

WAKE-UP CALL

FROM THE AMERICAN SLEEP APNEA ASSOCIATION

S P R I N G 2 0 0 8

ASAA A.W.A.K.E. NETWORK NEWS

A number of A.W.A.K.E. groups mounted special programs in observance of Sleep Apnea Awareness Day on March 6. The most ambitious of these was put on by **West Metro A.W.A.K.E.** in St. Louis Park, Minn., which held an all-day sleep fair that featured the official public premiere of the American Sleep Apnea Association's "What Is Sleep Apnea?" movie. Executive Director Edward Grandi was on hand to introduce the movie and take questions from the large and appreciative audience. The DVD was also aired during SAAD events at **Carroll Hospital Center A.W.A.K.E.** in Westminster and **A.W.A.K.E. of Salisbury**, both in Maryland, and at **Southwest Mississippi A.W.A.K.E.** in McComb. We urge all A.W.A.K.E. coordinators to consider making the video the centerpiece of an upcoming meeting.... The focus was squarely on sleep – or the lack thereof – at the spring meetings of several groups. At the April meeting of **Tangipahoa A.W.A.K.E.** in Hammond, La., pulmonologist Lauren L. Davis posed the question: "Is Your Sleep Schedule in Tune With Your Body Clock?" **A.W.A.K.E. in Duncan**, in Okla., presented a talk by Mary Ann Ross on melatonin and its relation to the sleep-wake cycle. **Central Indiana A.W.A.K.E.** in Carmel listened to Dr. Hany Haddad speak about "Insufficient Sleep." At **A.W.A.K.E. in the Mid Hudson Valley** in Kingston, N.Y., respiratory therapist Tony Pickston expounded on "The Dangers of Sleep Deprivation," while at **Tampa General Hospital A.W.A.K.E.** in Florida, Dr. Karen Milo spoke about insomnia....

A.W.A.K.E. - ALERT, WELL, AND KEEPING ENERGETIC

HOOKING UP AT HOME

Medicare Approves Coverage for Home Sleep Studies

Countless snorers have no doubt thought, as they packed up their jammies and headed to the sleep lab for an overnight study, "Boy, it sure would be nice if I could do this at home in my own bed." In fact, home studies – also known as portable monitoring – have been around as long as CPAP. But persistent questions about their reliability, and the consequent refusal of most insurers to pay for them, have kept them out of the mainstream of practice.

That's all changing. In March, the Centers for Medicare and Medicaid Services, whose reimbursement rules are generally adopted by private insurers, dropped its long-standing opposition to home studies. According to the National Coverage Determination that was released that month, a diagnosis of Obstructive Sleep Apnea can be made – and CPAP therapy covered – on the basis of a clinical evaluation coupled with a home study using a device that measures, at a minimum, airflow, heart rate, and oxygen saturation.

A positive diagnosis is established if: The apnea-hypopnea index as measured by the portable device is 15 or more (15 apneas an hour) or the AHI is between 5 and 14 and the patient has documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, hypertension, ischemic heart disease, or history of stroke.

The NCD specifies that the home study must be ordered and supervised by the treating physician. It also limits the initial coverage of CPAP to a 12-week trial period.

Previous to its 2008 decision, the CMS had considered – and rejected – home studies on four occasions. In its last rejection, in 2005, the government body declared that there was insufficient evidence to support the contention that portable monitoring was a valid diagnostic tool.

It was asked to revisit the issue by the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS). An association of specialists who treat conditions of the ear, nose, and throat, the AAO-HNS in its petition to the CMS maintained that the prevalence of Sleep Disordered Breathing, combined with a paucity of laboratories that could perform the required polysomnographic studies, resulted in unacceptable delays in diagnosis and treatment. Citing a number of studies, the organization stated that "home sleep testing is a validated alternative" to lab testing, and declared that "it is incumbent upon CMS to lead the way to improve diagnostic and treatment paradigms" by covering portable monitoring.

