

SLEEPWORLD

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**HIGH-HUMIDITY
HIGH-FLOW**
in the Pediatric Sleep Lab

**Oral Appliance Therapy in
ATRIAL FIBRILLATION**

**HI-TECH HELP FOR
HARRIED DOCS**

SLEEP NAVIGATORS
A Roundtable Discussion



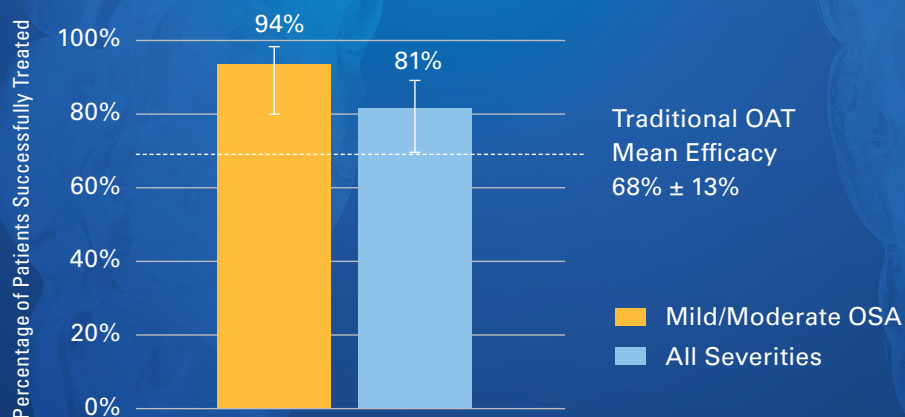
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¹Mosca E; Remmers J; et al. In-home mandibular repositioning during sleep using MATRx plus predicts outcome and efficacious positioning for oral appliance treatment of obstructive sleep apnea. *Journal of Clinical Sleep Medicine*. Vol. 18, No. 3, March 2022.

²Sall E. Precision Oral Appliance Therapy: The Prime - Time Treatment for OSA. *World Sleep Congress, Rome, Italy. Poster Abstract #289, March 2022.*

³Smith K; et al. Efficacy of a Novel Precision Iterative Device and Material. *World Sleep Congress, Rome, Italy. Poster Abstract #081, March 2022.*

⁴Murphy M; et al. Device Design's Impact on Dose in Oral Appliance Therapy. *Journal of Dental Sleep Medicine*. Vol. 8, No. 3 2021. Abstract #004.

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SLEEP TECHNOLOGIES

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New Name, Same Mission

Well, here we are in 2024 with a new name but the same mission: to provide the sleep community with timely and interesting information. In this issue, we explore using high-humidity high-flow (HHHF) in treating pediatric obstructive sleep apnea. Pediatric treatment options are limited compared to adults. Michael McLeland, Ph.D., RPSGT, provides a comprehensive overview of its use and practical information on incorporating it into your sleep clinic.

Atrial fibrillation is common in patients with sleep apnea. Maria Sokolina, DDS, shares a case study exploring oral appliance therapy (OAT) use in a patient with concomitant OSA and AFib. We also share the stories of four sleep navigators who provide the readers with their experiences in this emerging role.

Two things of note, particularly from a regulatory perspective, that impact our world. Oral appliance therapy (OAT) is typically indicated for use in mild to moderate OSA patients. However, an OAT device recently received FDA 510(k) clearance for severe OSA. It will be interesting to see how this change is embraced in the sleep world. Currently, Medicare Local Coverage Determination (LCD, L33611) already allows for payment for severe cases where:

- "The AHI > 30 or the RDI > 30 and meets either of the following (a or b):
 - (a) The beneficiary is not able to tolerate a positive airway pressure (PAP) device or,
 - (b) The treating practitioner determines that the use of a PAP device is contraindicated

Lastly, Philips has reached a consent decree with the FDA. This agreement halts all Philips' CPAP device sales in the U.S. Masks and supplies will remain available. In addition, Philips announced that other products will be discontinued, including their sleep diagnostic systems. [See the complete list here.](#)

It will be interesting to see how this year plays out.

Robyn Woitdtko
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ABOUT THE COVER:

Using high-humidity high-flow (HHHF) therapy as an alternative to CPAP can be an effective therapeutic option for pediatric sleep patients.

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Sleep Advice Is All Around Us: That's Not a Good Thing

Jay K. Joshi, MD

When everything around us is an exaggeration, it's hard to tell fact from fiction. There's no frame of reference. It all blurs into some interpretive oblivion of half truths and white lies.

That's how most advice on sleep hygiene feels. Some purported guru conducts some small-scale pilot or finds some antiquated centuries-old text and just like that, a new trend appears. Very little of it has any scientific basis. But that's the problem—there's very little scientific evidence in sleep hygiene.

Sure, we know all about the REM cycle and the various phases of the sleep cycle and its associated brain waves. But little of it translates into practical advice for the patient. In this void between scientific knowledge and practical clinical advice comes a myriad of supposed experts, miracle cures, and can't-fail remedies.

