

COMING SUMMER 2008!

Sleep HealthCenters® Corporate Sleep Program

The Corporate Sleep Program is an all-inclusive sleep disorders screening, diagnostic and treatment program for employee groups across the United States.

Sleep screening is particularly important for companies who wish to improve worker alertness and reduce the risk of fatigue-related accidents.

Companies in the transportation industry, those with multi-time-zone travel, professional drivers or shift workers would benefit from a Corporate Sleep Program.

Stay tuned for more information and please let us know if you have a specific group you would like us to contact.



Sleep HealthCenters is a network of sleep medicine centers staffed by experts in the field of sleep medicine. Our integrated care system provides all the services needed to diagnose and treat patients with the entire array of sleep disorders including obstructive sleep apnea, insomnia, narcolepsy and restless legs syndrome.

In this issue of the Sleep HealthCenters Newsletter...

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Massachusetts Affiliations: Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Faulkner Hospital, Hallmark Health, Marlborough Hospital, Massachusetts Eye and Ear Infirmary, McLean Hospital, New England Sinai Hospital, Southcoast Hospitals Group; *New York Affiliations:* Beth Israel Medical Center

Massachusetts Locations: Bedford, Beverly, Boston, Brighton, Framingham, Jamaica Plain, Marlborough, Medford, North Dartmouth, Stoughton, Weymouth, Worcester; *New York Locations:* Manhattan

For more information, please contact us at: 1-877-SLEEPHC (1-877-753-3742) or visit our website at www.sleephealth.com.

Requisition forms are available on our website.

Sleep HealthCenters® Newsletter

Lawrence J. Epstein, MD, Editor

Spring 2008

Dear Colleague,

In this issue of the Sleep HealthCenters Newsletter, Christopher Landrigan, MD, MPH, Director of the Sleep and Patient Safety Program at Brigham and Women's Hospital writes our feature article on the vital topic of Drowsy Driving. Whether due to getting an insufficient amount of sleep or having any of a variety of sleep disorders such as sleep apnea or narcolepsy, patients with sleep problems are at increased risk for motor vehicle accidents. Dr. Landrigan is uniquely qualified to address this topic. In addition to his work on patient safety and resident work hours, Dr. Landrigan has studied the effect of sleep deprivation on performance and is currently involved in attempts to write legislation to decrease fatigue related accidents and educate drivers on the risk of drowsy driving.

In his article, Dr. Landrigan discusses the scope of the problem of sleep-related motor vehicle crashes and describes the mechanisms by which sleep deprivation impairs performance and leads to crashes. In addition to identifying those at risk for sleep-related accidents, he also explains countermeasures that are effective in reducing the risk of a drowsy driving crash.

In March, the Center for Medicare and Medicaid Services (CMS) released a new National Coverage Determination policy for the coverage of continuous positive airway pressure (CPAP) for patients with obstructive sleep apnea (OSA). In response to new evidence, they have approved coverage of CPAP if the diagnosis of OSA is made using portable monitors for home testing in addition to the standard in-laboratory polysomnogram. In a special section, Paul Valentine describes Sleep HealthCenters' home sleep testing program. Sleep HealthCenters has been performing home sleep tests for more than 10 years and is already capable of providing high quality testing as well as comprehensive evaluation and management of patients with OSA.

Finally, Sleep HealthCenters would like to congratulate Charles A. Czeisler, MD, PhD, Chairman of the Division of Sleep Medicine at Harvard Medical School and Brigham and Women's Hospital. Dr. Czeisler was recently honored by the National Sleep Foundation with a lifetime achievement award for his dedication to excellence in sleep science, commitment to mentoring young investigators and advancement of sleep in public health policies.

If you have any questions about sleep disorders, our services, our affiliations, or our locations, please feel free to contact us.



