

Initial Public Comments for
Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive
Sleep Apnea
(CAG -00093R)—Round 2
Public Comment Period (June 25-July 25, 2004)

Commenter: Phillips, Barbara, MD, MSPH

Organization: University of KY College of Medicine

Date: July 2, 2004

Comment:

I wish to comment on the use of portable monitoring in the management of patients with suspected sleep apnea. I write as an individual, and am not representing any organization. However, I have served on the Board of the American Academy of Sleep Medicine and on the Advisory Board of the National Center for Sleep Disorders Research. I have been President of the American Board of Sleep Medicine, and a recipient of a Sleep Academic Award from the National Institutes of Health. I continue to serve on the Board of the National Sleep Foundation, on the Health and Science Policy Committee of the American College of Chest Physicians, and on the Clinical Practice Committee of the American Thoracic Society. In the interest of disclosure, I note that I also serve on the Medical Advisory Board of ResMed, makers of CPAP machines. More importantly, I practice Sleep Medicine full time, seeing more than 1,500 patients with sleep disorders a year, and I have directed a sleep center for more than 20 years. This last activity represents the truest conflict of interest, since, like all those who profit from interpretation of polysomnography, I have much to lose should demand for the services of my sleep center decline. Opponents of portable monitoring and autotitrating CPAP (APAP) demand more and better proof that portable monitoring is reliable (despite excellent results with this technology in the Sleep Heart Health and Cleveland Family Studies {1,2}). They also point out that the diagnosis of sleep apnea outside a sleep laboratory will only be cost effective if autotitrating CPAP “works.” A recent metanalysis of 9 randomized trials of 282 patients (3) concluded, “Compared to standard CPAP, APAP is associated with a reduction in mean pressure. However, APAP and standard CPAP were similar in adherence and their ability to eliminate respiratory events and to improve subjective sleepiness. Given that APAP is more costly than standard CPAP, APAP should not be considered first-line chronic therapy in all patients with OSA. However, APAP may be useful in other situations (eg, home titrations....”

In fact, the cost differential between CPAP and APAP at this point is minimal (4). More importantly, the cost difference between APAP and in-lab CPAP titration is HUGE! It is possible to purchase 3 APAP machines for the cost of one in-lab study, be it a diagnostic or titration study.

The Practice Parameter (5) promulgated by the American Academy of Sleep

Medicine (AASM), the American College of Chest Physicians (ACCP) and the American

Thoracic Society (ATS) cannot be ignored, and unfortunately affects the policies of insurers, attorneys, and governmental agencies who use it as a basis for decisions about diagnosis of patients with suspected sleep apnea. I voted against its approval in 2 of the 3 groups that developed it. The problems with this paper are:

it relies on the unreliable and constantly changing Apnea plus Hypopnea Index (AHI) as the gold standard

it does not include data from Sleep Heart Health Study (the largest and most important study using portable monitors to date)

it was outdated before it came to press.

Further, sleep apnea is simply too common and deadly to require an expensive, fallible and cumbersome hurdle (in-lab polysomnography) for every patient who needs CPAP.

The bottom line is that about 5% of Americans have sleep apnea (6,7), which can kill them and those on the highways with them (8-14). A significant minority of patients with sleep apnea can be diagnosed by history and physical examination alone (15-19). For some of the remainder, portable monitoring is a reproducible and predicts sequelae as well as does in-lab polysomnography (1-3, 20-23). It is extremely important to emphasize that screening tests can be used to rule disease in, but cannot be used to rule sleep apnea out. There will always be patients who need to visit the sleep center, including patients suspected of sleep apnea whose screening test is negative, those who don't respond to CPAP, those with coexisting pulmonary disease, and those with sleep disorders other than obstructive sleep apnea. But requirement of in-laboratory polysomnography as a prerequisite to treatment of sleep apnea in every patient directly opposes a major public health principle. We should remove, not impose, barriers between patients with deadly diseases and safe, effective treatments. CPAP, which actually costs less than in-lab polysomnography, is highly safe and effective treatment indeed (24-31).

In your second comment period, you pose two queries:

a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

Clearly, the most important measurement is oximetry (oxygen saturation), which can be used by itself as a diagnostic tool (32-38). Oxygen desaturations are common with sleep-disordered breathing, but do not always occur, especially in younger, thinner patients. Further, oxygen desaturation may occur in the presence of cardiopulmonary disease

unrelated to airway obstruction. In other words, oximetry can result both in false negatives and in false positives (The same is true of in-lab polysomnography!). The parameters typically reported vary, but the total number of desaturations, oxygen desaturation index (ODI), desaturations per hour,

highest, lowest and mean SpO₂, and cumulative time SpO₂ spent below 90% are all useful. A 4% desaturation is most commonly considered to be significant, and has the best predictive value, but 3% and 5% desaturations are also used. As with the AHI criteria (derived from in lab polysomnography!), there is no consensus as to the ODI which represents a normal or abnormal. Artifacts, inaccurate readings due to hypotension or abnormal hemoglobin, and low sampling rates can result in errors, so a visual print out of the oximeter trace is useful.

Oximeter sampling frequency is also an important variable.

Pulse oximetry is probably most useful in patients with a high suspicion for sleep apnea based on clinical features (as is in lab polysomnography).

Again, patients with a high clinical suspicion for sleep apnea who have a negative pulse oximetry trace or have significant concurrent respiratory or cardiovascular disease need further investigation.

Also useful are heart rate (as is used in the Watch Pat, described in earlier commentary on this site) or by Holter monitoring (39). Some measure of airflow is also helpful.

Measurement of periodic limb movements is not important, as limb movements are commonly seen with many sleep disorders, including sleep-disordered breathing (40, 41). They do not predict sleepiness (42). In the absence of symptoms of Restless Legs Syndrome (elicited by a history, not a lab test!), they should not be treated, and there is not much point in looking for them.

b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

What probably matters most is that a clinician who is experienced in the management of patients with sleep disorders evaluate the patient before the study, and carefully review the results of the study in the context of that patient's clinical presentation. It is appropriate that we spend at least as much time, effort, and money on caring for the patients as we do in the technologic diagnosis! Since not everyone who is suspected of sleep apnea actually has it, my bias is that patients suspected of having sleep apnea would be best served by physicians knowledgeable in the entire gamut of sleep disorders. My belief is that individuals who are boarded in Sleep Medicine (recently recognized both by the ACGME and by the ABMS) are most likely to provide the most effective comprehensive care for these patients, but I can't prove it.

It is also important that the diagnostic test not be administered by those who stand to profit by its outcome, which would include ENT surgeons and HME companies. (At this juncture, I feel compelled to point out that the scientific literature about the outcome of ENT surgery for sleep apnea is not particularly rigorous or positive {43, 44} and laser-assisted uvulopalatopharyngoplasty is even worse {45}. In fact, oral appliances perform better than does

surgery {46}). Patients who are undergoing portable monitoring should have a phone number to call during the study in case they have concerns or problems. They should be given written material about sleep apnea itself, what the test is

expected to accomplish, and what they can expect in terms of follow-up. Thank you for the opportunity to comment on this issue. Because of its prevalence and consequences, and because it can cause damage to those not personally afflicted (by causing automobile accidents), sleep apnea is a significant public health problem. It is important that we expedite the management of these patients.

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Commenter: Spanos, Nick

Organization:

Date: 07/12/04 07:04PM >>>>

Comment:

I would like to respond to the consideration of unattended portable sleep testing in the diagnosis of sleep apnea as compared to facility based polysomnography. It's incomprehensible there's significant time invested in this comparison, but I would like to state differences that I'm aware of with my seven years of experience, including management, in the sleep field.

The most significant difference between the two is facility based sleep studies are more cost-effective than portable testing. Certain individuals make the arguments for home testing being less expensive. This simply, in my experience, isn't the case. Although the apparent portable study itself may be cheaper; the costs of undiagnosed, misdiagnosed, and mistreated patients would be significantly higher than the cost of an accurate facility based sleep study which provides the patient the most accurate diagnosis and treatment possible. For example, we've had studies where a patient previously had a portable study and it showed an AHI of 12 and stated a mild case of obstructive sleep apnea with a projected CPAP pressure of 8.0cm. On our facility based study, this individual had a severe AHI of 88 and required a CPAP pressure of 15.0cm. Based on the home study, a physician lacking experience in sleep medicine may or may not recommend CPAP treatment because of only mild sleep apnea. In the case of recommending CPAP, with results from the home study, it wouldn't allow the best possible chance at compliance due to the wrong estimated pressure and because of the limitations of an autopap machine. If untreated or mistreated, many other costs are increased whether it be from heart disease, diabetes, accidents, or death. Our sleep center has noticed several examples of this and unfortunately this would be a reoccurring theme if unattended portable sleep studies became the norm.

Another comparison to address is advocates for portable studies will mention these studies are in the natural environment of the patient. If this were the criteria required for many medical procedures than a blood pressure taken in the clinical setting should have little relevance. A psychiatrist shouldn't see their patient in their office. They should see their patients in the home of the patient since any individual would likely be more comfortable talking in their natural environment. The fact is to maintain a pursuit of excellence in the medical field, many procedures need to be administered in a clinical setting with trained medical professionals.

If portable studies are approved, their advocates point out physicians with a wide array of medical backgrounds could then order the study and evaluate them. This also doesn't make sense as most of these physicians would have no or limited experience in sleep medicine. When making decisions about sleep disorders, for their patients, the diagnosis and treatment should be from a sleep physician, just as a sleep physician wouldn't be relied upon for a diagnosis regarding cardiology or internal medicine. If a patient has a

sleep disorder, especially sleep apnea, the primary evaluation and treatment should be by a board certified sleep physician not an otolaryngologist or family physician. Allowing physicians with a wide array of medical backgrounds to diagnose and treat sleep apnea would push the sleep field back into the early days of development.

To address the question of what a portable study should encompass is very difficult because of the very nature of that type of study; however if the consideration is approved all parameters which are typically recorded during a facility based study should be included. Sleep staging is critical because it's difficult to calculate an AHI without recording whether the patient is asleep. An AHI calculated with 2 hours of sleep is diagnostically different from 8 hours of recording time. A 5 AHI with 8 hours of recorded time but only 2 hours of sleep is actually an AHI of 20. This may make the difference in CPAP treatment. Other outcomes of not recording sleep staging, in this example, would include the difference between mild and moderate sleep apnea. Other serious factors in the consideration of an accurate diagnosis of sleep apnea is recognizing if stage REM was achieved. An AHI of 5, but not recognizing if REM sleep was attained is a significant factor in determining a diagnosis of sleep apnea. The accurate recording of respiratory effort is vital to any sleep study when there's suspicion of sleep apnea. The respiratory monitoring should have the ability to recognize Cheyne-Stokes breathing pattern as well as appropriate determination to use BIPAP or a back-up rates for certain respiratory patterns. Oxygen recording is important in portable studies, but recognizing if there is artifact is necessary. In my experience, there are many examples of individuals improperly placed on oxygen because of inaccurate recording of overnight oximetry.

In reviewing many of the comments from the initial comment period, it's quite clear which medical fields are promoting portable studies and which are in favor of facility based sleep studies. The majority of portable study advocates are DME providers, portable study companies, or individuals and organizations in the field of otolaryngology. Facility based proponents are a wide range of individuals and organizations with experience in sleep medicine. I hope when making a consideration on the field of sleep medicine, the experience and background of sleep medical professionals, such as the American Academy of Sleep Medicine, is valued to a higher degree than those with a background in durable medical equipment and otolaryngology who may only have experience with portable sleep studies.

I think we all would prefer those professions such as pilots and bus drivers to be properly diagnosed from a facility based sleep center and treated by a board certified sleep physician, rather than diagnosed from an unattended portable sleep study and treated for sleep apnea by an otolaryngologist or family physician. It's my position that medicare maintain the current policy requiring facility based sleep studies for the diagnosis of sleep apnea.

Commenter: **Salemi, Michael, RPSGT**
Organization: California Center for Sleep Disorders
Date: July 19, 2004
Comment:

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

- a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?
 - b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?
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I am the General Manager of a large Sleep Testing Organization in Northern California. Additionally I was employed in the medical device industry for 8 years - directly involved in the development of diagnostic testing equipment and software – including several home testing devices.

Our labs currently offer both home and laboratory based studies. Over the past 18 months approximately 15% of our tests were done in the home environment. From our clinical experience home studies can be used to accurately diagnose sleep disordered breathing, but only in well-selected patient populations. We only perform home studies on the most obvious cases - patients who have histories that are clearly suggestive of excessive daytime somnolence, loud snoring, witnessed apnea, etc.

It must be clearly stated that in many cases home studies are not appropriate and should not be used. Due to the changing demographics in our patient population, we see a significant number of patients with lower BMI's and milder forms of sleep disordered breathing. Using home tests on this population will lead to a large number of false negative studies especially if the tests are not backed up by detailed clinical histories. Patients with lower BMI's are tested in-lab because they tend to have milder sleep disordered breathing that requires careful analysis of sleep architecture and arousal activity. Patients with BMI's > 40 may suffer from obesity related hypoventilation syndrome and potentially are at risk in an unattended auto-adjusting CPAP titration. Lastly we exclusively use diagnostic technologies with pressure based airflow transducers to help reduce the incidence of false negative studies.

One important factor in expanding the use of home studies is clarifying what constitutes an adequate set of diagnostic parameters. This is not a decision that can be made in a casual forum. Here are three important factors to consider:

- There is no agreement in the sleep literature on the specific technologies that should be included in a home sleep test. Current guidelines state that these devices should have among other things, “airflow” and “effort” channels. There are no standardized definitions for these critical parameters and due to this lack of guidance - manufacturers have created a myriad of well-intentioned, but largely unproven technologies. Without some degree of increased standardization there is absolutely no guarantee that a “home sleep study” in one community would be equivalent to another performed just miles away.
- In recent years a new trend has developed in which the company that performs home testing services also manufactures the proprietary diagnostic technology used in those studies. I see nothing inherently wrong with this model, but few if any of these proprietary technologies have been subjected to rigorous independent testing and rarely do these companies openly discuss the potential drawbacks of their systems. One popular service uses a device that does not meet the guidelines for a 95806 (Unattended cardio-respiratory study), but not surprisingly this is rarely disclosed to the non-sleep specialists who order these studies.
- Lastly - I am aware of no data that defines appropriate and up-to-date guidelines for patient selection for home testing. The AASM’s position papers on this issue are frankly far too conservative, but unfortunately most of the other published reports have been industry sponsored and have not been replicated in large-scale independent studies. I am unaware of any published retrospective assessments of clinical operations such as our, that have experience in both the home and lab environments. These data would be valuable for assessing the number of patients that needed re-testing after home studies and those who would have “fallen through the cracks” with false negative results had they not been directly involved with experienced sleep clinicians.

Home testing is a valuable component of our diagnostic tool chest and clearly this mode of testing will grow in the years to come. But it is not prudent to rush into a decision regarding home testing until the above issues are adequately addressed. The argument that home testing is needed because there is limited access to testing is absolutely false and misleading – at least in most metropolitan areas. In our 6 centers, the average wait for testing is 2-3 weeks. Secondly, the position that the home is a more “natural” environment for testing is not supported by the literature or our clinical experience. Patients that undergo sleep testing are not sleeping in a natural environment. They have probes attached to their body and have a strange machine next to their bed that often causes much anxiety and fear. Ironically, many of our patients refuse to be tested at home because they are afraid they will do something that could cause an unsuccessful test.

Make no mistake – the argument about home testing is ultimately about money. Insurance companies pay less for home testing (at least on the surface) and frankly, my lab (because we are in an area heavily penetrated by managed care), makes a higher net profit on home testing because there is less human interface! So on balance - do I support

home testing? – Sure. But the decision to relax home testing guidelines needs to be cautiously undertaken. Self-interest in this matter needs to be put aside to insure that a sane and competent decision is reached.

CMS should open the door to home testing in a way that compliments the current system that employs thousands of doctors, technologists, administrators and staff who are trained to practice sleep medicine. I firmly believe that a decision to expand the use of home testing should not be undertaken until CMS arrives at clear set of required channels and a well-defined list of acceptable technologies for each of those parameters. Like they recently did with redefining the qualifications for CPAP reimbursement, this decision should be undertaken with a complete review of the existing data and input from the AASM, independent sleep labs, national testing organizations and the diagnostic industry.

Commenter: Wilson, Kent S. , MD

Organization:

Date: July 21, 2004

Comment:

Good morning. It has come to my attention that CMS is currently reviewing multi-channel ambulatory sleep study technology with a view to possibly including coverage of this technology.

I'm an otolaryngologist who has been involved in the ENT aspect of sleep medicine for the past 25 years. I've had a great interest in ambulatory testing for at least the past 12 years, and have carried out studies and sponsored meetings dealing with that subject.

The clinical problems that I see on a day-to-day basis relative to obstructive sleep apnea include patient refusal to have a polysomnographic study done in a laboratory setting because of inconvenience or discomfort, poor sampling by standard PSG as a result of first night affect and short monitoring times, and the awkwardness and unreliability of older ambulatory testing devices which were "adhesive based." Another problem related to ambulatory testing relates to expense - currently I think the expense of sending a post surgical patient back to a sleep center for an overnight sleep study to determine the effect of surgery is both inconvenient and excessively expensive.

Our clinic has experience for the past year with WatchPAT-100 technology which is patient friendly, convenient, extremely fast and accurate in the assessment of sleep disordered breathing. You have on record, I'm sure, long bibliographic lists of articles supporting the physiology and technology associated with the WatchPAT-100 device and demonstrating its clinical both applicability, reliability and financial efficiency. I hope that you will approve the use of the WatchPAT-100 technology. Such approval would facilitate the most effective method of scientifically managing sleep disordered breathing, in my opinion, namely the use of ambulatory, unattended testing (WatchPAT-100) followed by self titrating CPAP is indicated, or surgery if indicated followed by WatchPAT-100 post operative testing.

Commenter: Chmiel, James F, MD

Organization: Buffalo ENT Society

Date: July 20, 2004

Comment:

I would like to speak out strongly in support of certain multichannel home sleep study devices such as the Watch-PAT. The testing of peripheral arterial tone represents what I believe is the 5th vital sign. As an ENT doctor many of my patients decline to go to sleep labs to get necessary testing to rule out sleep apnea. For instance, I have several patients who are single mothers. These moms cannot find or afford babysitters who can safely watch their children overnight while

they go to a sleep lab. With a home testing device, they would be able to have this testing at home.

At one lab in my area there is a four month waiting list to schedule an appointment. The lab is uncomfortable and unclean.

As technology continues to do things that only a few years ago were thought to be impossible, the public will ultimately become aware of this technology and will demand it.

I hope these comments are helpful. I strongly encourage approval of home multichannel sleep study devices.

Commenter: Sateia, Michael J., MD

Organization: American Academy of Sleep Medicine

Date: July 20, 2004

Comment:

In response to the latest questions posed by CMS the AASM offers the following for your consideration:

1. How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

The American Academy of Sleep Medicine again reiterates its strong opposition, as noted in our previous letter, to the portable monitoring proposal put forth by Dr. Terence Davidson. It is our position that there is insufficient data to support the application of this technology at the present time. If this proposal is approved, the widespread application of portable monitoring, which would surely follow, will be counterproductive to public health and cost effectiveness.

