



Long Hours, Little Sleep Bad Medicine for Physicians-in-Training?

Lynne Lamberg

ARLINGTON, VA—A nationwide prospective study will test the hypothesis that long hours with little sleep jeopardizes both clinicians' health and the safety of their patients. It aims to survey all US physicians and dentists in the class of 2002 monthly through their first postgraduate year and perhaps beyond. Most physicians in training in US hospitals are required to work 80 hours or more per week and shifts of more than 30 consecutive hours every third or fourth night. About 80% of physicians and 20% of dentists participate in programs that impose such demands. In some programs, resident physicians allegedly work more than 130 hours per week and are on call every second night.

An intervention study, conducted concurrently, will examine the impact of a schedule designed to minimize extended sleep deprivation in interns in their 3-week rotation in a medical intensive care unit (ICU) or a coronary care unit at Brigham and Women's Hospital (BWH), Boston. The researchers will compare the performance and health of interns working the current national standard ICU resident work schedule—more than 30 continuous hours every third night—with that of those working no more than 12 continuous hours in the ICU, in compliance with a new guidance for residents on ICU duty issued by the Association of American Medical Colleges (AAMC) in October 2001.

Charles Czeisler, PhD, MD, who directs BWH's division of sleep medicine, and a multidisciplinary team of colleagues at Harvard Medical School

will lead both studies, with funding from the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Healthcare Research and Quality (AHRQ).

Czeisler outlined plans for the studies at a national conference on sleep, fatigue, and medical training here in October. Conference speakers reviewed current knowledge of how sleep deprivation affects performance, discussed ways to curb fatigue, identified information gaps, and proposed research opportunities. The conference was funded in part by an AHRQ grant and sponsored by the American Academy of Sleep Medicine, the American Medical Association Council on Medical Education, the National Center on Sleep Disorders Research at the National Institutes of Health, and the Sleep Research Society.

Impetus for the conference and for the BWH studies came from Institute of Medicine (IOM) estimates that medical errors cause more than 1 million injuries to patients in US hospitals each year and may trigger as many as 98 000 deaths annually (Kohn LT, et al. *To Err Is Human*. Washington, DC: National Academy Press; 2000).

A petition calling for establishment of national work-hour limits for resident physicians, filed with the US Occupational Health and Safety Administration (OSHA) in April 2001, also heightened interest in the conference. Signers included Public Citizen, a Washington, DC-based consumer advocacy group; the American Medical Students Association (AMSA); the Committee of Interns and Residents; Bertrand Bell, MD, author of New York's health code restricting resident work

hours; and Kingman Strohl, MD, director of the center for sleep disorders research at Case Western Reserve University, Cleveland.

While physicians' working conditions may contribute to the frequency and severity of medical errors, Czeisler said in a postconference interview, systematic data on fatigue in medical settings is lacking. The 287-page IOM report includes only four brief mentions of fatigue. More than 30 published studies compare job performance by sleep-deprived residents with that of those who supposedly are well rested. Results are inconsistent. Most of these studies are flawed, including his own, Czeisler maintained. "Researchers called residents 'rested' if they slept 7 hours one night," he said. "We know now that is incorrect because residents are chronically sleep-deprived. Attempts to detect differences between them may have been lost in the noise."

The nationwide survey aims to document hours interns actually work, Czeisler said, since some trainees allege discrepancies between their schedules and those their programs report to the Accreditation Council for Graduate Medical Education (ACGME). Work-hour requirements currently vary by specialty. The ACGME, which accredits 7800 post-MD medical training programs in 110 specialties and subspecialties in the United States, does not release information about a specific program's work schedules to the public.

Survey participants will respond to a monthly Web-based questionnaire. About 15 000 new physicians and 4000 new dentists will be eligible for the study. They will report hours worked, medical errors, motor vehicle crashes,



exercise, illnesses such as hypertension and diabetes, pregnancy complications, divorces, and other health and quality-of-life issues that may be adversely affected by sleep deprivation and fatigue. A sampling of participants will wear around-the-clock activity monitors to document their sleep/wake schedules objectively.

