



Waking Up to the Risks of Online Direct-to-Consumer Advertising of Sleep Apnea Screening Tests

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EDITORIAL

Sleep apnea now impacts millions of patients around the world, and though still largely underdiagnosed, is now prevalent in developed and resource-poor settings.¹ While the connection between sleep apnea and comorbidities such as hypertension, cardiovascular disease, diabetes, stroke, and occupational health and safety have gained greater attention, widespread screening and detection for sleep apnea itself remains a challenge.¹

Emerging technologies, such as portable screening devices and home sleep testing (HST) options, which provide patients with greater comfort and convenience in diagnosing sleep apnea, may represent watershed events in the global crusade to raise awareness and provide needed therapy for sleep apnea. These new diagnostic tools can provide patients with more cost-effective and accessible screening, compared to traditional polysomnograms requiring an overnight sleep study, and have recently had their U.S. Medicare coverage approved.²

Yet with growing awareness of associated risk factors and increasing consumer attention to sleep apnea, other unproven and scientifically unsupported HSTs have begun to emerge on the Internet via direct-to-consumer advertising (DTC). With patients increasingly turning to the Internet for health information,³ questionable HSTs that are available without a prescription and purport to be both “accurate” and “advanced,” may be endangering public health and patient safety by bypassing the important role of health professionals in disease screening. This phenomenon is not unique to sleep, as other studies have previously shown questionable screening tests and even illicit online pharmacies using DTC to sell health care products directly to unsuspecting patients, often using false advertising.^{4,5}

As an example, Nasivent’s “Sleep Apnea Home-Test” is actively marketed online and even made available on the global marketplace amazon.com (available at: http://www.amazon.com/gp/product/B003QNG52U/ref=s9_simh_gw_p121_d0_g121_i2?pf_rd_m=ATVPDKIKX0DER&pf_rd_s=center-2&pf_rd_r=1AE09XFSBGNF90E3BWCY&pf_rd_t=101&pf_rd_p=470938631&pf_rd_i=507846). It is advertised as the “most advanced and cost-effective method for accurate screening of Sleep Apnea Syndrome (SAS)” and is purported to have been validated by “international sleep experts.” The product website even misquotes the American Medical Association and describes preventing sleep apnea as

the equivalent of preventing Alzheimer disease, a potential off-label and false advertisement of the benefits of the product. In addition, the vendor of the product utilizes DTC social media by providing potential customers a tutorial via a YouTube video to advertise its benefits and provide instructions on use (available at: <http://youtu.be/u-ikLvzkg5g>).

However, upon further inspection, the product is a single channel-only device, and the few scientific articles discussing its efficacy show mixed results, with some partial clinical support, but more importantly, recommendations against the use of the device as an HST.⁶⁻⁷ Indeed, both the American Academy of Sleep Medicine (AASM) and Medicare coverage requirements specify that more than one channel is necessary to appropriately screen for sleep apnea.^{8,9}

The risks to patients who are lured into purchasing these questionable products over the Internet are clear. Lack of sufficient evidence for use and the potential risk of misapplied self-administration, misinterpretation of results, lack of health professional involvement/counseling, and possible misdiagnosis could result in patients foregoing necessary treatment for a disease that is already severely underdiagnosed. Consumers also incur financial injury purchasing health care products that may not provide accurate results, especially given that these products are generally non-reimbursable.

Yet, even with these risks, DTC of sleep apnea HSTs is poised to continue to expand in an unregulated and still untapped eHealth environment. With spending on DTC rapidly increasing and the U.S. Food and Drug Administration still years away from adequately regulating online and social media forms of DTC, it is likely that these questionable HSTs will continue to proliferate.¹⁰ This places progress towards effective and clinically based screening, detection, and treatment of sleep apnea at risk. Health care professionals and policy makers need to be alert and address the inherent dangers of online DTC of HSTs and work to promote patient use of evidence-based screening tools in consultation with sleep health care professionals.

CITATION

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