As described in our previous response, clinical research in Sleep Medicine has provided a body of peer-reviewed published literature to help guide decision-making regarding the utility of portable monitoring in the diagnosis of obstructive sleep apnea. This published literature regarding portable monitoring has been exhaustively reviewed and guidelines have been cooperatively developed by the three societies of practitioners who provide care for obstructive sleep apnea patients. Decision-making regarding the role of portable monitoring as compared to facility-based polysomnography should rely heavily on this extensive body of literature as well as the exhaustive efforts to organize and interpret this literature using standardized methods of evidence-based medicine and construction of guidelines. This extensive and broad-based evidence review and guideline paper has just been published on portable monitoring (1) with

participation and endorsement from three professional organizations: the American Academy of Sleep Medicine, the American Thoracic Society, and the American College of Chest Physicians. Evidence that was graded included a 1997 review by the Agency for Healthcare Research and Quality (AHRQ) as well as subsequent published literature. Evidence was graded according to a standardized process and recommendations were based on levels of evidence. (2,3) This guideline paper on portable monitoring detailed the range of monitoring from single parameters to multichannel recording and portable polysomnography. Of the clinical evidence grading that was performed on 51 studies, there were four published studies using multichannel unattended monitoring excluding EEG as compared to facility-based polysomnography. In these studies, home monitoring showed highly variable and often low specificity for a correct diagnosis of sleep apnea, with variable false-positive results that ranged as high as 31% of those testing positive. Based on this limited data showing highly variable and questionable performance, the published guideline of the three societies does not recommend portable monitoring that excludes EEG without direct supervision of a technician (i.e., unattended portable monitoring).

It is also important to note that there are significant reliability problems with home portable monitoring as well. In three investigations, poor quality necessitated exclusion of 5 to 20% of polysomnographic recordings performed in the home.(4-6) One study noted a four-fold higher rate of failure in home vs laboratory polysomnography.(5) Disease misclassification rates have recently been reported in up to 65% of patients with limited channel home recordings. Lack of standardization of definitions and recording techniques may also result in tremendous variations in the metric that is being used to determine the presence and severity of disease. Varying the criteria for the definition of respiratory events, for instance, can result in differences in disease prevalence ranging from 11% to 83% in the same population.(6) All of these technical limitations of non-standardized techniques in monitoring may result in misclassification of disease with inappropriate use of therapy such as CPAP or even surgical intervention.

Finally, diagnostic strategies incorporating home monitoring do not necessarily optimize the issue of cost efficiency of care. As compared to single night facility-based diagnostic studies that incorporate continuous positive airway pressure, home portable monitoring may a) increase the need for repeat diagnostic studies because of a higher rate of study failure, and b) increase the need for repeat therapeutic studies in order to determine therapeutic CPAP pressures. One study demonstrated only modest cost savings when repeat testing in the whole population was considered. (15)

In summary, current evidence suggests that facility-based polysomnography using standardized techniques performs superiorly to home portable monitoring without EEG, which has poorer specificity, higher failure rates, and undetermined cost effectiveness.

In addition to these considerations, it is essential that CMS also recognize that the problems of diagnostic specificity and reliability, as evidenced in carefully controlled clinical investigations, are almost certain to be magnified many fold in the routine and potentially indiscriminate application that would follow an approval of this proposal. Uniform methods for patient selection and technology application do not exist. Likewise, there are no standards for home portable monitoring with respect to technician qualifications, patient evaluation, treatment application, or monitoring of quality and performance measures, such as those that currently exist in accredited sleep centers.

Sorely missing from the conditions cited in the questions posed by CMS is the skill set of the clinician ordering the study. Obstructive sleep apnea is a syndrome that often presents with an array neurocognitive, behavioral, and cardiovascular consequences. In many cases, the presenting symptoms may be quite subtle. A correct decision for performing any polysomnographic study is based on an appropriate clinical evaluation of patient complaints and identification of any alternative or contributing causes for symptoms as diverse as daytime sleepiness, depressed mood and increasing peripheral edema. These symptoms may reflect etiologies as diverse and common as insufficient sleep, restless legs syndrome, depression and venous insufficiency. The ability of the practitioner to determine whether a respiratory disturbance index of 9 on a polysomnographic study in a symptomatic patient is clinically significant will depend on the clinician's skill set. (CPAP therapy for an RDI of 9 is currently reimbursable in symptomatic patients and this RDI was the median value in an unselected random patient population in the Sleep Heart Health Study). The skill of the clinician making the determination of when to order a polysomnographic study and how to act on the results is variably determined by type of training and clinical experience. Thus, the greatest expertise will be exemplified by those clinicians who are certified as Sleep Medicine specialists.

Increasingly, outcomes research has demonstrated that care for a number of common conditions is better delivered by specialists in that field. The value and importance of specialist care has been addressed in cardiology and intensive care settings. (7) (8) (9) Emerging data in the field of Sleep Medicine does support the premise that specialists deliver better and more cost effective care than non-sleep specialists.(10) This conclusion with respect to sleep apnea and polysomnographic monitoring has been

formalized by both the Canadian and American Thoracic Societies as well as the American Academy of Sleep Medicine.(11-13)

The AASM believes that certification in Sleep Medicine is ideal although not always available or necessarily required of all practitioners providing diagnosis and therapy for patients with sleep apnea. Physicians who are board certified in Pulmonary Medicine and have had extensive training in sleep medicine as part of their pulmonary training program are qualified to diagnose and treat sleep apnea. However, all pulmonary training programs do not offer extensive training in Sleep Medicine. Expertise in Sleep Medicine is ensured in sleep laboratories and full-service sleep centers accredited by the AASM: a) all AASM accredited sleep centers must employ a practitioner who is certified in Sleep Medicine and must comply with practices which demonstrate expertise in Sleep Medicine, b) directors of AASM accredited sleep laboratories, which specialize in sleep apnea, are required to be Board Certified in Pulmonary Medicine and Board eligible in Sleep Medicine and are required to fulfill specific requirements demonstrating clinical expertise in sleep.

Patient outcome is dependent on a variety of complex aspects of care, including 1) reliable diagnosis, based on adequate integration of comprehensive patient assessment, by a clinician skilled in the field of Sleep Medicine, with correctly scored and interpreted polysomnographic data; 2) application of treatments that are appropriately targeted to the patient's needs; 3) patient education, support and follow-up, including adjustment of treatment and intervention for treatment related complications. Clearly, this approach is best delivered within a medical system, such as a sleep center, that is designed specifically for this purpose. The desired patient outcomes will not be achieved by wholesale application of unattended portable monitoring.

Finally, it appears that much of the case for home portable monitoring rests on the argument that many patients are being deprived of needed diagnosis and treatment as a result of major waiting lists for facility-based sleep studies. While there may be some facilities with significant waiting lists (as is the case for many diagnostic and therapeutic interventions), we are not aware of any objective data that demonstrates a serious problem in this respect. The AASM is currently conducting a survey that will gather data to address this issue. We believe that most centers and labs operate within an acceptable range of service delivery time. It is also the case that these programs routinely arrange for expedited studies for those patients whose conditions require immediate care. It is certainly true that the majority of patients with obstructive sleep apnea in this country remain undiagnosed and untreated. This is not primarily a problem of sleep testing wait times. It is a problem of recognition of the signs and symptoms by patients and appropriate recognition and referral by physicians. To

suggest that the solution for this problem is application of unproven and potentially unreliable technology is, at the least, misguided.

The AASM remains committed to providing the most effective, reliable, available and cost-efficient technologies for patients with sleep disorders. We are examining and will continue to systematically and objectively examine these technologies and the systems in which they are applied, and to support those that are in the best interest of the patients we serve. Such is not the case with unattended home portable monitoring at this time and we urge CMS to deny this proposal.

Due to our concerns about the assumptions inherent in Parts a) and b) of the question, we have chosen to incorporate our comprehensive response to all sections within the above.

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Commenter: MacDonald, Lawrence, MD
Organization: Sinai Grace Hospital Sleep Disorders Clinic
Date: July 21, 2004
Comment:

I have personal experience in the care of thousands of patients with a variety of sleep disorders (neonates through old age). This care has involved taking a detailed history, perhaps (not always) ordering and interpreting polysomnographic studies, communication with other practitioners, participation in multidisciplinary conferences, and followup of patients.

Some observations and thoughts:

1. The most important part of a sleep evaluation is the history taken by a qualified sleep specialist. Some individuals with an interest in performing surgical procedures for obstructive sleep apnea have an interest in circumventing an appropriate evaluation because a non surgical approach will probably be recommended (consider the implications of mass screening by individuals wishing to advocate surgical procedures of questionable efficacy).
2. Most patients with sleep problems have more than one sleep problem. Unless they are all addressed, the patient will have no or less than optimal benefit. Any polysomnographic test will be less than helpful unless coupled with an evaluation by a sleep specialist. There is a tremendous potential for abuse by those not qualified to perform a comprehensive evaluation.
3. Arousals and sleep architecture are crucial in the appropriate evaluation of individual patients with sleep disorders, especially sleep apnea.

4. There is no shortage of labs to study patients with sleep problems in house.
5. Individuals with interest in selling portable equipment have also an interest in promoting their use through governmental regulations and coverage
6. Many other, more appropriate measures may be taken to make coverage of sleep evaluation and treatment more affordable. These should include monitoring of compliance and payment only for treatment which is actually used (ie demonstrable compliance with CPAP). Given the literature documentation of compliance, this would eliminate 25-50% of reimbursement costs for CPAP

I may have other thoughts to share as well.

Commenter:	Boone, Allen, RPSGT, Director
Organization:	Integrated Sleep Resources, Inc.
Date:	July 21, 2004
Comment:	

(See next page)

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July 21, 2004

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Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
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RE: Commentary on Ambulatory (home-based) Sleep Testing (CAG-00093R)

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

- a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?
- b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

In my nearly 20-years in sleep disorders technology, I have had frequent experiences with “home-based”, “portable”, ambulatory sleep diagnostic recording units. My first experience with ambulatory recording systems started in the early ‘90’s with one of the very first ambulatory “sleep” units in the US. This came about at a time when we recognized we had greater demands than what our current, static sleep medicine facilities could reasonably handle. Using ambulatory recording systems gave the sleep centers another tool for providing care for a burgeoning population.

In recent years, the industry has stepped forth with new innovations and technology, thus improving the recording characteristics of ambulatory systems. And after having made continued, concerted efforts to evaluate unattended ambulatory sleep testing systems units, it is my personal opinion that ambulatory sleep testing is appropriate for a very narrow percentage of well-selected patients.

Are the ambulatory system operations comparable to polysomnography in the lab? Given many of today’s technological advances, yes, they are –but only when compared on an apples-to-apples basis. In other words, the operations of these units can only be compared when looking at identical recording parameters, such as EOG, EEG, EMG, and other respiratory channels. Whether or not the study is conducted in the laboratory or in an ambulatory setting, there should be no differentiation in number of recorded parameters. When laboratory recordings are analyzed (typically referred to as “Scored”), the technologist and physician both use all available parameter data in the recording to verify events as they present on each epoch. We look for associated arousals, interweaving limb movements, dysrhythmias, and any others events –all based on upon the foundation of sleep as found in the EEG. Yet, it has been a historical trend to in ambulatory recording to do away with the very items that provide that foundation of sleep; namely the EEG. Omission of EEG data in the past was primarily due to the cumbersome space it took in relationship to a small storage area. This argument is no longer valid in the current technological environment, as several manufacturers have demonstrated ambulatory systems with full laboratory capabilities. Despite what others might think, the EEG data is an invaluable part of the recording & analysis process, and more sleep professions pay attention to it than not.

There is little question the majority of patients present with OSA; however, a material number of these same patients encounter other crossover disorders (e.g.: Periodic Limb Movement disorder, parasomnias, narcolepsy, epilepsy) as well. With this in mind, the insurance and medical communities should not look to ambulatory recording as a means to cut costs by utilizing equipment of lesser parameters. In my opinion, using lesser-than-laboratory-standard equipment would appear to be a way to beat the odds that patients will suffer only from a singular pathology. Additionally, I believe parameter reduction represents a false means of easing recording analysis while turning a blind eye to the potential of other disorders. I strongly feel this approach does not have the patients' best interest in mind.

I do not believe there is an apples-to-apples comparison between the laboratory and ambulatory equipment in terms of performance; with the patient being the primary factor in this determination. Ambulatory monitoring greatly minimizes patient-provider interaction –this is a given. While it can be successfully applied on a very limited basis, it is not an optimal condition for the masses in general. Many patients require a greater level of support than what instruction cards, web sites, and telephone assistance can provide. Laboratory patients, on the other hand, are provided constant human vigilance –not only to intercede in emergent (and non-emergent) situations, but also to insure correct equipment application, sensor integrity throughout the recording, and provide thorough analysis and documentation of the patient's stay (especially for those events the recording equipment cannot decipher). And for as big an issue it has been in recent years, I cannot imagine what will happen to CPAP compliance rates in the population if titration's eventually end up being conducted in unattended conditions.

Which leads to the question: "Is the home more natural than the lab?" No. No matter where the study is conducted, it's just not "natural" to have a battery of electrodes and/or sensors attached all over one's body –much less just before bedtime and then trying to sleep. I have found ambulatory patients voice greater levels of anxiety in the fear of having electrodes fall off or for doing something that might render the study unreadable.

I understand the argument of insufficient access to sleep medicine; however, I feel it was a legitimate complaint in years past. As sleep awareness has increased over the years, the medical community has responded with an increase in testing facilities, trained personnel, and academic-based physician training. As a result, there has been a mushrooming growth of sleep facilities across the country – especially in the larger metropolitan communities.

There are several questions that have surfaced as a result of this review:

- a. What will be the determining factor(s) in decided coverage for ambulatory or facility-based sleep testing?
- b. What ramifications will there be in terms of reimbursement for current PSG facilities?
- c. Should a home study fail in the face of continuing patient complaint, will a laboratory study be reimbursable?
- d. Should ambulatory diagnostics lead to CPAP treatment (via auto-titration), how will the issue of BiLevel (or BiPAP®) application be addressed in an unattended scenario?
- e. If ambulatory sleep recording is allowed, when can we expect approval & reimbursement of Actigraphy for the treatment of insomnia, circadian rhythm disorders, and confirmation of medication efficacy?
- f. Is CMS prepared to handle the potential influx of ambulatory charges –that will dovetail with a markedly increased dispensing of CPAPs?

Lastly, I find it highly contradictory of CMS to press for IDTF accreditation in Region IV through the American Academy of Sleep Medicine (LMRP for Outpatient Sleep Studies, L14056), while opening the door to unsupervised, home-based apnea diagnostics and potential treatment. I also suspect the latter to be ripe for opening a Pandora's box for over-utilization.

In closing, I would strongly urge CMS to consider this review very carefully. I believe there is a place for ambulatory sleep testing, as well as Actigraphy –but only as a compliment to already existing accredited sleep disorders centers. To this end, I firmly believe CMS is at the initial footsteps of researching this topic, and is in great need of additional, unbiased input from the AASM, independent sleep centers, and the sleep diagnostic manufacturing industry as a whole. Until such time all parties are formally queried and responses collected, this decision should be tabled.

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Commenter: Irwin, Richard S., MD, FCCP, President
Organization: American College of Chest Physicians
Date: July 22, 2004
Comment:

The American College of Chest Physicians (ACCP) is the leading pulmonary and critical care organization in the world, pledged to the provision of patient-focused care. It not only represents the largest membership of pulmonary and critical care physicians in the world, but also the largest number of physicians who practice sleep-disordered breathing. The following is in response to two questions posed by CMS regarding the “NCA Tracking Sheet for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R).” The unique multidisciplinary nature of the ACCP enables examination of this topic from a perspective encompassing an extraordinary wealth of diverse specialty knowledge in sleep breathing disorders.

Response to CMS question posed on its Web site about aspects of portable sleep monitoring:

CMS question:

- a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea, which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

Response:

If we take the position posed in the CMS question that unattended portable monitoring is as effective as polysomnography in diagnosing obstructive sleep apnea we believe that the cardiorespiratory parameters of oxygen saturation by continuous pulse oximetry, airflow monitoring with a sensitive measure of change in airflow, respiratory effort, body position and EKG are required at the minimum. Although straightforward sleep disordered breathing could be diagnosed with cardiorespiratory monitoring alone, in some clinical situations, sleep EEG monitoring and leg movement monitoring will be important as well.

We further believe that the most important aspect of the diagnostic process for sleep apnea from home-based studies is the interpretation of the test results. Appropriately trained physicians need to guide and supervise the testing and the interpretation of the results. This requirement is no different than what exists now for polysomnography, the so-called “gold standard” for sleep apnea diagnosis; this test likewise is dependent on appropriate interpretation. Understanding the clinical context of the test is at least as important, if not more so, than the test itself or its individual component measures.

CMS question:

- b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea, what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

Response:

We feel that the most important factors in the use of unattended home studies are:

1. that the patient be evaluated by a physician who has comprehensive training in all aspects of sleep disordered breathing problems including obstructive sleep apnea,
2. that the test be interpreted by such a physician with recommendations for further management.

These factors will allow proper patient selection and a mechanism for dealing with the "false positive" and "false negative" studies that will be generated, as well as enhanced management of sleep disorders other than obstructive sleep apnea.

We also feel that such testing should not be placed in the hands of those who would profit by a certain diagnosis with consequent treatment (e.g. DME companies, ENT surgeons, dentists, etc. who provide treatment) without the interpretive involvement of qualified physicians well-trained in sleep medicine who have no financial interest in the diagnostic outcome and treatment. Also important is the need for the use of adequate technology in the portable systems for data acquisition and analysis with review by a sleep specialist, rather than the use of computer-generated results. Subordinate to these issues are the need for training of patients and families in the usage of the equipment and the need for adequately trained technologists in the preparation of patients and families.

Additionally, I would like to reiterate several points from my correspondence to Dr. Steve Phurrough of CMS dated July 13, 2004. The ACCP believes that there is ample information that sleep-related breathing disorders can be expertly managed by pulmonologists who, through their extensive training, are qualified to treat such disorders, and board-certified pulmonologists can also competently manage and/or work in a sleep laboratory. Advanced, ongoing continuing medical education and program and curriculum requirements for pulmonologists ensure thorough knowledge of and training in sleep-disordered breathing. Examples include, among others, the "sleep disorders" required area of study in the Accreditation Council for Graduate Medical Education's Program Requirements for Residency Education in **Pulmonary Disease** and Critical Care Medicine; and the ABIM's content section of the Subspecialty Examination in **Pulmonary Disease** that deals with "sleep-disordered breathing." Pulmonologists' education requirements and competency in sleep-related breathing disorders cannot be dismissed or ignored.

Commenter: Guevara, Beth Keefer, Manager
Organization: Respironics
Date: July 22, 2004
Comment:

Thank you for the opportunity to comment on the appropriate use of portable sleep testing. If a policy allowing portable sleep testing for the qualification of patients with OSA is adopted, it is important that appropriate parameters be implemented and that testing is done under certain required conditions.

To that end, the following provides information helpful in determining the requirements for portable sleep testing:

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

According to the American Academy of Sleep Medicine (AASM), there are over 80 identified sleep disorders. Sleep apnea or obstructive sleep apnea (OSA) is one of the most common disorders which are evaluated in the sleep lab. It affects ~2-4% of the adult population, and is gaining recognition as a problem in adolescents as well. OSA is characterized by numerous episodes during sleep where the airway obstructs due to a number of factors such as large tonsils and/or adenoids, excessive tissue in the airway, or other anatomical anomalies such as micrognathia (recessed/small lower jaw). When the airway is obstructed, the patient with obstructive apnea continues to have a drive to breathe, and effort is seen to occur in the chest and/or abdomen in the absence of airflow. As a result there are tremendous pressures developed in the chest cavity, and due to the increased work of breathing, the patient generally desaturates their oxygen level. There are generally also cardiac effects as well, which can be observed as heart rate changes.

It is appropriate to consider use of portable sleep testing when a physician trained in sleep has a high suspicion that the patient has OSA and additionally, the physician does not suspect that the patient has other underlying sleep disorders or an underlying poorly managed respiratory or cardiac disorder. Use of an OSA-specific screening questionnaire can rule in OSA while use of an overall sleep questionnaire can help to rule out other sleep disorders. The Berlin Questionnaire is an example of an OSA-specific screening questionnaire that has been validated in the primary care setting. It has 89% predictive probability. This means that if the results of the Berlin Questionnaire are positive, the patient would benefit from a diagnostic test and 89% of the time, the diagnostic test will

be positive for OSA. If there is any doubt of the likelihood of OSA or there is the possibility of other sleep disorders, the patient should be tested in a Sleep Lab.

