

VASM Task Force on Out of Center Sleep Testing: Issues and Answers

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I. What is Out of Center Testing (OCST)?

A minimalist definition of out of center sleep testing (OCST) to diagnose and treat obstructive sleep apnea consists in an abbreviated version of in-lab testing monitoring fewer parameters. The in-lab test is still considered the gold standard by the AASM, but the OCST is allowable under defined circumstances¹. The recommended minimum device standards of AASM are: 1. Air flow; 2. Respiratory effort; and 3. Oximetry. Various names for this abbreviated testing include: 1. Portable monitoring; 2. Ambulatory monitoring; 3. Home sleep testing; 4. Limited channel testing; 5. Out of center testing; and 6. Out of center sleep testing. Devices are placed in order according to the numbers of parameters monitored and designated by number in a 1994 ASDA practice parameter paper into four types: Type I: Full attended polysomnography (greater than or equal to 7 channels); Type II: Full unattended polysomnography (greater than or equal to 7 channels); Type III: Limited channel devices (usually 4-7 channels); and Type IV: 1 or 2 channels usually using oximetry as one of the channels.² The customarily utilized devices for OCST are Type III and this is recommended by the VASM task force, although CMS has allowed coverage for all four methods, except to define coverage for a Type IV at least 3 channels to qualify.³

II. Why home studies (OCST) and why now?

There are certain drivers of change that have occurred and brought about market pressures. The success of sleep medicine has been its downfall in some cases. Hopefully, we can avoid the Massachusetts experience where all 19 of the Sleep Health Centers abruptly closed and went into receivership. In addition, the Chief Medical Officer of this Harvard Medical School operation, Dr. Lawrence J. Epstein's position as CEO was a casualty when OCST was approved by insurance as the primary diagnostic modality for OSAS.⁴

There has been a rapid growth in demand for our services. In Virginia, as in all other states, sleep centers have been developed and become accredited and

now provide services accessible to all geographic areas of the state. The original criticism of availability of evaluation and management of sleep pathology seems to have been answered by this expansion, along with the rapid growth in diagnostic testing and therapy. The growth has raised concerns about cost and, with the availability of new technology, the introduction of cost containment policies. The confluence of the economic downturn, the increased cost of evaluation and management of sleep patients, and the change in the direction of the third party payors have brought about a need to reassess our strategies and policies. Most immediately is the decision of the Blues in developing a new policy using guidelines for utilization management in approving OCST⁵. It would seem that now a large plurality of patients will be required to go through OCST as the primary method of diagnosis. Some insurance companies have contracted with utilization management firms to outsource a sleep management program. Each insurance company handles this differently, but salient points include the increased demand for testing, the lower cost of the alternative testing, the fragmentation of care, the DME lack of accountability, and the ability to track compliance with technology⁶.

There are a variety of ways each insurance company will respond in their approach to test preauthorization. The vehicles for doing this may be the insurance company's staffing to do the authorization or by using a utilization management firm.

There is clearly an argument to be made here that fragmentation of care, instead of being ameliorated by such a process, will make care delivery worse, more time-consuming, and more frustrating to patients, resulting in a larger drop-out rate than already existed, especially with the ascent of IDTFs (independent diagnostic testing facilities)--independent of hospitals or physician offices--in charge of setting up the OCSTs and coordinating the direction of purchase of equipment through a local preferred provider or a national company. It especially behooves us as members of the VASM to monitor these IDTFs with respect to ethical, economic, and clinical quality. Guidelines have been published for their operation and we should be aware of them and alert to any deviation from standards⁷, which some of you no doubt have already observed. The final point is the finding of non-inferiority of OCST vs. in-lab evaluation, with three studies, Kuna et al, Rosen et al, and Lettieri et al,^{8,9,10} having provided "evidence-based" cover as justification.

III. Preparing for the encounter with third parties

What does all this mean to us as clinicians? It means two basic things: 1. We need to know the criteria for and against OCST based on clinical parameters and evidence-based literature; and 2. we need to make adjustments in our business

model to avoid disruption of our services. It would seem that facts of life we can count on are that OCST and outpatient autotitration are here to stay. In making adjustments to the reality, we need to know what the OCST best practices are, using AASM guidelines, balancing cost and quality.

