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LETTERS TO THE EDITOR

The Importance of Evidence-Based Medicine and Clinical Guidelines: Meaningful and Clinically Actionable Information Cannot be Compromised for the Convenience of Consumer Sleep Data

Solveig Magnusdottir, MD, MBA

MyCardio LLC, Denver, Colorado

"Would you tell me, please, which way I ought to go from here?"

"That depends a good deal on where you want to get to."

"I don't much care where –"

"Then it doesn't matter which way you go."

—Alice and The Cheshire Cat, *Alice in Wonderland* by Lewis Carroll

In their letter to the editor of *Journal of Clinical Sleep Medicine*, Watson et al.[1] raise important questions worth dissecting in light of the response from the American Academy of Sleep Medicine (AASM) Technology Presidential Committee.[2]

Not many market segments can claim an addressable market to be "everyone." This has not escaped various savvy businesses that have sprung up over the past decade to bring innovative consumer solutions with unsubstantiated claims from measuring sleep quantity and sleep quality offered to improve health outcomes. Some businesses may think that because the market is so large, it does not make any difference where you go from here, to quote Alice in Wonderland asking the Cheshire Cat for directions. If sleep was not so important for overall health and well-being and if consumer sleep technology (CST)[3] would only claim what has been properly validated, this discussion would not be necessary. The issue arises when CST manufacturers claim that their output is "close to clinical grade sleep measures," implying that it is actionable, yet offering limited documentation to substantiate the claims.

Because poor sleep is associated with both compromised quality of life as well as some of the most prevalent, costly, and deadly diseases[4,5]—such as cardiovascular and cardiometabolic diseases, diabetes, obesity, and depression—it matters whether information consumers rely on is accurate. This is a matter of public health, not a matter of opinion. Evidence of documented consequences from untreated sleep disorders[6] is escalating, and as Watson and colleagues[1] point out, population sleep health has not improved for decades, with 85% of the patient population having undiagnosed and untreated sleep disorders.[7] This is not acceptable, and likely there would be public outcry if these statistics were true for other diseases. To achieve tangible change, sleep needs to be perceived as an aspect of primary health care. Primary care is where the consumer is most likely to bring outcomes from CST devices to seek guidance. A combination of lack of education, accreditation, or understanding of the squiggly lines of a polysomnography (PSG) or home sleep apnea test (HSAT) may have contributed to the absence of sleep care in primary care. For sleep health to be incorporated into primary care, simple common sleep language is important. Introducing non-validated data from CST to an already overburdened primary care workforce is not likely to be successful. If primary care providers are to accept sleep data to make recommendations or clinical decisions, the data must be practical, validated, and standardized according to regulations set by governing bodies.[8]

Watson and colleagues make a good point that CST is able to objectify sleep longitudinally to empower individuals to assess how their behavior affects sleep quality.[1] But without an independent academic process to validate the output metrics of a CST device, it has limited value as a tool to start a dialogue between patients and primary care clinicians or in clinical sleep management. Data validated only by the CST manufacturer are not acceptable in clinical practice because the stakes for patients and their physicians are just too high. Even though CST devices do not intend to claim diagnosis, they need go through recommended validation processes if clinicians are to rely on the output, given the consequences incorrect output can have on patient health. In medicine, a reference standard is always important. That polysomnography has limitations is not a good argument to avoid being held to it as a standard, before making claims such as "close to clinical grade sleep measures."

The US Food and Drug Administration (FDA) addresses this finding, as the AASM Technology Presidential Committee points out in response to Watson and colleagues, through a pathway for "Software as a Medical Device" (SaMD).[2,8,9] SaMD is not an easy path, nor should it be given what is at stake: peoples' quality of life and health. The guide for SaMD is based on consensus among the International Medical Device Regulator's Forum (http://www.imdrf.org) that has defined the patient/practitioner interaction to use data from SaMD to either "inform" or "drive" clinical management. Every conversation

needs a mutual language. To communicate effectively, the health care industry needs a common "sleep language" based on processes cleared by the FDA.[9] FDA terminology must be the yardstick for comparison, whether the intent is to create a consumer or medical product for clinical management. Claiming to measure sleep quality is meaningless if the measurements do not indicate how sleep quality was derived, what it means, and how poor sleep quality may be associated with other measures of a person's health.

The AASM has a leadership obligation to facilitate increased public awareness of sleep disorders and to support improved integration of sleep health into medical care in a responsible manner. To establish common ground, the AASM needs to embrace innovation in sleep medicine and CST manufacturers need to respect the process of peer-reviewed clinical validation compared to a reference standard if the goal is to use the product in clinical management. Common ground needs to be defined by processes and definitions agreed upon in the international community for consumers and clinicians to rely on. These two worlds can only complement each other if everyone follows the same guidelines and agree that a "common sleep language" has to be meaningful and validated, using FDA-cleared terms, be that for CST devices used in clinical management or diagnostic devices. As Watson and colleagues[1] correctly point out, there is enough night-to-night variability in sleep, that a single night's data "collected in a strange environment, in an obtrusive manner" is no longer acceptable. Clinically valid methods, suitable for multi-night testing in the individual's natural sleep environment, will without doubt improve diagnosis of sleep disorders and clinical management of sleep health. This process, if successful, could democratize sleep and include sleep among the vital signs with commonly understood units of measure.

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Address correspondence to: Solveig Magnusdottir, MD, MBA, Medical Director, MyCardio LLC, 3513 Brighton Blvd., Suite 530, Denver, CO 80216; Tel: (970) 445-7831; Email: solveig.magnusdottir@sleepimage.com

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