Therefore to assess OSA, there are a minimum number of channels that should be used. These include:

- **Airflow** – this can be accomplished by one of two methods typically,
 - **Pressure transducer via a nasal cannula interface.** This measurement is endorsed by the American Academy of Sleep Medicine (AASM), the American Thoracic Society (ATS) and the American College of Chest Physicians (ACCP). It is gaining broad acceptance as the desired method for determining airflow. It can better indicate subtle airflow changes from the following:
 - Snoring
 - Hypopnea (shallow breathing) events
 - Airflow limiting events from partial obstructions etc.
 - **Thermal Airflow (Thermistor or Thermocouple) measures airflow as a temperature change at the nose/mouth as the patient breathes.** This method is still used in clinical practice although the trend is toward an increased use of pressure transducer via a nasal cannula. This produces a sinusoidal type of waveform relating to the airflow. It is not as sensitive to the subtle changes in airflow as the pressure transducer.
- **Breathing Effort** – This requires one to two belts placed over the patient's chest and when two belts are used, over the abdomen as well. These measure the patient's effort to breathe. A minimum of one effort belt is required. This helps in the classification of the apnea types (obstructive, central, and mixed).
- **Oximetry** (Blood Oxygen Level) – Necessary to determine physiologic consequence of respiratory events.
- **Heart Rate** – This can be obtained from the oximetry sensor.
- **Body Position** – Minimum of supine (on the back) or any other sleeping position. Events primarily occurring in supine may contribute to the treatment decision.

b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

For the channels described above to assess OSA, patient instruction can be minimal. This level of device can be reviewed with the patient by a clinician trained in sleep. Training

and initial fitting of the sensors can be accomplished in 15-30 minutes. The sensors can later be applied, and the study initiated (device turned on) by the patient when they are ready to go to sleep.

More extensive devices exist that can record other parameters, which can extend the diagnostic capabilities of the device. However, by adding parameters such as Leg Movement, ECG, Sleep Parameters such as Eye Movement, Actigraphy, EEG, etc., the patient instruction and set-up may necessarily be substantially expanded. Application of EEG or EMG electrodes would require a technician trained in sleep.

These devices typically record to internal memory and the data later downloaded to a PC when the patient returns the device following the study. If there is a problem with the data, the study can be repeated, though the incidence of repeat studies is generally less than 10% of those performed. Any troubleshooting during the study would be limited generally to sensor placement or device operation. These questions can generally be addressed via phone. Those administering the tests should maintain 24-hour technical support to address any issues that may occur.

While software associated with the devices generally has “auto-scoring” analysis, clinician review of the data is generally regarded as important to correct areas of the data where the auto-analysis may have erred as a result of the data not being clear, such as during events following a body position change. This basic cardiopulmonary data is fairly straight forward waveform data, which can be reviewed/scored in approximately 30 minutes by a technician. The reported results from such a study include parameters such as the Respiratory Disturbance Index (RDI), associated oximetry and heart rate changes, and events by body position. A qualified physician must then interpret the study results and make any required treatment recommendations.

Again, thank you for allowing comments on the use of portable sleep testing. I would welcome the opportunity to provide further clarification or assistance to you, as appropriate.

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Commenter: Clymer, Lois, RN

Organization:

Date: July 22, 2004

Comment:

I would like to see unattended portable home sleep testing become available to the elderly population who are fearful of facility-based polysomnography. I have seen the Watch PAT 100 give similar results to facility-based polysomnography. The simplicity and accuracy of the Watch PAT 100 makes it a favorite with patients.

Commenter: Cuervo, Asela M., Senior Vice President

Organization: American Association for Homecare

Date: July 23, 2004

Comment:

The American Association for Homecare (AAHomecare) submits the following comments on the Centers for Medicare and Medicaid Services' (CMS') reconsideration of the national coverage decision (NCD) on the use of continuous positive airway pressure (CPAP) devices for the treatment of obstructive sleep apnea (OSA) in adults. Currently, the NCD states that only a polysomnogram performed in a facility-based sleep study laboratory may be used to identify patients with OSA who will require CPAP. In response to a request from Dr. Terence M. Davidson, CMS has opened the NCD for reconsideration on whether CMS should permit the use of portable multi-channel sleep testing devices in the home site of service as an alternative to facility based polysomnography for individuals with a high pretest probability of OSA.

CMS opened a comment period on the reconsideration on April 8, 2004. Based on its review of the public comments, CMS has initiated another thirty (30) day comment period soliciting comments on how the diagnostic performance of unattended portable multi-channel sleep testing compares to facility based polysomnography in the diagnosis of OSA. The notice also solicits comments specifically addressing the following two issues:

- a. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?
- b. If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e., patient education, technician support) are required so that it is done correctly in the home?

Background

AAHomecare represents member companies in every line of service within the homecare community. Our members include home health agencies and suppliers and manufacturers of durable medical equipment (DME) services and supplies and assistive and rehabilitative technologies. AAHomecare submitted comments in support of a revision to the current NCD for CPAP to permit the use of portable multi-channel sleep testing devices in the home site of service as an alternative to facility based polysomnography for the evaluation of OSA. Our comments noted that many private sector payers currently recognize the use of home sleep studies for the diagnosis of OSA because this technology is reliable and affordable. Importantly, the use of portable multi-channel sleep testing in the home site of service would relieve the barriers to treatment for OSA that results from a lack of timely access to facility based polysomnography.

Comments

Diagnostic Test Performance of Multi-Channel Home Sleep Studies

CMS has requested comments on the performance of multi-channel home sleep testing when compared to facility based polysomnography in the diagnosis of OSA. Several studies have compared unattended portable multi-channel home sleep studies with facility based polysomnography in the diagnosis of OSA. These studies found a high degree of correlation in diagnostic performance between the two tests. For your reference, these studies can be found in Attachment "A." The chart in Attachment "B" provides a brief summary of the studies' findings. These studies confirm the reliability of multi-channel home sleep studies as a diagnostic test for OSA when compared to facility based polysomnography.

Parameters for Sleep and Cardiorespiratory Function and Test Conditions

CMS has also specifically requested comments on the appropriate parameters of sleep and respiratory function that multi-channel home sleep studies should measure. The

notice also solicits comments on the conditions necessary to ensure that the sleep study produces reliable results in the home. We suggest that CMS use the parameters identified in the current CPT code descriptor for unattended sleep studies. Specifically, the CPT code provides:

95806	Sleep study, simultaneous recoding of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist.
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The studies we cited in Attachment “A” provide data and analysis on the performance of multi-channel home sleep studies measuring the parameters identified in the descriptor for 95806. They show, as we stated above, a high degree of correlation with the diagnostic performance of facility based polysomnography. These studies further describe the level of environmental support that was necessary to achieve reliable outcomes. Generally, test subjects received instruction from a technician on the operation of the device. One study included remote monitoring by a technician during the night. Based on a review of the literature, we recommend that CMS adopt the cardiorespiratory measures identified in the descriptor for CPT code 95806 and that CMS include a requirement for patient education as a condition for the sleep study. Finally, we also encourage CMS policy to include the requirement that a physician interpret the home sleep study. This will ensure that OSA patients receive appropriate care following their diagnosis.

Conclusion

CMS should allow the use of home sleep studies for the diagnosis of individuals with OSA under the current CPAP national coverage policy. The clinical literature shows that the diagnostic test performance of multi-channel home sleep studies correlates highly with that of facility based polysomnography for OSA. CMS should adopt the cardiorespiratory parameters under the current CPT code for unattended sleep studies for diagnosing OSA. The clinical literature supports the use of these parameters for achieving a reliable diagnosis for OSA. Test subjects should receive appropriate instruction prior to the sleep study to ensure a reliable diagnosis. Finally, CMS policy should require that a physician interpret the home sleep study so that patients with OSA receive appropriate follow-up care.

We appreciate the opportunity to submit these comments and remain available to discuss them with you in greater detail. Please feel free to contact me if you have any questions.

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Redline, Susan, Tosteson, Tor, Bouchen, MaryAnn, Millman, Richard, **Measurement of Sleep-Related Breathing Disturbances in Epidemiologic Studies**, *Chest* 1991; November; 1281.

White, David P., Gibb, Thomas, J., Wall, John M., Westbrook, Phillip R., **Assessment of Accuracy and Analysis Time of a Novel Device to Monitor Sleep and Breathing in the Home**; *SLEEP* 1995; 18: 2.

Author/Article	Device Used	Conclusions	Titration Discussed	Technician work needed
White et al – Assessment of Accuracy and Analysis Time of a Novel Device to Monitor Sleep and Breathing in the Home	HealthDyne's NightWatch – measures ventilation, respiratory effort, heart rate, O2 sats	<ul style="list-style-type: none"> Diagnostic correlation with polysomnography was 0.92, with good sensitivity and specificity Patients could sleep as long as they liked and had greater sleep efficiency Could not always tell whether the patient was asleep Authors contend that "symptomatic (hypersomnolent) patients with a high probability of sleep apnea could be studied in the home." 	<ul style="list-style-type: none"> "An additional titration night would be required if CPAP was the therapeutic choice" 	<ul style="list-style-type: none"> Patient reported to sleep lab day of test for thorough instruction on equipment application and data recording Technician followed via modem all night – data was transmitted every 30 minutes
Redline et al – Measurement of Sleep-Related Breathing Disturbances in Epidemiologic Studies	Puritan Bennett's EdenTrace – measures parameters listed above	<ul style="list-style-type: none"> High level of agreement of respiratory events between the portable monitor and polysomnography Valid and highly reproducible index for assessment of sleep-related respiratory disturbances Epidemiological study of 29 patients 	<ul style="list-style-type: none"> Not mentioned 	<ul style="list-style-type: none"> Not discussed
Coppola et al – Management of Obstructive Sleep Apnea Syndrome in the Home; The Role of Portable Sleep Apnea Recording	EdenTrace as above	<ul style="list-style-type: none"> A strongly positive unattended sleep apnea recording is diagnostic and further diagnostic evaluation is not necessary if the patients' conditions improve with appropriate therapy 	<ul style="list-style-type: none"> Home titration was started at 5 cm to 7.5 cm (for patients with severe AHI and large body mass index) Phone follow-up after 3 nights of CPAP – pressure levels increased by 2.5 cm increments until the patient reported a reduction in snoring and improvement in daytime somnolence Inpatient titration planned if patient symptoms not corrected at 10 cm of CPAP 	<ul style="list-style-type: none"> Application of the recording device was done in the home by a technician who instructed the subject and bed partner on the performance of the overnight recording. The technician spent 1-2 hours with the patient and family. The technician returned the next morning to retrieve the recorder. "The patients' spouses were able to determine when signs of abnormal breathing had disappeared." Sleep apnea recording was repeated after at least two weeks of the final CPAP level to make sure titration was successful.

<p>Series – Accuracy of Unattended Home CPAP Titration of Obstructive Sleep Apnea</p>	<p>Puritan Bennett's auto-CPAP Device</p>	<ul style="list-style-type: none"> • A short auto-CPAP trial at home for 1-2 weeks could be proposed by home care services before setting fixed CPAP therapy • Auto-CPAP titration at home must be accompanied by strict follow-up • If home CPAP titration fails, conventional CPAP titration in the hospital/sleep lab setting should be performed • When effective pressure reached, patient was placed on fixed therapy with a conventional CPAP device 	<ul style="list-style-type: none"> • See conclusions 	<ul style="list-style-type: none"> • Printout and interpretation of auto-CPAP report after two weeks of therapy; adjustment of effective pressure
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Centers for Medicare & Medicaid Services

NCA Tracking Sheet for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R)

Submitted to: Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted by: Circadian Technologies, Inc.
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Summary

Circadian Technologies Inc. (Circadian) strongly supports the use of portable multi-channel home sleep testing by responsible physicians and encourages the Centers for Medicare & Medicaid Services to review their national coverage decision regarding the diagnosis of patients with obstructive sleep apnea (OSA) requiring CPAP therapy.

In response to the re-opening of this comment period of NCA-CAG-00093R, Circadian offers evidence to the CMMS that large numbers of patients in certain populations go undiagnosed when the only option for diagnosis is facility-based polysomnography, causing increased costs for medical provision for other disorders exacerbated by OSA, and increased risk of accidents in the same population.

In addition, research clearly demonstrates that portable multi-channel home sleep testing is an effective alternative to facility-based polysomnography in the evaluation of OSA when undertaken by responsible clinicians and can increase the percentage of patients diagnosed and treated for OSA in a population, thereby decreasing additional medical costs and accident risks.

The education of technicians and patients in the use of portable devices within Circadian's OSA screening programs for shiftwork populations has been straightforward and successful. Simple solutions such as telephone access to technical support around the clock and patient information sheets on how to use the devices have been well received and highly successful.

Of particular note, Circadian would like to highlight their findings that patients who are happy to attend a sleep lab usually choose to do so even when home-testing is available. We predict that making home testing available would not alter the patient flow into the sleep labs, and should not be viewed by Sleep Physicians as harmful to their business revenue. Portable multi-channel home sleep testing simply allows a group of patients to

be diagnosed that would otherwise continue to suffer with the disorder and continue to have excess costs and risks.

Significant under-diagnosis

Several studies have described average prevalence of OSA in the different populations, ranging from 2% to 24% (Young, 1993; Agency for Healthcare, Research and Quality, 2000). However, a steady increase in the proportion of obese people in the US population will directly increase the prevalence of OSA going forward. Circadian's own databases of 10,000 extended hours workers in the US show a prevalence of OSA of 11.6%.

Currently, only a very small percentage of individuals with OSA severe enough to require treatment are diagnosed and treated. Some studies have found that at least 80% of moderate to severe SAS in middle-aged adults is likely missed (Young, 1997).

Several factors contribute to this fact:

- Few individuals consult their physicians about sleep problems and the minimization of sleepiness-related symptoms in these patients is well known (Engleman, 1997).
- Education of physicians, especially generalists, has lagged behind. In general, primary care physicians are not trained to identify OSA and there is an absence of any recognition strategy in primary care providers.
- The obstacle of the overnight polysomnography visit which, in our experience, patients usually do not wish to attend.

Costs of OSA

The evidence of the harmful health effects of undiagnosed apnea is clear:

- 40% increase in Excessive Daytime Sleepiness (Ulfberg, 1996),
- Twice as many traffic accidents per mile (Horstmann, 2000),
- Three fold risk of occupational accidents (Ulfberg, 2000),
- 1.3 to 2.5 times more hypertension (Krieger, 2002; Smith, 2002),
- 2.2 times increased risk of nocturnal cardiac arrhythmia (Smith 2002),
- 3.9 times more likely to have congestive heart failure (Smith, 2002),
- 1.6 times increase chance of stroke (Moore, 2001; Shahar, 2001),
- 1.4 to 2.3 times more risk of heart attack (Saito, 1991; Shahar, 2001),
- 40% increased risk of depression (Smith, 2002).

The evidence of the cost of undiagnosed apnea is clear:

- more than twice the number of physician claims (Kryger, 1996; Kapur, 1999; Smith, 2002),
- 1.9 times more cardiovascular medication (Otake, 2002),
- 2.7 times more hypertension medication (Otake, 2002),
- 50% more hospital stays (Smith, 2002),
- 2.63 times the amount of absenteeism (Servera, 1995),
- 20% reduction in performance (Ulfberg, 1996),

- increased costs for accidents, injuries, absenteeism and overtime, workers compensation, property damage, etc. (Kerin, 2003)

Circadian Technologies has calculated that a highly conservative excess cost of undiagnosed OSA in the working population of the USA is \$6,091 per worker, per year. The excess medical costs alone are calculated to be \$2,718 per undiagnosed apneic per year. In addition to the health and lifestyle benefits provided to the patient, the cost effectiveness of finding and diagnosing sleep apneics to reduce this annual loss is obvious.

Technological advances

Historically, Circadian has found that encouraging patients to go to a sleep lab has been the most difficult obstacle to overcome in successfully diagnosing and treating apneics. However, novel technology in portable multi-channel home sleep testing has allowed patients to be measured non-invasively while they sleep in their own bedroom.

Circadian finds that the cardiorespiratory parameters measured in portable multi-channel home sleep testing (airflow via pressure transducer, breathing effort, blood oxygen saturation and heart rate) are sufficient to diagnose OSA when a knowledgeable physician has used a pre-screening questionnaire to rule out other types of sleep disorders in the populations we have worked with. Research has clearly demonstrated the same diagnosis results using home testing as clinic-based polysomnography when used by responsible physicians, saving the cost and obstacle of the overnight study (Parra, 1997; Kristo, 2001; Golpe, 2002).

Previously, the sleep lab visit was also necessary to determine and prescribe the correct pressure level for the CPAP treatment device. Technological advances in this field have provided “self titrating” CPAP units that constantly vary the pressure levels to deliver the minimal pressure necessary to keep the airway open during sleep. Studies have clearly shown that home self-titration of CPAP has been proven to be as effective as in-laboratory manual titration in the management of patients with OSA (Massie, 2003; Fitzpatrick, 2003).

Circadian would like to highlight their findings that patients who are happy to attend a sleep lab usually choose to do so even when home-testing is available. We predict that making home testing available would not alter the patient flow into the sleep labs, and should not be viewed by Sleep Physicians as harmful to their business revenue. Portable multi-channel home sleep testing simply allows a group of patients to be diagnosed that would otherwise continue to suffer with the disorder and continue to have excess costs and risks.

The technology has reached a level where we can safely and confidently screen patients for OSA using portable multi-channel home sleep testing. We would urge MCS to reexamine the research and technology currently available in order to open up OSA diagnosis options to the patients in their system.

About CIRCADIAN: Circadian is the leading international research and consulting firm assisting companies with extended hours operations to improve profits by increasing productivity and reducing the increased costs, risks, and liabilities of human factors. Circadian has been providing OSA screening programs to corporate populations with

extended hours workers since 1990. Extended hours operations encompass all work environments with irregular schedules, night and evening shifts, or extended hours, typically outside the hours of 7 a.m. and 7 p.m. Since its incorporation by Dr. Martin Moore-Ede in 1983, more than half the Fortune 1000 has benefited by working with Circadian.

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Commenter: Remmers, John E., MD
Organization: hi
Date: July 23, 2004
Comment:

I am responding to your request for information regarding the use of portable monitoring in diagnosis of obstructive sleep apnea. I and my colleagues at the Southern Alberta Sleep Disorder Centre have been using a validated home monitor for diagnosis of uncomplicated sleep apnea for the past eight years. Since April 1 2002, this home monitor has been used throughout the city of Calgary as the exclusive method for diagnosis of uncomplicated sleep apnea. The lack of clinical misadventures, apparent cost savings and obvious patient convenience have been strongly appreciated by physicians, providers and clients. In addition, access to diagnosis has been enhanced so that patients with severe obstructive sleep apnea and obstructive sleep apnea plus heart disease have been identified and have received in-hospital polysomnograms.

Validity of Home Testing for Diagnosis of Sleep Apnea

Technical Proficiency. The pioneering work of Douglas *et al* (Douglas NJ, Thomas S, Jan MA. Clinical Value of polysomnography. *Lancet* 339:347-501992) showed that monitoring sleep and sleep related variables did not improve diagnostic accuracy or management decisions in obstructive sleep apnea. Vasquez *et al* (Vazquez J-C, Tsai WH, Flemons WW, Masuda A, Brant R, Hajduk E, Whitelaw WA and Remmers JE. Automated analysis of digital oximetry in the diagnosis of obstructive sleep apnoea. *Thorax* 55:302-307, 2000.) described an algorithm for automatic analysis of arterial oxygen saturation. This algorithm is incorporated in a commercially available monitor, the Remmers Sleep Recorder. A large randomized trial compared the RDI from an in-hospital polysomnogram with the RDI automatically calculated by the Remmers Sleep Recorder. The results revealed high correlation ($R=.97$), diagnostic accuracy (sensitivity and specificity 88-98 per cent) and excellent agreement by the Bland Altman analysis. Direct comparison between this oximeter algorithm and a home polysomnogram has been recently completed in Montreal and shows similar results. In view of the uncertain clinical utility of the respiratory disturbance index, the agreement between the portable monitor and the polysomnogram appears to be more than adequate for diagnosis of uncomplicated sleep apnea.

