Changing the Direction of Sleep Medicine: Business can Boom, but it is Not as Usual

Robert Joseph Thomas, M.D., M.M.Sc., F.A.A.S.M.¹; Matt Travis Bianchi, M.D., Ph.D.²

¹*Division of Pulmonary, Critical Care and Sleep Medicine, Beth Israel Deaconess Medical Center, Boston, MA;*

²*Division of Sleep Medicine, Department of Neurology, Massachusetts General Hospital, Boston, MA*

We applaud Quan and Epstein for their candid editorial regarding the abrupt dissolution of the massive Sleep Health Centers (SHC) operation.¹ Indeed a perfect storm combination of factors contributed to the SHC demise. This is a critical time to take stock in what sleep specialists offer, but not lose sight of several key issues surrounding care models specifically for patients with sleep apnea.

First, it is commonly assumed that out-of-center testing is cost-effective simply because it costs less than laboratory polysomnography (PSG) to implement a single night of testing. As pointed out in a recent pro-con debate in this journal,² this arguably myopic cost assumption has been questioned: quantitative cost-benefit analyses show that the out of center model is not clearly more cost-effective,³⁻⁶ and may even be more expensive,⁷ compared with the traditional (inpatient) testing model. This should come as no surprise for several reasons. One is that the testing phase for sleep disordered breathing is only a fraction of the expense related to the chronic management costs. Moreover, as pointed out by the AASM 2007 guidelines,⁸ the modest sensitivity and specificity of home testing devices renders them inappropriate for all but the highest echelon of risk (specifically, 80% pre-test probability of at least moderate OSA). While there is little validated decision support to help providers quantify OSA pre-test probability (it is harder than one would think⁹), the spirit of the recommendation is that one should use out-of-center testing to confirm those with high OSA suspicion and, if negative, follow with gold standard laboratory PSG. The follow-up PSG is sensible from a Bayesian standpoint: negative test results of imperfect tests in the face of high pre-test probability of disease are likely to be falsely negative. On the other end of the spectrum, concerning those with lower OSA suspicion or lower severity, one runs further diagnostic accuracy risks, in particular because home device performance is questionable in the mild range. The reason for interpreting these studies in the context of formal sleep evaluation is to abrogate these risks—but yet we must be mindful that even a sleep specialist evaluation has only modest sensitivity and specificity for predicting OSA.⁹

Second, the clinical trials cited as supporting home diagnosis and home auto-titrations, while important steps in a comprehensive evidence-based approach to largely undiagnosed OSA, should not be assumed to generalize. As with any study, the methodological details must be scrutinized in order to gauge external validity. For example, a recent randomized trial of specialist versus generalist diagnosis and management of OSA concluded that generalist approach is non-inferior.¹⁰ Deconstructing the details is enlightening, as the generalist group had intensive in-service training for MDs and for nurses, which is certainly not the standard in common practice. Second, the primary endpoint was a decrease in Epworth Sleepiness Scale, not clinically tangible outcomes. Although compliance rates were similar, the study was not powered to detect differences in any of the secondary measures. Given that the analysis was non-inferiority, non-powered secondary metrics are all but ensured to be non-inferior, the lowest statistical standard in the comparative trial world. In addition, nearly three times as many patients dropped out of the study in the generalist arm. Despite these non-trivial caveats, this study joins a growing list of comparative trials increasingly cited as proof that specialty testing, or even specialty care, is not essential.

Third, patients and providers alike must understand the nature of insurance regulations, including instances in which insurance decisions differ from published guidelines. This is particularly important as most patients referred for PSG come from non-specialist providers, who may not have the resources or experience to determine whether their patient is appropriate for out-of-center testing, not to mention whether they can decipher and navigate the prior authorization process itself. It is clear that the insurer's criteria, often outsourced to an independent company to coordinate prior authorizations, are not following the AASM guidelines. Can we expect primary care physicians to be familiar with the nuances of insurance guidelines and patient's clinical presentations and thus shoulder the burden of prior authorizations that may involve a dispute with the insurer's criteria?

Push back from insurers with newly minted guidelines and pathways have been predictable. While home sleep testing has been traditionally researched/evaluated in those with moderate to high clinical probability of sleep apnea without medical comorbidities, and typically obese males, in Massachusetts, insurers use a far higher threshold to allow an initial laboratory assessment (e.g., Class III or IV congestive heart failure, COPD requiring oxygen, stroke, and dementia). Prior authorization requires an Epworth Sleepiness Score, despite numerous manuscripts documenting its weak association with OSA severity, including our recent machine learning and information theory approaches that failed to elucidate a predictive relationship with OSA.¹¹ There is often a default reliance on auto-CPAP and auto-bilevel devices. Prior authorization peer-to-peer discussions can readily degenerate into arguments—ultimately, appropriate therapy is simply delayed in many instances. These “peers” may or may not be sleep medicine trained physicians. It is not far-fetched to envision that empiric home trials of adaptive ventilation may soon be insisted on as initial approaches for central/complex apnea, or that volume target ventilators be “tried” for hypoventilation syndromes.