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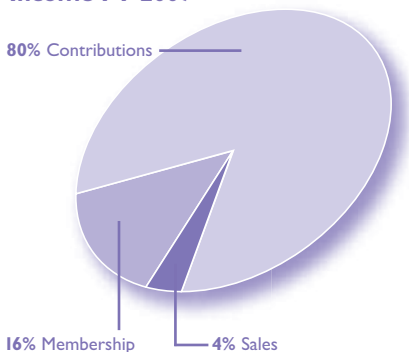
AMERICAN
S L E E P
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A LETTER FROM EDWARD GRANDI

The spring newsletter coincides with the anniversary of my appointment as executive director of the American Sleep Apnea Association and the completion of the audit of our financial records. I use my letter to deliver a brief summary report to our readers.

First, the good news. As I begin my fifth year of leading the ASAA, I am heartened by what we have accomplished. I believe we have had a positive impact on the lives of apnea patients through the resources we offer: this newsletter, our patient education bulletins, our network of A.W.A.K.E. support groups, our online Apnea Support Forum. Through our media outreach, we have succeeded in raising awareness of sleep apnea as a serious health concern, and people are recognizing the ASAA as the leader in the field of sleep apnea education.

Income FY 2007



The Centers for Medicare and Medicaid Services decision on home studies (see cover story) will have a significant effect on the American Sleep Apnea Association. The increased availability of diagnostic tools is likely to increase the number of people contacting the ASAA for unbiased and objective information about their options.

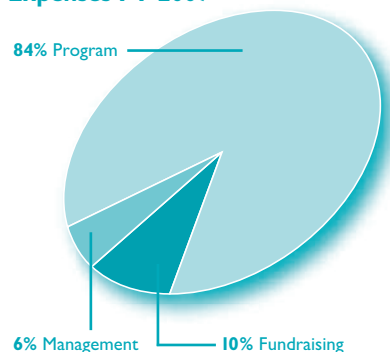
We are fortunate to have a new educational DVD that physicians everywhere can use to educate their patients. I encourage you to tell your doctors about it, and suggest they have it playing in their waiting rooms.

I am also pleased that our Apnea Advocacy Action Project is still up and running, thanks to the renewal of a grant from ResMed. Participants in the project last year helped secure a congressional allocation of \$800,000 for the Centers for Disease Control and Prevention to

monitor sleep disorders in the United States. The ASAA will go back to Congress this year to make sure the funding continues in 2009. We are working with various organizations to identify other issues of concern to apnea patients and their families. You can monitor the legislative issues and make your voice heard by visiting www.sleepapnea.org/advocacy.

Now, the news that isn't so good. The finances of the association for the fiscal year that ended on June 30, 2007 are a bit unsettled. Though the charts show an increase in the amount of unrestricted support over last year, this is more of an accounting adjustment than an indication of increased funding. We are down in all of our revenue streams: corporate and foundation contributions, memberships, and the sale of video/publications. Meanwhile, the expenses associated with our

Expenses FY 2007



outreach efforts increased, resulting in a deficit for the year. We welcome members' assistance in identifying new sources of funding that will help improve our numbers. If there is a bright spot in all this, it is that the cost of management and fundraising is only 16 cents for every dollar raised by the association.

The coming year will be one of change. After 10 years in the same downtown D.C. location, the association is moving its offices on Aug. 1. The plan had been to stay downtown to be close to other associations that partner with us, but the economic realities dictate that we move to the outskirts of the city where rents are more affordable. We are grateful to those who made contributions to our "move fund" and we continue to ask for your help as we relocate. If you are in the area, please consider coming into the office and lending a hand as we sort and pack. ■

ASAA IN BRIEF

The American Sleep Apnea Association participated in the first-ever consumer health show dedicated to sleep on May 9 and 10 in Rosemont, a suburb of Chicago.

The Big Sleep Show combined educational presentations and an exhibit hall to provide Chicagoans with a wealth of information on healthy sleep and products that can help them achieve it. In addition to exhibiting, the ASAA, through an A.W.A.K.E. group coordinated by board member Dave Hargett, supplied a number of volunteers who helped on both days of the event. Mr. Hargett was also a presenter, providing a patient's perspective on living with sleep apnea.

Plans are under way to hold other Big Sleep Shows in other large cities around the country. The ASAA sees these as an excellent way to reach out to the public and looks forward to participating in them in the future.

