How a program designed to serve women who are post-menopausal will revolutionize sleep medicine

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Executive Summary

Current sleep-disorders medicine in America is **disorder-based and relies heavily on the diagnosis and treatment of obstructive sleep apnea for its financial health**. This is a self-limiting (and gradually dissolving) approach because of multiple weaknesses: It treats patients transactionally and releases them before measurable outcomes occur; Expensive specialists doing relatively simple work (in the majority of cases) make it a payor target, so margins are ever decreasing; and it focuses on a male-dominated patient base.

We contend that this model should be supplemented by **a more modern approach**, governed and controlled by appropriate AASM committees and task forces. We propose that the PCP be the main (and trusted) contact for the patient and would 'unblock the funnel' for access. Instead of being disorder-based, we propose using an **AASM-approved treatment matrix** to tackle any abnormalities in a new **Universal Sleep Panel** of sleep metrics. This would stimulate industry to both create new technologies to measure sleep and wakefulness and also to automate the process, reducing both subjectivity and cost. Focusing on a sleep panel would insure that attention would be given to issues that were of causal significance for disease or, as importantly, that contributed to subjective dissatisfaction.

We propose starting with a sleep program for **women who are post-menopausal**. This group, growing in number and currently over a billion women worldwide, suffers heavily from multiple sleep problems that individually often fail to meet the criteria for diagnosable sleep disorders. Changes associated with menopause, including poor sleep, lead to performance issues (such women are disproportionately likely to receive promotion to the most senior levels) and also decreased cardiovascular health. Cardiovascular disorders are the leading cause of death in this group.

How would this benefit the field of sleep medicine? With 42M US women who are menopausal, and over 70% expressing dissatisfaction with sleep, the market is huge. We estimate that if the USP becomes part of the mandated evaluation for women who are menopausal, there is the potential for an **additional $1.6B per year for sleep services**.

Money isn't everything. This proposal, by focusing on the real sleep concerns of a particular group that is not male and not currently receiving the care that they desire or deserve, will serve as a model to adapt for other groups that are similarly underserved.

Introduction

One form of disruption is a paradigm shift. We are proposing a paradigm shift in the way that sleep medicine is provided in America and in the way that the American Academy of Sleep Medicine (AASM) leads and governs that shift.

The focus of our proposal is to systematically tackle the sleep of one group, women who are menopausal, using a new approach which is based on a Universal Sleep Panel rather than traditional diagnoses; an objective treatment matrix; familiar, trusted communication; and the inclusion of a goal to solve subjective as well as objective sleep concerns

Situation Analysis

Historically, sleep medicine has been **disorder based**. The field has been proud of its role in elucidating the identification and treatment of about a hundred such disorders, many common, some exotically rare.(ref 2) Great strides have been made, and literally tens of millions of patients have benefited. The world-wide influence and success of the AASM should be, and is, widely acknowledged.

But there are problems. Consider Dawn, a sixty year-old healthcare worker who is recently post menopausal. She snores a little, but not enough to qualify for a 'moderate to high' likelihood of obstructive sleep apnea. She has crippling insomnia, but Trazodone leaves her groggy. Web-based self help doesn't help. Statistically she will likely die from cardiovascular disease, and have been told repeatedly, as nauseum almost, that a huge contributing factor to the development of cardiovascular disease is poor sleep.

Solution Framework

The essence of our 'disrupting' proposal is that the AASM should lead the charge to supplement disease-based sleep medicine with **patient-based sleep medicine**. (We're aware that this sounds like PR-department hype, but stick with us...). This will necessitate readily available quantitative metrics that describe the complexity of the patient's sleep accompanied by expected patient-specific 'normal' values i.e., **a universal sleep panel (USP).** In turn, that will require **panel governance** by a to-be-formed AASM committee to determine both what elements of sleep are required to be represented on the panel and also what technologies are acceptable to measure those elements and meet standards.

The **data-acquisition technologies** required for the USP will need to be significantly different from those used today. Currently, and broadly speaking, we have wearables (ref 3),home sleep

apnea testing (HSAT) devices, and in-lab sleep studies (PSG). It is a simplification, but not much of one, to suggest that these were all designed to package existing technologies and not to seek physiological answers. The ASM will again need to have a leading role in using the USP to create the technologies that will populate it. Not only will these technologies need to perform from a physiological point of view, they will also need to meet consumer acceptance. A bonus will be achieved if we can successfully accomplish 24-hour or longer studies with these technologies.