The ICU intervention study, Czeisler said, “will bring to bear all the tools we’ve developed over the past two decades to study sleep, circadian rhythms, and performance.” The researchers hope to enroll 20 to 25 interns, whose participation in the crossover study will be voluntary. Interns, who will serve as their own controls, will enter after 2 to 3 weeks on a no-call elective to reduce the impact of prior sleep deprivation.

Throughout the 3-week research periods, during which usual patient protection measures will be in place, they will wear ambulatory digital sleep recorders developed for use on space flights by Czeisler and colleagues (*Am J Physiol Regul Integr Comp Physiol*. 2001;281:R1647-R1664). An observer will continuously monitor their performance, with emphasis on detecting medical errors, lapses in attention, and nodding off. A trained nurse and an intensive care specialist will review charts of all patients under the interns’ care. Errors interns make in a computerized medication order entry system will be flagged. Nurses will be asked to report errors. The interns will be asked to self-report errors, and all self-reports will be verified. The interns also will take computerized performance tests, and their salivary melatonin and cortisol secretion levels—biological indicators of alertness and sleepiness cycles—will be monitored.

“SLEEP DEBT” IS HARMFUL

The concept of “sleep debt” is central to the understanding of fatigue’s impact, Mary Carskadon, PhD, who directs the sleep research laboratory at Bradley Hospital and Brown University School of Medicine, East Providence, RI, said at the conference. Although individual sleep needs vary, most adults need about 8

hours of sleep per day for optimal functioning. Getting less than optimal sleep undermines mental abilities. With less than 5 hours of sleep, performance degrades markedly in most people. Those who consistently shortchange themselves on sleep accumulate a large sleep debt, becoming progressively sleepier as days pass. A single night of “catch-up” sleep won’t reverse a chronic sleep debt.

Fatigue prompts wide-ranging neurobehavioral and cognitive deficits, said David Dinges, PhD, director of the Unit for Experimental Psychiatry at the University of Pennsylvania School of Medicine. As lapses of attention increase, alertness and vigilance become unstable. Cognitive slowing occurs, and time pressure increases errors. Working memory declines.

People may begin tasks well, he said, but their performance slips when they must work fast. They tend to persevere on ineffective solutions and neglect activities they deem nonessential. Involuntary microsleep attacks occur. People then must work harder to act appropriately, and their risk of critical errors rises. Stimulation can mask these cognitive deficits. “A physician may respond to a medical emergency,” Dinges said, “yet fail to recall critical information relevant to patient care or to enter it in a chart.” Unintentional human error is the most common cause of workplace accidents, he noted, and contributes to 30% to 90% of all serious accidents across industries.

Studies of fatigue’s impact on medical trainees consistently show that sleep deprivation undermines mood, said Steven Howard, MD, associate professor of anesthesia at Stanford University School of Medicine. But few researchers, he said, have investigated the impact of irritability, hostility, and indifference on patient-physician relations and physician performance.

RESIDENTS’ CRASH RISK HIGH

Residents are at increased risk of motor vehicle crashes, near-misses, and traffic violations, according to Allan Pack, MD, ChB, PhD, who directs the

center for sleep and respiratory neurobiology at the University of Pennsylvania School of Medicine. Specific risk factors for drowsy-driving crashes, he said, include working at night, sleeping less than 5 hours, feeling sleepy, and having been awake 20 or more hours before the crash. Drowsy-driving crashes—and workplace errors—peak between 4 AM and 8 AM, when human performance dips to its daily low.

One study found more than half of nearly 1000 emergency medicine residents reported one or more near-crashes, and 76 residents (8%) had been in 96 crashes, the vast majority after a nightshift (*Acad Emerg Med*. 1999;6:1050-1053). About 70% of these crashes were single-vehicle crashes, Pack said, as is typical of drowsy-driving crashes. Some 60% of drivers in such crashes suffer injuries. “How much longer are we going to wait to do something about this?” Pack asked.