Clinical Utility. We have completed a large randomized trial which compares the utility of the Remmers Sleep Recorder with the in-hospital polysomnogram. Subjects were seen by a group of sleep physicians and the primary outcome variable was accuracy in predicting success with nasal CPAP. The information provided by the polysomnogram provided no clinical utility over that provided by the home respiratory test.

Clinical Application of Home Monitoring for Diagnosis of Obstructive Sleep Apnea

Sleep Variables to be Recorded. In addition to oxygen saturation, body position has proven to be extremely important in understanding the occurrence of obstructive sleep apnea during the night. Snoring sound is helpful as many clients encounter snoring as a social problem. Finally, respiratory airflow, as measured by nares pressure, is particularly useful in identifying inspiratory flow limitation and episodes of high upper airway resistance.

Conditions Required. Considerable experience with our recorder shows no intervention in the home is required. An initial education session provides adequate education for the patient. Because the patient receives visual analogue feedback regarding signal integrity at the time of applying sensors, the failure rate is extremely low (approximately two per cent). The validated automatic analysis means that the test is highly cost effective. Overall, both the purchase price and the cost per test are approximately one tenth using the home monitor as compared to the in-hospital polysomnogram. Our perception is that most patients prefer the home test over the polysomnogram both in regard to convenience and social circumstances. In addition, home monitoring provides more relevant information since it more closely mimics usual sleep with regard to body position, exposure to allergens and ingestion of alcohol.

The home recorder we have used is referred to as the Remmers Sleep Recorder and is manufactured by SagaTech Electronics Inc. (www.sagatech.ca). It is available throughout Canada and FDA approval is pending. Overall, our extensive experience in Calgary and other sites in Canada, together with Level 1 evidence of technical proficiency, reassures us that for diagnosis of uncomplicated sleep apnea using our in-home respiratory test method is clinically valid, more convenient and more cost effective.

Commenter: Barone, David, M.Sc., MBA
Organization: Barone & Associates
Date: July 23, 2004
Comment:

This letter is written in response to the pending review of the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography required to initiate treatment for obstructive sleep apnea (CIM 60-17), and specifically, to your recent request for additional comments on the questions outlined below.

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

Numerous studies reported that for significant percentage of patients with suspected obstructive sleep apnea, the efficacy of diagnosing sleep apnea at patients' homes using multi-channel testing devices (categorized by the American Academy of Sleep Medicine

as “Level III Sleep Study”) is similar to the efficacy of studies conducted in a sleep laboratory. It is important also to recognize that a number of publications have reported on certain limitations of unattended studies. In most instances, these reviews point to limitations of technologies developed years ago, such as (i) compromised data as a result of sensors falling off during the night, and (ii) lack of information on sleep states and sleep fragmentation. Yet, a number of new technologies introduced in recent years for the specific function of ruling out sleep apnea in an unattended setting, overcome such limitations, as evidenced by multiple papers published in peer-reviewed journals.

If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea, which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

One of the best documented devices for verifying sleep apnea in an unattended setting is the Watch-PAT system. The performance of this device provides similar results to well-performed polysomnography studies (1-4). When used in an unattended setting, the Watch-PAT performance correlates very well with polysomnography, and with over 700 patients participating in multiple controlled studies, the overall reported sensitivity was 93%.

The Watch-PAT identifies apnea events by monitoring reactions to breathing disturbances by the sympathetic nervous system, enhanced by blood oxygen desaturation. This signal, reported in the literature as “Peripheral Arterial Tone”, provides for a very useful clinical substitute to the problematic and less reliable air flow measurement used in many of the older devices. The science behind this signal is also well documented in many publications (5-14). Furthermore, the published data confirms that measurement of peripheral arterial tone eliminates many of the failures seen in sleep studies due to inaccurate or unreliable air flow measurement. The non-invasive and non-intrusive measurement of the PAT signal is also preferred by patients, and thus, enhances patients’ ability to undergo successfully the sleep study. The Watch-PAT device also provides important information about sleep and wake states. With this information, the accuracy of the results is enhanced, and the physician managing the care of the patient can also evaluate sleep fragmentation during the night, information otherwise not available, unless EEG signals are recorded.

It is recommended that CMS modifies its guidelines to state which clinical information is required to perform a diagnosis of sleep apnea, rather than dictate the specific methodology, as methodologies may undergo frequent changes due to enhanced scientific and technological enhancements. Based on the published data, as well as the actual experience gained in recent years by many users of newer technologies, CMS guidelines should require the availability of the following clinical information in any sleep study, whether attended or unattended:

Measurement of apnea events or respiratory disturbances (using any of the applicable measurements such as airflow, nasal pressure or recording of the sympathetic reactions through a peripheral arterial tone signal)

Oxygen desaturation levels

Heart or pulse rate

Sleep fragmentation information (e.g. sleep / wake states).

In addition, any device used in unattended sleep studies should be specifically approved by the Food and Drug Administration for that specific purpose.

If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea, what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

As is the case in many other disease states, physicians should have multiple diagnostic options, and should discuss such options with their patients. For those patients presented with symptoms suggesting sleep apnea, the decision of whether the study should be conducted in a lab setting or at the patient's home is best left to the managing physician. Presently, primary care physicians or other specialists, including sleep specialists treating Medicare beneficiaries, have only two options: conduct a sleep study in a sleep laboratory, or not conduct any evaluation at all. It is only prudent to offer them another option. If the physician elects to order an unattended sleep study, the patient should receive an explanation of how to use the device. Such explanation can be provided in the physician's office, or alternatively, at the patient home by a medical technologist. This proposed approach is similar to that taken by CMS for other diagnostic evaluations, such as for cardiovascular diseases, where the patient's primary care physician or a specialist can choose any of the available diagnostic modalities, such as in-office rest ECG, stress test, echocardiogram, etc., or alternatively, an ambulatory and unattended Holter recording.

In summary, it is well recognized that the large majority of patients with obstructive sleep apnea are yet to be diagnosed and treated. The largest impediment to changing this paradigm is increasing the awareness of additional physicians to the disease and involving them in a more proactive manner in identifying these patients. Additional diagnostic options will lead to an earlier therapeutic intervention, a key to affecting the prognosis of these patients. In light of the published data and the experience gained by providers in recent years, we reiterate our recommendation to CMS (outlined in previous communication to the Agency) to modify its guidelines to incorporate the following points:

Patients that do not present significant symptoms of sleep disorders other than sleep apnea, or patients undergoing a follow-up review post initial therapeutic intervention for sleep apnea, may be tested either in a sleep laboratory or at other settings, including the patient home, as long as the multi-channel device used in the diagnostic evaluation provides the following clinical data: the presence and duration of apneic events, including oxygen desaturation and pulse or heart rate, as well as information of sleep fragmentation, recognizing periods of sleep and wake during the study. Initiation of CPAP therapy or other treatments for sleep apnea will be covered following any of the sleep studies discussed above.

Patients testing negative for sleep apnea using an unattended study, but continue to present symptoms of hypersomnolence or reported episodes of breathing cessations during sleep, should be referred to a sleep specialist for further evaluation. Patients refusing test in a sleep laboratory, or patients not able to undergo a diagnostic study in a sleep laboratory due to physical limitations, may undergo a study at home, using multi-channel sleep testing devices that meet the requirements outlined above.

Modifying the current guidelines will enable Medicare beneficiaries the option of undergoing sleep studies in a sleep lab or in an unattended setting, when such a test is compatible with their medical needs and is recommended by their physician. Unattended sleep studies using multi-channel devices, approved for this purpose by the Food and Drug Administration, complement very well the more elaborate polysomnography study, allowing sleep specialists and other physicians to apply the optimal modality when managing their patients.

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increased inspiratory effort to breathe, against the obstruction of the upper airway

- body position parameter of sleep dynamics on airflow conditions which supports diagnosis and treatment options

- oxygen saturation defining the inter-relationship of the cardiorespiratory system and severity of apneas associated with decline in oxygen delivery

- heart rate cardiorespiratory indicator for severity of disease

* When performed judiciously home sleep testing will provide diagnostic information for interpretation and improve pathways for patient care plans and OSA treatment.

* Home sleep testing conditions required for the diagnosis of obstructive sleep apnea would include:

- patient education should include written materials with details of sensor applications and should be verbally reviewed with the patient

* healthcare professional with documented training in the aspects of sleep disorders and home sleep testing

- data download and review to meet quality standards for handling patient data with knowledge of sleep diagnostic tracings

* healthcare professional with documented training in the aspects of sleep disorders and home sleep testing

- data analysis and interpretation requires the in-depth knowledge of the many aspects of sleep disorders breathing for a differential diagnosis

* physician with documented training in the aspects of sleep disorders and home sleep testing, board certified in sleep medicine preferred

- clinical/technical support should be available 24 hours/day to address any patient questions or concerns related to the study process and techniques of monitoring or sensor position

* healthcare professional with documented training in the aspects of sleep disorders and home sleep testing

In a disease management model, healthcare costs and utilization of services will benefit with a comprehensive program for OSA. The patient-centric model provides education throughout the process from identification of co-morbid conditions, home sleep testing, coordination of diagnosis and treatment with compliance management to compliment the CPAP treatment plan.

Commenter: Lerman, Amir, M.D., F.A.C.C.
Organization: Chest Pain and Coronary Physiology Clinic
Date: July 23, 2004
Comment:

This letter is to strongly and enthusiastically support the use of Watch-PAT as a noninvasive ambulatory device for assessment of sleep disorders.

Sleep apnea currently has reached the level of an epidemic, and as a cardiologist, I have seen a lot of overlap between cardiovascular disease and sleep apnea. Our group recently reported the association between sleep apnea and atrial fibrillation which also serves as a major concern of morbidity and mortality in the elderly population.

The availability of ambulatory outpatient devices to assess sleep apnea certainly will have a significant impact on our practice as well as on our ability to identify patients with sleep apnea and treat them. The relationship between the incidents of sleep apnea and other cardiovascular disease is emerging, and the appropriate treatment for these patients I believe is going to have a significant impact on cardiovascular events.

I had the opportunity to work closely with the Watch-PAT as well as other noninvasive devices from the same company for identifying vascular disease. I was deeply impressed by the reliability and the novel technology of these devices, and we are currently in the process of integrating these devices into our clinical practice.

In summary, as a cardiologist and investigator, I strongly support the integration of the Watch-PAT into our clinical practice.

Commenter: Mahowald, Mark W., MD
Organization: Hennepin County Medical Center
Date: July 24, 2004
Comment:

The MN Regional Sleep Disorders Center at Hennepin County Medical Center has been using the Watch-PAT device for a number of years - primarily in research projects involving sleep-disordered breathing in patients with complicated neuromuscular disease. We also have experience with

thousands of home studies with other cardio-vascular devices (performed as part of the NIH-sponsored Sleep Heart Health Study). It is clear that the Watch-Pat device is not only equal, but in some areas, superior to the standard cardio-vascular devices. Our group strongly endorses inclusion of Watch-PAT in the CMS approval of such devices. It would be regrettable to exclude such a well-validated and valuable technology.

Commenter: **Weaver, Edward M., MD, MPH**
Organization: University of Washington
Date: July 25, 2004
Comment:

HOW DOES THE DIAGNOSTIC TEST PERFORMANCE OF UNATTENDED
PORTABLE MULTI-CHANNEL
HOME SLEEP TESTING COMPARE TO FACILITY-BASED
POLYSOMNOGRAPHY IN THE DIAGNOSIS OF
OBSTRUCTIVE SLEEP APNEA?

Unattended portable multi-channel home sleep testing compares well to facility-based polysomnography in the diagnosis of obstructive sleep apnea.

First, one should recognize the limitations of facility-based polysomnography.

Facility-based polysomnography itself remains non-standardized and is performed by practitioners of varying levels of training. For example, airflow is measured in very different ways in different accredited laboratories. Pressure transducers are extremely (overly?) sensitive to airflow reductions, while thermistors are less sensitive yet still commonly used. Apnea and hypopnea definitions vary from laboratory to laboratory, even though the definitions impact the rate of diagnosis of sleep apnea. Please note that technicians, not the sleep physician, score polysomnographies in most laboratories. Standardization of technician scoring is variable as well.

In addition, there is an inherent limitation to the physiological measurements of sleep apnea. It has been well documented that the standard physiological parameters derived from polysomnography hardly correlate with other important subjective and objective measures of disease burden in sleep apnea patients (1-10). The sleep testing parameters are useful, but it is not clear how accurately they are measured or how precisely they need to be measured on polysomnography.

Split-night polysomnography (2-3 hours of diagnostic testing followed by 3-6 hours of CPAP titration) is covered by CMS for the diagnosis and treatment of obstructive sleep apnea. Diagnosis on split-night polysomnography yields

results different from full night polysomnography, because sleep apnea severity tends to worsen later in the sleep period when split-night polysomnography is no longer measuring disease severity. There are very limited data of sufficient statistical power to show equivalence of split-night polysomnography to full-night polysomnography for the quantification of sleep apnea severity. The data supporting unattended portable multi-channel home sleep testing are of higher quality and are more extensive than those for CMS-covered split-night polysomnography.

Second, there is good evidence supporting unattended portable multi-channel home sleep testing.

A recently published evidence review (11) was cited by commenters as evidence against home sleep testing. While this review demonstrates excellent rigor, the interpretation of the results may be vulnerable to the inherent bias of the polysomnographer authors. The bottom line is that the review found evidence that supports the ability of portable sleep tests to rule in and to rule out sleep apnea. Eight of nine studies of Type 3 monitors (like those proposed in CMS policy change request) that were compared to polysomnography in the lab were level I or II evidence. They all had very low or reasonably low likelihood ratios (meaning excellent negative predictive value) and small false-negative rates (4 - 8%), specificities >90%, and very high sensitivities. When tested at home in four studies (two were level II studies), they also performed well with low likelihood ratios and false-negative rates (17%), and specificities of 66-100%, after correcting for sleep position differences between the lab and home.

Evidence-based medicine dictates that the best available evidence, combined with clinical judgment and patient preference, guide clinical decision-making (12). The available evidence (including in lab comparison) supports the role of unattended portable multi-channel home sleep testing for evaluating sleep apnea.

For uncomplicated sleep apnea, sound clinical judgment supports home testing. And, as a clinician who sees many patients with sleep apnea, I can assure you patients prefer the idea of home testing over facility-based testing.

A. IF UNATTENDED PORTABLE MULTI-CHANNEL HOME SLEEP TESTING IS AS EFFECTIVE AS POLYSOMNOGRAPHY IN THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA WHICH PARAMETERS OF SLEEP AND CARDIORESPIRATORY FUNCTION (I.E., SLEEP STAGING, BODY POSITION, LIMB MOVEMENTS, RESPIRATORY EFFORT, AIRFLOW, OXYGEN SATURATION, ECG) ARE REQUIRED?

Measures of ventilatory signal (e.g., airflow), oximetry, and obstructive versus central apnea (e.g., respiratory effort) must be included in multi-channel sleep testing. Limb movements, ECG, body position, and sleep staging are not

necessary to diagnose routine sleep apnea, even if they may be helpful for some patients. It should be noted that body position can vary significantly from night to night, so that a single-night measure is of unclear utility. As discussed above, split-night polysomnography measures sleep apnea severity for just 2-3 hours, and thus often does not measure sleep apnea in all stages of sleep. Thus, among those accepting split-night polysomnography (including CMS and the American Academy of Sleep Medicine), there is implicit agreement that sleep staging is not necessary to diagnose obstructive sleep apnea.

B. IF UNATTENDED PORTABLE MULTI-CHANNEL HOME SLEEP TESTING IS AS EFFECTIVE AS POLYSOMNOGRAPHY IN THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA WHAT CONDITIONS (I.E., PATIENT EDUCATION, TECHNICIAN SUPPORT) ARE REQUIRED SO THAT IT IS DONE CORRECTLY IN THE HOME?

Patients must be educated on proper set-up of the home sleep testing equipment.

Depending on the testing equipment, it may require instruction from a technician or it may only require written instructions. For technical failures, repeat home testing or facility-based polysomnography must be available. For diagnostic ambiguities, facility-based polysomnography should be used; however, polysomnography back up testing would be required in less than 20% of patients.

Similar to 24-hour Holter monitors or 48-hour continuous blood glucose monitoring, the set-up can be managed through physician offices. Alternatively, many homecare companies have the technical expertise to provide adequate home sleep testing services. Sleep test results must be interpreted by a licensed physician. Like with EKG or chest x-ray, no specialized certification is required to interpret the results; however, specialty consultation may be available from physicians trained in sleep medicine for complicated cases.

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Commenter: Jensen, Scott M., MD and Whisler, Curtis, MD
Organization: Catalyst Medical Clinic
Date: July 23, 2004
Comment:

The physicians at Catalyst Medical Clinic in Watertown, MN support the use of unattended portable multi-channel sleep testing. We believe that unattended testing for sleep apnea shows excellent result

comaprison to polysomnography. Utilizing at-home sleep testing allows us to reach a broader patient range and provide a higher level of care to our patients who are unable to attend a sleep laboratory due to health issues, time availablity, or inability to travel. The inability to travel is a large concern of ours with our Medicare patients, many of whom are not capable of traveling or arranging transportation to a sleep laboratory. Because of this, patients with probable sleep apnea are unable to undergo the proper tests, the result of this is that many patients are unable to receive proper care that could significantly improve their quality of life.

We believe that with proper physician training in the use of the unattended sleep test, patients are capable of performing the necessary preparation steps. At our clinic, the patient meets with the physician for 30 minutes and is taught the proper techniques for using the at home sleep device. We believe that this is a more than adequate method of obtaining sleep information and we have been pleased with our success in this area.

In summary, formal PSG testing can be intrusive, difficult to access, and very expensive. In contrast, unattended home studies have allowed providers at Catalyst Medical Clinic to appropriately test patients for OSA, interpret results, and remarkably improve the health of our patients. In fact, we have seen significant blood pressure reductions with appropriate CPAP therapy, and this has been a wonderful outcomefor OSA diagnosis and therapy.

Commenter: Thomas, Michael, President and CEO
Organization: Sleep Solutions, Inc.
Date: July 26, 2004
Comment:

The American Academy of Sleep Medicine's argument against multi-channel in home sleep apnea testing devices is specious. Many, if not most, of the AASM members own or operate their own sleep labs. The introduction of in home sleep study reimbursement is a direct, competitive threat to their lucrative sleep lab businesses. This conflict of interest was never made public when the AASM, ATS, and ACCP published their position statement on portable sleep studies. Their attempt to monopolize OSA diagnosis has failed in many regions of the US, as well as in other areas

of the world. Please consider this when making your evaluation of their comments.

Their unethical suppression of technological advancements with appropriate validation utilizing evidence-based medicine for the diagnosis of obstructive sleep apnea is unconscionable.

Magalang, et. al. reported in CHEST 2003;124:1695 between 21% and 27% of patients did not show up for their sleep study. What good is having a facility based sleep study if patients are unwilling to suffer through the sleep lab experience in order to get therapy?

One night of PSG in a facility has been documented over the last 20 years to have a false negative rate of around 25% (Le Bon, CHEST 2000;118:353-359). With such a flawed "gold standard", how ethical is it not to allow patients a choice in the setting of their sleep study in order to expedite the process to therapy selection?

The AASM is quick to attack the accuracy of some portable sleep study devices, but they are loath to acknowledge the imprecision of the facility based PSG and sleep technician scoring variability.

Our company has hundreds of physicians and dozens of VA medical centers referring patients for use of our device for in home testing for OSA. We have over 100 million covered lives under contract for reimbursement for managed care organizations. Regardless of the AASM's desire to protect their members' income stream, specialists, primary care physicians, and managed care medical directors are choosing well validated devices, such as NovaSom QSG, as their preferred choice for OSA diagnosis. It seems incredibly unfair that our nation's seniors do not get the same level of choice as the 100 million Americans covered by our company's managed care contracts.

