

PATIENT ADVOCATES AND PROFESSIONAL SLEEP SOCIETIES SQUARE OFF ON PORTABLE TESTING *by Steven Grenard RRT, RPSGT*



In a civilized but subtly contentious exchange of letters, the American Sleep Apnea Association (ASAA) and the American Academy of Sleep Medicine (AASM) recently debated the subject of portable (at home) testing of people with suspected obstructive sleep apnea. (J Clin Sleep Med 2(3):361-4, July 15, 2005) The action that triggered this exchange was the decision last year of the Centers for Medicare and Medicaid Services (CMS) that they would only pay for facility based testing. And while this decision covers a specific subset of patients, those on Medicare and/or Medicaid, other third party payers sometimes sign on to CMS's policies and enforce them as well. To practitioners, however, they are all patients and all entitled to what is best for them based on a combination of data, results, evidence and logic.

There are several levels on which this argument is waged and they were present in the points raised by both sides to the debate although sometimes they are

shrouded in the rhetoric employed. To cut through this rhetoric, the arguments can be simplified.

The ASAA feels that all patients, rich or poor, Medicare/Medicaid, privately insured, HMO'ed, or uninsured are entitled to the same high level of competent and qualified diagnostic services, treatment and follow-up care for sleep apnea. Their argument is that this is just not happening or happening fast enough. They argue that there are too little facility based sleep-testing beds available and that they are too far between. They also argue that wait times are too long, follow-up care spotty, and alternatives to CPAP for patients who fail acceptance of this gold standard treatment are rare. Without saying so directly, they believe that approval by CMS of home or portable testing would solve these problems. Their third point is that they feel patients have the right to quality care independent of where they receive it, whether it be at in a hospital or free standing full testing lab or at home. They concede that home testing has not been shown to have the same high level of confidence for diagnosing sleep apnea compared with in-lab testing. They also demand that patients with symptoms who fail to be diagnosed with home testing must have access to "currently accepted" tests until alternative testing has been shown to have the appropriate predictive value compared to currently accepted norms. Their letter, published signed by all its 16 member physician and non-physician board members, provides no statistics, studies or references which might be worthy of inclusion. Their position is that all patients with sleep apnea should be guaranteed access to diagnosis and treatment by some qualified entity within a hundred miles of their home and within 30 days of initial referral. They place their faith in the probability that some day (future technology) home or portable testing will exist on a level comparable to that possible with facility based polysomnography. They call for the need for additional reports and studies from providers and payers such as the Veteran's Administration who are known to employ portable or home testing in spite of the lack of evidence that it is as sensitive as in-lab testing. This small revelation that our nation's veterans are once again involuntarily relegated to guinea pig status, while disconcerting, is the subject for an entirely separate debate. For all we know the portable testing methodology used by the VA may be getting diagnostic services and treatment to vets quicker, closer to home but not necessarily as accurately as facility based testing.

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The absence of evidence is not evidence of absence so one simply doesn't know.

The measured and skeptical response to portable testing by the ASAA as a patient advocate should be applauded. Their call for definitive, well designed studies comparing various types of portable versus standard 16+ channel in lab polysomnography is long overdue. They challenge professional societies involved in sleep research and clinical investigation to foster dialogue on alternative healthcare delivery and testing systems as well as to take a lead role in evaluating and setting goals to improve outcomes. And finally they call for broader physician participation. They want to see primary care providers schooled in the recognition, treatment and follow-up of this common illness, the prevalence of which is as great if not greater than many other disorders now treated by PCPS and a wider spectrum of specialists.

The response to the ASAA missive by the President and President-elect of the AASM (Lawrence J. Epstein, MD and Michael H. Silber, MB, ChB) emphasizes that organization's dedication and concern with providing a high standard of quality care to "ensure the health and well-being of our patients." As the professional organization in the debate the AASM letter provides statistics and 8 peer reviewed published references (mainly from the Journal Sleep and the J of Clinical Sleep Medicine) which raise a number of concerns in defense of the progress to date that the field has achieved.

They emphasize that while the challenge of how to best utilize available resources is important they state that there are even greater concerns on the table, the absolutely most significant of which is the continued failure to recognize the true public health problems that sleep apnea and other disorders which interfere with sound sleep cause. These include a panoply of cardiovascular risks and diseases, neurobehavioral disorders, occupational and vehicu-

lar accidents and poor quality of life that includes failure at work, with relationships and in school. The problem, they claim, is not that the underlying cause of these problems cannot be diagnosed but that a majority of people suffering these problems, some for many decades, remain oblivious to the possibility that a sleep disorder is at the root of their problem.

Secondly, the AASM authors state is the concern that once the problems have been identified on the basis of symptoms as being the result of a probable sleep disorder, is to insure they get effective long term treatment. They believe the solution is to continue increasing public and professional awareness that the need to obtain sound, restful sleep on a daily basis is essential to good health.