Several speakers explored practical considerations that bear on possible changes in the medical training environment. Michael Suk, MD, JD, MPH, chair of the American Medical Association’s Resident and Fellow Section and an orthopedic surgery resident at Montefiore Medical Center, New York City, said regulations limiting work hours generally fail to address the balance between service and education. “Residents perceive that lowering hours of service also lowers hours of education,” he said. He called for a broader focus on work conditions that would address such issues as understaffing, and a need for more nursing and ancillary staff to support residents. Although the ACGME offers residents a mechanism for reporting excessive work hours, he said, “nobody wants to be identified as a whistleblower.” There is currently no reporting mechanism, he said, that directly links resident concerns with institutional accreditation.

Marvin Dunn, MD, director of residency review committee activities for the ACGME, noted that it receives relatively few complaints about programs from residents. Among the top five complaints, inadequate work environ-



ment and excessive duty hours ranks second, behind inadequate or no due process and lack of grievance procedures. In 2000, the ACGME cited 8% of programs and institutions it reviewed as being in violation of its work-hour requirements. Programs most cited for work-hour violations were pediatric surgery (44%), general surgery (35%), thoracic surgery (21%), pediatrics (16%), and neurology (14%). The ACGME work group on resident duty hours and the learning environment is scheduled to present its recommendations for making resident duty hours more standard across specialties to the ACGME board next month.

It's difficult to standardize hours in surgical training, said Lazar Greenfield, MD, chair of the surgery department at the University of Michigan School of Medicine. If complications occur in a patient a resident has operated on, he said, it's important for the resident to follow through and see what the problem was. The hallmark of graduate education in surgery, he asserted, is commitment to patient care without regard to time, day of the week, hours worked, or on-call schedule. Studies suggest that technical errors are more likely to occur after care of a patient is transferred to another resident, he said, and that transfers of care lower patient satisfaction.

Robert M. Dickler, MHA, senior vice president for health care affairs at the AAMC, cautioned that reducing residents' hours will increase hours by nurses and other ancillary personnel, changes that would be costly.

CALL FOR ATTITUDE CHANGE

The real work of this 2-day conference began on the second day in morning focus sessions in which meeting attendees sought to identify priorities for future action. Afternoon reports to the group highlighted an overarching theme, a need to create a climate receptive to change, with broad involvement by individuals and professional and lay groups, and a focus on patient safety and outcomes, as well as on the health and safety of health care providers.

Citing a lack of consensus on the impact of sleep deprivation and fatigue on medical trainees, the research panel called for a consensus panel to evaluate existing evidence. It endorsed the nationwide survey of resident schedules. It recommended a retrospective study of Department of Motor Vehicle databases to assess crash risks in house officers and a relevant control group, and establishment of a national registry of motor vehicle crashes in which residents are involved. It called for further study of the role of fatigue on patient outcomes and on resident health outcomes, and of fatigue countermeasures that might involve limited or flexible work hours, new schedule design, strategic use of napping, and appropriate use of caffeine and other wakefulness-promoting agents.

The panel targeting educational priorities called for enforcement of ACGME standards. It said training programs need to teach residents that sleep loss and fatigue are barriers to learning, and to instruct them in good sleep and fatigue management strategies. It also suggested that sleep and fatigue management be included among ACGME general competencies.

Among its wide-ranging suggestions, not all of which may finally be incorporated into practice, the panel recommended changes in the institutional environment, such as a reduction of "scut work," better use of technology, improved call-room comfort, and instruction for ancillary staff on ways to protect residents' sleep. It called for attending physicians to spend more time with residents, and suggested that an attending physician be held liable for knowing a house officer is impaired and allowing that person to continue to work or drive.

