the increasing human and economic costs related to ignoring the effects of these physiologic disruptions.

Safety Risks

There have been several high-profile accidents where fatigue was identified as either causal or contributory. For example, although alcohol is often cited as the central reason in the Exxon Valdez marine grounding, the National Transportation Safety Board investigation identified fatigue as one of the probable causes of the accident.⁹ Similarly, circadian factors were identified as contributing to the errors that resulted in the nuclear accidents at Three Mile Island and Chernobyl.^{10,11} Fa-

tigue resulting from the work-rest patterns of managers was also acknowledged as an important component of the flawed decision-making that contributed to the space shuttle *Challenger* accident.¹²

Fatigue-related accidents have been identified in every mode of transportation and can be found in many around-the-clock operational settings. Clearly, there are a variety of adverse outcomes such as economic costs, disrupted service, injuries, and even fatalities that result from these accidents. For example, the Exxon Valdez grounding was associated with environmental cleanup operations and legal cases involving billions of dollars, and Space Shuttle operations were suspended for several years after the *Challenger* disaster.

Fatigue-related safety risks affect us at both individual and societal levels. A recent poll by the National Sleep Foundation indicated that one of two drivers reported having driven while drowsy in the past year,‡‡ and one of five acknowledged having "nodded off" while driving. Fatigue contributes to 100,000 crashes annually that result in 76,000 injuries and 1,550 fatalities, according to estimates by the National Highway Traffic Safety Administration.¹³ Recently, an international group of scientists estimated that fatigue is causal in 15–20% of all transportation accidents, that official statistics underestimate the scope of the problem, and that fatigue exceeds the combined contribution of alcohol and drugs in transportation accidents.¹⁴

Performance Changes

Fatigue caused by sleep loss and circadian disruption can degrade performance and reduce many aspects of human capability.¹⁵ Known performance effects include reduced attention-vigilance, impaired memory and decision-making, prolonged reaction time, and disrupted communications.¹⁶⁻²⁰ These degraded performance outcomes create a situation where there is increased risk for the occurrence of errors, critical incidents, and accidents.¹⁵ Fatigue also creates increased performance variability, with cyclic reductions in alertness and performance.²¹ Fatigued workers have a tendency to slow down work processes to maintain accuracy, a classic effect known as the speed-accuracy trade-off.²² It takes only a moment of reduced performance during a critical task to have a negative outcome. Even if a lapse in performance occurs during a noncritical task, the system vulnerability shifts to a less safe state.

Fatigue-related accidents are sometimes considered to be a result of falling asleep. Performance gaps can be the result of these "microsleeps," which are brief, uncontrolled, and spontaneous episodes of physiologic sleep.⁸ There can be significant performance reductions that are sufficient to create safety risks prior to and immediately after the occurrence of a microsleep.^{23,24} Slowed cognitive throughput, reduced memory, slowed reaction time, lowered optimal responding, and attention lapses can

^{‡‡}National Sleep Foundation Web site. Summary of 2001 Sleep in America Poll. Available at: http://www.sleepfoundation.org/publications/2001poll.html. Accessed July 1, 2002.

create an increased opportunity for errors to occur.²⁵ Consider the circumstance where an anesthesiologist's response to an alarm is slowed and an inappropriate decision guides an incorrect action. The practitioner may have been "awake," but fatigue-related performance decrements could be contributory to the occurrence of any error, incident, or accident that resulted from the action.

The decrement in psychomotor performance resulting from sleep deprivation have been correlated with those resulting from the impairments associated with ethanol ingestion.²⁶ Performance on a hand- eye tracking task declined such that the impairment was equivalent to a blood alcohol level of 0.05% after 17 h of wakefulness. At 24 h of sustained wakefulness, the impairment in psychomotor function was equivalent to a blood alcohol concentration of 0.1%, at or above the legal limit for driving in most states. These data could be useful to help quantify fatigue-related effects with a drug that the public and policy makers better understand.

Specific clinical skills of importance to the practice of anesthesiology deteriorate as a result of fatigue. On a simulated monitoring task where subjects were asked to monitor and record the time of significant deviation of clinical variables (*e.g.*, heart rate, blood pressure), Denisco *et al.* reported lower "vigilance scores" in the group that had been on call.²⁷ The ability to interpret electrocardiographic changes and to do simple mathematical calculations is compromised among sleep-deprived house officers.²⁸ The speed and quality of intubation was diminished among emergency department physicians working the night shift as compared with their performance while working during the day.^{29,30}

Many of the fatigue-related decrements in performance identified in residents are potentially worse in older physicians. Aging is associated with a tendency toward early awakening, an exaggerated dip in arousal midafternoon, and a decreased tolerance of late-night and shift work.³¹ The unique demands of night call on older anesthesiologists are more onerous than those found in other specialties.³² Among recently retired anesthesiologists, night call was identified as the most stressful aspect of anesthetic practice and the most important reason for retirement.^{33,34}

Health Correlates

Beyond the safety risks and performance decrements associated with sleep loss and circadian disruption, there are a variety of personal health concerns. Several studies have shown that long-term exposure to shift work represents an independent risk factor for the development of both gastrointestinal and cardiovascular diseases.³⁵⁻³⁹ A recent study found that women working the night shift had a 60% greater risk for breast cancer compared with women who never worked the late shift.⁴⁰ There is evidence that some adverse pregnancy outcomes are

related to working conditions.⁴¹ A meta-analysis of 29 studies, including more than 160,000 women, evaluated the association of physically demanding work, prolonged standing, long work hours, and cumulative "fatigue score" with preterm delivery, pregnancy-induced hypertension, and small-for-gestational-age infants. There was a positive association between physically demanding work and preterm births, pregnancy-induced hypertension, and delivery of small-for-gestational-age infants. Shift work alone was found to increase the incidence of preterm births.⁴¹

