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SPECIAL ARTICLES

Consumer Sleep Technology: An American Academy of Sleep Medicine Position Statement

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Consumer sleep technologies (CSTs) are widespread applications and devices that purport to measure and even improve sleep. Sleep clinicians may frequently encounter CST in practice and, despite lack of validation against gold standard polysomnography, familiarity with these devices has become a patient expectation. This American Academy of Sleep Medicine position statement details the disadvantages and potential benefits of CSTs and provides guidance when approaching patient-generated health data from CSTs in a clinical setting. Given the lack of validation and United States Food and Drug Administration (FDA) clearance, CSTs cannot be utilized for the diagnosis and/or treatment of sleep disorders at this time. However, CSTs may be utilized to enhance the patient-clinician interaction when presented in the context of an appropriate clinical evaluation. The ubiquitous nature of CSTs may further sleep research and practice. However, future validation, access to raw data and algorithms, and FDA oversight are needed.

Keywords: consumer sleep technology, polysomnography, patient-generated health data (PGHD)

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INTRODUCTION

The American Academy of Sleep Medicine (AASM) is the leading clinical professional society dedicated to promotion of sleep health. The AASM improves sleep health and fosters high-quality, patient-centered care through advocacy, education, strategic research, and practice standards. The AASM endeavors to advance sleep health policy that improves the health and well-being of the public.

The number of connected devices surpassed the number of people in the United States in 2011.[1] Consumer sleep technology (CST) utilization continues to increase, and sleep apps remain among the most popular apps downloaded for Apple and Android devices.[2] See definitions in **Table 1**.

As CST use increases, the sleep clinician encounters these products with increasing frequency in a typical sleep clinic visit. Patients are eager to share patient-generated health data (PGHD) with their sleep clinician to gain a deeper understanding of their sleep. There is an implicit expectation that the sleep clinician will be able to provide guidance to the patient regarding the utility and accuracy of sleep apps and gadgets, including wearables. As CST matures, sleep clinicians need to understand the wide range of CST-generated data and have a plan for how to utilize these data in the context of a clinical visit.

BACKGROUND

The number of available CSTs is continually growing, and a multitude of them claim to track and define sleep-related metrics, improve sleep quality, and even screen for sleep disorders. Unfortunately, minimal validation data exist regarding the ability of CSTs to accurately perform these functions. Sleep apps infrequently utilize empirical evidence or national guidelines to support their purported function or the information they disseminate.[6] Rather than being sold as medical devices or apps, most CSTs are self-described "lifestyle/entertainment" devices that are not subject to United States Food and Drug

Table 1—Definitions.

Consumer sleep technology (CST): Non-prescription devices directly marketed to consumers that may make an assertion to perform sleep monitoring, tracking, or sleep-related interventions.

App: An application, typically a small, specialized program downloaded onto mobile devices.[3] This may support a wearable or other assessment instrument, or be an independent application.

Wearable: Technology devices that can be worn by a consumer for entertainment and communication that, at minimum, may track health and fitness information.[4]

Patient-generated health data (PGHD): PGHD are paper or electronic health-related data that are generated directly by patients, not health care practitioners, during or between clinical visits. Examples include health or treatment history, biometric data, self-reported observational data or symptoms, and lifestyle monitoring.[5]

Table 2—General principles of CST engagement.

- Clinicians should have a general awareness of CST and a readiness to discuss CST with patients.
- Clinicians should understand the general framework of devices and apps available and have a basic knowledge of available evidence or lack thereof.
- Most CSTs are not FDA cleared or validated clinical devices/applications, but widespread accessibility and use by patients (and potential patients) may augment patient engagement.
- Data can be utilized as a tool for opening discussions with patients.
- Clinicians should recognize the patient's use of CST as a commitment to focus on sleep wellness.

CST = consumer sleep technology, FDA = United States Food and Drug Administration.

Administration (FDA) oversight. The FDA has published a position statement with accompanying documents explaining how (and when) they will regulate mobile applications,[7] and to date almost no mobile sleep apps have undergone such review. The lack of validation data and absence of FDA clearance raises concerns about the accuracy of CST data. The CST-generated data is not standardized, and raw data and proprietary algorithms are typically unavailable to clinicians. Despite the lack of validation and evidence-based guidelines, the clinician may be asked to review and render an opinion on these CST-generated data.