Also in May, the ASAA was an exhibitor at the annual meeting of the **American Thoracic Society** in Toronto. The ATS has a unique program called the Public Advisory Roundtable, designed to be a forum for the patient's voice. ASAA Executive Director Edward Grandi is a member of the Roundtable, which consists of representatives from 15 patient interest organizations. One of the tasks for PAR members is to identify speakers to present the patient perspective at the annual meeting, which this year devoted a considerable amount of time to sleep. The ASAA arranged for three people with OSA to speak at four separate sessions.

In addition, the ASAA this year offered a \$500 travel award to help defray the costs of a sleep apnea researcher's attendance at the meeting. Our award was presented to Dai Yumino of Japan for his research abstract entitled "Prevalence and Physiological Predictors of Sleep Apnea in Heart Failure."

The ASAA educational DVD on "What Is Sleep Apnea?" made its medical conference debut at this meeting. Physicians from around the world stopped by our booth to watch the video and purchase copies of the Spanish-language as well as the original English version. The film is now playing in Poland, Qatar, Portugal, and Venezuela. ■

Clearly, the CMS found the AAO-HNS argument – which was buttressed by testimony from numerous individuals and organizations, among them the ASAA – compelling. But the change in CMS policy does not reflect a consensus among practitioners. During the deliberative process, the CMS heard objections, some strenuous, from medical professionals and organizations (including the American Academy of Sleep Medicine) unconvinced that change was called for and that the new policy will prove to be in the best interest of patients.

Some of the disagreement revolves around how difficult it actually is for patients to access in-lab studies and consequent care. Another dispute has to do with how much data is needed to make a diagnosis. (Some doctors will tell you, off the record, that most of the time they don't really need a sleep study of any sort – they can look around their waiting rooms and pick out the people with sleep apnea. They're the ones who, rather than impatiently leafing through a magazine or talking on a cell phone, are taking a nap.)

But some physicians' qualms about home studies go to the fundamental nature of sleep disorders, and of sleep itself. Dr. Steven Feinsilver, a specialist in sleep medicine who teaches at New York University, points out that while a portable device that measures airflow can detect disordered breathing, it can't diagnose sleep-disordered breathing, since it can't tell whether a person is, in fact, asleep.

"You can't monitor sleep at home," Dr. Feinsilver says flatly. "Without an EEG [an electroencephalogram, which measures brainwave activity], you have no way of knowing if somebody is asleep or awake.

"A home study doesn't take the place of a laboratory sleep study," he continues. "Spending a night in a sleep lab has enormous benefits for relatively little cost. But the sleep community has not voiced that view. It's just rolled over and played dead. It's terrible."

On the other hand, physician Michael Coppola, a board member of the ASAA, is delighted with the CMS decision. He himself, frustrated with the long waits his patients endured before they could schedule a lab study, and sympathetic with their anxieties about traveling long distances to sleep in a strange place, was using

ASAA'S GRANDI IS PUT TO THE TEST



As the executive director of the American Sleep Apnea Association, I am often asked if I myself have sleep apnea. I usually respond with a half-joking "not yet." I knew I snored, and suspected that there might be more to my snore. But I wasn't sure if I really wanted to know.

Still, I felt that I should have a sleep study, if only to understand better the experience of our members. In light of the CMS ruling on portable monitoring, I opted to have a two-night home study that would measure respiratory effort and airflow, oxygen saturation, pulse rate, and, of course, snoring.

The process began with an online sleep apnea screening questionnaire, which indicated that I had a high probability of having a mild case of sleep apnea.

Next, a package arrived at my home via Fed Ex. It contained a hard plastic case, which in turn contained the following: a set of instructions, a tape measure, another questionnaire, and a device consisting of a headband holding a bundle

of sensors in a small box along with a two-pronged nasal cannula.

I followed the instructions and adjusted the headband so it would fit comfortably around my head. I set the nasal cannula so the ends were just inside my nose. Then it was lights out.

I typically fall asleep on my side, and hoped that I would be able to sustain that position. I was concerned that if I moved around too much, I would dislodge the sensors, and the data would be incomplete. In fact, I did spend part of both nights on my back, and that proved to be key to my diagnosis.