The patient safety panel sought data from controlled trials, surveys, retrospective studies, and other sources to clarify how sleep deprivation and fatigue affect patient safety, and to verify that minimizing these problems improves patient safety. It called for study of medical errors and near-misses to identify desirable systemwide changes.

It also highlighted the need to show that fatigue management is cost-effective in improving patient safety.

The residents' panel addressed work conditions, calling for a standard definition of work hours, with attention to total hours and intensity. It sought clarification of a distinction between service and education, addressing health and quality of life of residents and students. It urged research on optimal learning environments and times of day, and time-motion studies to study such issues as whether the number of pages at night could be limited. It also highlighted the need to involve the entire hospital community in fostering ways to diminish fatigue. Additionally, it advocated giving more power to the ACGME, residency review committees, and other supervisory bodies, possibly through fines, the judicial system, and public disclosure.

A report detailing these recommendations and plans for their implementation is scheduled for publication later this year.

CONGRESS GETS INVOLVED

New York currently is the only state with resident work-hour regulations. Adopted in 1989, its rules limit residents' workweeks to 80 hours and shifts to a maximum of 24 hours. Massachusetts may become the second. The Massachusetts Medical Society adopted a resolution in November 2001 calling for restrictions comparable with those in New York, and urging its board to propose state legislation to enforce these rules.

Also in November, Rep John Conyers, Jr (D, Mich) introduced federal legislation that would limit resident physician work hours. The Patient and Physician Safety and Protection Act of 2001, HR 3236 (<http://thomas.loc.gov/>), would limit the work week of residents to 80 hours and any one shift to 24 consecutive hours (12 hours in emergency departments). It also would provide residents with a minimum of 10 hours off between shifts, at least one day off out of seven, and one full weekend off per month. It would limit on-call shifts to one in every three nights. The proposed leg-



islation also would provide for public disclosure of hospitals found in violation of work-hour limits, and allow the US Department of Health and Human Services, with help from the medical community, to develop regulations to

ensure appropriate supervision of resident-physicians. The bill calls for annual surveys of resident working conditions. It also provides for anonymous resident complaints about work-hour violations, civil penalties for hospitals

with excessive work hours, and funds for additional hospital staff to relieve residents of the burden of noneducational activities.

For more information, see <http://www.amsa.org/hp/reswork.cfm>. □

Integrating Complementary Therapy Into Care

Janet M. Torpy, MD

CHICAGO—Physicians were given a glimpse of the world of alternative and complementary medicine last month at the third annual conference sponsored by the University of Chicago Center for Alternative Therapies and the Tang Center for Herbal Medicine Research, where practitioners of nontraditional methods of health care suggested how they might be integrated into primary care and specialist practice.

TREATING OBESITY SAFELY

John La Puma, MD, director of the Cooking, Healthy Eating and Fitness (CHEF) Clinic, Santa Barbara, Calif, spoke about the increasing prevalence of obesity and various approaches to its treatment. “I advocate making small changes . . . and self measurement,” he said. “We give patients pedometers, to let them monitor their physical activity.” Patients who seek La Puma’s advice for weight loss undergo medical evaluation then are encouraged to set goals and count weekly steps toward meeting them. “Identifying how patients eat is as important as what they eat,” he said, because people eat out of boredom, anxiety, habit, convenience, and timing, not just because they are hungry. He said that food, ubiquitously available to most Americans, “has a psychological aspect, it’s a comfort, warm and companionable, and it makes you feel good for a short time.”

Commenting on the epidemic of obesity—now a problem so serious that it was the subject of the recent surgeon general’s report, *Call to Action to Prevent and Decrease Overweight and Obesity*—La Puma stated, “It’s a jungle out there, you

can’t walk down the street without seeing a [gourmet coffee shop], or having somebody offer you a candy bar.” Most people struggling with extra pounds have an unrealistic perception of possible weight loss, he said, explaining that losing 10% of body weight, while helpful for decreasing risks of complications due to obesity, doesn’t measure up to expectations of greater than 30% weight loss. “Most people, when polled, find even weight loss of 25% of body weight unacceptable,” he asserted.