What's missing is the expertise of physicians and scientists. Those who diagnose sleep ailments and those who study sleep clinically. It's not their fault. Clinical medicine leaves a gaping hole in the realm between sleep disorders and what most commonly experience: poor sleep hygiene. Researchers focus on waveforms and data from cumbersome sleep studies that are hardly scalable. The clinical and scientific advancements have revolutionized our understanding of sleep pathology.

But majority of the population don't suffer from sleep disorders. They suffer from poor sleep hygiene. The discrepancy might feel subtle, but it's the difference between asking your physician for sleep advice vs. performing an internet search and selecting the highest-ranking website.¹

We need physicians and those who research sleep to enter the fray and fill the void currently taken by those more skilled in marketing gimmicks than providing sound clinical advice. This begins by educating physicians and researchers on established guidelines for sleep hygiene. While most of the research focuses on sleep disorders and waveforms, there's a growing body of literature establishing sound clinical advice for proper sleep hygiene.

Oddly enough, this field began in the 1970s as a branch of behavioral economics. It quickly blossomed into the clinical realm with the formation of academic societies such as the American Academy of Sleep Medicine. With just a quick review of the AASM site, physicians and researchers can find protocols to treat or address common sleep-associated ailments.²

However, the problem, as with most things in medicine, is the lack of awareness among most physicians. Many physicians trained in primary care spend less than a month studying sleep hygiene. And most of that time is spent glancing hazy-eyed over sleep waveform studies. There's simply a lack of awareness among primary care physicians, who see most of the patients presenting with symptoms of poor sleep hygiene.

This is not to disparage my fellow primary care physicians. Rather, it's to highlight the gap between when physicians feel comfortable pursuing a diagnosis of sleep disorder vs. just brushing off the symptoms or complaints as sub-clinical. It's not something unique to primary care or

to sleep hygiene as a clinical condition.³

All of medicine faces this issue of figuring out how to address common ailments that aren't significant enough to merit a formal diagnosis or disease classification, but still affect patients.

As primary care physicians, we have to be as much patient advocates as physicians. These conditions—though they may appear sub-clinical according to our medical textbooks—are still pertinent. When we proactively discuss them with patients, we use the power of conversation to guide patients toward clinically sensible solutions or behavioral changes. When we don't, patients are left to fend for themselves in the digital Wild West.

An abundance of knowledge doesn't translate into wisdom. Just like easy access to spurious cures for poor sleep hygiene doesn't mean they're the correct solutions.

Before the advent of evidence-based medicine and the influx of technology, healthcare was as much about the conversation as it was the treatment. Many ailments were cured just by discussing them. And through conversation, a solution would be found.

As primary care physicians, we need to revert back to that era of medicine. In today's medical parlance, we call it patient advocacy. But the concept is the same.

Proactively speak with patients about their sleep hygiene. Glean details that might not appear clinically significant but matter to patients. Inform patients where they can find clinically sound solutions or learn about beneficial behavioral changes.

It's not complicated. It just requires a certain level of awareness.

To help physicians combat misinformation and provide instructive clinical advice to patients, we provide the following recommendations:

- 1. Ask your patients to provide information on where they learned about different sleep hygiene tools or techniques.**
- 2. Determine whether any of the benefits touted have clinical studies verifying them or are endorsed by medical societies such as the American Academy of Sleep Medicine.**
- 3. If the benefits appear clinically unsound and do not have any clinical data or publications to back them up, then explain your findings to the patient.**
- 4. A lack of robust clinical data doesn't automatically disprove the benefits, but it should call into question whether the benefits are likely from a placebo effect.**
- 5. Take extra time to speak with your patients and learn what concerns they might have about sleep and how you can work together to address those concerns.**

(continued on page 26)

Want to expand your options for treating sleep apnea?


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Sleep Navigators: A Roundtable Discussion

Introduction: Robyn Woidtke

The field of sleep health continues to expand into the acute care/inpatient environment. Over the years, more and more hospital leaders have started to see the importance of sleep as a vital component of the hospital experience.

A recent scoping review undertaken by Suen et al. found that undiagnosed obstructive sleep apnea in cardiovascular patients was shown to have a negative effect on outcomes.¹ In addition, those with a diagnosis were seldom provided with continuous positive airway pressure devices.

A very interesting nationwide, single-day study conducted in the Netherlands found that sleep quality and quantity were impacted in hospitalized patients, with the most cited reasons being hospital noise from other patients and medical staff, pain, using the restroom, and medical devices—all of which can potentially be modified to improve sleep for patients.² Another article explored the link between poor inpatient sleep and delirium in older patients, which can impact their ability to perform self-care and rehabilitation.³ These are just a few examples of the data that is emerging in this arena. Many of these realizations have necessitated creating a role for an inpatient sleep navigator.

This article discusses the role of the sleep navigator from the perspectives of several individuals who capture their experiences to share with you. We are happy to provide this vital discussion on this role and know you will enjoy hearing and learning from these individuals. We thank Kelly, Kim, Kier, and Donnie for their time, passion, and contributions to patient sleep well-being.



Kelly Gladden, RRT, RPSGT, RST, CCSH

Sleep Navigator
Wellstar North Fulton
Roswell, GA

How many of you love working directly with patients on the night or day shift and have the desire or passion to broaden your clinical skills? How many

of you work the night shift and are at a point in your life where you really would like to work the day shift, but those early-morning hours are not for you, and a later time would work best? As a sleep navigator, one can adjust their eight-hour workday to see patients at the hospital.