While compliance requirements may at face value seem reasonable for uncomplicated sleep apnea, the fixation on the first 90 days and “4 hours 70% of the time in any 28-day period” seems out of touch with the biological reality of challenging life-long sleep-breathing therapeutic requirements of say, respiratory failure, neuromuscular disorders, obesity hypoventilation, chronic obstructive lung disease, complex sleep apnea, or congestive heart failure. It is disheartening to see paper after paper published in leading journals use this “4 hours 70% of the time” compliance mark as some sort of holy medical grail—just one more instance in sleep medicine when a criterion that is a threshold for insurance payment becomes a scientific standard. Even for the uncomplicated patient, the insurance minimum compliance consists of only 35% of the total sleep time for the person averaging 8 hours of sleep. There is no change in requirement be it a healthy 25-year-old with mild sleep apnea or a 60-year-old with congestive heart failure and severe periodic breathing—how can this make clinical or biological sense? We are genuinely concerned that the push to control cost will adversely impact the optimal management, especially of “sick sleep in sick patients,” if we continue to head toward a drive-through style of sleep medicine. We need to resist this downgrade of expectations.

What should be our identity? Sleep center and laboratory services could do with a more aggressive disease and patient centric model. An increased proportion of patients evaluated and managed by sleep medicine trained physicians are desirable versus providing merely a testing service. Phenotyping of sleep (fragmentation propensity, sleep homeostatic/slow oscillation kinetics), sleep disordered breathing (obstruction, chemoreflex, and hypoventilation),¹² sleep hemodynamics (blood pressure profiles, vascular reactivity), and sleep metabolism (glucose handling, neurohumoral activation) with provision of phenotype-based therapy should be a major goal. As noted recently in this journal, the apnea-hypopnea index as a primary end point for sleep medicine is highly undesirable.¹³ The attainment of these goals will require substantial investment in equipment (end-tidal and transcutaneous CO₂ monitoring), physician

time in technician training, and improved scoring precision. Programs for chemoreflex-driven/complex apnea, congestive heart failure, and hypoventilation syndromes should be developed. While the typical sleep service is “flat”—the next open bed for the next patient run by the next available technician—this new style of service could be “pyramidal,” in that the needs of the patients are matched to the skills of the technician and the requirement of medical oversight is appropriately triaged. At the peak of the pyramid could be physician-guided sleep laboratory nights with the physician on site assisting in the management of the most complicated patients, which also serves the purpose of training technicians in the increasing medical challenges in the sleep laboratory. The referral source of such a service could be enriched for complexity by robust outreach to and use by specialists including those in neurological specialties, cardiac electrophysiology, congestive heart failure, respiratory failure and chronic lung disease, and rheumatology.

A home testing service should cater to the relatively uncomplicated obstructive sleep apnea patients according to AASM guidelines, while the laboratory should focus on an increasingly complex and medically ill population. All patients, including those who have a home sleep study, should be tracked for high residual machine-detected apnea-hypopnea index and machine wave form analysis as felt clinically necessary, besides compliance and clinical improvements. Such analytics will increase detection of persistent central/complex apnea or patients doing poorly, including incorporation of the recently proposed effective AHI for those “compliant” individuals using PAP less than 100% of their habitual sleep time.¹⁴ This results in a triage to sleep laboratory testing and greater direct physician engagement. Such an approach is defensible in this day and age—it is fair to patients, physicians, and insurance companies—that those who are failing a less expensive approach are offered testing to troubleshoot and improve therapeutic outcomes, yet the less complicated are not pushed to the in-laboratory assessments. While it is not being proposed that there is one solution to a complicated challenge, the viability of the sleep field is going to be based on the provision of expert management of patients with complex sleep disorders or sleep apnea in medically complicated patients, not straightforward obstructive sleep apnea.

Technology and homecare respiratory support has advanced to the point that if the primary care physician (PCP) is willing to deal with the irritations of obtaining prior authorizations for home sleep testing and then that of tracking compliance, a sleep center is not required for uncomplicated sleep apnea (the bread and butter of most sleep services today). This is no different than the PCP taking care of, for example, uncomplicated patients with bronchial asthma and gastroesophageal reflux. However, there should be a minimum training/competence bar for the PCP that will need collaboration with sleep medicine specialists to set up the appropriate care modules and clinical pathways.

Sleep medicine fellowship training should also reflect this new world of sleep medicine. For example, Fellows should spend substantial time in the sleep laboratory with challenging patients learning the usefulness and limitations of technology—time perhaps better spent than the ACGME mandated scoring of 25 sleep studies. Training should also include learning a host of

ambulatory approaches and the basics of mathematical theory in relation to appropriate test utilization, namely Bayesian inference.¹⁵ A critical part of the new reality will be transferring care of uncomplicated sleep apnea away from the sleep center to primary care providers and patient-centered homes, empowering the latter entities with understanding of the relevant technology. Reaching out to medical subspecialties will skew the proportion of patients we see and manage in sleep clinics to those who really need our expertise.