Perhaps paradoxically to some people, we anticipate that this work will greatly stimulate the demand for advanced in-lab sleep studies. A disadvantage of the rush to HSAT studies has been the concurrent rush to the lowest common denominator, i.e., a crude binary decision as to whether or not the patient has sleep apnea. By focusing on the USP, clinicians will once again become more inquisitive about their patients' sleep physiology and will strive to make improvements benefiting the patient. From a payer's perspective there will be a much clearer match between payment and outcome justifying more complex studies and greater investment in their patients health. This is described in more detail in the section below entitled 'payment'.

The use of **novel automated-scoring techniques** will be mandated as a guarantee of objectivity, scalability, and to reduce costs. Acceptability of each automated scoring system and the services that provide them will be governed by the AASM, perhaps in conjunction with the FDA. It is anticipated that the backbone of the automatic-scoring will involve AI processing of the results of advanced Fourier analysis (ref 4).

Note that AI methodologies alone will not be sufficient, however helpful they appear to be in the short term, partly because they are only as good as the existing scoring practices on which they are based (ref 8). These are themselves flawed and insufficiently objective. The current development of casual AI methodologies is hopeful for the future. Note also that Fourier, not Fast Fourier, analysis will be required (ref 5).

The infrastructure and organization required to conduct these analyses is likely to result in the adoption of two or three enterprises. The competitive advantage of each will be dependent on the reliability and efficiency of their products. These organizations will likely be a mix of those who provide the testing as well and those who do not. The AASM should have a large role in the development of these enterprises and the possible expansion into other fields of medicine. We anticipate that this will eventually be a global market.

Let's return to 'patient-based' sleep medicine. To give this meaning, it should not be used in a vague 'everyone matters' kind of way. Instead, it should mean that there is an **intentional focus** on the sleep of a **specific demographic**. The universal sleep panel should be customized for that group and the **delivery vehicles** (by which we mean the specific interactions, relationships, etc.) customized for individuals within that demographic group.

It is essential that **inclusivity** is a fundamental guiding principle, and that this is accomplished in as apolitical a way as possible. We suggest that this is accomplished at the individual level by

recognizing, and accepting as a challenge, that **social and behavioral** influences on sleep can be as strong or stronger concerns than direct morphological or physiological causation. The universal sleep panel will therefore need to have items addressing such influences (more details below). Ideally the items would be **unobtrusive and non-judgemental**, a simple privilege scale, for example. A corollary is that the 'normal values' by which sleep-medicine metrics are evaluated should be as specific as possible with regards to diversity. Clearly, this will create a new set of challenges in evaluating the relative importance of within and between group norms, but that challenge should be viewed as a future opportunity.

We propose that **women who are post-menopausal** should be the initial focus demographic. There are many reasons for choosing this group. 1. Women have more objective sleep disorders than men. 2. Women who are post-menopausal have more objective sleep disorders than women who are pre-menopausal. 3. Women in general have more subjective suffering from sleep problems than men. 4. Definitions of sleep disorders, and application of such definitions, are male centric. 5. The presentation of sleep disorders by men often appears 'more obvious' and easier to characterize. 6. This is a large population - over one billion worldwide. 7. Cardiovascular disease is the commonest cause of death in this group and sleep issues obviously impact cardiovascular disease. 8. This group is largely dissatisfied with the healthcare that they have received for sleep disorders. 9. From a business perspective, this is a largely untapped market for sleep-disorders medicine.

A general summary of the health issues and current practices regarding women who are post-menopausal in the USA is available (ref 1). Recommendations regarding standards of care for this group are summarized in appendix One. Notably, they do not include anything about sleep.

What do post-menopausal women say? There were several themes in our interviews. We are aware of the dangers of anecdote and stereotyping, but that shouldn't prevent us paying attention to the patient's voice. **Trust** was in the forefront. This is not just trust in the science and medicine but also in the messengers themselves. Trust takes time to develop, and therefore primary care relationships are valued more than specialist visits in this regard. Similarly, **in-person encounters** were preferred to virtual encounters.
These observations are not scientifically validated to warrant basing a program on them. Nonetheless they are definitely items that need further research as being potentially important in program design. **Value** was also an issue. These are savvy consumers. In terms of sleep-study technology, **bracelets and rings** were preferred to boxes, electrodes, and watches.

How should these elements come together to produce an efficient sleep-medicine delivery system for this demographic? The AASM should recommend and lobby for a **USP as part of a standard post-menopausal assessment** as conducted by her PCP.

Examples of the anticipated types of elements of the USP are outlined in Appendix Two.

The USP must result in sufficient detail to determine: 1. Whether there is **impaired sleep**; 2. What cardiovascular and other **risks** those impairments suggest; 3. What **subjective distress** is present; and 4. The most-appropriate **treatment matrix**.