This small minority of physicians are no match for the will of the market. The market (physicians, VA facilities, military hospitals, managed care organizations, patients, equipment and device manufacturers and suppliers, healthcare service providers/home health firms) has evaluated, chosen, and currently use many types of in home sleep apnea diagnostic devices.

Unlike most healthcare innovations, our technology provides an immediate cost savings. NovaSom QSG sleep studies cost insurance companies less than half of what they pay facility based PSG studies. During a time of hyperinflating healthcare expenditures, it seems most prudent for CMS to approve advanced technologies that can expedite cost reduction while providing comparable or superior level of care and significantly increased patient choice/options.

Listed below is some selected information regarding our product, NovaSom QSG, that has been validated to accurately rule in and rule out OSA. No EEG is required for accurate diagnosis with NovaSom QSG. The parameters measured are:

1. Oxygen saturation
2. Snoring (in dB)
3. Oral airflow
4. Nasal airflow
5. heart rate
6. respiratory effort
7. apnea
8. hypopnea

The NovaSom QSG meets the AHRQ's established parameters for diagnostic comparison between standard PSG and other techniques.

Clinical validation of the Bedbugg in detection of obstructive sleep apnea
Claman, D, et al; Otolaryngology-Head and Neck Surgery, Sept. 2001

The NovaSom QSG[®] was originally called the "Bedbug". In this study conducted at the University of California at San Francisco (UCSF) Medical Center, 42 consecutive patients who were referred for a formal sleep lab study because of suspected sleep apnea underwent in lab PSG and were simultaneously studied with the Bedbug[®]. The AHI was determined by both PSG and the Bedbug[®] in an independent and blinded fashion. The key findings include:

The correlation between the AHI between PSG and Bedbug was $r=0.96$

The sensitivity of Bedbug for detecting AHI >15 was 85.7%

The specificity of Bedbug for detecting AHI <15 was 95.2 %

The positive predictive value of Bedbug based on an AHI of 15 was 94%

The negative predictive value of the Bedbug based on an AHI of 15 was 85.5%

No studies were lost because of data acquisition problems.

The overall specificity of the device was an excellent 95%, allowing for diagnosing subject with little or no apnea vs. previous portable devices, which were unable to be particularly accurate at low AHIs and often requiring a follow-up PSG.

Low rates of false-positive and false-negative AHI results were found in providing accurate clinical studies.

Conclusion, "this study demonstrated the accuracy of the Bedbug in diagnosing sleep apnea as compared to the gold standard in lab PSG through a high degree of both specificity and sensitivity"

Positive Likelihood Ratio (LR) of 17.2

Negative LR of 0.15

Comparison of the NovaSomQSGTM, A Novel Sleep Apnea Home-Diagnostic System and Polysomnography
Reichert et al.; Sleep Medicine 4(2003) 213-218

51 consecutive patients with suspected OSA who were referred to the sleep lab underwent simultaneous in lab PSG and NovaSom QSG ¹. Patients also received NovaSom QSG ¹ at home for three nights. Two separate comparisons were made between PSG and NovaSom QSG ¹: the simultaneous in lab readings and the NovaSom at home readings. The key findings include:

In lab NovaSom had a sensitivity of 95% and specificity of 91%

Home NovaSom had a sensitivity of 91% and a specificity of 83%

If an AHI cutoff of 18 were utilized, in home NovaSom has a specificity of 100%

The authors conclude that the NovaSom QSG ¹ is a valid and reliable home diagnostic system for testing adults suspected to have sleep apnea

Study validated use in the setting in which it is intended to be used

Positive Likelihood Ratio (LR) of 11

Negative LR of 0.06

Utilizing the NovaSom QSG

The Sleep Solutions Report

Sample NovaSom QSG ¹ reports are found in Appendix 3. Note that the referring physician receives an AHI, which is crucial in the evaluation and diagnosis of patients with suspected OSA. Furthermore, the graphical presentation of the data allows the physician to visualize the episodes during the three-night period. This decreases the possibility of false interpretations if the patient is awake.

The NovaSom QSG is not a screening tool or an add on. It is to be utilized in patients with signs and symptoms suggestive of OSA and the predictive value of the study is sufficient to rule out OSA or make the diagnosis of OSA. Referral for in lab PSG following NovaSom QSG is not necessary.

Clinical Review:

NovaSom QSG™

*An accurate and clinically validated alternative
to in-lab sleep studies for the diagnosis of obstructive
sleep apnea (OSA).*

Clinical Review: NovaSom QSG™ (QSG=Quality SomnoGram)

An accurate and clinically validated alternative to in-lab sleep studies for the diagnosis of OSA (obstructive sleep apnea)

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Overview

The NovaSom QSG™ is a portable device allowing for the in home evaluation of patients suspected of having obstructive sleep apnea (OSA). Use of this FDA approved device has been validated in clinical studies demonstrating a high degree of correlation with polysomnography (PSG) performed in sleep labs.

The NovaSom QSG™

- Is a portable monitoring device that has demonstrated a high degree of sensitivity, specificity, and predictive value for the diagnosis of OSA when compared to in lab polysomnography in rigorously conducted clinical trials.
- Has been studied in a manner consistent with American Academy of Sleep Medicine (AASM) criteria and appropriate principles of evidence based medicine
- Meets a growing need for an accessible, convenient, cost effective and accurate alternative to sleep lab studies for the diagnosis of OSA.

Obstructive Sleep Apnea (OSA)

▪ Background

OSA is a sleep disorder characterized by a constellation of symptoms caused by recurrent episodes of partial and/or complete closure of the upper airway during sleep.

The prevalence of this syndrome is estimated to be 2%-4% of the general population with male gender, postmenopausal status and obesity as important risk factors. Clinical features include daytime somnolence, headaches, and witnessed apnea episodes during sleep, loud snoring and daytime cognitive impairment. Consequences of OSA include accidents, hypertension, myocardial infarction, stroke and congestive heart failure exacerbations.

“prior to diagnosis, patients with OSA consume twice as many healthcare resources and spend nearly three times as many days in the hospital as patients without OSA.”

Bahammam, A et al. *Health care utilization in males with obstructive sleep apnea syndrome two years after diagnosis and treatment.* Sleep 1999 Vol.22:No. 6

▪ Diagnosis

The presence of OSA is established when a patient with clinical suspicion of the disorder undergoes a sleep study that demonstrates a significant number of apneas as well as hypopneas, which are associated with drops in oxygen saturation. A common summary measure used to describe respiratory disturbances during sleep is the AHI (apnea hypopnea index): the total number of episodes of apnea and hypopnea during sleep divided by the hours of sleep time. The cutoff AHI value that is diagnostic of OSA has been debated and has evolved. Some have considered 15 the cutoff for clinically significant OSA. However, in recent years, values between 5 and 15 associated with clinical improvement with CPAP have also been felt adequate to substantiate the diagnosis and have been eligible for Medicare

reimbursement. Another term used is the respiratory disturbance index (RDI), which most often refers to the number of times per hour that oxygen saturation falls more than 3%. At this time, AHI is the more commonly used measure.

Given the clinical importance of OSA, in recent years there has been an effort to better educate the general public and the medical community regarding the condition by the National Sleep Foundation and The American Sleep Apnea Association. Indeed this effort has resulted in an increasing number of patients referred for sleep studies thus placing a burden on sleep labs to provide access.

There has also been an effort to better define the modalities utilized in the diagnosis of OSA. The American Academy of Sleep Medicine (AASM) agreed to differentiate four levels of sleep monitoring devices:

- Level 1: **Standard Polysomnography (PSG)** performed in a sleep lab
- Level 2: **Comprehensive Portable Polysomnography** with a minimum of 7 channels, including EEG, electrooculogram, chin electromyogram, ECG or heart rate, airflow, respiratory effort, and oxygen saturation
- Level 3: **Modified Portable Sleep Apnea Testing** with a minimum of 4 channels monitored including ventilation or airflow (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation
- Level 4: **Continuous Single Bioparameter Recording** with one or two channels, typically including oxygen saturation or airflow

▪ **Limitations of Standard PSG**

Although sleep lab PSG testing has been considered the “gold standard” for the diagnosis of OSA, there are serious problems with this approach:

- It is well known that there is a great deal of variation between sleep labs related to equipment and technical expertise. Not all labs produce reliable studies.
- Sleep labs do not have the capacity to meet the needs of testing in many communities. Many patients have prolonged waits for testing and are suffering the consequences of unrecognized and untreated OSA.
- A sleep lab is not a normal sleeping environment. The “first night” effect is well known and will often generate the need for multiple in lab studies.
- Many patients live in communities distant from sleep labs and must travel great distances for study. These patients often do not get studied and remain undiagnosed and untreated.

"the widely accepted standard diagnostic method (overnight full PSG) attended by trained personnel in a sleep lab) is intrusive, costly and the interpretation can be difficult"

Ross, S, et al, *Systematic review and meta-analysis of the literature regarding the diagnosis of sleep apnea*. Sleep, Vol 23 No.4 2000

"I think getting into sleep centers is a national problem. There is not enough infrastructure to currently handle the demand for services" John Shepard MD, Director of Mayo Clinic's Sleep Center

"Delays in sleep studies have become a major public health problem." Michel Chalhoub, MD
University of Houston,

Gibbons, M. *Hurry up and wait; tech shortage is delaying testing in the nation's sleep labs*. Advance f or Managers of Respiratory Care, 2001, Vol 6

"Clinicians should be aware that there is a tremendous variability among polysomnography technologists regarding the scoring of polysomnograms." "These differences are likely due to different rules used to score events as well as differences in the technologist's interpretation of the rules"

Collop, N. A. *Scoring variability between polysomnography technologists in different sleep laboratories*. Sleep Medicine 3 (2002) 43-47

" A negative first night-night study is insufficient to exclude OSA in patients with one or more clinical markers of the disease"

Meyer, T J, et al *One negative polysomnogram does not exclude obstructive sleep apnea*, Chest Vol 103,756-760,1993

The NovaSom QSG and Sleep Solutions Inc (SSI)

- **Self-Administered Testing for the Diagnosis of OSA at Home**

The NovaSom QSG™



NovaSom QSG™ allows patients to undergo testing for Obstructive Sleep Apnea in the comfort and privacy of their own home. Cleared by the U.S. Food & Drug Administration and available by prescription through Sleep Solutions' diagnostic service, NovaSom QSG™ is delivered directly to the patient for unattended, self-administered use.

The NovaSom QSG™ consists of a bedside console and three small, comfortable sensors, which are easily applied by the patient before going to sleep, following simple instructions and voice prompts. The system is designed to collect sleep data for up to three nights.

The NovaSom QSG™ is compact, self contained, and provides 5-channel measurement of:

- apneas
- hypopneas
- oxygen saturation
- pulse rate
- respiratory effort
- snoring intensity

Thus NovaSom QSG™ meets the AASM criteria for a Level 3 device and provides all of the parameters necessary to monitor sleep breathing and provide definitive diagnosis of OSA.

Sleep Solutions, Inc. (SSI)

The process is simple. Upon receipt of the prescription from the physician, Sleep Solutions ships the NovaSom QSG™ System directly to the patient's door. An instructional guide, video, and voice prompts from the device direct the patient through the easy set-up. A 24/7 toll-free help line is available.

After three nights of use, the patient returns the system to Sleep Solutions in a pre-addressed overnight shipping package. The collected data are processed, downloaded into Sleep Solutions information system, and immediately made available to the prescribing physician. The report can be delivered via fax and is also posted to the www.sleepsolutions.com secure, HIPPA compliant Web site, giving the physician immediate online access if desired.

Because SSI ships the diagnostic system directly to the patient's home, the patient and attending physician avoid all of the well-known drawbacks of traditional in-lab OSA testing.

- Patient-tested and very easy to connect at home and use without assistance
- More comfortable patient testing in "real-world" home sleeping conditions
- Referral to a sleep lab not is not required
- Three night study improves sensitivity and reduces the need for repeat studies

Clinical Validation of the NovaSom QSG

The issue of alternatives to sleep lab testing has been controversial in part because many sleep specialists have a vested interest in performing studies in their labs, but also because several portable sleep monitoring devices have not been appropriately studied or have performed poorly when studied.

In contrast to the other products, the NovaSom QSG™ has sufficient peer-reviewed studies to warrant a device specific technology assessment.

Furthermore, the results of these studies fulfill the requirements set forth by technology assessment in regard to both the design of the studies and the predictive value of the device.

It is a disservice to patients to “lump” all portable devices together when the NovaSom QSQ™ has been rigorously studied. The NovaSom QSQ has been validated in two peer reviewed, published, controlled clinical trials comparing the sensitivity, specificity and predictive value to the ‘gold standard’ in lab sleep study (PSG).

Clinical validation of the Bedbugg in detection of obstructive sleep apnea

Claman, D, et al”; Otolaryngology-Head and Neck Surgery, Sept. 2001

The NovaSom QSQ™ was originally called the “Bedbugg™”. In this study conducted at the University of California at San Francisco (UCSF) Medical Center, 42 consecutive patients who were referred for a formal sleep lab study because of suspected sleep apnea underwent in lab PSG and were simultaneously studied with the Bedbugg™. The AHI was determined by both PSG and the Bedbugg™ in an independent and blinded fashion. The study is attached in Appendix 1 and key findings include:

- The correlation between the AHI between PSG and Bedbugg was $r=0.96$
- The sensitivity of Bedbugg for detecting AHI >15 was 85.7%
- The specificity of Bedbugg for detecting AHI <15 was 95.2 %
- The positive predictive value of Bedbugg based on an AHI of 15 was 94%
- The negative predictive value of the Bedbugg based on an AHI of 15 was 85.5%
- No studies were lost because of data acquisition problems.
- The overall specificity of the device was an excellent 95%, allowing for diagnosing *subject with little or no apnea* vs. previous portable devices, which were unable to be particularly accurate at low AHIs and often requiring a follow-up PSG.
- Low rates of false-positive and false-negative AHI results were found in providing accurate clinical studies.
- Conclusion, “this study demonstrated the accuracy of the Bedbugg in diagnosing sleep apnea as compared to the gold standard in –lab PSG through a high degree of both specificity and sensitivity”
- Positive Likelihood Ratio (LR) of 17.2
- Negative LR of 0.15

Comparison of the NovaSom QSG™, A Novel Sleep Apnea Home-Diagnostic System and Polysomnography

Reichert et al.; Sleep Medicine 4(2003) 213-218

51 consecutive patients with suspected OSA who were referred to the sleep lab underwent simultaneous in lab PSG and NovaSom QSG™. Patients also received NovaSom QSG™ at home for three nights. Two separate comparisons were made between PSG and NovaSom QSG™: the simultaneous in lab readings and the NovaSom at home readings. The study is attached in Appendix 2 and key findings include:

- In lab NovaSom had a sensitivity of 95% and specificity of 91%
- Home NovaSom had a sensitivity of 91% and a specificity of 83%
- If an AHI cutoff of 18 were utilized, in home NovaSom has a specificity of 100%
- The authors conclude that the NovaSom QSG™ is a valid and reliable home diagnostic system for testing adults suspected to have sleep apnea”
- Study validated use in the setting in which it is intended to be used
- Positive Likelihood Ratio (LR) of 11
- Negative LR of 0.06

Utilizing the NovaSom QSG™

▪ The Sleep Solutions Report

Sample NovaSom QSG™ reports are found in Appendix 3. Note that the referring physician receives an AHI, which is crucial in the evaluation and diagnosis of patients with suspected OSA. Furthermore, the graphical presentation of the data allows the physician to visualize the episodes during the three-night period. This decreases the possibility of false interpretations if the patient is awake.

The NovaSom QSG™ is not a screening tool or an “add on”. It is to be utilized in patients with signs and symptoms suggestive of OSA and the predictive value of the study is sufficient to rule out OSA or make the diagnosis of OSA. Referral for in lab PSG following NovaSom QSG™ is not necessary.

▪ Clinical Examples

- Used in over 6,000 patients to date

See Appendix 3

➤ #1 Negative Study

The NovaSom was sufficient to rule out OSA and an in lab PSG was not necessary.

➤ #2 Moderate OSA

The NovaSom established the diagnosis of moderate OSA and an In-lab PSG was not necessary

➤ **#3 Severe OSA**

The NovaSom established the diagnosis of severe OSA and an In-lab PSG was not necessary

▪ **Economic Impact**

The cost of NovaSom QSG is approximately half that of a full PSG in the hospital sleep lab.

AASM Position Regarding Portable Sleep Studies

For several years the American Academy of Sleep Medicine (AASM) has been struggling with the issue of portable monitoring devices for the diagnosis of OSA. At this time the society is still not ready to endorse level 3 studies for the diagnosis of OSA. Current position papers from the AASM are found in Appendix 4.

The NovaSom QSG deserves an assessment independent of other portable devices in accordance with the AASM position on this issue. Please see Appendix 5 for a discussion regarding the case for a specific assessment of the NovaSom QSG™.

The AASM is clearly committed to the recognition and treatment of sleep disorders and has elaborated criteria for the appropriate study of portable devices. If one looks at the Claman and Reichert validation studies of the NovaSom QSG™ and the AASM criteria for appropriate study of portable devices, the position taken by AASM, although justifiable for other portable sleep testing devices, is not applicable to NovaSom. The AASM's recent Practice Parameter: SLEEP Vol. 26 No. 7, 2003 states: "All device in a given category are not the same," and that "results obtained for a particular device are applicable only to that device and cannot be extrapolated to other devices, even those in the same class." However the Reichert study was not available at the time of the analysis. Appendix 5 contains a cross walk examining the AASM criteria and the studies by Claman and Reichert.

The NovaSom QSG™ meets the AHRQ's established parameters for diagnostic comparison between standard PSG and other techniques:

Parameters Adoption of these recommendations plus acceptance of research principles outlined by the Task Force of the American Academy of Sleep Medicine on defining SRB Disorders & measurement techniques*	First Study Clinical Validation of the Bedbugg™ in detection of obstructive sleep apnea Claman, et al	Second Study Comparison of the NovaSom QSG™, A novel Sleep Apnea Home-Diagnostic System & PSG Reichert, et al
1. Gold standard PSG performed / all patients for a full night	✓	✓
2. Apnea & Hypopnea criteria should be defined clearly	✓	✓
3. AHI should be reported for total sleep time	✓ **	✓ **
4. When reporting sensitivity & specificity standard diagnostic AHI thresholds should be used <5, 5-30 & >30	No	✓
5. Patient groups should be defined using AHI alone	✓	✓
6. The order of tests in diagnostic tests should be random	N/A	✓
7. Systems proposed as pre-qualified replacements to PSG must be validated in the intended setting they are to be used	No	✓
8. Test readers should be blinded to the results of the other test	✓	✓
9. The frequency of signs & symptoms should be noted	No	✓
10. The subject population should include a wide range of pre-test likelihood patients, including normals and the prevalence in the study population should be assessed	Normals No Prevalence ✓ In study pop.	Normals No Prevalence ✓ In study pop.

