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LETTERS TO THE EDITOR

Consumer Sleep Technologies: How to Balance the Promises of New Technology with Evidence-Based Medicine and Clinical Guidelines

Response to Watson et al. Will consumer sleep technologies change the way we practice sleep medicine? *J Clin Sleep Med.* 2019;15(1):159–161.

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Watson and colleagues raise some intriguing issues in their letter to the editor.[1] We agree that consumer sleep technology (CST) has become a permanent part of the current and future medical landscape, and that the American Academy of Sleep Medicine (AASM) is proactive in helping our members understand and integrate these products into practice and research. We further agree that many of these devices, even when they cannot be strictly considered medical devices, serve as an important entrée with patients and the public regarding their sleep concerns.

The AASM Technology Presidential Committee supports increased public awareness of sleep disorders. Without compromising this mission, we also have a responsibility to our patients and general membership to frame both the benefits and limitations of current CST advancements.

At present, there is inconsistent transparency regarding the algorithms, sensors, and data that drive many of these products. Although there are exceptions, the majority have not been validated.[2] Some developers will not seek US Food and Drug Administration (FDA) clearance, although there is an *implication* that these are medical devices. As clinicians and researchers, we recognize the potential consequences of false negative and false positive testing results for our patients. By challenging our colleagues in industry to provide robust data and produce reliable technology, we hope to expand the tools of sleep medicine in a responsible manner.

We agree with the authors that the lack of longitudinal, objective sleep recording in the home environment deprives clinicians of relevant information for the diagnosis and treatment of sleep disorders. CSTs are a reasonable proposed solution to this need; however, the letter to the editor is predicated on the uncertain assumption that many of the unvalidated devices accurately measure sleep including its stages. Further, clinicians may be overwhelmed with interpreting a variety of CST data during busy patient visits, as illustrated in **Figure 1**. A committee member simultaneously utilized six devices, assembled the data (**Figure 1**), and noted that all appeared limited in identifying a 3-hour wakeful episode. An enthusiastic CST supporter, this member commented that data trending could be helpful and that interpretation could be enhanced with added validation in patients with sleep disorders. While this example is revealing, patients are vulnerable to more serious ramifications of inaccurate data. A primary and practical committee goal remains to prepare clinicians for current and future CST data interpretations in the context of patient symptoms and visits.

In order to be utilized in clinical practice, validation, standardized data measures, and practice guidelines are needed for clinicians. Due to the rapid evolution of CST types, the committee hopes to communicate CST-related concerns (**Table 1**) and provide a practical guide on how to assess the many different CSTs that are presented to clinicians by their patients. The committee continues to conduct assessments of CSTs and will post summaries for clinicians as a free resource for members on the AASM website.

Watson and colleagues consider "the need for FDA approval and rigorous validation against gold standards" to be a "high bar," but this bar is set by the FDA and the Federal Trade Commission.[3–6] As early as 1976, the FDA foresaw the future value and potential applications of wearables and apps in medical care.[3] In the context of retail product marketing to consumers, differences between entertainment and mobile medical devices often are unclear. This noted, there is tremendous potential for CST for both clinical and research uses. For instance, the collection and use of longitudinal sleep-related data are particularly promising. As Watson and colleagues point out, the lack of such data has been a shortcoming in the comprehensive evaluation of some sleep disorders, and this data can be complementary rather than competitive. However, many current products utilize proprietary "black box" sensors,

Figure 1—Comparison of overnight sleep diary data (top row) to data from six CSTs that were simultaneously collected.

Data collected using Sleep Cycle, FitBit Alta, Apple Watch, Sleep Score, Sleep Score Max, and S+. For the sleep diary data, red represents self-reported awake and white represents sleep. CST = consumer sleep technology.

Table 1—Committee CST concerns.

- Lack of standardization of data acquisition, specific measures, reporting formats, and uses
- Inconsistent transparency of acquisition, data storage/ownership/HIPAA, calculations, algorithms, and AI models
- Lack of specific device/app designation as entertainment or as mobile medical CST
- Providing calculated or internal algorithmic "scores" without clear "normal" data ranges for specific measures for both patient and clinician interpretations
- Lack of ability for clinicians to review raw data
- Absence of guidelines for determining false positive and negative data

AI = artificial intelligence, CST = consumer sleep technology.

data collection methods, and/or data analytics (including metric calculations, algorithms, and artificial intelligence [AI] models). Data reports and metrics may vary between products, thus making standardized practice guidelines and clinical use quite challenging.

The FDA has offered a pathway for "software as medical devices" (SaMD) development, has established a Digital Health Program within its Center for Devices and Radiological Health, and provides weblinks for digital health technology models and policies.[3–6] Peer review, transparency of algorithms and calculations, and validation of the data behind these variable technologies will limit patient risks (such as false positives and negatives), increase clinical confidence, and enhance the use of standardized metrics and practices for those CSTs that are intended to be utilized as medical devices. With the current capabilities of data storage and sharing, manufacturers of CSTs have vast opportunities for validation of both the sensors used and algorithms applied to the derived data. However, if stakeholders like the AASM do not set benchmarks for industry, CSTs will not reach their potential as adjunctive clinical tools.

In summary, the committee agrees with the authors' position that there are great variabilities of CST types, sensors, data acquisitions, uses, and calculations/algorithms/AI models. In particular, a distinction is needed between CST entertainment devices/apps and those CSTs intended to be used for medical screening, testing, and treatment. Beyond opening discussions with patients about sleep concerns, CST use for sleep testing and treatment requires validation and practice guidelines as are done for all general and specialty medical testing and treatment. The committee eagerly supports the development and uses of validated, innovative CST testing and therapies as per FDA standards for all SaMD.

We also agree with Watson and colleagues on the incredible potential of CST to improve sleep health. However, cautious optimism will be critical for successful integration of CST into practice and to provide true individual health benefits.[7] We look forward to amicable conversations with our colleagues in industry to advance the utility and validity of CST.

CITATION

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