If you answered “yes” to any of the above questions, become a sleep navigator or start your own program in the hospital system where you work. My role as a sleep navigator is the best job I have worked during the last 20-plus years of my sleep and respiratory career. Why, may you ask? I use my respiratory clinical and night-shift sleep center assessment skills while educating patients about their comorbidities related to sleep health. There has not been *one* health condition that I cannot associate with the patient’s overall health improvement. I often make patients laugh or crack a smile despite the pain they may be experiencing.

As technologists working in a sleep clinic, we may have little opportunity to interact with other health team members. As inpatient sleep navigators, we interact with everyone from nursing, respiratory, physical therapy/occupational therapy, radiology, physicians, security, lab techs, social workers, housekeeping, and other department educators. Interacting with all these staff members may be intimidating for some introverts, but do not dismiss the role if you have the passion and love in your heart to help others.

Sometimes, we need to take a leap of faith and come out of our comfort zone to get to where we would like to be. That voice in your head that tells you that you cannot do something or you are unworthy needs to be discarded. If you fail trying to start this program, do not give up. Get back up and try again, either at the same organization or go to another organization where you can thrive. I pitched this sleep navigator role at another organization that did not pan out before I was hired at Wellstar Health System where our AVP, Massey Arrington, MBA, RPSGT, CCSH, and our medical director, Hitendra Patel, MD, both had the vision and dedication to create such a role to help our patients.

If you are fortunate enough to have a sleep navigation program at a local hospital in your area or if you are willing to move near a hospital system that has such a program and you have your Certification in Clinical Sleep Health (CCSH), apply for the open position. Or to help get your foot in the door when an open position presents itself, network

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with the sleep center staff or management team at a hospital that has a sleep navigation program you would like to work with.

Most of you will have to start your own program at your current hospital. For some, this may be an easy endeavor, but for many, you will have to network and get a leader in the hospital system to listen to your idea and understand how your role will help decrease readmissions and improve patient outcomes. Your role will also increase revenue for the sleep center and for the outpatient sleep physicians' office visits. Once you have secured that buy-in, create your program.

Wellstar Health System uses Epic as our electronic medical record system. Our Epic team investigated other hospital system builds when this role was approved, and there was no one else with a sleep navigation type build that we could use or tweak to what we wanted. If your hospital uses Epic, your Epic hospital team should be able to copy our build to make this easier for you. If your hospital does not use Epic, you can use my book, *A Diary: Build and Grow a Hospital Navigation Program*, to see how this build occurred. Visit my website www.clinicalsleephealtheducator.com to find more information about my book as well as a link to purchase the book, if you're interested.

I find joy in helping patients who I know need a sleep study as soon as possible and who may have issues with scheduling or getting into the lab on time. For those patients, I give them my cell number to call me so I can help them if they hit a snag. We are their sleep advocates and with some patients, they need someone to help them get across that finish line and not give up.

I hope to see the sleep navigator as a type of physician extender role in the future. The expanded role would allow the sleep navigator to order the sleep study or sleep consult without having a hospitalist sign off after us, or enable us to follow up with non-complicated sleep apnea patients to free up physicians to spend more time with the complicated ones. If you are enthusiastic about helping people become healthier, expand your skill set into sleep navigation. You will not regret your decision.



Kim Balie, RPSGT, RST, CCSH

Sleep Navigator
Wellstar Douglas
Douglasville, GA

As someone who's been working in the field of sleep medicine for 20 years, I've seen a lot. When I started, I wondered how many people had sleep problems and if this job would last. Well, it turns

out, a lot of people have sleep problems, and it's not slowing down. Throughout my different roles—from night technologist to manager and now, sleep navigator—each position has offered unique insights. However, the aspect of patient care and the opportunity to enhance patients' quality of life remains my absolute favorite and the driving force behind my continued dedication.

In my prior roles, patients arrived at the sleep center well aware of their sleep issues, having already discussed concerns with their doctors. However, in my role as an inpatient sleep navigator in a hospital setting, the dynamics differ significantly. I encounter patients at their most vulnerable, struggling with various health issues like heart attacks, strokes, atrial fibrillation, chronic obstructive pulmonary disease (COPD), respiratory failures, and even cyclical vomiting syndrome.

Their primary focus is on their current health problems, and thinking about sleep is the last thing on their minds. My role as a sleep navigator allows me to have a conversation about how their sleep health and how sleep at home can affect their current medical conditions.

What I cherish most about being a sleep navigator is the chance to make a difference in each patient's life. Some patients already know they have sleep problems. Some do great with treatment, but others struggle with positive airway pressure (PAP) therapy, insomnia, and other sleep disorders. This gives us a chance to find out what's going on and help them in different ways. We can troubleshoot problems or talk about other treatments that might work better. Sometimes, while discussing sleep apnea and sleep health, you witness that aha moment, knowing they will seek testing and treatment. But it's not always easy—sometimes, we lose patients.