The board certified and eligible sleep physician (based on completion of fellowship awaiting boards) is uniquely qualified to both diagnose OSAS and provide long-term management for OSAS patients supporting the concept that the board certified sleep physician, through an accredited lab, should be at the center of the diagnosis and treatment of OSAS and other sleep disorders.¹¹ It is further asserted that a board certified sleep specialist consultation prior to a diagnostic PSG or OCST significantly improves adherence to therapy as shown in a carefully controlled study at the University of Chicago Sleep Disorder's Center. The AASM recognizes that out of center sleep testing (OSCT) is an acceptable alternative to in-center polysomnography for the diagnosis of obstructive sleep apnea (OSAS) in patients with high pre-test likelihood and without significant comorbidities.¹ The AASM recognizes that unattended APAP can be used to determine fixed CPAP treatment pressure in patients with moderate to severe OSAS without significant comorbidities.¹³ The exclusion criteria, based on medical and sleep comorbidities, include: 1. Congestive heart failure, cardiomyopathy, and symptomatic coronary disease; 2. COPD; 3. Nocturnal hypoxemia for medical reasons and oxygen dependency for any reason; 4. Obesity/hypoventilation syndrome; 5. Previous stroke and other significant neurological disease; 6. Pulmonary hypertension; 7. Poorly controlled asthma; and 8. Central sleep apneas. Sleep comorbidities include: 1. Insomnia, which in the home study would falsely elevate the total sleep time by inflating the denominator in the apnea/hypopnea index expression; 2. Circadian rhythm disorders; 3. Suspicion of concomitant narcolepsy; 4. Nocturnal parasomnias and seizures; and 5. Periodic limb movements in sleep. Not all of these are recognized by the insurance industry by any means. After the OCST and when the patient returns, if the study is indeterminate in a patient with a high pre-test likelihood, the bulk of the literature supports in-lab polysomnography. This is determined in Kuna, and Rosen^{1,8,9,13} by an RDI (by convention) of less than 15. If there is study failure of two successive studies, then an in-lab study is needed⁸.

It is our understanding that certain third party payors won't cover indeterminate or two failed studies on the same patient. The VASM objects to this practice of covering only those studies which are positive and of not covering those studies which fail to provide a diagnostic answer. This post hoc fallacy of payment only for positive studies is an untenable practice, yet the studies are "required" by the insurers. An indeterminate study may be all the device can provide in the individual patient and the data in that instance are useful in pointing to the need for an in-lab study. It is also not appropriate to withhold coverage in a setting where the patient is incapable of following directions invalidating the evaluation and not because of any misfeasance on the part of the technicians attaching the electrodes. Medicine does not warranty its work based on results in this fashion.

Such a practice would be akin to withholding coverage for indeterminate lab work of any indicated lab test or appropriate treatment that did not have the desired result. Such a practice for sleep medicine means the cost of a valuable technician's time and the wear and tear on equipment must be unfairly borne by those providing the service.

In summary, the OCST should be done: 1. In conjunction with a comprehensive sleep evaluation by a board certified/eligible sleep practitioner as an alternative to PSG in patients with a high pre-test likelihood of moderate to severe OSAS; and 2. to monitor non-CPAP treatment.¹