And finally Epstein and Silber point to the all-too-familiar problem of patient compliance. While CPAP or Bi-Level PAP therapy remains the gold standard of treatment with practically no serious side effects, sleep specialists and technologists are also familiar with the frustrations endured with cajoling patients into acceptance of this therapy. The litany of problems cited by sufferers range from claustrophobia, inability to breathe, dryness, burning of the nasal passages to general or undefined discomfort bordering on intolerable. These authors state that studies indicate 25% to 50% of patients treated with some form of PAP either refuse to consider even trying the treatment or simply just don't tolerate it. So the best treatment available is no treatment at all if the patient won't use it. Industry has responded to many of these concerns by making heated humidification available for dryness and nasal "burning" sensation, a variety of masks and nasal interfaces for claustrophobics and facial discomfort, and bi-level with flexible flow rates for people having difficulty exhaling (breathing). Far too

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of drug to be given via the aerosol route are the prostaglandin derivatives for regulating and controlling pulmonary arterial pressure. These agents (e.g., Flolan®, Ventavis®) hold a great deal of promise as a replacement for inhaled nitric oxide and we are sure to see new delivery systems and administration devices designed specifically for them. Also on the horizon are new antibiotics specifically formulated to prevent and/or treat ventilator associated pneumonia in the ICU. New agents for tackling both traditional gram negative organisms such as Pseudomonas, and gram positive bugs such as MRSA that are wreaking havoc in the contemporary ICU, are under development. It will be interesting to see how these will be given, how they will be introduced into the ventilator circuit and how they will affect our practice. Stay tuned.

Also on the drawing board I have planned a number of articles about what goes on behind the scenes inside the aerosol lab. We're going to expose some of the trade secrets and reveal the true answers to nagging questions such as: How are those pesky little aerosol particles actually measured? What is the MMAD and how is it determined? Do different nebulizers really have different particle sizes? Is particle size as important as everyone seems to think it is? Stay tuned. And let's take a closer look at the new generation of electronic nebulizer and the various control schemes for "tailoring" the inhaled dose to the patient's breathing pattern. And what about the regulatory landscape? Once upon a very long time ago, anyone could bring a new nebulizer on the market. Now, nebulizer designers and manufacturers must receive premarket approval, the so-called 510(k), in order to bring a new device on the market. We'll look at this 510(k) process as it applies to nebulizers to try to reveal what it really means. Meanwhile, pharmaceutical companies must go through a similar but vastly more complicated and expensive process known as an NDA (New Drug Application) for any new agents they plan to bring on the market. The regulatory landscape rarely gets simpler; it is usually more complicated over time. Combine a brand new drug (NDA), with a brand new device (510(k)) and consider how complicated, how expensive and how many years it might take to get this through the bureaucracy and onto the hospital formulary. Stay tuned and please join me in subsequent issues as we explore the nebulous world of Aerosols in Medicine.

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many of these patients, especially from the past when these advances were not available, are out there. Many of these folks have been given up as lost causes by themselves and by their doctors who have not kept up with the need to update and try again. Many sleep labs don't open for clinical business until night testing begins so the availability of technical and clinical personnel accessible by patients with problems falls on primary care doctors or medical equipment dealers with poor to non-existent results. This in turn is related to the bottom line since there is no means to pay for or reimburse outpatient technical follow-up. The creation of Certified PAP Coaches or PAP Trainers whose services will be reimbursed or otherwise funded can go a long way to solving the compliance problem but surprisingly no one has suggested this. Our lab is fortunate in having several clinical and technical people available during normal business hours so currently provides such services free of charge as needed and/or ordered by a patient's doctor, under the rubric of "de-sensitization" which is a debatable term with the objective of making the patient insensitive to PAP. In effect the objective should be to make the patient highly sensitive to the need to use PAP and to try and eliminate all the patient's complaints one by one by providing them and their doctors with the options they don't know are out there.

Published surveys currently indicate that the wait time for a sleep study on average nationwide is 22 days with some areas under-served and others over-served. There are currently 2500 facility based labs in the US with news labs being set up all the time. In the past 5 years the number of accredited labs doubled. Medicare reported a 160% jump in the number of studies it reimbursed between 2000 and 2004. Demand, Epstein and Silber contend, is being met and will continue to be met but the larger problems they highlight persist. There is no reason to logically expect they will be ameliorated by home based testing, especially when PAP titration and coaching enter the picture.

In conclusion, Epstein and Silber believe that before we throw a wider net of less proven diagnostic techniques without a high level of confidence in their ability to rule-in or rule-out obstructive sleep apnea, the bread and butter issues they brought up need to be addressed immediately if not sooner. The risk to home testing besides its lack of specificity is that it removes the patient from the sleep center or lab, diminishes contact between technologist and patient and creates an unintended barrier to determining and addressing patient follow-up and compliance problems. And that makes limited channel home testing just slightly better than nothing and then for only some patients: the perfect, highly aware, well educated in sleep problems, and the highly compliant ones who love what we are trying to do for them. We need to bring the rest of our patients closer, not cast them farther away.

The other risk to portable testing is that it will, like it or not, greatly increase the number of solo polysomnographers with home testing equipment in the trunks of their cars who will test anybody, anywhere for a low cost that doesn't include the cost of reliable and professional interpretation, professional follow-up and the (currently) non-reimbursed follow-care demanded of the patient advocate group. The problem cases for follow-up will fall on the facility based labs that will be deprived of testing income and these too would then fail causing the demands of the patient advocates to fall on no ears at all... because they just won't be there anymore.