POSITION

It is the position of the AASM that CST must be FDA cleared and rigorously tested against current gold standards if it is intended to render a diagnosis and/or treatment. Given the unknown potential of CST to measure sleep or assess for sleep disorders, these tools are not substitutes for medical evaluation. However, CSTs may be utilized to enhance the patient-clinician interaction when presented in the context of an appropriate clinical evaluation.

DISCUSSION

Sleep professionals must acknowledge CSTs as patients are gathering information at home with the aid of these devices, and then seeking the opinion of the sleep professional. In today's reality of ever-changing technology, sleep practitioners should have a working knowledge of epistemology and methodology of these technologies, even if they are unfamiliar with the specific devices. See **Table 2** for guiding principles for these encounters. An initial schema for categorization of CSTs has been suggested by Watson and colleagues.[8] Many CSTs share common traits and may utilize similar technology and reflect similar data. In addition, sleep clinicians should have an approach to the patient that recognizes the limitations of CSTs, yet capitalizes on their popularity and public interest in them. **Table 3** highlights possible advantages and disadvantages of CSTs in the clinical care setting. In addition, it is quite likely as these devices become increasingly sophisticated that some may undergo validation to have a role in clinical care and scientific inquiries. The uses could range from individual patient management to "big data" collection through bioinformatics tools.

Patients' engagement with CST allows sleep professionals to have a dialogue with them about their expectations of the CST as well as their underlying sleep concerns. For example, a patient utilizing a sleep time tracking CST may have insomnia concerns and may be an ideal candidate for cognitive behavioral therapy for insomnia. A patient tracking their snoring may be at risk for obstructive sleep apnea and may require validated testing.

The "internet of things" is ubiquitous. The challenge is to provide a succinct yet flexible clinical guide for sleep professionals who are presented with CST data by a patient during a visit. Clinicians require a practical approach to discuss CST data and related sleep concerns with patients. A suggested approach is outlined in **Table 4**.

How should sleep professionals navigate this ever-changing technology? The initial framework for categorization that has been suggested by Watson will certainly evolve as technologies continue to progress. Why should sleep professionals familiarize themselves with technology without validation data? Watson points out that patients may not be as concerned about this lack of validation. Furthermore, as consumers gain experience with wearables, limitations in the attainment of valid and actionable information may result in a more pragmatic assessment of their utility. While wearable technology has become well entrenched, there has been some transition in the market from the more fixed fitness and health-related single use gadgets to smartwatches and other multifunctional platforms, focused on entertainment and connectivity. Recognizing some of the limitations of wearables, "equity funding plummeted to around $300 million last year [2016] from the more than $1.3 billion the industry raised in 2014, according to the Sports Innovation Lab."[9] Consumers seem to recognize some shortcomings of consumer health-related technology.

Table 3—Advantages and disadvantages of consumer technologies.

Advantages	Disadvantages
Tool to engage patient awareness and patient-provider interaction	Largely unproven clinical tool: • Inability for providers to analyze overwhelming amounts of unvalidated PGHD • CST may have uncertain clinical validation: Raw data collection and algorithms are not standardized, disclosed, or validated for stated purposes[11,*] • Resource utilization required to analyze and document PGHD may outweigh value added to clinical discussions • Largely unproven to accurately measure sleep[12]; possible data misrepresentation or improper use of data
Popular, inexpensive, readily accessible for consumers	CST are generally advertised as "entertainment" • May not be FDA cleared or validated for clinical use • CST technology advances more rapidly than can be studied systematically
Real time and visual data feedback for consumers • May increase sleep awareness and patient engagement • May encourage patients to seek formal sleep evaluation	May have unintended clinical consequences: • Negative impact on sleep hygiene (screen time/light) • Overestimation of the presence of a sleep problem may cause unnecessary anxiety • Underestimation of a sleep problem may cause delayed evaluation and treatment
Potential to become more meaningful with CST validation and ongoing technology advances • For EHR integration and telemedicine use • For remote consumer generated data between visits • Long-term data collection	Potential problems with clinical use of technology and remote PGHD: • PGHD may not adhere to HIPAA security standards[13] • Unvalidated data may be documented in patient charts without provider review • Increased CST training, personnel, and IT cost burden for clinical, EHR integration, and telemedicine use • Reimbursement may be less than care delivery costs