There is evidence that sleep restriction alters physiologic function. Significant detrimental effects on immune function can be found after a few days of total sleep deprivation or after several days of partial sleep loss.^{42,43} Sleep restriction of 4 h per night for six nights is associated with harmful effects on carbohydrate metabolism and endocrine function.44 This degree of sleep restriction resulted in abnormal glucose tolerance, decreased thyrotropin concentrations, increased evening cortisol concentrations, and increased sympathetic nervous system activity (as measured by heart rate variability). Sleep deprivation and circadian disruption affect cerebral metabolic and cognitive function. In a study of changes in regional cerebral glucose utilization (i.e., positron emission tomography) during 85 h of consecutive sleep loss, decreases in cerebral metabolic rate were observed primarily in the thalamus and prefrontal and posterior parietal cortices. Alertness and cognitive performance declined in association with these brain deactivations.⁴⁵ A recent study of aircrew members suggests there may be a linkage between long-term exposure to time-zone changes (i.e., circadian disruption), temporal lobe atrophy, and deficits in learning and memory.⁴⁶ Investigations using functional magnetic resonance imaging technology contradict some of the aformentioned findings and reveal compensatory changes of increased activation in the prefrontal cortex and parietal lobes during verbal learning after sleep deprivation.47-50

Studies show altered mortality with sleep loss and circadian disruption. Circadian disruption in hamsters and *Drosophila* reduce life span from 11 to 15%.^{51,52} A prospective investigation of more than one million individuals conducted by the American Cancer Society found that men who reported "usual" daily sleep times of less than 4 h were 2.8 times more likely to have died within a 6-year follow-up as men who obtained 7.0–7.9 h of sleep.⁵³ The risk for women was increased by 48%. Conversely, men and women who reported sleeping 10 h or more per day had about 1.8 times the mortality rate of those who reported 7.0–7.9 h of sleep.

Physiologic Factors that Underlie Fatigue

The two primary determinants that underlie fatigue and interact in a dynamic manner are sleep homeostasis and circadian rhythms.⁵⁴ An individual's level of alertness (*e.g.*, on the job) or potential for sleep (*e.g.*, during a rest period) will be determined by a complex interaction of these factors. Performance and alertness decrements may occur when either of these elements is disrupted.⁵⁵ Factors other than fatigue, such as workload, environment, stress, boredom, motivation, and professionalism, also influence the ability to perform.⁴ In addition, there are large interindividual differences on the effects of fatigue.⁵⁶

The Sleep Factor. Sleep serves a vital physiologic need.⁵⁷ Like other basic physiologic requirements such as food and water, sleep plays a fundamental role in survival. Sleep homeostasis is the balance between sleep need and quality and quantity of sleep obtained by an individual. On average, the adult human requirement for sleep appears to be greater than 8 h (8 h:14 min) per 24-h period.^{58,59} The range of sleep need varies from 6 to 10 h, and this requirement is probably genetically determined and cannot be "trained" to a different sleep need.⁶⁰ Estimates suggest that most American adults obtain about 1-1.5 h less sleep than needed.§§ This lost sleep accumulates to produce a "sleep debt."8,58 For example, an individual who obtains 1.5 h less sleep per night over a 5-day work week will begin the weekend with 7.5 h of sleep debt. This deficit is roughly equivalent to the loss of a full night of sleep and requires about two nights of at least 8 h of sleep for recovery.²⁰ Sleep debts are not repaid hour for hour, but instead through an increase in deep sleep or nonrapid eye movement stages 3 and 4.20

A variety of factors can affect sleep quantity and quality. Perhaps some of the most dramatic changes in sleep occur as a normal function of aging. Approaching age 50 and beyond, sleep becomes more disrupted with frequent awakenings. There are reduced amounts of deep sleep, and sleep becomes less consolidated.⁶¹ Nocturia in men and menopausal symptoms in women are likely to contribute to sleep disturbances in older individuals. There are also age-related increases in complaints of insomnia and depression that negatively impact sleep. Sleep need does not necessarily decrease with age, and increased daytime sleepiness can be the consequence of reduced sleep quantity and quality. There have been no formal studies assessing whether these changes in sleep quantity and quality affect the performance of older anesthesia providers.

There are approximately 90 known sleep disorders that have been described and classified in a diagnostic nosology.⁶² The causes for these disorders range from physiologic to psychological to environmental. Some sleep disorders are relatively prevalent in the population

and have well-documented negative effects on waking alertness and performance.^{63–65} Often, the affected individual is unaware of their disorder, and the bed partner may be the first to identify the problem. Obstructive sleep apnea is a common example of a sleep disorder that has implications in operational settings. There are many health consequences associated with sleep apnea, but, in addition, it has been shown to be associated with a twofold to sevenfold increase in risk for automobile accidents.^{66,67} Consistent with this, Powell *et al.* demonstrated that individuals with mild to moderate sleep apnea had a decrement in performance equivalent to that of an individual with a blood alcohol concentration of 0.05-0.08 g/dl.⁶⁸

Alcohol is the most widely used sleep aid, and its use is typically intended to provide relaxation or to promote sleep.⁶⁹ However, alcohol is a potent suppressor of rapid-eye-movement sleep, especially in the first half of the night.⁷⁰ As the blood alcohol concentration declines, there is a rapid-eye-movement rebound in the second half of the night, producing more rapid-eye-movement sleep with increased awakenings and a reduction in total sleep time. Therefore, although alcohol may be consumed as an aid to promote sleep, it actually has the potential to significantly disrupt it.