***Ross, et al, Systematic Review and Meta-analysis of the Literature Regarding the Diagnosis of Sleep Apnea, Sleep, Vol 23 No 4 2000. Please note our first study was completed and submitted for published prior to the publication of this study**

****AHI (PSG) for total sleep time compared to AHI (device) for total record time, We do not exclude any sleep time, SSI's NovaSom included total recording time vs. total sleep time for the PSG***

(Table 1 Cont.) Please note additional comments on parameters:

Parameters	NovaSom QSG Validation Studies
I. Double –blind randomized studies (not suggested, but have been asked by different plans)	<p>The concept of double blinded applies when there are two different therapies/treatments being checked for effectiveness or two different approaches being compared to some objective measurement. These studies or any other study comparing home to in-lab testing can not be done in this fashion due to the logical impossibilities. The PSG & NovaSom or any other device will not be compared to some objective measurement, rather the device will be compared to the PSG. In addition, data generated by the tests are different. It would be hard to blind a researcher as to which test they were interpreting or the subject as to which test are being taking. However, the researchers are blinded to the results of any other test when evaluating a given test nor will they know the results of other, if any, on the same pt. The patient is also blinded to the results.</p>
II. Validation in the environment in which the device is intended to be used	<p>The second study above, published in <i>Sleep Review</i>: May 2003 accomplished this. Three separate comparison were made:</p> <ol style="list-style-type: none"> 1. In lab NovaSom QSG™ vs. PSG; 2. Home NovaSom QSG™ vs. PSG 3. In lab NovaSom QSG™ vs. Home NovaSom QSG™ <p>In addition to Sensitivity & Specificity, Kappa Coefficient and Intra-class correlation coefficient were used. Kappa coefficient: Estimate beyond change agreement between two measurements (< 0.4=poor, 0.4 =moderate, >0.6=excellent) Intra-class correlation coefficient (ICC); Chance –adjusted measure of intra-subject reliability Results: - Home NovaSom QSG™ to PSG using AHI= 15 kappa value: 0.734 +/-0.101 excellent - In-lab NovaSom QSG™ to PSG using AHI= 15 kappa value: 0.864 +/-0.076 excellent - In-lab NovaSom QSG™ to Home NovaSom: ICC for night-to-night home data: 0.88 excellent</p> <p>This study validates the NovaSom QSG™ in the home environment. Comparing the NovaSom QSG™ at home to the PSG in the lab requires comparing the AHI from two different nights. Several studies (LeBon et al <i>Chest</i> 2002, Golpe et al <i>Chest</i> 2002, Meyer et al 1999) have demonstrated that AHI varies from night to night. Even with this inherent variation, the NovaSom QSG™ provides excellent correlation to the PSG.</p>
III. Test population should include normals	<p>Normals were not included in the first two validation studies. All studies were conducted on patients with a clinical suspicion of OSA. The end results of the studies showed that this population included patients without OSA. There were wide ranges of values, including normals. Since the device is being used as a diagnostic device and not a screening device, the studies were designed on intended use of the device.</p>

Summary

- OSA is a major health problem affecting 2-4% of the population. Consequences of OSA include accidents, hypertension, myocardial infarction, stroke and congestive heart failure exacerbations.
- Patients with unrecognized OSA are more costly for the health care system and have been shown to have an increased rate of hospitalization.
- In lab sleep studies are:
 - Expensive
 - Inconsistent in the quality of their results
 - Not readily available to the population at need
 - Suffer from "first night effect" and other artifacts of the artificial sleep lab environment
- The NovaSom QSG™ is a 5 channel level 3 device that provides convenient, easy to use testing in the patient's home.
 - Sleep Solutions, Inc. provides results to the ordering physician in a complete, easy to read, graphical report
 - The three-night study provides enough information to rule out or make the diagnosis of OSA. Follow-up study in a sleep lab is not needed.
- The accuracy of the NovaSom QSG™ has been validated in two published, peer reviewed studies demonstrating a high degree of predictive value
- The studies validating the NovaSom QSG™ meet the criteria for study design as established by ARHQ and are consistent with the levels of evidence required by technology assessment bodies such as the BCBSA.
- NovaSom QSG™ provides actionable data for the clinician to use
- Economic savings are substantial: 50% less expensive than the full PSG in the hospital
- Given the data elements included in the Claman and Reichert studies, the AASM's position is justifiable for the other portable diagnostic sleep study devices, but not for NovaSom QSG because the AASM position statement did not have the benefit of the Reichert study.
- The NovaSom QSG™ has enjoyed a great deal of clinical acceptance and positive coverage decisions involving over 97 million lives

Appendix 1
Validation study- Claman et al

Clinical validation of the Bedbugg™ in detection of obstructive sleep apnea

David Claman, MD, Andrew Murr, MD, Kimberly Trotter, MA, RPSGT
San Francisco, California

Objective: To validate the accuracy of the Bedbugg™, a new home monitoring device for diagnosis of obstructive sleep apnea.

Study Design and Setting: Simultaneous sleep monitoring was performed by formal polysomnography and by Bedbugg. Monitoring was performed in a university sleep center in 42 subjects who had previously been scheduled for polysomnography.

Results: The correlation for the apnea-hypopnea index (AHI) between polysomnography and Bedbugg was $r = 0.96$. The sensitivity of Bedbugg for detecting an AHI > 15 was 85.7%. The specificity of Bedbugg for detecting an AHI < 15 was 95.2%.

Conclusion: The Bedbugg device provides an accurate assessment of the apnea-hypopnea index. (*Otolaryngol Head Neck Surg* 2001;125:227-30.)



"Bedbugg Clinical
Validation.pdf"

Appendix 2

Validation study- Reichert et al

Comparison of the NovaSom QSG™, a new sleep apnea home-diagnostic system, and polysomnography

James A. Reichert^a, Daniel A. Bloch^b, Elizabeth Cundiff^a and Bernhard A. Votteri^a

^a Sequoia Hospital, Sleep Disorders Center ^b Stanford University School of Medicine, Department of Health Research & Policy, Division of Biostatistics

Background: Obstructive sleep apnea (OSA) is a serious, common, and under-diagnosed disorder that challenges health care resources. While polysomnography (PSG) represents the standard diagnostic test for OSA, portable devices provide an alternative diagnostic tool when issues of cost, time, geographic availability, or other constraints pose impediments to in-lab testing. This study compares the NovaSom QSG™, a new sleep apnea home diagnostic system, to PSG both in the laboratory and in the home.

Methods: Fifty-one consecutive adults referred to the sleep lab for suspicion of OSA underwent one night of in-lab, simultaneous recording of PSG and NovaSom QSG in addition to using the NovaSom QSG at home for three nights. Two separate comparisons were made using the apnea-hypopnea index (AHI): in-lab PSG to in-lab NovaSom QSG and in-lab PSG to home NovaSom QSG.

Results: Using a clinical cut-off of AHI=15, the sensitivity and specificity of the in-lab NovaSom QSG vs. PSG were 95% and 91%, respectively. For home NovaSom QSG vs. in-lab PSG, the sensitivity was 91% and specificity was 83%. The intra-class correlation coefficient for the agreement between three separate nights of NovaSom QSG home data was 0.88.

Conclusions: In a patient population suspected of having OSA, the NovaSom QSG demonstrated acceptable sensitivity and specificity both in the lab and self-administered in the home, when compared to PSG. (**Sleep Medicine 2003; Vol 4, Issue 3:213-218.**)



"Comparison
NovaSom to PSG.pdf"

Appendix 3 Sample Reports

Normal OSA



"x450 Concise
Normal.pdf"



"x450 Interp Normal
.pdf"

Moderate OSA



"x893 Concise
Moderate.pdf"



"x893 Interp
Moderate.pdf"

Severe OSA



"x471 Concise
Severe.pdf"



"x471 Interp
Severe.pdf"

Appendix 4 AASM Positions

Chesson, Andrew, et. al. Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea. *Sleep* 2003; 26 (7):907-13.



"2003 Practice
Parameters.pdf"

Flemons, W. Ward, et. al. Home Diagnosis of Sleep Apnea: A Systematic Review of the Literature. An Evidence Review Cosponsored by the AASM, ACCP, and ATS. *Chest* 2003; 124:1543-1579



"Home Diagnosis
OSA Systematic Review"

Appendix 5
The Case for a Specific Assessment of the NovaSom QSQ
Cross walk: AASM criteria and the studies of Claman and Reichert

Portable Monitoring Device Review and the NovaSom QSQ™



"NovaSom QSQ
validation review.doc"

Evidence Level Review of Claman et al



"Claman evidence
levels.doc"

Evidence Level Review of Reichert et al



"Reichert evidence
levels.doc"



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July 21, 2004

Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Second Public Comments for NCA for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (CAG-00093R) Public Comment Period (June 25, 2004 – July 25, 2004)

Submitter: Michael H. Bonnet, Ph.D.
Organization: Wright State University School of Medicine (Dept of Neurology)
Date: July 21, 2004
Comment:

This comment concerns the proposition that CMS should permit use of portable multi-channel sleep testing devices unattended in the home. This proposition contains three different and equally important factors that must all be considered: 1) the use of portable multi-channel sleep testing devices for sleep apnea/cpap testing; 2) recordings made in the home environment; and 3) unattended recordings. All factors require significant investigation prior to the consideration of rule changes.

- 1) The use of multi-channel portable monitoring devices for sleep apnea testing promises significant patient benefit to the extent that such devices can provide equivalent diagnostic capability as is currently provided by polysomnography. It is the case that a few of the many devices that are currently on the market are capable of providing 12-14 simultaneous channel recordings (including multiple EEG, EOG, EMG channels in addition to airflow, respiration, oxygen saturation, ECG, limb movement, position, and cpap pressure channels). Such devices can be used with benefit in ICU and other attended hospital settings. Unfortunately, the basis of the change request is to allow recordings with considerably fewer channels (typically 1-5) concentrating exclusively on respiratory variables (typically airflow, chest movements, oximetry, and cpap pressure). Such recordings omit crucially important physiological information. For example, if sleep apnea is not found in the recording, it may be because the patient never fell asleep (and it is impossible to know this without recording sleep). If the patient does have periods of apnea, it is impossible to calculate severity because all apnea indices are calculated by a formula that is number of abnormal respiratory events divided by total hours of sleep. Obviously, sleep time cannot be calculated if sleep is not recorded. Finally, it is well-known that sleep apnea is frequently worse during REM sleep and, on occasion, when patients sleep in the supine position. Recordings that do not include REM sleep and position data cannot be certified as containing REM sleep or supine position data. If these variables were observed, apnea might be significantly worse and required cpap pressures might be significantly higher. Without attention to sleep, such information cannot be known. Irregular respiration is also commonly associated with movement during sleep

(and periodic changes in respiration may accompany periodic limb movements). If limb EMG is not recorded, respiratory changes associated with movement may be mistakenly scored as periods of hypopnea. It is clear from these few examples that quality of care will diminish dramatically if current sleep variables are omitted from requirements. On the other hand, it is now possible to record good physiologic data in many environments, including the home environment. The important point is that all of the currently recorded information is essential and should continue to be required.

- 2) With current technology, it is possible to make reasonable sleep recordings in the home environment. However, it is sometimes more expensive to make similar recordings in a home environment as compared to a hospital environment because equipment must be transported to the home, and the attending technician, obviously, can only watch one patient. Unfortunately, "home recording" is usually a code word for "unattended recording," and, as discussed below, these have significant problems. In general, home environments pose less risk to patients in terms of exposure to other illness in the hospital, but there is also significantly less control of environmental factors (light, heat, noise, family, etc.) which may disturb the patient.
- 3) Most of those individuals asking for changes in sleep apnea/cpap standards are really looking for the license to perform unattended recordings (the recording apparatus is attached to the patient and the technician leaves – the study is automatically recorded and is then picked up in the morning for analysis). Clearly, an unattended recording could be done in a hospital environment as well. The problem with unattended recordings is quality. During a standard polysomnogram, the technician makes frequent adjustments to recording parameters – airflow may change whenever the patient moves, recording devices may be dislodged, equipment may break and need to be replaced. These changes are relatively easy to make in real time but they never occur in unattended recordings. Data is commonly lost and not interpretable, but this is typically not known until after the study is complete. There is no interaction with the patient (to be sure the pt sleeps part of the night on his back, to try a different cpap mask, to add low flow O₂, to understand why the patient is not sleeping well and adjust the study parameters). Complex procedures simply cannot be done well without human supervision – typically a requirement for patients in hospital settings. Patients with sleep apnea may be at significant medical risk, and there risk is multiplied without human response capability in real time at the patient site. For this reason, unattended monitoring of polysomnograms should not be reimbursed in the hospital or at home.

Sincerely,



Michael H. Bonnet, Ph.D.

** Re. NCA Tracking Sheet for Continuous (July, 22, 2004)
positive airway pressure therapy for
Obstructive sleep apnea (OSA)
Dr. Sanders: (CAG-00093R)

I have recently learned that you have requested comments concerning the use of unattended sleep studies, both pro and con in nature.

As a staff therapist at a Chicagoland hospital for many years, I have in recent years been involved in performing four-channel unattended studies on both hospital inpatients and patients in the home setting. Over the past seven or eight years we have had hundreds of patients who presented with the classic symptoms of OSAS, that we were able to give a conclusive diagnosis of obstructive apnea, and then continue on to provide the first line treatment using nasal CPAP.

Because in-home unattended testing is done "only" on patients that were given pre-test screening surveys, we are able to quickly, conveniently (for the patient) and cost-effectively achieve a reliable diagnosis of OSAS. Using the popular and most often used four-channel device we can measure heart rate, impedance airflow (nasal and oral), arterial oxygen saturation; the most critical parameters used to obtain an accurate diagnosis of OSAS. We do not need to obtain sleep staging for a diagnosis of OSAS. We do not need to obtain neurological data because the

(2)
description of the sleep apnea syndrome does not include neurological terms, but rather cardio pulmonary terms to describe the loss of patency in the upper airway, associated with air flow pauses with/without oxygen desaturation and heart rate response or lack of response.

Only if a doctor suspects other significant sleep disorders, would a costly polysomnography be required to be performed in a sleep lab.

One more point I'd like to make is: that restricting sleep testing to be done only ~~to be performed~~ by RPSGT personnel in sleep labs would certainly increase the cost of diagnosing obstructive sleep apnea and decrease timeliness of the diagnosis. I can speak to the fact that respiratory care practitioners (credentialed therapists) have an excellent broad based training and can achieve competence using the different multi-channel devices. Why should the testing and scoring of data be restricted to a small group of registered polysomnographic technicians? That restriction would increase costs and slow down the process of diagnosing and further treatment of the OSAS patient. At our institution only a few patients we tested for OSAS needed to be referred to sleep labs where they received various other sleep disorder diagnoses.

over

In conclusion, I wish to thank you for the opportunity to express my opinions and share my positive experiences using unattended multiphasic apnea diagnostic equipment.

Thank you

Kathy A. Murray CRTT, RCP

6980 W. Touhy # 309

Niles, Ill. 60714

STEPHEN M. KREITZER., M.D.

Diplomate American Board of Internal Medicine
Diplomate American Board of Pulmonary Disease
Diplomate American Board of Sleep Medicine

Fellow of the American College of Physicians
Fellow of the American College of Chest Physicians
Fellow of the American Academy of Sleep Medicine

July 23, 2004

Steve Phurrough, M.D., MPA
Director of Coverage and Analysis Group
Office of Clinical Standard and Quality Centers for Medicare and Medicaid Services
ATTN: Public Comments, S3-02-01
7500 Security Blvd
Baltimore, MD 21244-1850

Dear Dr. Phurrough:

I understand you are evaluating and reassessing the national coverage determination for diagnosis and treatment of obstructive sleep apnea and as part of that evaluation you are looking into the multiple channel home sleep testing as an alternative to formal overnight polysomnogram.

I would like to make the following points:

There are 84 sleep disorders involving neurological, psychiatric, pediatric, rheumatological, gastrointestinal, cardiovascular and respiratory function. It is well known that untreated obstructive sleep apnea associated with repeat nocturnal hypoxic events are associated with high levels of nocturnal sympathomimetic activity and catecholamine release. This results in a disproportionate number of cerebral vascular accidents, angina, acute myocardial infarctions in those individuals suffering from the condition. This is in addition to the excessive daytime sleepiness that results from repeat nocturnal arousals. These patients suffer from a lack of Stage 3, 4 and REM sleep. This in turn contributes to lack of memory, concentration, personality changes, depression, anxiety, loss of job function and marital discord.

Obstructive sleep apnea and the other 83 sleep disorders remains under diagnosed and as a result of this lives are lost and other lives are functioning at a much lower level. For example, 40% of the patients on anti-depressants that I see from psychiatrists come off their anti-psychotic and anti-depressant medications when the appropriate sleep diagnosis has been made.

There are a significant number of the 84 sleep diagnoses that can be made when a sleep study is performed formally in an overnight sleep laboratory. Sleep medicine involves accurate history, physical and diagnostic studies. Sleep medicine is not a quick

and dirty home test to try to find a few sleep apnea patients for a surgeon to operate (of which only 20% benefit by surgery) nor is a sleep laboratory designed for a quick and dirty study to see if a durable medical equipment company can order CPAP.

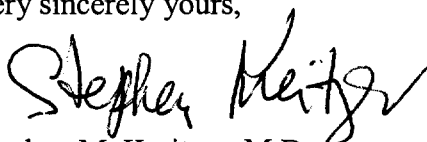
There is no question that there are many reports in the literature sponsored by health maintenance organizations looking for an inexpensive method of making the diagnoses required by a sleep specialist and that a few of the in home studies do indeed pick out the worst, most extreme cases. The majority of individuals will not only remain undiagnosed in terms of obstructive sleep apnea by home sleep testing but the other 83 sleep diagnoses will be missed. When this happens the patient's referring doctor and the patient will inadvertently assume that there is no sleep disorder and the patient will receive inappropriate and inadequate treatment.

The disadvantages of multiple channel home sleep tests are several:

1. Although they are performed in a patient's own home, if a technician is not present; that is if the sleep study is unattended, then the technical adjustments that have to be made throughout the night will not be made and the data will be inappropriate and possibly useless.
2. If the multiple channel home sleep study is performed correctly and because it is a limited study by definition, the other 83 sleep diagnoses are ignored and only the most extreme case of obstructive sleep apnea will be picked up.

The American Board of Sleep Medicine, the American College of Chest Physicians, the American Thoracic Society, the American Thoracic Society, all the neurological academies have never suggested that a quick and dirty home study which can only pick up the most extreme cases of one sleep diagnoses become the standard. Good quality sleep medicine as any other medical specialty requires accurate diagnosis and treatment of all 84 sleep disorders. I feel there is no role for home study polysomnography.

Very sincerely yours,



Stephen M. Kreitzer, M.D.

SMK:wb

CC: Terry Leapaldt

July 13, 2004

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
S3-26-27
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: NCA Tracking Sheet for Continuous Positive Airway Pressure (CPAP)
Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R)

Dear Dr. Phurrough:

SNAP Laboratories would like to comment on the request for modification of policy CIM 60-17 forwarded to CMS by Terence M. Davidson, MD. It is our understanding that this application incorporates a request for the approval of unattended sleep apnea testing as an alternative to attended polysomnography in Medicare patients with (suspected) obstructive sleep apnea for the purpose of prescribing CPAP.

The goal of sleep testing from a clinical perspective is the diagnosis of Sleep Apnea. Obviously, appropriate utilization of sleep studies is essential to the cost-effective management of OSA. Given the recognition of the prevalence and significance of OSA as well as the growing demand for sleep studies, a need for more cost-effective methods to document OSA has developed. This parallels the development and utilization of ambulatory testing and monitoring in other fields of medicine.

Unfortunately, this evolution has not been welcomed by members of the medical profession who have a vested interest in laboratory based sleep testing (polysomnography). As Pack *et al* (7) noted regarding a Standards of Practice Statement by the American Sleep Disorders Association regarding ambulatory sleep testing: "The ASDA statement appears to have been formulated only by Sleep physicians and hence the conclusions have the appearance of self-interest."

"A large and growing body of evidence demonstrates excellent correlation between multi-channel home sleep testing and PSG," Dement wrote. Unfortunately the sleep establishment may not accept this. They claim that the small reported deviation between home sleep testing and laboratory-based PSG is clinically significant and justifies the cost of a laboratory-based PSG. What they fail to point out is that studies show that in fact the variance between home-based sleep studies and laboratory-based PSGs is significantly less than the variance between

night-to-night hospital-based PSG studies, and it is also less than the variance among hospital PSG technologists in the scoring of a PSG hospital-based study.

