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Sleep Medicine: The Shot Heard Around the World

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Background

EDITORIAL

There has recently been concern about the future of sleep medicine in response to the "disruptive technology" of home sleep testing (HST) and its embrace by the medical insurance industry in the USA.^{1,2} A reader might surmise that the first contract by an insurance carrier in Massachusetts to mandate HST as a first step in apnea diagnosis was the shot heard around the world that would change sleep medicine forever. The original shot heard around the world referred to the first skirmish of the American Revolution (incidentally only about 30 miles from the headquarters of the insurance carrier in Massachusetts) was simply a step in a process that had its genesis long before. Similarly, the genesis of this shot affecting sleep medicine was long ago, and the reader must recognize that this is a shot heard around America, not the around the World.

There have been many "disruptive" technologies and treatments in medicine, and in general they have improved patient outcomes. We can now prevent poliomyelitis and many childhood viral diseases; we can cure most bacterial, mycobacterial, and fungal infections; we seldom require surgery to treat diseases caused by gastric acid hypersecretion; we use "noninvasive" surgery using laparoscopic and thoracoscopic techniques to treat many patients who a generation ago would have required large incisions, dissections and excisions, and prolonged hospital admissions. We can now determine the presence of cancer in many cases using PET/MRI imaging.

Disruptions in Sleep Medicine

Sleep medicine is a young field, and there have already been several disruptions. In the field of sleep apnea some of the disruptions have been technical, while others were based on new knowledge. There have already been several shots heard around the world of sleep. Some of the shots have been quiet, while some have very loud. Such shots might include the following: the description of CPAP³; the first description of data acquisition for respiratory variables during sleep by a microcomputer⁴; the notion that respiratory sleep data can be obtained outside the laboratory⁵; the publication of data suggesting that apnea patients have more automobile accidents⁶ and increased mortality⁷; the implementation of an integrated home sleep testing system⁸; the monitoring of CPAP compliance⁹; and the realization that sleep apnea is a very common problem.¹⁰

Based on the latter, there was an explosion worldwide in the following decade in the capacity to diagnose sleep apnea. The ability and capacity to diagnose apnea clinically was related to local medical practice, funding, and available technology. Home sleep testing has been integrated as an important diagnostic option in the Veteran Administration Healthcare System.¹¹ In some countries comprehensive polysomnography was used; in others the testing evolved to include (sometimes exclusively) limited-channel monitoring, and resources were directed towards treatment.¹²⁻¹⁴ In the United States (a notable exception being the Veterans Administration System), there was an entirely different path directed by two entities: the American Academy of Sleep Medicine that set the clinical benchmarks, and Centers for Medicare Services (CMS) which set the reimbursement benchmarks. At the end of the day, the decisions by CMS trumped the standards of the AASM.

There were several important milestones related to the definition of apnea and when CMS would pay for treatment that lead to the current situation:

- 1986—CMS defined sleep apnea as "at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of sleep" using "facility-based, attended polysomnogram."
- 2001—CMS defined sleep apnea as "AHI > 15, or AHI between 5 and 15 with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke."
- 2008—CMS for the first time defined apnea without requiring an in-lab PSG as "The AHI and/or RDI may be measured by polysomnography (PSG) in a facilitybased sleep study laboratory, or by a Type II home sleep test (HST) monitor, a Type III HST monitor, or a Type IV HST monitor measuring at least 3 channels." Initially there was no fee code for HST. Initial coverage for CPAP reimbursement was 12 weeks and the patient had to show compliance for CMS to pay for CPAP.
- 2009—Home sleep testing fees approved.

In these milestones and other decisions during the years, CMS actually ventured into the medical realm and *de facto* defined the disease (at least for the USA) and how it should be diagnosed and treated. The *Medicare hypopnea* has even found its way into the scoring manual published by the American Academy of Sleep Medicine as Hypopnea Rule A.¹⁵

Chaos

Once home sleep testing fees were approved by CMS, entities not previously involved in sleep (doctors, clinics, companies marketing HST equipment and services) all of a sudden expressed tremendous interest in the field of sleep medicine (more

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precisely sleep apnea), and rapid transitions and sometimes chaos ensued. There was marketing of types II, III, and IV HST monitoring units and services to medical practitioners who often had no training in sleep and whose medical practice often did not involve patients who would benefit from such services. Since many of these new purveyors of sleep medicine services had little or no training in sleep, the interpretations of the studies were done by "board-certified sleep specialists" whose name, location, and state of medical licensure were often unclear or undecipherable on their reports. Doctors with almost no knowledge of sleep medicine were now ordering positive airway pressure (PAP) equipment from DMEs based on recommendations indicated on the HST study interpretations by doctors who actually never saw the patient and relied on questionnaires. Thus, the situation is such that some patients with a lifelong condition are currently being managed by clinicians out of their depth, and the patients are never actually seen by a practitioner with expertise in sleep.

Where Are We Now and What Does the Future Hold?

Out of chaos often comes order, and some patterns seem to be emerging. Home sleep testing is here to stay, because it does offer an excellent diagnostic option for many patients and health care systems. Does that mean that sleep labs are obsolete? Not at all. There are too many patients with sleep disorders who have problems that require in-lab evaluations including children, patients with complex comorbidities, patients requiring complex PAP titrations, and patients with a variety of diseases that cannot be properly evaluated with HST technology that is designed only to document apnea. In the author's experience about 20 % of HSTs are non-diagnostic and require additional, usually in-lab evaluation. However programs that offer only inlab sleep testing may see their days numbered.

There will be new practitioners entering the sleep field from a variety of specialties. Some have taken the ABMS sleep certification exam. Indeed there was a large bulge in taking the exam whose results were available in early 2012. Most of the test takers were able to take the exam via the practice waiver, without having taken sleep medicine training. Thus, many will be in the field not ever having any comprehensive sleep training. There will be specific educational challenges so that these practitioners obtain the knowledge to evaluate and manage long-term sleep disorder patients.

It is likely that the trend of insurance carriers mandating screening or initial diagnosis of OSA by HST and covering testing only when done by their preferred provider will continue and expand. I believe that this is potentially harmful to patients because it takes sleep doctors out of an important loop in managing patients. The question remains whether insurance carriers have the expertise and know-how to evaluate whether their preferred HST provider has the proper equipment, staffing, and experienced interpreting physicians to offer patients what they deserve and expect. One challenge in the management of patients is not the diagnosis, but long-term adherence to treatment. With society's focus on prevention, will insurance carriers fund true screening for apnea which in many cases is already a burden a decade before patients are formally assessed for the first time?¹⁶

Although on the surface, home sleep testing seems to be the most cost-effective approach to managing patients with sleep apnea without other comorbidities that may confound diagnosis, there is still debate about whether this approach is actually the most cost-effective.¹⁷ In addition to be able to rapidly respond to inevitable reimbursement shifts, it is likely that sleep medicine programs that are flexible in adopting new technologies (diagnostic and therapeutic) and that also maintain some in-lab capability and have long-term management programs will be the most successful. What is important that the target is understood: long-term patient outcomes. There will be innovations to come; we must evaluate them and, if effective, embrace them.

CITATION

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DISCLOSURE STATEMENT

Dr. Kryger has indicated no financial conflicts of interest.