The memory of a particular patient stays with me. Even though he knew he had sleep apnea, he kept putting off scheduling a sleep study. When he eventually decided to schedule it, he passed away the day before the appointment. This loss was devastating, and a reminder that we can't save everyone. It reinforces the importance of persistently advocating for sleep health, planting seeds of knowledge, and supporting those who are willing to be helped.

Sleep medicine is evolving, with home studies and auto PAPs on the rise, accompanied by an increase in complex sleep apnea cases. Despite the increasing awareness of the importance of sleep health, there is a noticeable shortage of sleep technologists and sleep navigators. The field calls for more sleep educators to train the next generation of sleep technologists.

Healthcare systems should prioritize developing comprehensive training programs to meet the growing demand for these professionals. By increasing the number of skilled sleep technologists and introducing the essential role of sleep navigators, we can provide better care and support to individuals struggling with sleep-related disorders, ultimately improving their quality of life. The field of sleep medicine is full of exciting opportunities, making it an attractive option for those looking to pursue a meaningful and fulfilling career in healthcare.



Keir M. Noe, RSPGT, RST, CCSH

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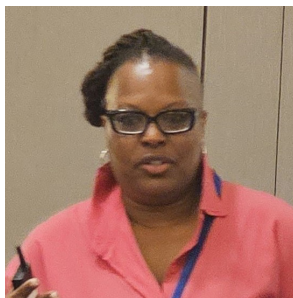
Sleep is an evolving and ever-changing field. I am very excited to be a part of a new role in sleep. A sleep navigator is an essential liaison between the in-

patient and outpatient worlds. Our program has been active for over three years now. By screening inpatients for sleep disorders, our team has seen a decrease in readmission for the four groups of patients we have been tracking. We track patients with the following comorbidities: stroke, congestive heart failure, myocardial infarction, and COPD. Of course, all these conditions are worsened by untreated sleep issues, especially obstructive sleep apnea. By tracking and collecting data on these patients, we can show empirical proof that better sleep leads to better health and reduced healthcare costs!

I have been in sleep medicine for over 30 years, and this is my fa-

avorite role. Daily interaction with different patients and staff ensures that no day is like the previous one. Teaching is a large part of our daily responsibilities. We educate patients on the importance of good sleep hygiene and sleep health. I often find that I also educate fellow staff members. I have screened patients during therapy or an echocardiogram or at the bedside while they are receiving medications or having some other procedure. Sometimes, the same staff member who was in the room with me would later pull me aside with sleep questions! They may be asking on their own behalf or for a family member or friend for which they have concerns. You never know who is listening and who may benefit from sleep screening.

As the sleep world continues to change and grow, we need to, as a field, create new roles, recruit new sleep professionals to replace the old ones (like me!), and be able to envision a future that includes flexible schedules, new responsibilities, and autonomy in patient care.



Donnie Brown-Hill, MPH, RPS-GT, CPC, CCSH

Sleep Navigator
Wellstar Paulding
Hiram, GA

In recent years, hospitals have recognized the critical role of quality sleep in patient recovery and overall well-being.

In addressing this vital need, my position as an inpatient sleep navigator emerges as a guiding light, aiding patients in their quest for better health outcomes.

Empowering my patients with knowledge and skills to manage their sleep health post-discharge is a fundamental aspect of my role. Each patient receives targeted educational sessions, which include conducting sleep navigator screening assessments. These assessments involve the consideration of factors like patient medical history, current medications, sleep habits, and the home environment. Gathering this information allows me to create a personalized sleep plan that aligns

with the patient's needs and medical requirements. This guidance empowers patients to actively participate in their sleep health management and overall well-being.

As a sleep navigator, I shine a light on the significance of sleep in the healing process, fostering a more restful and supportive environment for patients, ultimately contributing to improved overall well-being and recovery. In the journey toward holistic patient care, my role as a sleep navigator is a beacon, guiding patients toward the restful nights they need for a healthier tomorrow.

The one thing vital for anyone transitioning from sleep technologist to sleep navigator is the way communication must evolve. I describe the communication as I^2CU^m . Most days or nights of a sleep technologist involve Interaction + Instruction = I^2 because once a patient arrives, there will be interaction and then instruction. Sometimes, during the patient's stay, there can be very little communication, particularly on the night shift. However, an inpatient sleep navigator needs Interactions + Communication + yoU because interactions occur with patients, staff, physicians, and leaders, and you must be able to communicate with everyone. That is why yoU are so vital in the equation because, without yoU, you cannot fully say to others ICU and mean it.

As an inpatient sleep navigator, I represent a pivotal aspect of patient-centered care, recognizing the importance of addressing holistic needs beyond medical treatments. As healthcare continues to evolve, integrating specialized roles like the sleep navigator highlights a commitment to improving patient outcomes and experiences. ■

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Telemedicine and Home Sleep Testing: A Perfect Match

Haramandeeep Singh, MD, D.ABPN

The intersection of telemedicine and home sleep testing represents a significant leap forward in the field of sleep diagnostics. This powerful synergy, fueled by technological advancements, is reshaping how we approach the assessment and management of sleep disorders. In this exploration, we delve into the seamless integration of these two realms, discussing the ways in which technological progress is facilitating remote sleep diagnostics, ultimately creating a perfect match for patients and healthcare

providers seeking to streamline their sleep testing.