IV. Technical Aspects

Technical specification can be found in a 2011 article in the Journal of Clinical Sleep Medicine to assist in the selection of appropriate out-of-center testing devices. The article, in essence, stated that an OCST device should be used in patients with a high "pre-test probability" for OSAS, the higher the pre-test probability, the higher the post-test probability of OSAS occurring. It was determined that the device for testing a patient should have a likelihood ratio (which is the odds of having OSAS post-test, divided by the odds of having OSAS pre-test) of at least 5 or greater. The minimum value for sensitivity (which is the ability for a test to identify positive results) is established at 0.825. (As sensitivity approaches 1, the more accurate a test can be. Sensitivity is calculated by the number of true positives, divided by the sum of true positives and false negatives, the higher sensitivity, the more accurate a test.) Such rigor seems to be reasonable given the seriousness of the diagnosis in terms of both long- and short-term complications related to safety and health. It is unclear whether any of the devices meet these criteria and we are unaware of any studies that demonstrate such rigor. The reasons given for such rigor include: 1. To reduce repeat tests, both OCST and in-lab; and 2. To have 2/3 of the population diagnosed accurately. The SCOPER schema (an acronym standing for sleep, cardiovascular, oximetry, position, effort and respiratory measures) was developed as a way to classify OCST devices as the previously accepted categorization is unsuitable. Please refer to that paper for further technical discussion. The VASM prefers not to comment on the full concluding recommendations except to report: 1. the literature is inadequate to recommend a thermal sensing device alone as adequate to diagnose OSAS; 2. a thermal sensing device supplemented by two effort belts (could be piezoelectric belts which may be less expensive and more durable than RIP) are acceptable; 3. Nasal pressure and oximetry with either two piezoelectric or RIP belts (not one piezo) are acceptable; and 4. The authors could not comment on whether both thermal and nasal pressure devices are necessary.¹⁴

V. **Business model considerations**

- Your lab should seek accreditation in OCST testing; see AASM website¹⁵.
- New equipment will be needed.¹⁴
- If you don't have your own equipment and you are having this thrust on you, then outsourcing is an option. Care should be taken in this process. You will be held to standards for the outsourced work. You should have the raw data available and review it. The outsourcing process must be HIPAA-compliant. You should contract with them and bill for the services, and not be in an arrangement where a contracted party submits the bill. Remember that you may also be held accountable for outcomes in future reimbursement. A 24-hour on-call schedule needs to be maintained by the lab, as well as by the company with whom the contract is made. For equipment issues, this is vital for the contracting company to be responsive.¹⁶ Consider restructuring your sleep center. Plan for fewer in-lab studies. Carefully look at the staff you have. Could you withstand a 70% decrease in in-lab studies? Reassign techs to hook-up and monitor OCST patients and to take care of equipment. Consider attrition as a method to reduce staff.
- OCST equipment is subject to greater damage and non-return. Consider a security deposit or insurance.
- AASM will have a cost analysis coming out soon.¹⁷ Be on the lookout for it.

VI. **Critique of OCST**

- All of the studies used to justify OCST have low compliance rates with the greatest majority of patients not meeting Medicare criteria for compliance/adherence. RMH Center for Sleep Medicine in Harrisonburg, VA had 82% compliance on its own DME patients last year. This compliance is likely because that center has more control over the care of patients with its own DME. Will we, as sleep physicians, be held to outcomes over which we have no control, since most do not have their own DMEs?¹⁸ It will prove helpful for sleep centers to start tracking adherence numbers, anticipating that the answer to the question is "yes".
- One reason we anticipate that, with in home CPAP trials the studies may have a high failure rate in execution, might be because instead of multiple trial mask fittings over elapsed time during formal CPAP titration, patients will have trial and error mask use at home without the immediate intervention afforded by a technician to change an unsuccessful mask as in the more formal in-lab setting²³. Mask fitting therefore will be more haphazard with home CPAP raising real concerns about time wasted and numbers of masks used in each individual trial.

- Auto-CPAP works well in some patients, but not in others, with response rates being a problem with different proprietary algorithms, some more successful than others depending on the patient's physiology. Studies showing the drawbacks and benefits of three different proprietary algorithms are cited.^{19,20,21}
- We will lose the ability to detect certain co-occurring sleep disorders.¹³
- A study by Pietzsch, et al, showed that in-lab polysomnography was more cost-effective than OCST based on the Markov model used to predict. Will we even be able to have long-term studies to verify this projection?²² The studies done and reviewed by CMS were **efficacy** studies to base the decision for approval of OCST. Parthasarathy argues that real-time longitudinal clinical studies in the real medical market place, of **effectiveness** need to be done to truly answer the question of whether there is clinical non-inferiority and whether there is clinical superiority of one method over another.²³ Compliance rates should certainly be looked at and would hopefully be better than the studies on which the decision was made to go with OCST was based. These studies^{8,9} showed compliance rates over the monitoring periods of the studies of only 30-50%, generally tending to be lower than the national average.²³ The VASM has to question whether indeed these are acceptable outcomes. The studies showing "non-inferiority" do nothing to address long-term compliance. The VASM would argue that studies should be done demographically, looking at the centers with best practices and whether those best practices can be achieved using OCST with head-to-head trials to in-lab studies, using more representative patients in the real market place. Certainly, we should expect that any such weighty decision based on these studies should take into consideration the low compliance of the subjects who, taken as a whole, in real life clinical situations, as much as half, would not receive approval for coverage for CPAP equipment, ironically using CMSs own standards. The decision was made based on two papers that "demonstrated the mode of testing did not impact the patient's use of CPAP," rather than showing that the OSA population was comparable in both groups, OCST versus in-lab.^{24,25,26}