Dr. Nancy Collop (12,13) says, “given the outdated sleep staging rules, inconsistent equipment between labs, variable scoring parameters...it is a wonder that there can be any consistent scoring of PSGs [between trained sleep professionals].” She goes on to state, “No matter how experienced the personnel are, I routinely require rescoring of portions of studies due to disagreement with the scores [when reviewing studies from my own sleep center].” Furthermore, she reports that data from 10 different PSGs were sent to 10 sleep centers to compare results in scoring. In this study they found substantial deviation in scoring – the most significant variance being in scoring respiratory events. In fact, one patient’s study was scored as an AHI of five by one trained sleep technician and an AHI of 74 by another trained technician scoring the exact same record on the same night. This means that one professionally trained PSG technician found hundreds of events not found by the other professionally trained PSG scorer. Dr. Collop concluded that study with the statement: “Clinicians should be aware that there is tremendous variability among polysomnography technologists regarding the scoring of polysomnography.”

A substantial body of research has proven the night-to-night variability of sleep apnea PSG (10-16). For example, Mosko *et al* (15) reported that with cutoff of five events per hour, the first night classification differed from the classification given on at least one of the two other nights in 43% of the subjects. Likewise, Lord *et al* (14) reported that the first night results failed to predict the second night results in 36% of the patients when a cutoff of five events per hour was used and in 21% of the patients when a cutoff of 15 events per hour was used. Those numbers would have been far worse if these articles were to report the percentage of disagreement in assessing “Apnea severity”.

The fact is that home sleep testing is held to a different standard than the sleep industry holds itself. The sleep community has been aware for years of the high level of disagreement between two trained professionals scoring the same record on the same night. Why should they be surprised when home sleep test results vary? Perhaps one should ask how we can accept the data from sleep centers when the study costs the patient two to three times more, is remarkably more invasive for the patient, and the scoring agreement is far less accurate than those reported by a home test.

Some critics have stressed the need to neurophysiologically stage sleep and feel that staging may be compromised in the non-laboratory environment. After studying 200 sequential patients Douglas (9) concluded “Recording sleep electrophysiologically was of no diagnostic value and SAHS (the Sleep Apnea-Hypopnea Syndrome) could be as accurately defined by A+H per time in bed as A+H per time asleep.”

Note that some sleep researchers have recognized Home Unattended Sleep Studies to be an accurate tool and are using it for major research projects, e.g. “Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community - Based Study” *JAMA*, Nieto F.J. *et al*, Vol. 283, No. 14, April 12, 2000. (8)

The RDI criteria that are used universally to make the diagnosis of OSA clearly will have a direct and significant bearing upon the incidence of the “disease” in the population tested. Some sleep laboratories report positive sleep apnea rates up to 85% using RDI levels of 5. Other laboratories, using an RDI cutoff of 10, report incidences in range of 50%. At SNAP Laboratories the incidence of patients found to have an RDI of ≥ 15 is 40%. A stratification of patients with OSA based upon the severity of their disease (level of RDI) is an important factor to consider with regards to selection of treatment. Obviously if the RDI cutoff point is moved from an RDI of 5 to an RDI of 15, this can result in cost savings of $> 35\%$ overall.

The following are tables demonstrating the kind of savings associated with home sleep study today.

	Patient with OSA			Patient with Non-OSA	
	PSG	SNAP		PSG	SNAP
PSG	\$750			\$750	
CPAP Titr.	\$811				
Home Test		\$208			\$208
CPAP Equip.	\$1,290	\$1,290			
TOTALS	\$2,851	\$1,498		\$750	\$208

Thus, home-testing yields cost savings of 47.5% for patients with OSA and 72% for those without. Assuming 35% of patients are categorized as having OSA (using an RDI cutoff of 15): Average cost per patient (population) for a hospital based PSG = $(2,851 \times 0.35) + (750 \times 0.65) = \$1,485.35$. Average cost per patient for Home SNAP Lab testing = $(1,498 \times 0.35) + (208 \times 0.65) = \659.50 .

Thus, home testing can yield a saving of 56% of total costs (including treatment) that rises to 72% when CPAP is excluded (i.e. purely diagnostic costs).

The SNAP test was validated via simultaneous side-by-side, double blind recording with PSG at multiple premier sleep laboratories, with very impressive results.

Attached you will find some interesting references regarding Outpatient Sleep Apnea testing.

Please let me know if you require additional information. Thank you for this opportunity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gil Raviv', with a stylized flourish extending to the right.

Gil Raviv, Ph.D.
President/CEO SNAP Laboratories
800-762-7786 ext. 202

Attached: References
Articles

REFERENCES

A) SNAP Laboratories Sleep Apnea Studies:

1) *Preliminary Validation of an Acoustic Analysis of Respiration During Sleep*. Richard S. Rosendberg; Gil Raviv; Ron Elesh; Joseph Finely; Charles Weingarten; Thomas Kehoe, Evanston Hospital Sleep Center, Northwestern University. Sleep Research, 1995, presented at the APSS Meeting, Nashville TN.

2) *Validation of Acoustic Apnea Screening*. Vanessa Smith, *et al.* Cleveland Clinic Foundation, Dept. of Otolaryngology. 1997 Triological Society Poster Session.

3) *A Comparison of Polysomnography and A Portable Home Sleep Study in the Diagnosis of Obstructive Sleep Apnea Syndrome*. Su S., Baroody F.M., Kohrman M., Suskind D., Department of Surgery and Sleep Disorders Center, the University of Chicago. This study was presented at the 2003 AAO-HNSF Annual Meeting in Orlando, FL September 21-26, 2003. It has been submitted for publication.

B) Validity of Home Testing:

4) *Home Diagnosis of the Obstructive Sleep Apnoea/Hypopnea Syndrome*. Douglas N.J., Sleep Medicine Reviews, Vol. 7, No.1, pp.53-59.

5) *Measurement of Sleep-Related Breathing Disturbances in Epidemiological Studies: Assessment of the Validity and Reproducibility of a Portable Monitoring Device*. Redline S., Tosteson T., Boucher M.A., Millman R.P., Chest, November 1991, Vol. 100 pp.1281-1286.

6) *Verification of Sleep Apnea Using a Portable Sleep Apnea Screening Device*. Emsellem H.A., Corson W.A., Rappaport, B.A., Hackett S, Smith L.G., Hausfeld J.N., Southern Medical Journal, Vol. 83, No. 7, July 1990, pp. 748-752.

7) *Guidelines for In-home Testing: As Need for Reassessment*. Pack A., Remens J., Roth T. *et al.* Sleep, Vol. 18, 1995, pp.136-137.

C) Home Testing In Large Research Project:

8) *Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community-Based Study*. Nieto F.J., Young T.B., Lind B.K., Shahar E., Samet J.M., Redline S., D'Agostino R.B., Newman A.B., Lebowitz M.D., Pickering T.G., JAMA, Vol. 283, No. 14, April 12, 2000.

D) The Value of Neurophysiological Data in the Investigation of SAHS:

9) *Clinical Value of Polysomnography*. Douglas N.J., The Lancet, Vol. 339, 1992, pp.347-350.

E) Variability and Hypopneas:

10) *Effects of Varying Approaches for Identifying Respiratory Disturbances on Sleep Apnea Assessment*. Redline S., Kapur V.K., Sanders M.H., Quan S.F., Gottlieb D.J., Rapoport D.M., Bonekat W.H., Smith P.L., Kiley J.P. Iber C., American Journal of Respiratory and Critical Care Medicine, Vol. 161, 2000, pp. 369-374.

11) *Hypopnea, a Floating Metric: Implications for Prevalence, Morbidity Estimates, and Case Finding*. Redline S., Sanders M., Sleep, Vol. 20, No. 12, 1997, pp. 1209-1217.

12) *Scoring Variability Between Polysomnography Technologists in Different Sleep Laboratories*. Collop N.A., Sleep Medicine, Vol. 3, 2002, pp. 43-47.

13) Advance for Managers of Respiratory Care, Collop N., April 2004.

14) *Night-to-Night Variability of Disturbed Breathing During Sleep in an Elderly Community Sample*. Lord S., Sawyer B., O'Connell D., King M., Pond D., Eyland A., Mant A., Holland J.T., Hensley M.J., Saunders N.A., Sleep, Vol. 14, No. 3, 1991, pp. 252-258.

15) *Night-to-Night Variability in Sleep Apnea and Sleep-Related Periodic Leg Movements in the Elderly*. Mosko S.S., Dickel M.J., Ashurst J., Sleep, Vol. 11, No. 4, 1988, pp. 340-348.

16) *What is Hypopnea, Anyway?* Moser N.J., Phillips P.A., Berry D.T., Harbison L., Chest, Vol. 105, No. 2, February 1994, pp. 426-428.

1997 TRIOLOGICAL SOCIETY ABSTRACT FORM

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TITLE: Validation of Acoustic Apnea Screening

The standard diagnostic study for obstructive sleep apnea syndrome (OSAS) is the polysomnogram (PSG), an expensive test requiring an overnight stay in the hospital. We have been studying an alternative diagnostic study to the PSG, the "SNAP" system, which consists of a small microphone and tape recorder used at home. The recording is then sent to SNAP Laboratories for digital acoustic analysis. Eighteen patients thus far have undergone simultaneous PSG and SNAP study in our sleep laboratory. The two studies were analyzed independently in a double-blinded fashion. The SNAP system was 100% as sensitive and 91% as specific as PSG in diagnosing OSAS. The SNAP study offers the benefit of lower cost and greater patient comfort through home use. Its correlation with the PSG in detecting apneas and hypopneas is excellent.

NAME (corresponding author) Vanessa Smith, M.D. ADDRESS CCF, Dept of Otolaryngol. A71,
TELEPHONE (216) 444-4945 FAX (216) 445-9409

Consideration for Resident Award? ☐ Yes ☐ No ☐ Slide presentation ☐ Video presentation

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Corresponding author's signature Vanessa Smith

A Comparison of Polysomnography and A Portable Home Sleep Study In the Diagnosis of Obstructive Sleep Apnea Syndrome

Stephanie Su MD, Fuad M. Baroody MD, Michael Kohrman MD, Dana Suskind MD

Department of Surgery, Section of Otolaryngology-Head and Neck Surgery
The University of Chicago

Corresponding author: Stephanie Su, MD
ssu@surgery.bsd.uchicago.edu

ANNUAL MEETING
of the
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SEPTEMBER 21-24, 2003

**A Comparison of Polysomnography (PSG) and a
Portable Home Sleep Study in the Diagnosis of OSAS
in Adults**

Stephanie Su MD (*presenter*); Dana L Suskind MD; Fuad M
Baroodi MD; Michael Kohrman MD
Chicago IL; Chicago IL; Chicago IL; Chicago IL

Objectives: OSAS is increasingly recognized as a significant contributor to neurocognitive and cardiovascular sequelae. While PSG is the gold standard for diagnosis, its limited availability, long waiting lists, and high cost make at-home sleep studies an attractive alternative. We sought to evaluate a commercially available at-home sleep study (SNAP) in comparison to standard polysomnography for the diagnosis of OSAS in adults.

Methods: A prospective evaluation of 60 adult patients referred for a PSG to rule out OSAS. Simultaneous SNAP and PSG studies were conducted. Both studies were read and scored according to predetermined criteria by independent investigators blinded to the results of the other evaluation.

Results: Interpretable data were available for both techniques in 50 of 60 patients. There were 32 females (64%) and 18 males (36%) with an age range from 20 to 69 years. The Respiratory Disturbance Index (RDI) was 27 ± 4.2 with PSG and 21 ± 4.0 using SNAP (mean \pm SEM). The correlation coefficient between RDI obtained using both tests was $r_s = 0.81$ ($P = 0.0001$). When compared to PGS, sensitivity and specificity for SNAP were 84% and 100% for an RDI >5 , and 88% and 84% for an RDI >15 , respectively.

Conclusions: Our data show a strong and significant correlation between RDIs obtained from both studies and a good sensitivity and specificity of SNAP compared to PSG. While SNAP does not provide data about stages of sleep and end-tidal CO₂ levels, our data suggest that it is a useful alternative for PSG in the diagnosis of OSA. Furthermore, it offers the advantages of performance in the home setting.



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July 23, 2004

Tiffany Sanders, MD
Francina C. Spencer
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Sanders,

I am writing in support of Dr. Davidson and others regarding the request to include and recognize in Medicare coverage policy the use of portable multi-channel home sleep testing devices as an alternative to facility based polysomnography in the evaluation of Obstructive Sleep Apnea (OSA).

Attached are copies of two validation studies in peer review journals demonstrating the precision of an unattended device, NovaSom QSG, for use in diagnosing OSA vs. a full polysomnography.

Clinical validation of the Bedbugg in detection of obstructive sleep apnea
Claman, D, et al"; Otolaryngology-Head and Neck Surgery, Sept. 2001

The NovaSom QSG™ was originally called the "Bedbugg™". In this study conducted at the University of California at San Francisco (UCSF) Medical Center, 42 consecutive patients who were referred for a formal sleep lab study because of suspected sleep apnea underwent in lab PSG and were simultaneously studied with the Bedbugg™. The AHI was determined by both PSG and the Bedbugg™ in an independent and blinded fashion. The study is attached in Appendix 1 and key findings include:

- The correlation between the AHI between PSG and Bedbugg was $r=0.96$
- The sensitivity of Bedbugg for detecting AHI >15 was 85.7%
- The specificity of Bedbugg for detecting AHI <15 was 95.2 %
- The positive predictive value of Bedbugg based on an AHI of 15 was 94%
- The negative predictive value of the Bedbugg based on an AHI of 15 was 85.5%
- No studies were lost because of data acquisition problems.
- The overall specificity of the device was an excellent 95%, allowing for diagnosing *subject with little or no apnea* vs. previous portable devices, which were unable to be particularly accurate at low AHIs and often requiring a follow-up PSG.

- Low rates of false-positive and false-negative AHI results were found in providing accurate clinical studies.
- Conclusion. “this study demonstrated the accuracy of the Bedbugg in diagnosing sleep apnea as compared to the gold standard in –lab PSG through a high degree of both specificity and sensitivity”
- Positive Likelihood Ratio (LR) of 17.2
- Negative LR of 0.15

Comparison of the NovaSom QSG™, A Novel Sleep Apnea Home-Diagnostic System and Polysomnography

Reichert et al.; Sleep Medicine 4(2003) 213-218

51 consecutive patients with suspected OSA who were referred to the sleep lab underwent simultaneous in lab PSG and NovaSom QSG™. Patients also received NovaSom QSG™ at home for three nights. Two separate comparisons were made between PSG and NovaSom QSG™: the simultaneous in lab readings and the NovaSom at home readings. The study is attached in Appendix 2 and key findings include:

- In lab NovaSom had a sensitivity of 95% and specificity of 91%
- Home NovaSom had a sensitivity of 91% and a specificity of 83%
- If an AHI cutoff of 18 were utilized, in home NovaSom has a specificity of 100%
- The authors conclude that the NovaSom QSG™ is a valid and reliable home diagnostic system for testing adults suspected to have sleep apnea”
- Study validated use in the setting in which it is intended to be used
- Positive Likelihood Ratio (LR) of 11
- Negative LR of 0.06

These validation studies clearly show that the parameters that NovaSom QSG™ measures is sufficient for accurate rule in and rule out diagnosis of OSA. NovaSom QSG™ provides measurement of:

- apneas
- hypopneas
- oxygen saturation
- pulse rate
- respiratory effort
- snoring intensity

Thus NovaSom QSG™ meets the AASM criteria for a Level 3 device and provides all of the parameters necessary to monitor sleep breathing and provide definitive diagnosis of OSA.

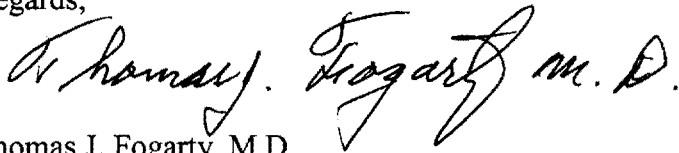
The company that manufactures the device and provides the in home testing service, Sleep Solutions, Inc., provides the following services in conjunction with each test:

1. Real time monitoring and patient advisories during set up and test
2. 24/7 help line availability
3. Patient prompts and interactivity during test set up
4. Easy to understand guides and instructional materials
5. Preparation and counseling of the patient via phone

Sleep Solutions, Inc. has tested over 6,000 patients with this device in the Veteran's Administration health system, military hospitals, and private insurance (over 100 million covered lives under contract). During this time, more than 92% of the patients successfully complete a three night in home sleep study utilizing NovaSom QSG™.

Thank you for your consideration.

Regards,

A handwritten signature in black ink that reads "Thomas J. Fogarty M.D." The signature is fluid and cursive, with the first name "Thomas" and last name "Fogarty" being more prominent, and "M.D." written in a smaller, simpler script at the end.

Thomas J. Fogarty, M.D.
Stanford University



American Academy of Otolaryngology — Head and Neck Surgery

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July 22, 2004

Tiffany Sanders, MD

Centers for Medicare & Medicaid Services

Office of Clinical Standards and Quality Coverage and Analysis Group

Attn: Public Comments, S3-02-01

7500 Security Boulevard

Baltimore, MD 21244-1850

Dear Dr. Sanders:

I am writing in response to CMS's second call for comments relating to the national coverage determination (NCD) for diagnosis and treatment of obstructive sleep apnea (OSA) to include multi-channel home sleep testing as an alternative to facility-based polysomnography (PSG). The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS/F) continues to support this proposal as a potential cost-effective alternative to PSG and as means of improving access to care for the large adult population at risk for sleep apnea. We believe that providing beneficiaries with coverage for home sleep studies will improve access to care for beneficiaries, and will provide a cost effective alternative to facility-based polysomnography for diagnosing and treating obstructive sleep apnea.

As CMS had specific questions posed in this second call for comments, please find our responses to these questions below:

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

Available evidence suggests that the diagnostic test performance of unattended portable home sleep testing is comparable to facility-based polysomnography for some patients. As with most diagnostic tests, there is variability in the quality of the equipment used, just as there is with facility-based equipment.

Dr. Edward Weaver cited in his May 7, 2004 letter to CMS regarding this issue a study conducted by the Group Health Cooperative in western Washington State that had excellent outcomes by implementing a home sleep testing program. Out of 698 home sleep studies performed in a two year period, only 56 (8%) required re-testing due to a lack of diagnosis or technical problem. Dr. David Lewis, the director of Group Health Cooperative Sleep Program, further described the benefits of their home sleep testing program in his May 6, 2004 comment letter to CMS.

If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

We believe that the following parameters are essential in the diagnosis of sleep apnea: 1) measure of ventilatory signal (e.g. airflow), 2) oxygen saturation, and 3) measure of central vs. obstructive apnea (e.g. respiratory effort by strain gauges). Body position, although helpful, should not be considered mandatory. The key features of a home sleep study are that there is no EEG and it is unattended. If the home sleep study is conducted properly, neither an EEG (sleep staging) nor attendance by health care personnel is required to diagnose and treat most routine cases of sleep apnea. Please note that split-night polysomnography, currently covered under CMS policy for the diagnosis and treatment of sleep apnea, does not accurately measure the relationship between sleep stages and sleep apnea. The diagnostic phase includes only the first part of the sleep period when most people spend little time in the stages of sleep most vulnerable to sleep apnea.

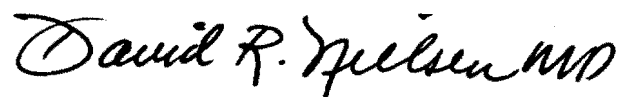
If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

Dr. Davidson's proposal would allow home sleep studies as a first line option for diagnosing and treating sleep apnea. We do not believe that home sleep studies should be limited to use as a screening service. Facility-based polysomnography is likely to be required for any technical failures that may occur in a home sleep study, diagnosis ambiguities, or severe/complicated sleep apnea. As mentioned earlier, the choices made for covered equipment will affect the consistency of measures. Covered home sleep study equipment should measure the parameters listed above using validated technologies.

Only a physician experienced in treating patients with sleep apnea and trained in the use of home sleep studies should prescribe a home sleep study and interpret the results. The physician or the physician's support personnel (also trained in the use of home sleep study equipment) should educate the patient on the use of the equipment, and advise the patient of the benefits and limitations of a home sleep study.

AAO-HNS/F thanks CMS for the opportunity to comment again on this potential policy change. If I can be of any further assistance, please call me directly at 703-519-1559.