While a diet rich in fruits and vegetables, with limits on portion size and moderation in saturated fat consumption, seems common sense to most physicians, helping patients sort through claims of rapid and dramatic weight loss with pills or supplements is no easy task. Herbal therapies and other nonprescription weight-loss products are used by 17 million people in the United States, said La Puma. He cited a multistate survey that showed that more than 28% of obese women in the country had used at least one nonprescription weight-loss product in the previous 2 years (*JAMA*. 2001; 286:930-935). When crafting a weight-loss plan for patients, La Puma said, “Figure out what each patient does well [and tailor the program accordingly]. These patients are not naive about weight management.”

A popular over-the-counter dietary supplement, Metabolife, contains ma huang (an herbal preparation of ephedra) and guarana (caffeine), along with other herbal ingredients. Someone taking this product, said La Puma, “will lose weight; it is an effective, but dangerous, product.” A recently published clinical trial (*Int J Obes*. 2001; 25:316-324) reported that of 35 patients

taking Metabolife, eight dropped out of the treatment group because of palpitations and chest pain. “I do not recommend these products to anyone with risk factors for or known cardiovascular disease or hypertension, to nursing mothers or pregnant women, or to any man with prostate cancer,” La Puma stated. Seventeen deaths and more than 140 other adverse events linked to ephedra have been reported to the US Food and Drug Administration’s MEDWATCH system, said La Puma.

HALTING HYPERLIPIDEMIA

In addition to products for weight loss, many herbal preparations and other alternative remedies exist for the purported reduction of hyperlipidemia. At the recent Chicago conference, Philippe Szapary, MD, assistant professor of medicine at the University of Pennsylvania School of Medicine, reviewed evidence for lipid modulation using over-the-counter products such as garlic, coenzyme Q10 (ubiquinone), red yeast rice, guggulipid, fish oils, and soy.

Garlic, often taken in pill or powder form, has shown inconsistent effects in reducing low-density lipoprotein (LDL) cholesterol, Szapary said. Guggulipid decreases LDL cholesterol and triglycerides by 15% to 20%, but has questionable effects on high-density lipoprotein (HDL) cholesterol. It appears to inhibit liver cholesterol synthesis. Trials are ongoing, said Szapary. He predicted the future would see marketing of “an increasing number and variety of functional foods and investigation of agents that have lipid-modulating effects and antioxidant, anti-inflammatory, and vasodilatory properties.” Functional foods have been defined as



“foods that contain some health-promoting component(s) beyond traditional nutrients” (*Intl Dairy J.* 1998; 355-362). They are also known as nutraceuticals, designer foods, medicinal foods, therapeutic foods, superfoods, foodiceuticals, and medifoods.

HYPERTENSION TREATMENT

“Garlic may be even more useful for treating hypertension than for reducing cholesterol, but we need more randomized trials,” Szapary said. He urged caution in interpreting blood pressure end points in studies that purport to show that ingesting garlic preparations reduces cholesterol (*J Hypertens.* 1994;12:463-468), because the patients in these trials did not have hypertension. Szapary stressed that cooked garlic exerts no antihypertensive effect and said that patients taking antiplatelet agents, [including] aspirin, should avoid ingesting garlic supplements because of their anticoagulant properties. (See also p 308.)

The mixed results from trials of vitamin C for treatment of hypertension led Szapary to stress the controversial nature of using supplements to treat patients with coexistent hypertension and coronary artery disease. Unpublished data from a recent American Heart Association meeting showed an increase in intimal medial thickness of the carotid artery in smokers with hypertension taking supplemental vitamin C, he said. Szapary said the action of vitamin C obtained from food may be different from that of supplements, citing a study that showed attenuation of the HDL cholesterol-raising effects of simvastatin and niacin in patients who took 1000 mg of vitamin C as part of an antioxidant cocktail (*N Engl J Med.* 2001;345:1583-1592). “The role of vitamin C supplements in patients with established coronary artery disease is unclear,” he concluded.