Sleep can be measured both subjectively, using a variety of questionnaires, and objectively, using standardized physiologic measures. Generally, humans are inaccurate subjective reporters of alertness.^{71,72} Individuals can report being awake and alert, when physiologically they could be asleep in minutes. This discrepancy between self or subjective reports and physiologic levels of alertness can have significant operational implications. First, it indicates that verbal reports of subjective alertness are generally unreliable sources to determine an individual's fitness for duty. Second, an individual with the subjective experience and report of being alert might be less likely to engage an alertness strategy (e.g., strategic caffeine or nap opportunity, as discussed in the section on alertness strategies) that could address the underlying disturbed physiologic state. It is important to note that when an individual reports a subjective experience at either end of the continuum (e.g., extreme fatigue or sleepiness), it is more likely to reflect the actual physiologic status.71

The Circadian Factor. The human circadian (*circa* = around, *dies* = a day) timekeeper is located in the suprachiasmatic nucleus (SCN) of the hypothalamus and is an active pacemaker for internal 24-h rhythms.⁷³ The most powerful and well-studied synchronizer of the SCN is light, while melatonin, a complementary synchronizer of the SCN, is secreted by the pineal gland at night and is suppressed by light.⁷⁴ A retino-hypothalamic pathway to the SCN provides direct access for light and dark exposure to affect the circadian clock. The daily light–dark cycle entrains the SCN to its 24-h pattern. The natural

^{§\$}National Sleep Foundation Web site. Summary of 2001 Sleep in America Poll. Available at: http://www.sleepfoundation.org/publications/2001poll.html. Accessed July 1, 2002.

tendency of the circadian clock is to run slightly slower (24.18 h) than our 24-h day,⁷⁵ which is the physiologic rationale to phase delay rather than phase advance work-rest cycles. In other words, rotation of shift assignments going from days to evenings to nights has a circadian physiologic justification, but this has not been a major solution to the problems of shift work.⁷⁶

The SCN controls a broad range of physiologic, behavioral, and mood functions. For example, it drives the 24-h sleep-wake pattern, daily digestive activity, hormone secretions, and mood, as well as alertness and performance levels.55 The underlying mechanisms regulating the cellular neurobiology of sleep are important and complex but are beyond the scope of this article and are reviewed elsewhere.^{77,78} Humans are programmed for increased sleepiness at two approximate times each day: 3-7 AM and 1-4 PM^{55,79} The circadian nadir, associated with the lowest levels of activity, alertness, and performance and greatest vulnerability to errors, incidents, and accidents, occurs at about 3-7 AM. As an example, it has been well established that a peak in fatigue-related single car accidents, without alcohol involvement, occurs roughly between 3 and 5 AM.⁸⁰⁻⁸³ The complementary periods of maximal alertness occur at approximately 9-11 AM and 9-11 PM.

Rotating to a different work schedule such as the night shift or crossing time zones disrupts the entrained circadian pattern. Jet lag will occur for days as the SCN synchronizes to the new local environmental cues (e.g., the light-dark cycle) after traveling through several time zones. Night work creates a different challenge by its disruption of the circadian pattern. When individuals are working at night, circadian programming drives sleep, and when they attempt to sleep during the day, the circadian clock is programmed for wakefulness. Generally, studies have shown that "adaptation" does not occur despite prolonged exposure to night work.⁸⁴ After an all-night shift, the individual returns home and is exposed to daytime light cues that maintain SCN programming for a day-active, night-sleep pattern. Social factors such as interacting with family and performing duties that can only be done during daytime hours also play a major role in the inability to readily alter the endogenous rhythm to night work.85

A study of unintentional dural puncture during epidural anesthesia has provided further support for a circadian difference in clinical performance among anesthesiologists.⁸⁶ The risk of dural puncture was greater at night (midnight to 8:00 AM) and among inexperienced practitioners. Although this investigation is supportive of a negative circadian effect on performance, it was limited by the low frequency of unintentional dural punctures as well as by not including important covariants such as patient body habitus and physician workload.

Table 2. National Transportation Safety Board Analysis of Crew Fatigue Factors

Physiologic factors

Sleep: acute sleep loss and cumulative sleep debt
Continuous hours of wakefulness
Time of day (evaluation of circadian influences)
Fatigue-related performance changes and their role in acciden
causation

Compliance with flight regulations and company policies related to fatigue

Data from Rosekind et al.95

Risks to Patients and Healthcare Providers

Subjective data from surveys of anesthesiologists⁸⁷⁻⁸⁹ and other healthcare personnel^{90,91} reveal that fatigue is perceived by practitioners as creating a significant risk for patients. In two studies of anesthesia caregivers, more than 50% reported having committed an error in medical judgment that they attributed to fatigue.^{88,89} Cooper et al., using the critical incident method of evaluating anesthetic errors, estimated that human error played a role in more than 80% of anesthetic mishaps and that fatigue was an associated factor in 6% of reported critical incidents.⁹² In a survey of New Zealand anesthesiologists, 58% reported that they exceeded their self-defined limit for safe continuous administration of anesthesia, and 86% reported having committed a fatigue-related error.⁸⁷ Data from 5,600 reports of critical incidents to the Australian Incident Monitoring Study from 1987 to 1997 revealed that fatigue was listed as a contributing factor in 152 reports (3%).⁹³ These data suggest that there is a specific association between fatigue and medication errors (syringe swaps) occurring at circadian low points (2-4 AM). The conclusions from these studies are limited since they are based on retrospective, self-report data, but the majority of respondents consistently indicate that quality of care is compromised and that some errors are attributed to working while fatigued.