REVOLUTIONIZING ACCESSIBILITY

One of the most profound impacts of combining telemedicine with home sleep testing is the revolutionization of accessibility. Traditionally, individuals seeking sleep diagnostics faced the challenge of geographical constraints. Sleep centers, often located in urban areas, posed a significant hurdle for those in remote regions. However, with telemedi-

cine, the diagnostic process transcends these barriers.

Patients, regardless of their location, can now connect with sleep specialists through digital platforms. This accessibility is particularly crucial for individuals in rural areas who may have limited access to specialized sleep clinics. By utilizing home sleep testing, patients can conduct sleep studies in the comfort of their own homes, eliminating the need for travel and making sleep diagnostics accessible to a broader demographic.

ENHANCING CONVENIENCE

Home sleep testing has already redefined convenience in sleep diagnostics. Allowing individuals to undergo sleep studies in their familiar sleep environments ensures more accurate results, as it reflects their natural sleeping conditions as opposed to a sleep lab. When coupled with telemedicine, this convenience is amplified.

Virtual consultations enable patients to discuss their sleep study results with specialists from the comfort of their homes. This virtual visit eliminates the need for time-consuming and often challenging travel to sleep centers. Patients can schedule appointments that suit their daily routines, leading to higher adherence rates and a more patient-centric approach to healthcare.

EFFICIENCY IN DIAGNOSTICS THROUGH REAL-TIME MONITORING

The integration of telemedicine and home sleep testing facilitates prompt monitoring of patients' sleep patterns. Sleep specialists can remotely access and analyze the data generated by home sleep testing devices because the data is automatically uploaded to cloud-based systems following a night's sleep. This allows for prompt and informed interventions, with physicians interpreting the data within minutes of uploading. During virtual consultations, specialists can provide immediate feedback, discuss preliminary findings, and address concerns raised by patients.

This real-time approach enhances the overall efficiency of sleep diagnostics, enabling more dynamic and responsive management of sleep disorders. Conditions that require timely interventions, such as sleep apnea, can benefit significantly from this accelerated diagnostic process so that therapeutic approaches, such as continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), or oral appliances, can be prescribed to avoid further life-threatening episodes while sleeping.

EMPOWERING PATIENTS THROUGH ENGAGEMENT

The combination of telemedicine and home sleep testing empowers patients by actively involving them in the diagnostic process. Patients become key participants in their own care—from setting up the sleep test at home to engaging in virtual consultations with sleep specialists.

The educational component of this engagement is invaluable. Patients gain insights into the significance of their sleep patterns and disorders, fostering a sense of ownership and responsibility for their sleep health. This proactive involvement not only demystifies the diagnostic process but also encourages patients to play an active role in managing their sleep disorders.

ADVANCEMENTS IN WEARABLE TECHNOLOGY

The perfect match between telemedicine and home sleep testing is further complemented by the ongoing advancements in wearable technology. Wearable sleep trackers and monitoring devices offer a more comprehensive understanding of an individual's sleep patterns. These devices track various parameters, including sleep duration, quality, and disturbances.

Integration with telemedicine allows for the seamless transmission of this wearable data to sleep specialists. This continuous monitoring provides a holistic view of patients' sleep behaviors beyond the confines of a single-night sleep study. Specialists can incorporate this rich dataset into their assessments, resulting in more personalized and targeted treatment plans.

OVERCOMING TECHNOLOGICAL BARRIERS

As technology advances, so does the compatibility and user-friendliness of home sleep testing devices. Modern devices are designed to be intuitive, allowing individuals to set up and use them with minimal effort. The integration of telemedicine further simplifies the process, with virtual support available for troubleshooting and guidance provided by trained sleep physicians and those most familiar with the variety of testing devices and user platforms.

The ongoing refinement of home sleep testing technology addresses concerns related to accuracy and reliability. Telemedicine platforms ensure a secure and efficient exchange of information between patients and healthcare providers, overcoming potential technological barriers that may have hindered remote sleep diagnostics in the past.

THE FUTURE OF SLEEP HEALTHCARE

The synergy between telemedicine and home sleep testing is not merely a fleeting trend but a glimpse into the future of sleep healthcare. As these technologies continue to evolve, the amalgamation of remote diagnostics and virtual consultations is poised to become the standard rather than the exception.

The perfect match created by telemedicine and home sleep testing is transforming how we approach sleep disorders. Patients can now undergo comprehensive sleep diagnostics, consult with specialists, and receive personalized treatment plans—all from the comfort of their homes. This shift not only addresses the current challenges in sleep diagnostics but also sets the stage for a more patient-centric and accessible future in sleep healthcare.

As technology continues to advance, this synergy offers a transformative approach that empowers individuals to prioritize their sleep health. By bridging the gap between accessibility, convenience, and efficiency, telemedicine and home sleep testing pave the way for a future where sleep healthcare is personalized, accessible, and patient-driven.