BENEFICIAL BREATHING

The mind-body connection, however, appears to be helpful in reducing blood pressure, Szapary said: “It is very useful and has been studied in patients with hypertension, and [patients] can use

techniques from various traditions.” Tai chi, he said, “may have its greatest impact in the elderly [who have] limitations from osteoarthritis or cardiovascular disease. It has been shown to reduce falls, and may have benefit on cardiovascular disease for people who are not as mobile as you would like.”

Selecting which technique to recommend may seem difficult, but Szapary advised, “It depends on what appeals to each patient, yoga or transcendental meditation or tai chi [or other techniques], but teaching them to breathe seems to have beneficial health effects, especially in patients with hypertension.” Other benefits of mind-body techniques, he said, include improved balance, flexibility, and sense of well-being.

RISK MAY OUTWEIGH BENEFIT

The adverse effects of garlic and other herbal remedies may outweigh their benefits in some patients, warned Charise Petrovich, MD, clinical director of the Department of Anesthesiology at Providence Hospital in Washington, DC. “Herbal products have been used for centuries, and there has been a huge rise in their consumption despite a lack of scientific data,” she said, “and some people believe that ‘natural’ is better, no matter what. They rely solely on testimonials, and use alternative therapies because there are no cures for many common diseases.”

Because herbal products make no claim to treat ailments and therefore are not considered medicines, Petrovich reminded listeners, no FDA regulation or oversight applies to them. “But herbals do have medicinal effects,” she said, “and since there are no quality controls or oversight, you may be consuming very expensive sawdust. You may be taking products contaminated with heavy metals, such as lead, arsenic, or mercury—so you may get a treatment, a placebo, or a toxic supplement.” Petrovich warned against herbs shown to have carcinogenic effects, such as borage, coltsfoot, comfrey, and life root. “Those contain pyrrolizidine alkaloids, and are linked to hepatic can-

cer in animals,” she said. Also shown to be hepatotoxic are chaparral and germander, which can cause jaundice, pruritus, fatigue, cholestasis, and hepatic necrosis in humans.

Addressing herbals’ danger to patients presenting for anesthesia and surgery, Petrovich stated, “The public is not aware of these adverse effects, they’re just looking to improve their condition.” Adverse effects of herbal preparations such as ephedra include hypertension, anxiety, palpitations, and hallucinations or paranoia. These effects may become magnified in the operating room under the influence of medications administered for anesthesia or sedation. “We see extreme hypertension, and [cardiac] dysrhythmias,” she said. “In Washington, DC, we assume it’s because of cocaine use, but these are often related to herbal supplements.”

The root of the problem, Petrovich said, is that “patients don’t tell their physicians about herbal products, because they believe [the herbals] are not medicines, or that the physician doesn’t know anything about herbals anyway.”

Anticoagulant effects of garlic, ginseng, ginkgo, feverfew, fish oils, fenugreek, and licorice, among other substances, can spell danger for patients at risk of bleeding during surgery. “Plastic surgery procedures in general, and facelifts specifically, can be devastated by bleeding,” Petrovich said. “There are compounding reasons for coagulation, and with herbals you may be bringing in the risk of an [otherwise] unnecessary transfusion.”

Efforts to reduce postoperative nausea and vomiting, a common problem that may influence surgical recovery, have led to scientific studies of prescription medicines, experimental drugs, and herbals, particularly ginger. “Ginger has shown some effects in the treatment of hyperemesis gravidarum, but unfortunately was ineffective for postoperative nausea, vomiting, or both,” said Petrovich. In conclusion, she said, “We know there’s something going on, but we don’t have the scientific studies or regulatory controls to track [herbals’] effects.” □