The old model makes us look unsophisticated. A new model of sleep medicine will require a substantial improvement in the skills of the average sleep technician and perhaps physician to learn the appropriate use of new technology and approaches to management of central and complex apnea and hypoventilation syndromes—including adaptive ventilation, volume assured ventilation, and CO₂ manipulation. Provent, Winx Oral Pressure Therapy, and hypoglossal nerve stimulation expand our therapeutic armamentarium beyond positive pressure, oral appliances, and surgery. Technologies that can monitor sleep and treatment effectiveness at home include both FDA approved (e.g., M1) and consumer devices, which complement the increasing sophistication of tracking capabilities for PAP delivery devices such as waveform analysis. Circadian assessment and tracking with activity monitors and salivary or urinary melatonin assessments are readily possible but rarely done in the clinic due to non-coverage by insurance. Ankle actigraphy for periodic limb movements faces the same challenge. These should be considered exciting times for the field—the science and technology are advancing rapidly and it is only appropriate that old models will be under stress and those who adapt to the new reality will not only survive but thrive. There is simply too much and we believe unjustified doom-and-gloom around the disruptive effects of home sleep testing, which is easy to blame for all of our ailments.

CITATION

Thomas RJ; Bianchi MT. Changing the direction of sleep medicine: business can boom, but it is not as usual. *J Clin Sleep Med* 2013;9(9):977-979.

REFERENCES

1. Quan SF, Epstein LJ. A warning shot across the bow: the changing face of sleep medicine. *J Clin Sleep Med* 2013;9:301-2.
2. Parthasarathy S. CON: thoughtful steps informed by more comparative effectiveness research is needed in home testing. *J Clin Sleep Med* 2013;9:9-12.

3. Chervin RD, Murman DL, Malow BA, Totten V. Cost-utility of three approaches to the diagnosis of sleep apnea: polysomnography, home testing, and empirical therapy. *Ann Intern Med* 1999;130:496-505.
4. Deutsch PA, Simmons MS, Wallace JM. Cost-effectiveness of split-night polysomnography and home studies in the evaluation of obstructive sleep apnea syndrome. *J Clin Sleep Med* 2006;2:145-53.
5. Benca RM, Peterson MJ. Insomnia and depression. *Sleep Med* 2008;9(Suppl 1):S3-9.
6. Pietzsch JB, Garner A, Cipriano LE, Linehan JH. An integrated health-economic analysis of diagnostic and therapeutic strategies in the treatment of moderate-to-severe obstructive sleep apnea. *Sleep* 2011;34:695-709.
7. Reuven H, Schweitzer E, Tarasiuk A. A cost-effectiveness analysis of alternative at-home or in-laboratory technologies for the diagnosis of obstructive sleep apnea syndrome. *Med Decis Making* 2001;21:451-8.
8. Collop NA, Anderson WM, Boehlecke B, et al. 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;3:737-47.
9. Skomro RP, Kryger MH. Clinical presentations of obstructive sleep apnea syndrome. *Prog Cardiovasc Dis* 1999;41:331-40.
10. Chai-Coetzer CL, Antic NA, Rowland LS, et al. Primary care vs specialist sleep center management of obstructive sleep apnea and daytime sleepiness and quality of life: a randomized trial. *J Am Med Assoc* 2013;309:997-1004.
11. Eiseman NA, Westover MB, Mietus JE, Thomas RJ, Bianchi MT. Classification algorithms for predicting sleepiness and sleep apnea severity. *J Sleep Res* 2012;21:101-12.
12. Eckert DJ, White DP, Jordan AS, Malhotra A, Wellman A. Defining phenotypic causes of obstructive sleep apnea: identification of novel therapeutic targets. *Am J Respir Crit Care Med* 2013 May 30 [Epub ahead of print].
13. Edwards BA, Wellman A, Owens RL. PSGs: more than just the AHI. *J Clin Sleep Med* 2013;9:527-8.
14. Boyd SB, Walters AS. Effectiveness of treatment apnea-hypopnea index: a mathematical estimate of the true apnea-hypopnea index in the home setting. *J Oral Maxillofac Surg* 2013;71:351-7.
15. Bianchi MT. Screening for obstructive sleep apnea: Bayes weighs in. *The Open Sleep Journal* 2009;2:56-9.

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication June, 2013

Accepted for publication June, 2013

Address correspondence to: Robert Joseph Thomas, M.D., M.M.Sc., KB 023, Pulmonary Office, Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215; Tel: (617) 667-5864; Fax: (617) 667-4849; E-mail: rthomas1@bidmc.harvard.edu

DISCLOSURE STATEMENT

Dr. Thomas is a co-inventor and patent holder for an ECG-based technique for sleep and sleep apnea phenotyping, and patent holder for a method to use CO₂ to treat central and complex sleep apnea. Dr. Bianchi is co-inventor on a pending patent for a home sleep-monitoring device.