A recently litigated case clearly demonstrates the effect of fatigue in the operating room. An anesthesiologist was accused of literally falling asleep while his patient, an 8-yr-old child, died.⁹⁴ During the litigation, testimony was given that the defendant had been repeatedly warned by supervisors about falling asleep during operations. He was convicted of criminal medical negligence and acquitted of felony counts of reckless manslaughter and criminally negligent homicide. The conviction was later overturned on a technicality as the statute of limitations on the misdemeanor charge had expired. Interestingly, using NTSB methods of accident analysis (table 2), the majority of errors and accidents that occur in the healthcare environment are likely to have fatigue as a contributing factor based on work schedules alone.⁹⁵

There is a well-documented association between long work hours or late work and an increased potential for injury from industrial accidents. The risk of an accident

Table 3. New York State Department of Health Regulations(Section 405)

Scheduled work week shall not exceed an average of 80 h per week over a 4-week period*

House staff shall not be scheduled for more than 24 consecutive hours *

Nonworking periods following scheduled on-duty or on-call periods must be provided

At least one 24-h period off-duty time per week

Dual employment or "moonlighting" by house staff must be monitored by hospitals and any such hours worked must be

considered as part of the work hour limitations

A limit of 12 consecutive hours on duty per day for emergency medicine residents

Resident supervision and ancillary support requirements were also included

"Moonlighting" reported and counted toward total weekly hours

*On-call duty of surgical residents was not included in the 80-h limit nor in the 24-h limit when there was adequate rest and the number of interruptions was infrequent and documented.

Data from New York State Department of Health Web site. Section 405.4. Available at: http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm. Accessed 7/1/02. The regulations state: "that each trainee notify the hospital of employment outside the hospital and the hours devoted to such employment. Postgraduate trainees who have worked the maximum number of hours permitted in subparagraphs (i)–(iv) of this paragraph shall be prohibited from working additional hours as physicians providing professional patient care services."

increases exponentially with each hour after the ninth consecutive hour of work.⁹⁶ This effect is exaggerated when extended work hours occur on a late shift. Needle stick injuries, among the most frequent of the occupational injuries suffered by anesthesia providers, are usually self-inflicted, occur during disposal or recapping of sharp devices, and are associated with carelessness from fatigue. Among residents and medical students, there is a 50% greater risk of sustaining a bloodborne pathogen exposure during night work than during days.⁹⁷

Studies have extended the previously described risks associated with drowsy driving to physicians.98-100 Fatigued physicians are at risk for accident and injury as they drive home after completing their duty cycle. In a study of an academic pediatrics department, 49% of residents (averaging 2.7 h of sleep while on call) reported falling asleep at the wheel compared with 13% of faculty members. These residents had almost twice as many traffic citations for moving violations than did the better-rested faculty members.⁹⁸ Residents in pediatrics and emergency medicine have been reported to suffer twice the expected number of accidents, in many cases while driving home after being on call.98-100 In a more recent retrospective study of driving-accident risk among anesthesia trainees, only eight accidents were reported, which did not differ from the control.¹⁰¹ The authors attributed this finding to the "protective" circadian alerting effect during the drive home (8-10 AM).

The effect of work hours on pregnancy outcomes in female resident physicians has been evaluated. These data reveal that there is an increased incidence of pregnancy-induced hypertension,¹⁰² preterm labor,¹⁰³ and small-for-gestational-age infants.¹⁰⁴ Another study documented an association between preterm delivery and residents who worked more than 100 h per week.¹⁰⁵

The Death of Libby Zion and Work Hours Regulations

As in other "24/7" settings, health care has experienced some high-visibility tragedies where fatigue was identified as causal or contributory.94,106-110 The most often referenced example is the death of Libby Zion, which focused attention on work hours and supervision of resident physicians. Although there has been much debate¹⁰⁶⁻¹¹⁰ as to whether her death was related to the fatigued healthcare providers who cared for her, a highprofile commission was formed in 1987 that issued recommendations to limit house staff work hours and to increase their supervision. These recommendations became part of the revised Section 405 of the New York State Health Code (table 3).¹¹¹ The Accreditation Council on Graduate Medical Education and its Residency Review Committees developed institutional and program requirements for resident supervision, duty hours, and work environment. Institutions were required to ensure that each training program established formal policies for resident duty hours that fostered education and facilitated care of patients. The Residency Review Committee for Anesthesiology specifies that in-house duty hours should not be excessive and suggested that, on average, residents should have "at least 1 day out of 7 free of routine responsibilities and be on call in the hospital no more often than every third night." Finally, if these policies are followed, residents are prohibited from "administering anesthesia on the day after in-house overnight call."

Subsequent evaluation suggests that the regulation of resident duty hours may not be the panacea that alone improves patient outcome. Data collected before and after implementation of the New York regulations found that there were no differences in in-hospital mortality rates, rate of patient transfer to intensive care units, or length of stay, and that there were more patients having at least one complication.¹¹² Petersen et al. demonstrated that preventable adverse events were more common when cross-covering house staff were caring for patients compared with times when a resident knowing the patient was involved with the care.¹¹³ A follow-up study revealed that improving the quality of communication during patient sign-outs improved the quality of care.¹¹⁴ This suggests that during some circumstances, use of cross-covering residents to relieve tired house staff may introduce the possibility of more medical errors, but that these errors might be mitigated in other ways.