* = this is unlike clinical diagnostic instruments; for example, clinical guidelines for the use of portable monitoring recommend that devices must allow for display of raw data and manual editing or override of automated scoring. CST = consumer sleep technology, EHR = electronic health record, FDA = United States Food and Drug Administration, HIPAA = Health Insurance Portability and Accountability Act, IT = information technology, PGHD = patient-generated health data.

FUTURE DIRECTIONS

Further CST data validation regarding device accuracy and application within clinical practice is necessary if these devices are to be considered part of medical evaluation and treatment. There is an evolving trend that blurs the lines between CSTs that are utilized for entertainment and those that are intended to render a diagnosis or treatment. How this new technology will affect the important outcomes of patient health, health care delivery and health care costs has yet to be determined. CSTs that intend to be diagnostic devices must fall under FDA regulations and must be rigorously tested against the current gold standards, while also understanding the availability and the limitations of current gold standards. The overwhelming amount of CST-derived PGHD available to clinicians and researchers has vast implications. In the clinical setting, mechanisms may be required for electronic health record integration, billing, and quality measurement. PGHD may transcend the one-on-one clinic visit and inform occupational health and safety programs as well as public policy. From a research standpoint, CST can generate exponentially larger data sets than traditional protocols, which may further the understanding of the role of sleep in health and disease. Due to CST popularity, future CSTs that are evidence based have wide-reaching potential to positively impact sleep.[6] Recent Fitbit data exemplifies

Table 4—Guidance for clinicians encountering data in a clinical setting.

- If/when data are presented by patients, it should be considered in the context of a comprehensive sleep evaluation and should not replace validated diagnostic instruments or treatments that have undergone rigorous scientific investigation.
- Discuss with the patient which biometric the CST is measuring (if known) and how this differs from gold-standard sleep measurement.
- Encourage the patient to evaluate their sleep based on subjective symptoms, clinical context, and validated diagnostic testing rather than CST data of unclear significance.
- Reconcile the patient's symptoms with the data presented by the CST, emphasizing that CST-derived information must be interpreted carefully in the context of clinical signs and symptoms.
- Present options for ongoing use of the CST (eg, to set personal goals, assess change over time).
- Patients utilizing CST may favor engaging with validated online therapies such as CBT-I
- If the patient has developed anxiety, unreasonable expectations, or inadequate sleep hygiene related to the use of the CST, consider encouraging the patient to discontinue use of the device either temporarily or permanently.

CBT-I = cognitive behavioral therapy for insomnia, CST = consumer sleep technology.

a potentially powerful CST to generate significantly larger scope of sleep data that would not otherwise be obtainable using conventional methods.[10]

With rapid advances in technology, medical professionals should have more open-mindedness and preparedness as we anticipate forthcoming changes in how we manage sleep disorders. Best practice would maintain an evidence-based, patient-centric approach while being receptive to changes brought by advances in technology.

CONCLUSIONS

CST is widespread and may improve patient engagement.[14] Benefits of CST include increased awareness of the importance of sleep and the need for evaluation and treatment of sleep disorders. CSTs may enhance the patient-provider interaction and as such, are adjuncts to clinical practice. Therefore, an understanding of the capabilities and limitations of CST is crucial. Analysis of CST data requires consideration of manufacturer claims in the context of the biometrics assessed and thoughtful interpretation of the output. PGHD derived from CST should be considered in the context of a comprehensive sleep evaluation and should not replace validated diagnostic instruments. CST delivered interventions are not substitutes for treatments that have undergone rigorous scientific investigation. Despite their limitations, CSTs may allow for meaningful conversations with patients and increase active participation in their health care.

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DISCLOSURE STATEMENT

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