On the third day, I packed everything back into the hard case and shipped it to the company that would download the data, send it to the physician to review, and send me a final report.

Ten days later, the report arrived, informing me that I do have mild sleep apnea, at least during the times when I sleep on my back.

Next steps for me: Train myself to sleep on my side, lose the extra weight I am carrying around, and get fitted for an oral appliance. ■

portable monitoring 20 years ago, as part of a collaboration with an HMO.

"It was my preferred methodology at the time," he says. "I'd do a home test, and give the patient a CPAP set at the lowest pressure. I'd ask the wife if her husband was still snoring, and raise the pressure until he stopped. Lo and behold, it worked. I very quickly ended up with a lot of healthy, happy patients."

Such a low-tech approach – which admittedly has the drawback of requiring a bed partner – is not likely to be the future of OSA therapy. At this point, however, it's not possible to say what that future will be. It may be that portable monitoring will be used in appropriate, selected populations of comparatively healthy patients with relatively simple SDB, with laboratory studies reserved for more complex situations, increasing access to care for all. Or it may be that financial considerations – a lab study costs about three times as much as a home study – will become paramount, making polysomnography a luxury item for those who can afford Cadillac care. Or, in an even worse-case

scenario, the market may be flooded with shoddy home devices that make proper diagnosis and treatment more elusive.

As mentioned earlier, the American Academy of Sleep Medicine is on record opposing the CMS coverage expansion. However, the Academy, anticipating the rule change, convened a task force in 2007 to develop guidelines for the use of portable monitoring. These were published in the *Journal of Clinical Sleep Medicine*, Vol. 3, No., 7, 2007.

The guidelines, which are highly nuanced and complex, cannot be summarized in this brief article. But one of the major points can serve as the conclusion here: Portable monitoring "should be integrated into a comprehensive program of patient evaluation and treatment under the direction of a sleep specialist board certified in sleep medicine."

Or perhaps we'll give Dr. Coppola the last word. "One doesn't get a test [i.e., a sleep study] the way one gets an X-ray," he points out. "Success isn't about the test, it's how the patient is managed before, during, and after the test." ■

As reported in depth in the cover story of this issue of the WAKE-UP CALL, **The Centers for Medicare and Medicaid Services (CMS)** adopted a new National Coverage Determination (NCD) for the diagnosis and treatment of Obstructive Sleep Apnea. This determination is significant for all apnea patients, because most private insurers follow the rules created by the federal agency.

The main feature of this determination is that a diagnosis of OSA can be made – and a prescription for a CPAP machine written – on the basis of a home sleep study. In addition, coverage for CPAP will initially be limited to 12 weeks. Further

CPAP therapy will only be reimbursed for patients who show improvement during the 12-week trial period.

The **Department of Transportation** has issued a ruling modifying its policy on respiratory assistive devices (RADs) on airplanes. The new ruling (which takes effect one year after it is published in the Federal Register) will require that all domestic airlines make provisions for passengers wishing to use breathing machines during their flights. In addition to CPAPs, the rule covers ventilators, respirators, and oxygen concentrators.

Passengers wanting to use RADs on board will have to advise the airline of their medical need when they make their reservations. At that time, they will be informed of any limitations on the size of

the device, the requirement that the device be labeled appropriately, any requirement for advance check-in, and that they should bring an adequate number of fully charged batteries. Some airlines have electrical outlets at the seats, but the rule does not obligate air carriers to provide priority seating near such outlets or otherwise enable passengers to use the aircraft's power supply.

CPAP manufacturers will be required to submit their machines for testing to determine whether the devices interfere with the communication or navigation systems on any type of aircraft. Machines in the future will be labeled to indicate that they are approved for use in flight.

The ASAA will continue to follow this issue and report on it in future issues of the newsletter. ■

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AMERICAN SLEEP APNEA ASSOCIATION

1424 K. St. N.W. Suite 302, Washington, D.C. 20005

202.293.3650 ■ FAX 202.293.3656

www.sleepapnea.org ■ asaa@sleepapnea.org