Sincerely,
Lawrence J. Epstein, MD
Medical Director
Sleep HealthCenters LLC



Drowsy Driving

Christopher P. Landrigan, MD, MPH

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On the morning of June 26, 2002, a teenage driver fell asleep at the wheel after staying up all night playing video games. He collided with and killed Major Rob Raneri of Holliston, MA just a week before his wedding. This tragedy set in motion a chain of events which resulted in the recent passage in Massachusetts of legislation that restricts teen drivers with junior operator licenses from driving their vehicles between 12:30am and 5:00am, and initiated driver training in the consequences of sleep deprivation.

How widespread is the problem of drowsy driving? What can be done to address it?

Epidemiology. Motor vehicle crashes (MVCs) result in approximately 43,000 deaths each year in the United States, making them the eighth leading cause of mortality at all ages; in individuals less than 35 years of age, they are far and away the leading cause of death. While the role of alcohol and drugs in MVCs has long been appreciated, the importance of drowsiness has only recently begun to be fully recognized.

The scope of the drowsy driving problem is astounding. Fatigue is cited by police officers as the cause of the crash in approximately 56,000 crashes per year and 1,550 fatalities (~3% of fatal MVCs). The true number is believed to be much higher as data on fatigue are not routinely collected by police officers in most states. Thirty-seven percent of drivers report having nodded off while driving, with 10% acknowledging having done so in the past month. One in three of these drivers woke up after drifting out of their lane or onto the shoulder of the road; 19% crossed the center line; and 10% ran off the road. The National Highway Traffic Safety Administration estimates that approximately 292,000 drivers were involved in a motor vehicle crash within the past six months due to nodding off at the wheel. Among commercial truck drivers, the National Transportation Safety Board has cited fatigue as the most common probable cause of fatal-to-the-driver heavy truck crashes, exceeding the number due to alcohol and drugs combined.

These estimates have been corroborated by recent research that has used intensive observational methods to collect prospective data on the causes of motor vehicle crashes. In the 100-Car Naturalistic Driving Study, investigators equipped 100 vehicles with multiple cameras directed at the roadways and drivers, gathering approximately 43,000 hours of data on drivers, motor vehicle crashes, and their causes under routine non-commercial driving conditions. They found that the drivers experienced 82 crashes and 761 near-crashes over the course of a year. Fatigue was a contributing cause in 22% of all MVCs and 16% of all near-crashes, a number far in excess of that suggested by police reports. Extrapolating from this figure to the annual number of MVC fatalities, as many as 8,000 fatigue-related fatal crashes could occur each year in the U.S.

Mechanisms of Drowsy Driving. Sleepiness and consequent performance is determined principally by two neurobiological systems: the sleep homeostat and the circadian system. The sleep homeostat is the system responsible for increasing sleepiness with increasing time awake, regardless of time of day. The longer one has been awake without sleep, the greater the drive to sleep. Being awake for 24 consecutive hours impairs reaction time as much as a blood alcohol level of 0.10. In addition, the drive to sleep can build up as a consequence of chronic partial sleep deprivation, that is, getting too little sleep for many days in a row. After 10-14 days with 6 hours of sleep per night, the average person's reaction time will deteriorate to a level equivalent to that induced by 24 hours of acute sleep deprivation. The circadian system superimposes a near-24 hour cycle of performance on top of the effects due to the sleep homeostat, with the nadir of performance normally occurring a few hours prior to waking (i.e., between approximately 3 and 6am for most people). In addition to these two systems, sleep inertia, an impairment of performance in the first few minutes after awakening that can be quite severe, can also lead to performance decrements. Each of these neurobiologic factors, alone or in isolation, can lead to lapses of attention that increase the risk of a drowsy driving crash (note: further information on these factors can be obtained by reading the article on Sleep Loss, Drowsiness and Performance by Dr. Shantha Rajaratnam, published in the October 2006 Sleep HealthCenters Newsletter). (continued on page 2)


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Sleep HealthCenters® Newsletter

(continued from page 1) Drivers operating in the middle of the night are at particularly high risk of reaction time slowing and a fatigue-related crash if they have been up for more than 16 hours and are operating near the circadian nadir. However, poor reaction time is only part of the problem. Drowsy drivers are also at risk of suddenly falling asleep at the wheel, thereby losing all ability to respond to dangerous situations.