The COVID-19 pandemic expedited the widespread adoption of telemedicine as the primary mode of healthcare delivery. With an increasing demand for convenience and a significant number of Americans grappling with undiagnosed sleep apnea and other sleep disorders, the combination of home sleep testing and telemedicine is poised to become even more prevalent. ■



Haramandeep Singh, MD is a board-certified sleep physician licensed in all 50 states and CEO of iSleep Physicians which offers sleep interpretations and telemedicine in all 50 states for both pediatric and adult patients.

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New Therapeutic Treatment—Equipment and Setup High-Humidity High-Flow in the Pediatric Sleep Lab

Michael McLeland, PhD, RPSGT

Pediatric sleep disorder management is challenging but rewarding. Compared to the adult sleep disorder population, we who work in pediatric sleep are limited in our available options for obstructive sleep apnea (OSA) treatment. As they say, children are not just little adults—so we embarked on a new therapeutic journey with our population.

Earlier research using high-humidity high-flow (HHHF) therapy in our pediatric sleep center has shown that this could be a therapeutic option within the pediatric sleep center as an alternative to continuous positive airway pressure (CPAP). The Fisher & Paykel Airvo 2 Optiflow™ High Flow therapy system can be a great choice for patients who are noncompliant with CPAP and even for those who may still be too young for CPAP therapy because it increases the risk of aspiration or suffocation at home. The U.S. Food and Drug Administration (FDA) has not approved PAP for children under age 7 or weighing less than 40 pounds (18 kg), but studies have shown CPAP to be safe and effective in all ages.¹ Even though CPAP is considered a second-line



treatment in treating OSA in the pediatric population, residual OSA after an adenotonsillectomy still occurs in approximately 13-29% of the population who are considered low-risk and 70% or more in the high-risk population (defined as those who are obese or with neurological disorders).² Similar to the adult population, the pediatric population exhibits low levels of compliance with CPAP, but unlike the adult population, this population is left without therapeutic alternatives.

This article will thoroughly explain the setup and parts used for HHHF so other sleep centers can successfully include this modality in their arsenal of alternative treatments for pediatric patients with OSA.

WHY USE HHHF?

HHHF has been around for almost a decade, and its original purpose was to treat spontaneous breathing patients who would benefit from heated humidification. The decreased need for a ventilator is achieved through the reduction of dead space and delivery of dynamic, positive airway pressure and by supplying airway hydration through high humidification. Both make HHHF comfortable for the patient. Commonly, HHHF is used in the hospital setting for acute hypoxemic respiratory failure (AHRF) patients to increase ventilation and oxygenation. Recently, HHHF therapy has been applied to chronic airway conditions such as COPD to aid in humidification with a lesser, but still important, emphasis on flow. In addition, new research is supporting the use of HHHF therapy for OSA non-compliance.

When it comes to treating sleep-disordered breathing, pediatric patients do not currently have the number of alternative therapeutic options we have for the adult population. Treating sleep-disordered breathing especially becomes more difficult for patients < 2 years of age if surgery is not indicated. Most often, patients are put on low-flow oxygen to help with their hypoxic burden until surgery can be performed or the child is old enough to wear PAP and have the ability to remove their mask.

CPAP in pediatrics should be carefully examined to determine the advantages vs. disadvantages and risks for the patient. Patients with neurological comorbidities or children under age 2 may not have the dexterity to pull the mask off, thus running the risk of aspiration if emesis occurs. There is also a risk in these populations that the mask may shift, block the nares, and result in suffocation due to the child's lack of reflex to open the mouth.

HHHF IS NOT PAP THERAPY

There are a couple of distinct differentiators between HHHF and PAP. One main difference is how the flow from each of the devices is measured—HHHF measures flow by liters per minute (lpm), whereas PAP flow is measured by centimeters of water pressure (cm H₂O). It is important to note that 5.0 lpm is not the same flow as 5.0 cm H₂O. HHHF also produces more humidity, close to 100%, compared to traditional PAP therapy. Milési's research on HHHF and using esophageal monitoring found that increasing HHHF by 1.0 lpm did not produce a positive flow until 7.0 lpm was achieved. Thus, they concluded that 7.0 lpm equates to 1.0 cm H₂O.³

Similarly, data from Fisher and Paykel estimates that 10.0 lpm of HHHF equals 0.5-1.0 cm H₂O. However, it is difficult to predict the actual amount of pressure being delivered due to factors such as mouth open vs. mouth closed, the fitting of the HHHF nasal cannula, and the fact that HHHF is not a closed system like PAP, meaning there is leakage that is uncontrollable.

Case study

A 23-month-old was referred to the sleep center for an HHHF titration due to ongoing severe sleep-disordered breathing after a post-adenotonsillectomy polysomnogram at six months.

Post-surgical polysomnogram results:

Apnea Hypopnea Index (AHI): 48.3/hour

Obstructive Apnea Hypopnea Index (OAHI): 46.3/hour

Obstructive Hypopnea Index (OHI): 37.2/hour

Obstructive Apnea Index (OAI): 9.1/hour

Below is a snapshot of the post-adenotonsillectomy polysomnogram (Figure 1).