VII. Conclusion

The VASM, furthermore, has to question the whole concept of non-inferiority when what we should be striving for as clinicians is superior outcomes. Indeed, that is what we are to be held accountable for. We see attempts to bypass well-delineated guidelines spelled out in the evidence-based literature as cited in this paper. The non-inferiority of OCST studies has not been demonstrated in long-term effectiveness studies in the usual patient populations as Parastharathy would argue. We assert that even the studies purported to demonstrate non-inferiority are potentially flawed, that OCST has a high intrinsic failure rate,

depending on how motivated or educated the population is,, that if the OCST arm of those studies excluded those who failed or even worse recycled the failed patients into the in-lab arm, that these patients so selected by test failure may well be a sub-population who, by their absence from the data, increase the adherence values of the OCST arm and potentially decrease the adherence of the in-lab arm. The issue of non-inferiority aside, there are third-party payers who would not even follow standard indications for OCST studies and those for in-lab studies. Will bypassing the standards result in more cost-effective care? The answer is that it depends on who is defining-cost effective. We hold it axiomatic that the best decisions regarding health care are made face-to-face where there is direct accountability and, indeed, there is evidence that such is the case. It is not surprising then that, as the University of Chicago sleep center study showed, as noted in the Pamidi study consultation and guidance by sleep specialists results in greater adherence to therapy. By that definition of cost effective, alignment of the greatest clinical effectiveness with cost-effectiveness would be the result expressed in better outcomes. The latter is true when one considers the plethora of sleep literature dealing with the risk factors of sleep apnea. These risk factors, many of which are well established, include increased accidental death and injury, sudden death, stroke, myocardial infarction, cardiac arrhythmias, cognitive impairment from long term intermittent hypoxia, increased peri-operative risk for morbidity and mortality, and increased cancer risk. It is therefore inarguable that reduction of these risk factors would reduce cost and improve clinical outcomes. We believe that as sleep physicians our value is established in that every day we return patients in the prime of life back to work safer, more cognitively intact, and more productive. That is cost-effective. On the other hand, cost-effective could mean that third parties contract with IDTFs for OCST studies,that they direct setting up patients with CPAP based on outpatient CPAP titrations, and set stringent criteria for adherence. We predict that this practice will not only result in very discouraged and confused patients, but will result in disastrous adherence, already problematic in the studies cited, the University of Chicago study cited above is an exception¹². It is only a short time ago in the 1980's and 90's that attempts at managed care through HMOs and capitation that did not have quality as a core value, resulted in less than stellar outcomes. To paraphrase Santayana, have we truly forgotten the lessons of history which led to the consortium of primary payers known as Leapfrog, who decided that paying for quality outcomes was, in the long run, less costly for them. We believe the proposed and partially implemented practice of going through IDTFs for CPAP studies and treatment will worsen an already fragmented care model. We believe that the sleep physicians should be held accountable for outcomes, but must not be emasculated in the sense that the physician's oversight becomes impossible by this diffusing and a fragmenting of care such that large segments of that care are not under his/her control. The least that should be required is that the available guidelines for high pre-test likelihood for OCST be followed and the exclusions to OCST and therefore in-lab studies be honored. It is, however, one thing to understand the objections to OCST which appear to be formidable and entirely another to have these

objections taken seriously. It ultimately may take tincture of time for these issues to work themselves out and to know whether the effect of such a disruptive technology introduced to the marketplace can be recognized as beneficial or not.