Risk Factors. In many respects, the crash that killed Major Raneri was typical of drowsy driving crashes: the driver who fell asleep was young, acutely sleep deprived, and suddenly drifted across the center line when he fell asleep and crashed. Known risk factors for drowsy driving crashes include the following:

- **Acute or chronic sleep loss**, as described above.
- **Driving at night.**
- **Shift work**, due both to circadian misalignment and often chronic partial sleep loss among shift workers.
- **Use of sedating medications.**
- **Young age.** Two out of three drowsy driving injuries are caused by drivers in their teens and twenties. Most young drivers, however, are completely unaware of the dangers of drowsy driving. Young men appear to be at particularly high risk.
- **Untreated sleep disorders.** Obstructive Sleep Apnea Syndrome in particular is associated with a seven-fold increase in risk of road traffic accidents. Narcolepsy has also been shown to convey an increased risk of MVCs.
- **Consumption of alcohol** synergistically interacts with sleep deprivation to degrade driving performance and increase risk more than would be predicted by a given amount of alcohol or sleep deprivation alone.

Beyond an assessment of these individual factors as risks for drowsy driving, clinicians should keep in mind that having multiple risk factors will tend to increase total risk.

Countermeasures. Several countermeasures have been demonstrated effective in reducing the risk of a drowsy driving crash. These are as follows:

- **Avoiding driving (when possible) between midnight and 6am**, near the time of the circadian nadir.
- **Napping.** Taking a nap prior to a long drive can decrease the risk of a crash. In addition, pulling over to take a nap when

a driver becomes drowsy has been shown to improve performance, though care must be taken to avoid sleep inertia (described above) immediately upon awakening. Even a 15-20 minute nap can be helpful, but ideally, drivers should wait an additional 15-30 minutes after awakening before driving again, to allow the worst effects of sleep inertia to dissipate.

- **Avoiding alcohol when drowsy.**
- **Drinking caffeine.** Caffeine has been found to be most effective as a countermeasure when small doses are taken frequently throughout the waking period, or throughout a long drive.
- **Treatment of Narcolepsy and Sleep Apnea Syndrome.** Successful treatment of OSAS with continuous positive airway pressure (CPAP) therapy has resulted in a six- to seven-fold decrease in driving accident rates.
- **Reduction of sleep deprivation through reducing the intensity/misalignment of work schedules and employee sleep hygiene.**

The following countermeasures have **not** been found to be effective:

- Listening to the radio.
- Opening the window.
- Talking to another passenger or on a mobile phone (in fact, speaking on a mobile phone has been found to increase crash risk in several studies).
- Chewing gum or eating.

Altogether, compelling data have emerged demonstrating that drowsy driving is a major public health problem, and one amenable to correction through a combination of safer policies, driver education, and clinician treatment of sleep disorders. Adequately addressing the problem has the potential to substantially reduce the burden of motor vehicle crashes in the United States.

For a fully referenced version of this article, visit the Sleep HealthCenters website at www.sleephealth.com.



RESEARCH ACTIVITIES

Sleep HealthCenters is proud to work with some of the premier sleep researchers in the country. The following research studies are currently underway in conjunction with our partners. To take part in a study or for more information, please contact us toll free at 877-SLEEPHC (877-753-3742). For a full listing of our research activities, please log onto our website at www.sleephealth.com.

Waking up unrefreshed day after day? Sleep is vital for us to function effectively. Yet there are many people who, day after day, wake up feeling unrefreshed or unrestored. This non-restorative sleep condition, or NRS, leaves you tired – impairing your thinking and your ability to perform at your best.

- Are you male or female aged 18-64?
- Have you been waking up unrefreshed and unrestored at least three times a week for the past three months despite getting to sleep and staying asleep normally?
- Do you feel your lack of restorative sleep impairs your daily performance and activities?