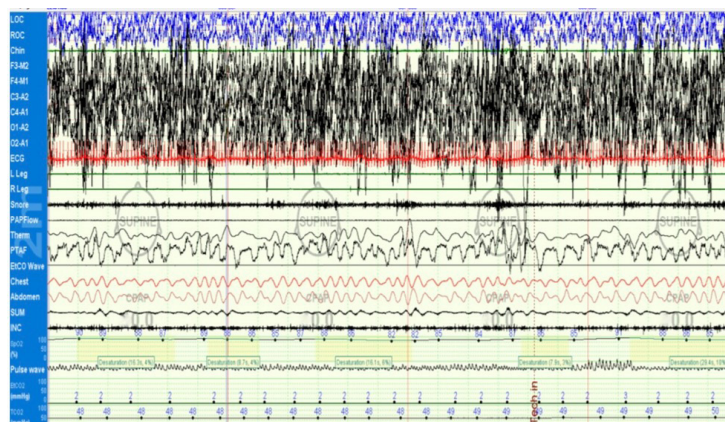


FIGURE 1. 23-month-old baseline two-minute epoch of the polysomnography with hypopneas and oxygen desaturations. This is an example of what was seen throughout the baseline study.

As our policy does not permit the application of PAP for patients <= 2 years of age, we routinely initiate HHHF. Our protocol includes an in-clinic visit to assess for the correct sizing of the HHHF Optiflow nasal cannula to ensure not more than 50% of the nares are occluded, to educate and train the parents on the application of the HHHF Optiflow nasal cannula, and to provide instructions on in-home use. Our goal is to have the patient use the HHHF Optiflow cannula on a nightly basis until the HHHF titration study. This is similar to what is done for patients who are scheduled for a PAP titration.

On the night of the HHHF titration, the patient was refitted with a new Optiflow nasal cannula, and at lights out, the patient was started on HHHF at 5.0 lpm. During HHHF titrations, our policy is to increase flow by 5.0 lpm increments every 20 minutes as needed, following the American Academy of Sleep Medicine's Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea.⁴ The patient was titrated to 10.0 lpm on HHHF, and the sleep technologist did not see a need to increase HHHF any further.

Results of the HHHF titration:

Apnea Hypopnea Index (AHI): 5.4/hour

Obstructive Apnea Hypopnea Index (OAHI): 3.2/hour

Obstructive Hypopnea Index (OHI): 3.3/hour

Obstructive Apnea Index (OAI): 0.0/hour

Below is a snapshot of the titration polysomnogram at 10.0 lpm (Figure 2).

We observed the same results in research we completed with 14 subjects between 11 months and 18 years of age in the pediatric sleep center. Our findings showed significant differences ($p < 0.05$) in the

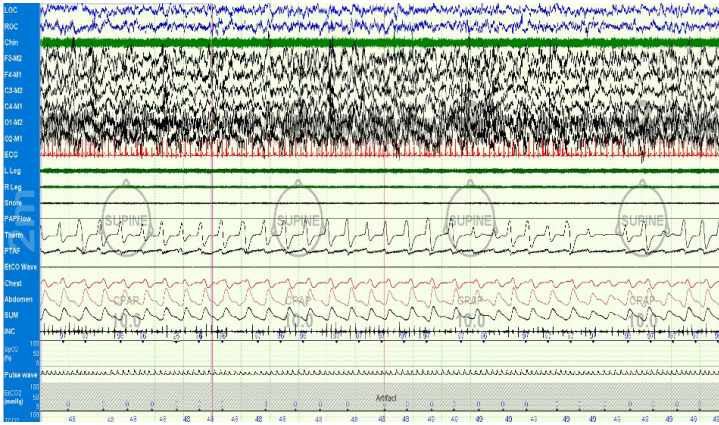


FIGURE 2. 23-month-old HHHF titration, two-minute epoch of polysomnography.

following categories using the Wilcoxon signed-rank test to compare changes between baseline and titration studies:⁵

- Obstructive apnea index (OAI) ($p = 0.004$)
- Apnea Hypopnea Index (AHI) ($p = 0.030$)
- Obstructive Apnea Hypopnea Index (OAHI) ($p = 0.019$)
- Rapid Eye Movement (REM) Sleep AHI ($p = 0.028$)

INTEGRATION OF NEW PROCEDURES

Setting up new equipment and procedures in the sleep lab can be a daunting task. Previous research on HHHF helped our pediatric sleep lab target the equipment and supplies needed to do HHHF titrations successfully. It was through trial and error that our sleep technologists were able to perfect the setting up and recording of HHHF titrations while using the American Academy of Sleep Medicine (AASM) guidelines of acceptable or recommended polysomnographic recording parameters.⁶

MEASURING FLOW

The first hurdle we needed to clear was measuring flow from the patient. HHHF does not produce airflow tracing as we see on traditional PAP machines. The first couple of HHHF titrations were performed using the traditional pressure transducers, which involves attaching the cannula to the HHHF circuit by way of a T-valve between the hose and the cannula of the HHHF (Figure 3). Although we could see the flow tracing, it was limited to short periods due to increased moisture. We were then required to change the pressure transducer cannula or use a syringe to remove moisture blocking the pressure transducer cannula. This was very time-consuming. As you can imagine, the sleep technologist often spend a lot of the night in the patient's room (Figure 4).