Sincerely,



David R. Nielsen, MD, FACS
Executive Vice President and CEO, AAO-HNS/F

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July 20, 2004

Centers for Medicare & Medicaid Services
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Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir:

The Centers for Medicare and Medicaid Services has asked for comments pertaining to clinical evidence for the need of specific features for ICDs. I have enclosed comments which I think pertinent.

1. What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implantation?

DFTs have been routinely performed in ICD testing since the first devices were implanted in 1981. An adequate DFT test is the only way to assure that the device will be functional in the setting of an acute clinical arrhythmia.

The assessment of DFT efficacy at the time of implant has long been the standard of care. It is intuitively reasonable to ensure that the system has an acceptable DFT safety margin at the time of implant.

The reliable sensing of VF and safe and effective defibrillation are crucial for effective ICD therapy, but assurance of both of these functions appears to require implant testing, and while the exact type of implant testing may need to be reappraised, there is yet no consensus regarding suitable surrogates for DFT testing.

2. What is the evidence of benefits and risks of adding antitachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

ATP was an important innovation in defibrillator technology in the 1990s. The lines of evidence for this are listed below.

Clinical evidence shows that 78% of inappropriate shocks may be avoided when the ATP features is used appropriately in an ICD.

July 20, 2004

Page Two

ATP can terminate 3 of 4 ventricular tachycardias and may safely reduce the morbidity of painful shocks.

ATP is safe and very effective and should be programmed "on" in all patients regardless of the predischage EP inducibility.

In MADIT-II 720 patient received an ICD, and 169 of these patients received 701 appropriate ICD therapies for VT or VF; 40% of all VT/VF episodes were terminated painlessly by ATP ($281/701 = 40\%$). In the absence of ATP, the only alternative therapy would have been DC shocks, resulting in unnecessary discomfort and alarm.

There is no additional lead necessary for ATP, thus no additional risk; the relevance of this part of the question then remains unclear. If the question is meant to explore the need for dual chamber ICDs as opposed to single chamber ICDs, this decision is best left to the treating physician. While it has become apparent that unnecessary RV apical pacing is potentially detrimental, this is more a function of device programming than of the presence or absence of an atrial lead. Previous studies have demonstrated the potential value of atrial based pacing for atrial arrhythmia detection and prevention.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

I do not see the importance of justification for an ICD patient registry. An enormous amount of information is available regarding these patients.

While the potential yield of a detailed registry is significant, the logistical challenges are daunting. Who would manage and ultimately own this process? Would the manufacturers, CMS, or some other organization be responsible? What incentives would need to be in place for thorough data collection and longitudinal follow-up? What parameters would be captured and who would bear the costs? At the moment it appears as though economic concerns are limiting access to large populations of patients at known risk and benefit. The additional and unspecified costs and infrastructure of such a registry would appear to exacerbate as opposed to alleviate this concern.

July 20, 2004
Page Three

I appreciate being able to respond to these questions. I hope CMS will consider these questions in the context of 25 years of successful device implantation techniques.

Sincerely,

A handwritten signature in black ink, appearing to read "David S. Cannom" with a stylized flourish at the end.

David S. Cannom, M.D.
Medical Director of Cardiology
Good Samaritan Hospital
Clinical Professor of Medicine
UCLA School of Medicine

DSC:jmz



**Memorial
Sleep Center**
Owned/Operated by Finao Corp

2919 Swann Avenue Suite 105-B • Tampa, FL 33609
(813) 870-2777 • Fax (813) 870-3433

July 24, 2004

TO: Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services

FROM: Terrance (Terry) E. Leapaldt
President
FINAO Corporation
Memorial Sleep Center

RE: Sleep Diagnostic Testing in the home

Our facility is an independently owned and operated sleep center. Our patients are of various ages and sexes as well as a wide variety of payors. Medicare is less than 20% of our total patient population base.

The reason I am writing this is my strong belief that a decision should not be made based upon financial reasons with some opinion based clinical reasons.

First, let me point out that Dr. Davidson is familiar with California activity, mainly. Health care costs in California have not been the norm for some time. Nor does Dr. Davidson comment on "freestanding, independent" sleep centers.

The fees for the studies we complete is 40%-60% less than hospital based sleep centers. The private insurance plans for which we are a provider have shared with us the difference in costs compared to a hospital-based center. You can compare the reimbursement for freestanding facilities to that of hospitals in just the Medicare fee schedules.

We provide just as good a study as hospitals following the same parameters they do. Our facilities are better designed with the patient's comfort in mind. We offer amenities that hospital based centers do not offer in most cases. This means the patients tested in our facility have a much better "attitude" about the facility and the test than when done in a hospital sleep center.

Our particular Center is in the process of becoming an Accredited Facility under the same standards any hospital-based facility would test.

We would be able to expand to many more beds in a different location to better facilitate the population much quicker than a hospital, as they will always have a lot of "red tape" to get through.

Now other reasons for not being in favor of home studies. Dr. Davidson is correct in that it would be in the home testing. Will the patient abstain from alcohol or caffeine? Will the patient be able to reconnect the lead wires if one comes off at night? Will the patient have a restful sleep if the environment is not a quiet environment, free from street noises and the like.

Our facility conducts the majority of our studies as non-split nite studies. We do have occasions where a patient de-saturates to such a level that a split nite study is necessary. All of our technicians are respiratory therapists. What happens when the patient de-saturates at home during the study and has complications? Who is responsible?

There is an enormous amount of clinical data being made available indicating additional problems with people who have sleep disorders of some nature that require the additional lead wires. There are in excess 80 different problems a patient could be having that is sleep related. Less lead wires will not help there.

Dr. Davidson's comment in 4,d. last sentence, is only an opinion.

In summary, I believe there is a need for potential "screening" in patient's homes in areas where the sleep centers are very overbooked. Once that screening is done, a bed must be made available as you now have a potential diagnoses or indication of a diagnosis and must treat as soon as possible.

I also believe that if more physicians were better trained to recognize patients with potential sleep disorders we could possibly treat them earlier and save million of health care dollars. I have been a C-PAP user for over 15 years and I can tell you it was a lifesaver for me.

I also feel that if home sleep testing is allowed, you will have a lot of "wild cat" companies only doing it for the money and the quality of care will be terrible.

My opinion only and thank you for your time and attention.

Yale University



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BARRY L. ZARET, M.D.
*Robert W. Berliner Professor of Medicine
Professor of Diagnostic Radiology
Chief, Section of Cardiovascular Medicine
Department of Internal Medicine
Medical Director, YNH Heart Center*

July 23, 2004

Dr. T. Sanders
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Watch-PAT

Dear Dr. Sanders:

I am writing to voice my strong support for the Watch-PAT technology which I believe is currently being reviewed by the Centers for Medicare & Medicaid Services Office of Clinical Standards and Quality. The issue of ambulatory sleep devices to detect alterations in breathing patterns is extremely important in cardiac disease. The ability to monitor patients at home and detect significant abnormalities is of fundamental importance, particularly in congestive heart failure and hypertension. The prevalence of apneic disorders in such patients is quite high and, when present, is associated with altered outcomes.

I have had personal experience with the Watch-PAT device and I have been extremely impressed with this technology with respect to its accuracy and ease of use. I urge you to act favorably upon this technology with respect to its implementation.

Sincerely,

Barry L. Zaret, M.D.

BLZ:ahs

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FOV #4

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R. MICHAEL BOWEN, M.D.
SUSAN L. BURTON, M.D.
WILFRED A. CORSON, M.D.
JOAN M. K. FOX, M.D.
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MARK R. STANG, M.D.
RALPH E. STEELE, M.D.
WAYNE L. STERN, M.D.
PATRICK J. WRIGHT, M.D.

PENNY M. VAIL
ADMINISTRATOR

July 23, 2004

Steven Phurrough, M.D.-N.P.A.
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid services.

Dear Dr. Phurrough:

I was only recently advised that Medicare was reviewing the possibility of payment for unattended nocturnal polysomnographic studies. I represent a group of board-certified sleep specialists by the American Academy of Sleep Medicine and the American Board of Sleep Medicine. We strongly oppose the payment of unattended portable studies. We believe this will greatly undermine the care given to the elderly and will open up inappropriate escalating uncontrollable cost. You have, I am sure, received a number of analyses in regards to the advantages of nocturnal attended studies and I will not repeat all of this. It has been confirmed in our experience that the attended studies offer much more information and therapy for the money than a screening test. At best, the unattended studies are screening tests. However, given our population, most of the time the clinical situation is an adequate screener and direct diagnostic and therapeutic, and educational value is obtained from the attended polysomnographic study. We find it interesting that the request for multichannel home study devices on an unattended basis is directed from a director of head and neck surgery. As you well know, especially in the elderly, obstructive sleep apnea is a nonsurgical disease and there are only a few exceptions to this. We do not see how indiscriminate screening of the elderly patient is going to improve care from a surgical point of view, since this is not an appropriate therapy at all.

In addition, if you look at the elderly population, it is clear that we are not just dealing with obstructive sleep apnea. We are generally dealing with patients who have also underlying cardiovascular disease, diabetes, neurological diseases, including cerebrovascular disease. We have found that these patients are a challenge to both diagnose, as well as treat. The elderly patient in our sleep lab requires multiple caregivers, which can only be given in a supervised setting. In addition, the patients may have one, two, or three active sleep problems, which require intervention, which can be supervised and instituted at the time of the nocturnal study. As you well know, many of these people have congestive heart failure, not only have obstructive sleep apnea, but central sleep apnea, which is treated significantly differently. One cannot produce any of these interventions at an unattended home study. Therefore, it becomes a screening study

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☐ 675 NICOLLET BLVD EAST #130
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☐ 500 OSBOURNE ROAD, #100
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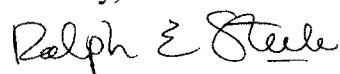
requiring a followup-attended study. This to me is a waste of not only energy, but also money. I think that this will spawn unnecessary testing.

Finally, again in regards to the patient, we have found that in order to improve compliance and, remember, diagnosis of a disease process means nothing without effective therapy. Effective therapy in this case is only afforded by compliance. The best therapy at this date is positive pressure devices, either CPAP or BiPAP, as well as oxygen if needed. We use the nocturnal attended study as an educational and compliance tool with family and the patient. This will be lost with the unattended study.

In conclusion, I think this will adversely affect our society as a whole in regards to the continuing cost of unnecessary, inappropriate care, and has the potential to do direct harm to our most fragile patients. In the state of Minnesota, many of the insurance companies are not convinced that unattended studies add any productive information to the care of the patient. I hope you will review this and find that this is the case as well. There is a preponderance of evidence that has been accumulated over the past 25 years regarding sleep apnea and further evolution is necessary. This can only be done by carefully considered studied medical therapeutic and diagnostic interventions. This should not be driven by DME companies or itinerant physicians.

I hope you will consider this letter seriously. We would be happy to confer at any time in regards to this.

Sincerely,

A handwritten signature in cursive script that reads "Ralph E. Steele". The signature is written in dark ink and is positioned below the word "Sincerely,".

Ralph E. Steele, M.D.
Diplomate, American Board of Sleep Medicine
RS/RI283

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July 23, 2004

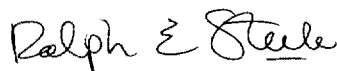
ADDENDUM

RE: Unattended portable studies.

In regards to the two questions posed of unattended portable home channel studies. Unattended portable multichannel studies are not as effective as attended nocturnal polysomnographing in the diagnosis of sleep apnea. It is deficient in regards to the educational component. It does not provide technical support, does not allow meaningful therapy investigation, and will force duplication by requiring a followup-attended study. The patient will not be served under these circumstances. Home channel study reliability has significant failure rates and fails to even provide any ability to intervene on behalf of this patient. In addition, it requires no minimal evaluation by a physician as to ascertain whether this is an appropriate test to be performed on a patient. Rather, it will be performed as the sole polysomnographic study and will be inferior in quality and therefore adversely affect patient care.

PENNY M. VAIL
ADMINISTRATOR

Sincerely,



Ralph E. Steele, M.D.
Diplomate, American Board of Pulmonary Medicine
Diplomate, American Board of Sleep Medicine
RS/RI283

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Bob Fairbanks, RPSGT
Ridgeview Steiner Sleep Disorders Center
Waconia, MN

I am commenting on the request for information relating to unattended portable multi-channel home sleep testing compared to facility-based polysomnography in the diagnosis of obstructive sleep apnea. This is a complex issue that has been addressed in the past and will continue to be debated as technology in diagnostic equipment improves. I believe we should look at the major differences between the unattended home-based studies and facility-based polysomnography studies:

1. Facility-based studies measure more parameters of sleep and cardiopulmonary functions than the majority of home-based studies.
 - Some patients will only have significant Apnea and Hypopnea events when they are in REM. If we cannot measure sleep staging during the study we cannot tell if the patient entered REM and thus patients may be misdiagnosed.
2. Facility-based studies are in an environmentally controlled room for the best possible sleep hygiene.
 - An issue that is usually made for the home-based study is that patients are more comfortable sleeping at home. The problem with that is people who have OSA usually also have poor sleep hygiene, i.e. sleeping with the T.V. on, pets sleeping in the bed, noises in the environment and bed partners getting up during the night. All of these can lead to inaccurate studies.
3. Facility-based studies are overseen by sleep physicians and have trained qualified technologists performing the studies.
 - Most home-based study programs are only looking for the diagnosis of OSA in the patients they study. These programs will have difficulty with patients who are suffering with excessive daytime sleepiness but are not meeting the criteria for OSA. Most of the technicians performing the set-ups and education for these patients have no medical experience and no formal training in sleep disorders.
4. Facility-based studies will have trained technologist fix any artifact during the study so the patient has a high quality study.
 - Unattended home-based studies will not have this option so the quality of the study is compromised and the possibility of the patient having to be restudied increases.
5. Facility-based studies may have a waiting list of 1 month or more to see a physician and then get a sleep study completed.
 - Home-based studies can be completed rapidly so patients should have a shorter waiting list.

6. Facility-based studies can diagnose and titrate the patient's CPAP pressure in one night.
 - Home-based studies will have the study completed, then the study will have to be downloaded and scored. This may take a few days because there are few trained technologists who can score the study. Patients are then set-up on an Auto-CPAP for a few weeks in order to find out what the proper CPAP titration should be. Patient is then set up on a CPAP (usually around a month or so from the original study). This doesn't look like it saves time as far as getting the patients treated compared to the facility-based studies.
7. Facility-based studies cost more than home-based studies.
 - Some studies have shown that with the man power needed to treat patients after having a home-based study actually costs more than if they were studied in a facility.

I do not believe that unattended portable home sleep testing is as effective as Polysomnography in the diagnosis of Obstructive Sleep Apnea. For the two questions that were presented for public comments:

- a. Keep in mind that sleep staging and the ability to document REM sleep is an important tool used to diagnose patients with OSA. In order to obtain this information and the cardiopulmonary functions we will need to record EEG, chin EMG, eye EMG, airflow, respiratory effort and oxygen saturations. The problem with this is the more electrodes that are recorded, the higher the chance of artifact affecting the study quality during an unattended study.
- b. One of the biggest problems that this patient population is having right now is the ability to remember things. Patients who have excessive daytime sleepiness have a learning disorder that is not easily defined. Educating patients or explaining how something works is not easy for them to learn. I recommend if possible have a family member available to learn with the patient any educational material. It might also be helpful for the family member help fill out any questionnaires or sleep charts.

Thank you for your time.



Sleep Disorders Center

Kettering Medical Center Network™

July 22, 2004

Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Second Public Comments for NCA for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (CAG-00093R) Public Comment Period (June 25, 2004 – July 25, 2004)

Submitter: Donna L. Arand, Ph.D.
Organization: Kettering Medical Center Sleep Disorder Center
Date: July 22, 2004
Comment:

I have significant concern in regard to the proposition that CMS should permit use of portable multi-channel sleep testing devices unattended in the home. Polysomnograms have been performed in accredited programs for some years. Such programs are certified to employ certified physicians and highly trained technicians to perform standard tests with universally accepted outcome measures. To change from these accepted standards in any significant way should require significant investigation.

The use of multi-channel portable monitoring devices for sleep apnea testing could provide patient benefit but mainly to the extent that such devices can provide equivalent diagnostic capability as is currently provided by polysomnography.. Unfortunately, the basis of the change request is to allow recordings with considerably fewer channels (typically 1-5) concentrating exclusively on respiratory variables (typically airflow, chest movements, oximetry, and cpap pressure). Such recordings omit crucially important physiological information. For example, if sleep apnea is not found in the recording, it may be because the patient never fell asleep (and it is impossible to know this without recording sleep). If the patient does have periods of apnea, it is impossible to calculate severity because all apnea indices are calculated by a formula that is number of abnormal respiratory events divided by total hours of sleep. Obviously, sleep time cannot be calculated if sleep is not recorded. Finally, it is well-known that sleep apnea is frequently

worse during REM sleep and, on occasion, when patients sleep in the supine position. Recordings that do not include REM sleep and position data cannot be certified as containing REM sleep or supine position data. If these variables were observed, apnea might be significantly worse and required cpap pressures might be significantly higher. Without attention to sleep, such information cannot be known. Irregular respiration is also commonly associated with movement during sleep (and periodic changes in respiration may accompany periodic limb movements). If limb EMG is not recorded, respiratory changes associated with movement may be mistakenly scored as periods of hypopnea. It is clear from these few examples that quality of care will diminish dramatically if current sleep variables are omitted from requirements. On the other hand, it is now possible to record good physiologic data in many environments, including the home environment. The important point is that all of the currently recorded information is essential and should continue to be required.

Most of those individuals asking for changes in sleep apnea/cpap standards are really looking for approval to perform unattended recordings (the recording apparatus is attached to the patient and the technician leaves – the study is automatically recorded and is then picked up in the morning for analysis). The problem with unattended recordings is quality. During a standard polysomnogram, the technician makes frequent adjustments to recording parameters – airflow may change whenever the patient moves, recording devices may be dislodged, equipment may break and need to be replaced. These changes are relatively easy to make in real time but they never occur in unattended recordings. Data is commonly lost and not interpretable, but this is typically not known until after the study is complete. There is no interaction with the patient (to be sure the pt sleeps part of the night on his back, to try a different cpap mask, to add low flow O₂, to understand why the patient is not sleeping well and adjust the study parameters). Complex procedures simply cannot be done well without human supervision – typically a requirement for patients in hospital settings. Patients with sleep apnea may be at significant medical risk, and there risk is multiplied without human response capability in real time at the patient site. For this reason, unattended monitoring of polysomnograms should not be reimbursed in the hospital or at home.

It is important that proposed changes be discussed fully with the professionals trained to perform and interpret them. It is essential that significant input be obtained from the American Academy of Sleep Medicine before changes in standards are considered.

Sincerely,

A handwritten signature in black ink that reads "Donna Arand, PhD". The signature is written in a cursive, flowing style.

Donna L. Arand, Ph.D.

From: <MGoetting@aol.com>
To: <TSanders@cms.hhs.gov>
Date: 7/21/04 9:41AM
Subject: home sleep studies

Sir:

I have practicing sleep medicine for 19 years. There are several irrefutable facts about OSA. First, it can cause a decreased quality of life, create accidents from drowsiness, and is linked to cardiovascular disease. Second, we diagnose a small fraction of those afflicted. Third, the economical burden of diagnosis and treatment of all those with sleep apnea would be dramatic using conventional techniques. ||

Like almost all in sleep medicine, I make most of my living by polysomnography. I recognize the inertia inhibiting change in diagnostic algorithms. But I am convinced that some less expensive and simpler device will serve a crucial role in reaching the millions of Americans with undiagnosed sleep apnea. ||
Peripheral arterial tonometry is the best choice presently.

We use PAT routinely and usually do not charge the patients. My read of the literature and personal experience has been very favorable.

I suggest that CMS does not close the door to home sleep studies but rather requires that they be used judiciously.

If I can be of any help, please let me know. Thanks.

Mark G. Goetting, MD
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812-476-5688 fax