If you answered 'yes' to the above questions, you may be eligible to participate in a ten-week research study of an investigational medicine for non-restorative sleep. If you qualify, you will receive study-related evaluations and investigational medicine at no cost, plus compensation for time and travel.

If interested, please contact Melissa Maywalt at Sleep HealthCenters by calling 617-783-1496 x121.

Do you snore? Sleep HealthCenters is looking for people who have never had an overnight sleep study. Is that you?

The purpose of this research study is to see how well devices called portable monitors work for diagnosing Obstructive Sleep Apnea at home. Participants will wear a portable monitor for two consecutive nights at home and will wear a portable monitor during their scheduled overnight sleep study.

If interested, please contact Melissa Maywalt at Sleep HealthCenters by calling 617-783-1496 x121.

Sleep Apnea and High Blood Pressure. Brigham and Women's Hospital in Boston seeks 20 to 75 year old males and females with high blood pressure (ranging from 135/85 to 160/100) and obstructive sleep apnea to participate in a research study investigating a new treatment for high blood pressure. The study involves using a breathing device every day at home for 8 weeks. You may continue to take your blood pressure medicines during the study. You will have your blood pressure measured for 24 hours every 4 weeks. You will receive up to \$550.00 payment for participation.

For more information on the "Hy-PAP study" please call Ashley toll-free at 1-877-1-SNORE2 x2 or email at hypap@partners.org.

Do you get out of bed to eat at night, after you have gone to sleep? Do episodes of repetitive eating at night feel out of your control? You may have Sleep-Related Eating Disorder, which can disrupt your sleep and health. The Sleep HealthCenter associated with Brigham and Women's Hospital in Brighton is conducting a research study on an investigational medication for Sleep-Related Eating Disorder. Qualified participants can receive study medication and medical evaluation at no cost.

If interested, please call Lisa at the Sleep HealthCenter associated with Brigham and Women's Hospital by calling 617-783-1496 x115 or email at sleepresearch@sleephealth.com.

CEO CORNER

Paul S. Valentine
President and
Chief Executive Officer

We were thrilled to take part in National Sleep Awareness Week® 2008 (NSAW), a public education, information and awareness campaign that coincides with the return of Daylight Saving Time, the annual "springing forward" of clocks that can cause Americans to lose an hour of sleep. This year, NSAW took place from March 3-9 and we participated by holding several events around Massachusetts and New York City in order to help raise awareness in the community about the importance of sleep. The open houses held at our Framingham and Brighton locations allowed the public to see what a sleep lab actually looks like and to ask questions of our knowledgeable sleep technicians, CPAP Therapists, physicians and administrators.

Several of our physicians reached out to the community by speaking at events promoting healthy sleep habits and discussing various sleep disorders. By teaming up with many of our affiliates, we were able to spread the word about the importance of getting a good night's sleep to interested members of our communities.

During National Sleep Awareness Week, the National Sleep Foundation hosted its 8th Annual Awards Dinner, during which our colleague, Dr. Charles A. Czeisler of Harvard Medical School and Brigham and Women's Hospital, was honored with a lifetime achievement award. Congratulations Dr. Czeisler on receiving this great honor.

In February, our CPAP Management Program was accredited by the Community Health Accreditation Program (CHAP). CHAP's purpose is to objectively validate the excellence of community healthcare practice through consistent measurement of the delivery of quality services. We are honored to have received this validation of the quality we provide to the community and to be associated with CHAP.

Finally, we are happy to announce the opening of our North Dartmouth satellite facility, which was created in order to satisfy the new Independent Diagnostic Testing Facility standards set by Medicare. This new facility is conveniently located at 84 Faunce Corner Road, across the street from our current facility. It features two private patient bedrooms.

We are proud of the continuing efforts of all members of our organization and hope that your patients continue to be satisfied with our services. Please do not hesitate to contact us if you have any questions.