IIIACGME common program requirements. Available at: http://www.acgme.org/index2.htm. Accessed July 1, 2002.

A variety of definitions of "fatigue"
Nonstandard timing for performance testing
No objective testing for degree of sleepiness in the baseline state
Lack of subject training to an asymptotic performance level
Failure to account for a practice effect in the interpretation of
results
Failure to account for chronic sleep loss
Small sample size that limits statistical power

Research Related to Fatigue in Health Care

There is little consensus among studies on the effects of fatigue on the performance of healthcare personnel.^{3,4,115-119} Previous authors have detailed the methodologic problems inherent in most of the studies (table 4).¹¹⁵⁻¹¹⁸ It is not surprising that the interpretation of this body of data are contradictory given these methodologic problems.

There is a tremendous inconsistency across studies in the definitions used for fatigue or sleep loss. Although studies of partial sleep deprivation consistently reveal that measurable performance decrements occur if sleep is restricted by as little as 1 h,¹²⁰ Bartle *et al.* used 4 h of sleep on the night prior to performance testing to distinguish between fatigued and rested subjects.¹²¹ There is no scientific basis for the assumption that sleep times of greater than 4 h should be considered as "rested." Many other investigations use similarly arbitrary study conditions.^{27,122-130}

An additional source of inconsistency in previous studies is the lack of a standardized instrument to test performance. A wide range of measures such as simple psychomotor tests and written standardized tests have been used.^{131,132} Only a few studies have used face-valid, healthcare-related tasks such as monitoring tasks²⁷ or tracheal intubation.³⁰ Also, measurement of "on the job" work is complicated by a paucity of tested metrics to adequately judge the components of satisfactory performance. This lack of standardization limits the ability to quantify the impact of fatigue in healthcare settings. A "lack of significant" findings in a study may be interpreted as a demonstration that fatigue does not represent a performance or safety risk, but the findings may be due to methodologic flaws or the use of inappropriate measures rather than a valid assessment of the effects of fatigue.

There are a growing number of well-controlled, scientifically sound investigations of healthcare personnel that test for performance impairment secondary to fatigue. Results obtained with virtual-reality simulators have shown significant reductions in the performance of sleep-deprived surgeons.^{133,134} In two studies of surgical dexterity, sleep-deprived surgeons (defined as zero¹³⁴ or < 3 h of sleep¹³³) made more errors and operated more slowly than they did

in the rested condition. Both speed and accuracy were negatively affected by sleep deprivation.

In a recent study of anesthesia trainees designed to mitigate the core methodologic flaws found in many previous studies,⁷² residents were tested in each of three experimental conditions in the sleep laboratory (a within-subjects design). In the baseline condition, residents were assigned to a typical general operating room rotation without any on-call period in the previous 48 h. In the postcall condition, subjects were studied after a 24-h in-hospital call period while rotating on a clinically busy service such as obstetric anesthesia or the intensive care unit. The third condition, termed sleep extended, attempted to produce a truly rested control condition by permitting four consecutive nights of increased sleep. Subjective measures and a standard physiologic measure of daytime sleepiness, the Multiple Sleep Latency Test, were used to quantify differences among the three conditions.^{135,136} There were three major findings of this study. First, there were no significant differences found in physiologic sleepiness between the baseline and postcall conditions. This was interpreted to demonstrate that the residents were chronically sleep-deprived to the extent that their baseline condition was equivalent to a postcall level of sleepiness. Second, in the extended condition, alertness levels were significantly increased compared with the baseline and postcall conditions. The subjects went from a level of sleepiness associated with severe sleep loss and sleep disorders (i.e., sleep apnea and narcolepsy) to a normal range of alertness after four consecutive nights of increased sleep. These observations cast doubt on prior studies that demonstrated no significant differences comparing a "baseline" condition to a "postcall" condition. Such findings more likely indicate that the "control" condition does not accurately reflect the rested state. Third, there was a significant discrepancy between subjective reports of fatigue and alertness and objective measures of physiologic status. Subjects were asked to provide a subjective rating of sleepiness for comparison to their physiologic measure as determined by their Multiple Sleep Latency Test score. On more than half of the occasions, when subjects reported they had been awake, they were actually asleep. This was a simple and straightforward demonstration that increased sleep is the most direct intervention that can improve waking levels of alertness.

Consistent Findings in the Literature of Healthcare Personnel

Survey Data on Work Hours and Fatigue-related Error. Several surveys have been performed evaluating work hours of anesthesia caregivers, including nurse anesthetists, residents, and practitioner anesthesiologists.^{87,89,137,138} Residents work longer hours (60–70 h/week) than their nursing and physician specialist counterparts (47.5– 52 h/week). This is in marked contrast to the surgical subspecialties that commonly report 80-100 h work weeks while caring for patients.^{90,139-141}

Mood. There are consistent findings that report impairment of mood as work is extended or done at night.^{14,28-30,121-124,128,130,142-151} Mood is typically measured using various subjective scales anchored at either end with descriptive words. In these studies, as time awake increases, levels of anger, confusion, anxiety, depression, and fatigue increase while positive emotions such as happiness and vigor decrease. The effects of negative moods on patient care have not been measured directly.

Results from a Meta-analysis. Pilcher and Huffcutt performed a meta-analysis using data from 19 of 56 published studies that met their acceptance criteria.¹⁴ The studies, assessing the effects of sleep deprivation on performance, included both medical and nonmedical participants (1,932 total sample size). Short-term total sleep deprivation was defined as less than or equal to 45 h; long-term total sleep deprivation, more than 45 h; and partial sleep deprivation, a sleep period of less than 5 h in a 24-h period. When all sleep deprivation categories were combined, the sleep-deprived subjects performed at a level 1.37 SDs lower than rested subjects, and the greatest impact was on mood and cognitive measures, with little change in motor performance. Compared with short- or long-term sleep deprivation, partial sleep deprivation had the greatest affect on mood and cognitive performance. Performance on complex and long tasks was reduced more by short-term sleep deprivation than performance on simple, short tasks.