Treating **Impaired sleep** is preferable to discussions of whether particular sleep disorders are present. Especially in this population it is quite common for multiple additive contributing factors to be present and significant individual sleep disorders to be absent.

It is important to recognize that we currently do not have a full and complete understanding of the causal pathways associated with impaired sleep and **cardiovascular risk (**ref 6). As a working hypothesis we might agree that any degree of sleep impairment will lead to cardiovascular risk. Of course this is not devaluing specific pathways that are known, but in general improving sleep will reduce the impact of those pathways.

The assessment of **subjective distress** is important in a number of ways. Subjective distress is likely a marker for sympathetic reactions leading to cascading effects on cytokinesis and cardiovascular health. Perhaps as importantly, it is viewed as a natural correlate of bad health for women. The almost-patriarchal view that such small chronic effects may be discounted should be resisted.

The test or tests are no longer to be **interpreted** in the traditional way. Rather, the PCP will make medical decisions based on the USP and according to the strict, clear guidelines established by the AASM. These guidelines will also be straightforward about the circumstances, including the adequacy of the tests, under which referral to a Board-certified sleep specialist is to be made.

Some sleep specialists will be reluctant to cede interpretation of any studies to primary care. They will point out that they have the specialized education and the experience to detect complexities and to manage sleep patients. They will perhaps also be reluctant to lose the typically easy money for interpreting relatively simple tests. However, there are strong counter arguments. First it is only likely that patients will receive mandatory postmenopausal sleep tests if the process is easy, efficient, and fast so it is likely that sleep specialists will lose this business anyway. Second, any loss of revenue from these tests will be more than made up for by the increased business downstream.

The AASM will have a significant role in defining the appropriate **treatment matrix.** The PCP should be involved throughout. This PCP management maintains the trusted relationship that is valued by the constituents of this demographic. However, the detailed and important work in the treatment matrix must be conducted by experienced, trained Board- certified sleep specialists under the guidance of the AASM. Even though a guiding principle of this process is that the goal is to improve sleep to acceptable standards (and not just treat traditional sleep disorders), traditional treatments will be the backbone of the matrix. Key here will be: Professional, guided CBTi, PAP, dental, etc..

Outcomes will need to be based on a longer timeframe than currently used. It will not be sufficient to just see that someone has adjusted successfully to PAP. Treatment should continue until the USP has normalized. We anticipate that all women who are post-menopausal should have repeat assessments on a cadence which is likely to be every five years for those with a normal USP and every two years for those who are in the treatment matrix.

One goal of this work is to make the program applicable to a **world market**. That would meet DEI goals, and also business goals for American sleep medicine.

A key concept in this proposal has been that the program is grounded around the USP. That would also be the basis and philosophy for the **revenue stream** associated with the program. We propose that each element in the USP should have a dollar value associated with 1. its determination, 2. with applying and managing the treatment matrix, and 3. with successfully accomplishing results.

Anticipated Impact

About 42M women in the USA were menopausal (ref 8). In one survey (ref 9) 78% reported sleep disturbances, and over 50% reported that such sleep disturbances negatively impacted the quality of their lives.

Assuming adoption of the Universal Sleep Panel, we can conservatively estimate that the lifetime average number of tests will be 2.5 and 4.0. 70% will only require the simplest tests (say $75) but 30% will have significant care (median $750), that is between $770M and $1.6B per year.

In addition, there will be a large impact on the PAP business and the identification and testing of more complex sleep disorders.

By necessity, we are using ‘back-of-envelope’ calculations - more details would be needed for a business plan.

Conclusion

Appendix One

From Reference One:
"Clinicians should use the pooled cohort risk assessment equations or another risk calculator every three to five years to estimate a woman's 10-year risk of atherosclerotic cardiovascular disease, including myocardial infarction and stroke. Major guidelines concur that women at average risk of breast cancer benefit from screening mammography at least every other year from 50 to 74 years of age. Several effective options for colorectal cancer screening are recommended for women 50 to 75 years of age. Cervical cancer screening should occur at three- or five-year intervals depending on the test used, and can generally be discontinued after 65 years of age or total hysterectomy for benign disease. Screening for ovarian cancer is not recommended. Clinicians should consider screening for sexually transmitted infections in older women at high risk. Postmenopausal women should be routinely screened for depression, alcohol abuse, and intimate partner violence."

Appendix Two

Examples of the anticipated element types in the USP

Privilege Score
Subjective Sleep Distress
Sleep location index
Pre-sleep ritual index
Validity of the test
Total time in bed
Total sleep time
Sleep-onset inertia score
Sleep-fragmentation score
Obstructive impact on breathing during sleep
Central impact on breathing during sleep
Hypoxemic burden during sleep
Hypercapnic burden during sleep
Arousal index

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