Home Sleep Testing for OSA

The sleep medicine community has been embroiled in a lengthy, sometimes heated, debate about the benefits and applicability of home sleep testing (HST) to justify the use of continuous positive airway pressure (CPAP) for obstructive sleep apnea (OSA) patients. Perspectives from all types of entities have been expressed on the topic and there are still many unanswered questions. However, Medicare recently changed their National Coverage Determination (NCD) policy on CPAP to allow the use of HST to diagnose sleep apnea and initiate CPAP therapy.

In addition to a number of other minor changes AND subject to local coverage determination limitations and requirements, there were two major modifications included in the March 13, 2008 memo. The first change now allows CPAP to be covered for adults when OSA is diagnosed using a clinical evaluation and a positive in-laboratory polysomnogram, OR a clinical evaluation and an unattended home sleep test using a Type II, Type III, or Type IV device (Type IV devices must measure at least three channels). The second change states that coverage of CPAP is initially limited to a 12 week period for beneficiaries diagnosed with OSA. CPAP is subsequently covered ONLY for those beneficiaries diagnosed with OSA whose OSA improved as a result of CPAP during this 12 week period.

With Medicare making this change, we are likely to see other payers consider the use of home sleep testing. In fact, Aetna issued an update to their policy earlier in March doing just that. We have been communicating with the local commercial payers as well as the local Medicare carriers to ensure that Sleep HealthCenters is well versed and aware of any changes to sleep study and CPAP insurance coverage policies. We are happy to share what we learn at your request.

At Sleep HealthCenters, we have been performing a limited number of home sleep studies for approximately 10 years. In fact, our requisition form has offered "Home Diagnostic Sleep Study. . .to be determined by clinical criteria and insurance coverage" for quite some time. In reality, these qualifiers still apply. Insurance coverage is very much still in question, depending on the payer and the local carrier or fiscal intermediary. Clinical criteria is still an unanswered question. We believe that patients eligible for home sleep testing include the following:

1. Patients suspected of having moderate to severe OSA as supported by symptoms of OSA, adjusted neck circumference, and presence of excessive daytime sleepiness.
2. Targeted high risk populations, such as bariatric surgery patients.

3. Patients unable or unwilling to be studied in a sleep laboratory.

We have also defined two patient populations that should be excluded from home sleep testing:

1. Those with co-morbid conditions including but not limited to moderate to severe pulmonary disease, neuromuscular conditions or heart failure.
2. Patients suspected of having sleep disorders other than OSA.

With regard to the CPAP requirement for OSA improvement, clearly it is critical that each individual patient is managed effectively. At Sleep HealthCenters, we provide the full continuum of care for all patients with sleep disorders. Our CPAP management program provides the key features identified to improve compliance: intensive patient counseling, education, monitoring and follow-up. Typically, the process begins during the consultation with one of our sleep specialists. They will educate the patient about OSA and discuss treatment options, then introduce the patient to an experienced CPAP Counselor for immediate PAP setup without the patient ever leaving the clinic.

During the setup appointment, the therapist ensures that the patient begins with the most appropriate interface and is educated about expectations for their initial experience. The patient returns for a follow-up visit one week later with a nurse practitioner or CPAP Counselor to review their comfort and compliance, and to address any side effects. Patients are then seen at intervals of one month, three months, six months, and one year by a member of the care team, which is comprised of a physician, nurse practitioner and CPAP Counselor. CPAP compliance, to both the therapy as well as the follow-up schedule, is tracked and progress reports are sent to the ordering physician to keep them informed.

In May, we will be offering a new service for those patients who may be suitable for home sleep testing, depending on their insurance coverage. Patients can be seen for an afternoon/late evening appointment to be set up and educated on the use of a HST device. They, then, return home and use the device that night. The next day they have a second appointment at our facility, at which time the study is scored and interpreted, they meet with a sleep specialist to review the study, and they are setup on CPAP before walking out the door of our facility. In effect, we are diagnosing and treating the patient within 24 hours!

We appreciate your trust in us and hope that we can continue to satisfy the needs of your office and your patients. If you have any questions for us regarding home sleep testing, please do not hesitate to contact us.