Managing Alertness in Health Care: A Proposed Solution

The two principal barriers to change in the healthcare work environment include its history and its complex economics. Tradition, or "that's the way its always been done," is a position that has impeded change. Economic and workforce limitations affect all aspects of the healthcare system and must be directly addressed if any potential change is to be accomplished. Reduction of fatiguerelated risks and enhancement of patient and provider safety poses complicated challenges. There are diverse operational requirements (*e.g.*, job tasks, shift schedules), individual differences (*e.g.*, age, experience), and complexity of the physiologic factors that preclude any simple or single solution. Given the complexity of the challenges, a comprehensive approach to managing alertness offers the greatest opportunity for change. A

Table 5. Recommendations for Naps as Part of an Alertness Strategy

For a short nap, allow up to 45 min for sleep*
A longer nap of approximately 2 h allows for a full NREM/REM
cycle
Allow a 15-min wake-up period following a napt
Do not take a long nap too close to a planned sleep period

*This reduces the likelihood of awakening in deep NREM sleep and experiencing the effects of sleep inertia. †This diminishes any effects of sleep inertia.

Data from Dinges et al.155

comprehensive approach involves at least the following four components: education, alertness strategies, scheduling policies, and healthy sleep.¹⁵²

Education. The foundation for any change in fatiguerelated risks begins with education. Basic knowledge of sleep medicine is critical to understanding the physiologic factors that underlie fatigue and the risks of performing in suboptimal conditions and for addressing widely held misconceptions about sleep. During 8 yr or more of medical school and residency, it is not uncommon for trainees to receive little or no information regarding sleep, sleep disorders, and related topics.¹⁵³ Lacking this knowledge, physicians are unlikely to appreciate the need for change. Successful educational modules have been developed for other high-risk domains that could be used as models for health care.¹⁵⁴##

Alertness Strategies. There are a variety of strategies that have been empirically validated to improve alertness and performance. Three examples include planned naps, strategic caffeine use, and good sleep habits.

Naps. Laboratory investigations have demonstrated that planned naps can improve subsequent alertness and performance.^{155,156} A NASA field study evaluated the benefit of naps in the cockpit.¹⁵⁷ In this study, a 40-min nap increased performance by 34% and physiologic alertness by 54% compared with a no-nap condition. Table 5 shows straightforward alertness guidelines for napping. Planned naps provide one of the most direct and basic interventions for sleep deprivation and do not require training or technology for effective use.

Caffeine. Caffeine is the most widely used stimulant to maintain wakefulness. The strategic use of caffeine involves ingestion at times that will promote alertness and performance during periods of vulnerability. Generally, the pharmacologic onset of caffeine occurs about 15–30 min after ingestion and its effect lasts about 3–4 h, although tolerance may reduce its alerting effects. A significant performance and alertness boost can be obtained from 200 mg of caffeine, with positive effects at doses ranging from 100 to 600 mg. Caffeine has a variety of adverse actions, such as tremors and heart palpitations, that are dose-related and may limit its usefulness in higher concentrations. A recent report from the Institute

^{##}In 1998, the Committee on Patient Safety and Risk Management of the American Society of Anesthesiologists sponsored the production of an educational video entitled, "Fatigue: Implications for the Anesthesiologist." The video provides basic information on the physiologic determinants of fatigue, describes some alertness strategies, and portrays some real-world scenarios demonstrating their application. The free video download is available at: http://gasnet.med.yale/ videos/index.php. Accessed July 1, 2002.

Table 6. Recommendations for Good Sleep Habits

Use a presleep routine to provide cues for relaxation and sleep Avoid negative sleep cues in the bed and bedroom (*i.e.*, don't

bring work or anxiety-related activities into the sleep setting) Have a light snack or drink if hungry or thirsty

Avoid caffeine intake at least 3 h before bed

Avoid exercise within 2–3 h of bedtime

- Follow a 30-min "toss-and-turn rule" such that if you are unable to fall asleep in 30 min, get out of bed, engage in some sleeppromoting activity, return to bed when ready
- Use relaxation techniques (can be very effective for getting to sleep or returning to sleep after an awakening)

Try to get 8 h of sleep every 24 h (consider a supplement nap) Limit intake of ethanol or nicotine-containing products close to bedtime

of Medicine^{***} provides guidelines on the operational use of caffeine.

Good Sleep Habits. There are a variety of good sleep habits that can promote sleep quality and quantity at home or in the hospital. Examples of good sleep habits are listed in table 6.

Other Drugs and Light Therapy. Other alertnessenhancing drugs have been studied, especially by the military (*e.g.*, *D*-amphetamine, pemoline, modafinil). Modafinil is a schedule IV, nonamphetamine, alertnessenhancing drug used in the treatment of narcolepsy. Off-label studies of the drug are underway among military personnel and shift workers (including physicians) to determine its effectiveness in the maintenance of alertness and performance.¹⁵⁸ Thus far, modafinil has been found to have significant alertness-promoting properties with fewer side effects and little effect on recovery sleep when compared with the amphetamine class of drugs.¹⁵⁹ The abuse potential for modafinil appears low, but it is unclear whether this drug would or should be accepted for use by medical professionals.