It is not assured that just because something is the best and most cost-effective and clinically effective way to go that the unfolding true patient interests will be honored. Hopefully, all stakeholders will be responsive to the outcomes, whatever they prove to be.

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References

1. Collop NA, Anderson WM, Boehlecke B, Claman D, Goldberg R, Gottlieb DJ, Hudgel D, Sateia M, Schwab R; Portable Monitoring Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med.* 2007 Dec 15;3(7):737-47.
2. Practice parameters for the use of portable recording in the assessment of obstructive sleep apnea. Standards of Practice Committee of the American Sleep Disorders Association. *Sleep.* 1994 Jun;17(4):372-7.
3. NCD: CAG-0093R2; 3/13/2008.
4. Boston Globe, 1/25/2013. White Coat Notes.
5. Network Update, June 11, 2013. Anthem Blue Cross/Blue Shield.
6. Epstein, J. Moving from a diagnostic service to a comprehensive care model. 2013, Winter Course, AASM.
7. IDTF Regulations, 10/1/2007. CMS Website.
8. Kuna ST, et al. Non-inferiority of functional Outcomes in ambulatory management of obstructive sleep apnea. *Am J Resp Crit Care Med.* 2011; 183(9): 1238-44.
9. Rosen CL, et al. A Multi-site randomized trial of portable sleep studies and positive airway pressure autotitration vs. laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: The Home PAP Study. *Sleep* 2012; 35(6): 757-67.
10. Lettieri CF, et al. Does home sleep testing impair continuous positive airway pressure adherence in patients with obstructive sleep apnea? *Chest,* 2011; 139(4): 849-54.

11. Kushida CA, et al. Practice parameters for the indication of polysomnography and related procedures: An update for 2005. *Sleep* 2005.
12. Pamidi S et al. The impact of sleep consultation prior to a diagnostic polysomnogram on continuous positive airway pressure adherence. *Chest*. 2012 Jan;141(1):51-57.
13. Morgenthaler TI, et al. Proactive parameters for the use of autotitrating continuous positive airways pressure levels for titrating and treating adult patients with obstructive sleep apnea syndrome: An update for 2007. *Sleep* 2008; 31(1): 141-7.
14. Collop N et al. Obstructive Sleep Apnea Devices for Out-Of-Center (OOC) Testing: Technology Evaluation. *J Clin Sleep Med*. 7(5); 2011: 531-548.
15. Standards of Accreditation OCST in Adult Patients, AASM, February, 2011.
16. Fleishman, S., email to AASM members, Feb 2013.
17. Noel J, In Press; AASM.
18. Fleishman S, Current negotiations ongoing with OIG and CMS regarding DME set-up in Sleep Centers.
19. C. Massie et al. Comparison between Automatic and Fixed Positive Airway Pressure Therapy in the Home. *Am J Respir Crit Care Med* 2003; 167:20-23.
20. G Nolan et al. Auto-adjusting versus fixed positive pressure therapy in mild to moderate obstructive sleep apnoea. *Sleep* 2007;30(2): 189-194.
21. F Series et al. Reliability of home CPAP titration with different automatic CPAP devices. *Respiratory Research* 2008;9:56.
22. Pietzsch JB, et al. An integrated health-economic analysis of diagnostic and therapeutic strategies in the treatment of moderate to severe sleep apnea. *Sleep* 2011; 34: 695-709.
23. Parthasarathy S, Thoughtful steps informed by more comparative effectiveness research is needed in home testing. *J Clin Sleep Med* 2013; 9(1); 9-12.
20. Simon S and Collop N. Latest advances in sleep medicine. *Chest* 2012; 142(6): 1645-51.
24. Whitelaw WA, et al. Clinical usefulness of home oximetry compared with polysomnography for assessment of sleep apnea. *Am J Resp Crit Care Med* 2005; 171:188-95.
25. Mulgrew AT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: A randomized validation study. *Am Intern Med* 2007; 146: 157-66.
26. Collop, NA. Home Sleep Testing: Appropriate screening is the key. (Editorial) *Sleep* 2012; 35(11):1445-1450.