Melatonin, a hormone produced by the pineal gland, has been claimed by some as a panacea for jet lag and for the problems associated with shift work. It has sleeppromoting effects if given in doses of 0.3-80 mg throughout the biologic day. Daytime sleep latencies are shortened, and self-rated sleepiness increases. When melatonin is administered close to the habitual nocturnal sleep episode (when endogenous melatonin increases), its effects on sleep latency and subjective sleepiness have yielded inconsistent results.74 Melatonin also has circadian phase-shifting effects with the direction of the phase shift dependent on the timing of its administration. This action can be masked by exposure to light, which exerts a much stronger influence on the human circadian pacemaker.⁷⁴ Studies evaluating the efficacy of melatonin in shift workers have yielded mixed results.^{38,160} Since melatonin is considered a food supplement and not a drug by the US Food and Drug Administration, its purity and dose in commercial preparations are often unknown, and it has not undergone rigorous safety testing.

Light therapy is also being studied as a fatigue countermeasure for shift workers.¹⁶¹⁻¹⁶⁴ The implementation and timing of light therapy is complex and has to be correctly applied to have the desired effects. Whether use of light will become a viable countermeasure remains to be seen.

Individuals need to be educated about effective alertness strategies and should have an appropriate skepticism for unproven, anecdotal techniques. Policies should be developed to support the use of strategies (*e.g.*, a hospital policy that permits appropriate napping) and explicit organizational assistance where needed (*e.g.*, appropriate nap facility). Organized policies regarding alertness strategies have traditionally not been provided for healthcare personnel. For example, napping during work hours often carries a negative connotation, is often interpreted as a sign of laziness and may be prohibited in the workplace.

Scheduling Policies. Issues related to scheduling are the most complex and contentious areas to be addressed in an alertness management program. Scheduling issues touch on resources, economics, lifestyle, and a range of other factors in addition to fatigue. Some of the specific physiologic issues that need to be taken into account in scheduling proposals include duty or shift length, offduty or minimum rest opportunities, effects of cumulative fatigue due to consecutive duties or reduced rest opportunities, recovery periods, direction of shift rotation, start and end times of shifts, and circadian effects. Alteration of scheduling policies will require a complete and thoughtful assessment of all of the above factors, and this has not been done for any medical specialty.

Some industries have specific regulations or policies that dictate the details of these scheduling factors. Table 7 provides an example of the complicated scheduling practices of different industries. Even though regulated, it is important to note that there are large differences in the number of work hours that can accumulate per unit time across these transportation modes. Legislation and regulation have not played a role in healthcare work practices, with the notable exceptions of Section 405 of the New York State Health Code, which only limits work hours of resident physicians. In an attempt to track compliance with the New York regulations, a survey, based on unannounced inspections, revealed significant violations as 37% of all residents exceeded 85 h per week. Surgical residents grossly exceeded the work hour limit, as 60% worked 95 h or more per week.¹⁶⁵ Ironically, part of the State's response to these findings was to increase fines and to provide financial support for greater enforcement of the limitations rather than allo-

^{***}Vanderveen JE (Chair), Committee on Military Nutrition Research: Caffeine for the sustainment of mental task performance: Formulations for military operations. Summary from the Institute of Medicine. Available at: http://www. iom.edu/iom/iomhome.nsf/. Accessed July 1, 2002.

Table 7. Work Hour Regulations in Transportation

Aviation (14 CFR Part 121; 14 CFR 135).

Pilots flying domestic air carriers, such as major airlines and cargo haulers, who fly large transport aircraft operations (Part 121) may fly up to 30 h/wk, 100 h/mo, and 1000 h/yr.

Pilots flying domestic commercial air carriers, commonly referred to as commuter airlines and air taxis (Part 135), may fly up to 34 h/wk, 120 h/mo, and 1200 h/yr.

If the scheduled flight time is < 8 h, the minimum rest period in the 24 h preceding the scheduled completion of the flight segment is 9 h. This time may be reduced to 8 h if the following rest period, to begin no later than 24 h after the commencement of the reduced rest period, is increased to 10 h.

If the scheduled flight time is 8 or 9 h, the minimum rest period in the 24 h preceding the scheduled completion of the flight segment is 10 h. This time may be reduced to 8 h if the following rest period, to begin no later than 24 h after the commencement of the reduced rest period, is increased to 11 h.

If the scheduled flight time is \ge 9 h, the minimum rest period in the 24 h preceding the scheduled completion of the flight segment is 11 h. This time may be reduced to 9 h if the following rest period, to begin no later than 24 h after the commencement of the reduced rest period, is increased to 12 h.

Rail (49 U.S.C. 211; 49 CFR Part 228)

Maximum duty limit of 12 h

Must be off duty for 10 consecutive hours after working 12 consecutive hours or off 8 consecutive hours if worked < 12 consecutive hours

Time spent in transportation to duty assignment counts toward on-duty time.

Time spent in transportation from duty assignment does not count toward on-duty or off-duty time.

Motor Carrier (49 CRE Part 395)

Drivers may drive for 10 h or be on duty for 15 h.

Drivers must have 8 consecutive hours off following a duty period of 10–15 h.

If drivers use a sleeper berth, they may split the 8-h period into two periods as long as neither period is less than 2 h.

Drivers may not exceed 70 h in 8 days if the carrier operates 7 days a week.

Drivers may not exceed 60 h in 7 days if the carrier does not operate every day of the week.

Maritime (46 U.S.C. 8104; 46 CFR Parts 15.705, 15.710, and 15.1111)

Hours-of-service or watch requirements vary depending on type of vessel.

An officer must be off duty for at least 6 h within the 12 h immediately before leaving port before taking charge of the deck watch on a vessel when leaving port.

On an oceangoing or coastwise vessel of not more than 100 gross tons, a licensed individual may not work more than 9 of 24 h when in port or more than 12 of 24 h at sea, except in an emergency or a drill.

On a tanker, a licensed individual or seaman may not work more than 15 h in any 24-h period or more than 36 h in any 72-h period, except in an emergency or a drill.

Officers in charge of navigational or engineering watch on board any vessel that operates beyond the boundary line shall receive a minimum of 10 h rest in any 24-h period. The hours of rest may be divided into no more than two periods, of which one must be at least 6 h in length. The hours of rest do not need to be maintained in an emergency. The hours of rest may be reduced to 6 h if no reduction extends beyond 2 days and < 70 h of rest are provided in each 7-day period.

Data from Code of Federal Regulations Web site. Available at: http://www.access.gpo.gov/nara/cfr/waisidx_02/14cfrv2_02.html. Accessed 7/1/02.

cating more funds to increase hospital resources such as to provide for extra staffing. Section 405 has not been uniformly effective at reducing resident work hours, which demonstrates the need for a comprehensive approach to fatigue management.

Implementing work limitations will not be sufficient alone to effectively manage fatigue. Two examples from attempted scheduling strategies in health care illustrate these challenges. In the first investigation, a cross-cover float system was instituted to provide a protected block of sleep time during the night for on-call residents in an attempt to minimize sleep loss.¹⁶⁶ However, the on-call residents did not significantly increase their sleep time because they chose to use the time to catch up on paperwork and other tasks. In another intervention study, participants were provided a variety of strategies and information to improve alertness and performance during night shifts in the emergency department.²⁹ Following the intervention period, the participants did not significantly change their amount of sleep despite the opportunities provided by scheduling changes. Although by limiting work hours they were given the opportunity to increase their sleep, participants were just as sleep-deprived during the intervention phase as during the baseline condition. This suggests that there is no guarantee that individuals will benefit from interventions intended to increase the amount of sleep.

Healthy Sleep. Given the current state of knowledge and the potential safety risks associated with sleep disorders, a comprehensive fatigue management program should include activities related to healthy sleep. These activities could take a variety of forms: (1) provide information on sleep disorders and resources for diagnosis and treatment; (2) provide tools to individuals that would promote their seeking evaluation where appropriate; or (3) identify individuals at risk in a more formal process (*e.g.*, sleep apnea screening). When addressing healthy sleep, it is critical to include family outreach, as this resource may be essential in the ultimate identification and treatment of an individual at risk.

Potential for a Long-term Plan. Sufficient scientific data and operational experience exist to recommend

changes designed to reduce fatigue-related safety risks in anesthesiology. In addition, there is also a clear need to develop a broad, comprehensive, long-term plan to address fatigue in all healthcare settings. Anesthesiology could be on the cutting edge of such reform. Anesthesiologists have already provided leadership in the advancement of patient safety activities.^{1,167} Inherent cultural attitudes and practices are the most challenging impediments to reforming the medical community's management of fatigue. A significant paradigm shift is necessary for universal recognition of fatigue-related risks and acceptance of scientifically validated approaches to improve safety and performance.

There are three steps that could be taken immediately. First, implement an education program regarding fatigue risks, physiologic factors, and effective countermeasures required for individuals throughout the healthcare system. Second, fully support the implementation of effective alertness strategies through education and appropriate institutional policies. Third, develop recommendations for work-rest schedules in health care similar to those that have been promulgated in aviation.¹⁶⁸ An outline of relevant scientific principles can be translated into recommendations that provide a structure that has appropriate flexibility to address unforeseen circumstances. Recommendations for work-rest schedules will have pertinence to the practice of anesthesiology just as they have in the high-hazard industry of aviation. Other safetysensitive, high-performance industries have already established standards for their workers. For example, each of the transportation modes under the Department of Transportation have federally established hours-of-service regulations that limit a variety of relevant scheduling factors. There are few, if any, such restrictions placed on the work hours of physicians. The practice of anesthesiology and patient safety would benefit from similar strategies intended to reduce fatigue and promote safety in these demanding work environments. Because implementation of specific work limits would likely have significant economic and workforce implications on the practice of anesthesia in many settings, limits should not be arbitrarily promulgated without supporting data.

Conclusion

Experimental and survey data from medical and nonmedical settings demonstrate the impact that fatigue has on mood as well as psychomotor and cognitive performance. Recent work suggests that residents may be functioning in a baseline state of long-term sleep deprivation.⁷² Disruption of the circadian clock during nightshift work is associated with decrements in performance of psychomotor tasks and with adverse health effects for personnel. The participants in most studies have been residents rather than older practitioners, and, therefore, the interaction between fatigue and aging remains unknown and must be elucidated.

Public debate on work hours for medical personnel has focused on trainees, and the New York State Health Code and Accreditation Council for Graduate Medical Education regulations are the only policies that have been implemented to limit work hours for healthcare practitioners. The current paradigm of work scheduling for nonresident anesthesiologists has generally remained unchanged, although the healthcare environment has undergone radical alterations over the past decade. As the public and federal agencies advocate practices to make health care safer, we should no longer ignore the accumulating body of data regarding the effects of fatigue and sleep deprivation on performance.

The "24/7" work demands for medical care impose a continuing challenge to all anesthesia providers. Fatigue has become a ubiquitous fact of our professional lives. Only by applying findings from scientific study and focused advocacy can we maintain a practice that is safe for the health of our patients and ourselves.

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