In view of the issues described, we used calibrated respiratory inductance plethysmography (RIP) sum as a backup during polysomnography. When patients were sleeping, sleep technologists would only have to enter the room during times of arousals or awakenings from sleep during the HHHF titrations. Calibrated RIP sum is not an ideal unique solution for measuring airflow from the patient and is only an option during polysomnography. The calibrated RIP sum is only the estimate of the airflow derived from the thoracic and abdominal belts, so having the traditional airflow from a pressure transducer and thermistor is important during any baseline study, especially for doing HHHF titrations.

EXPLORATION OF FLOW TRACINGS

After trialing several of the traditional thermistors and pressure

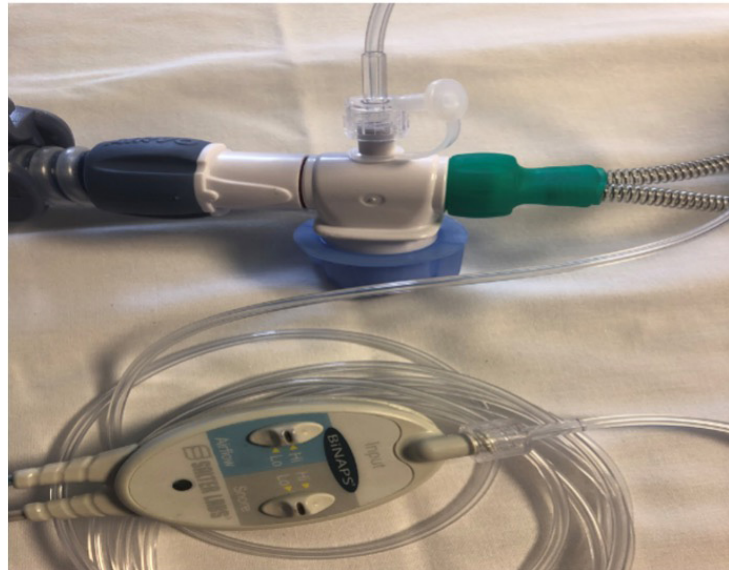


FIGURE 3. The T Valve (OPT016) was initially used between the FlexiTube and the Optiflow nasal cannula for the pressure transducer.

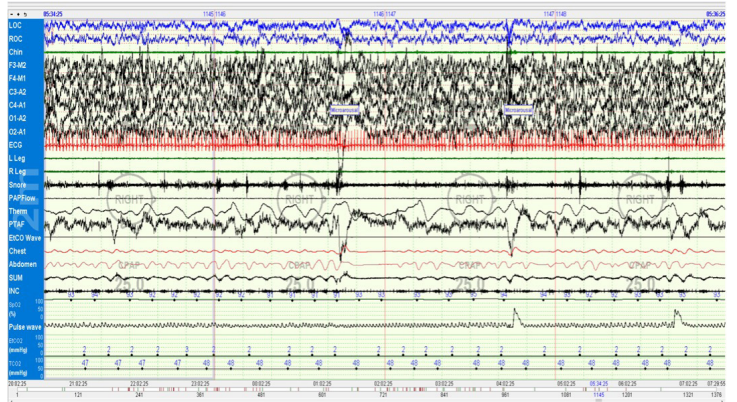


FIGURE 4. A two-minute epoch showing a representative example of the problem with the thermistor and pressure channel (PTAF) with HHHF.

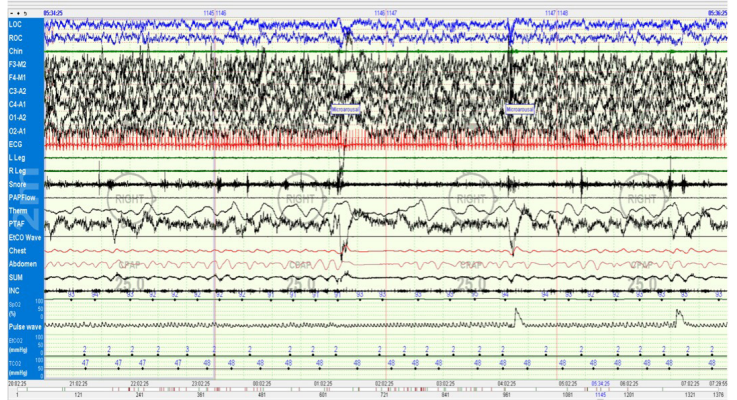


FIGURE 5. A two-minute epoch showing a representative sample using a PVDF airflow sensor for the thermistor and pressure (PTAF) channels using the Dymedix FM4 Airflow Filtration Module. Note the improved waveforms compared to Figure 4.

transducers, we were still unable to get them to work as we intended without blocking more of the nares. Since HHHF creates heat close to the body's temperature, a traditional thermistor lacks the ability to monitor fluctuations in the exhalation and inhalation of the breath's



FIGURE 6. HHHF sleep center setup. The circuit for the HHHF contains the water chamber, FlexiTube, and the Optiflow nasal cannula. The cannula must be fitted so it does not obstruct more than 50% of the patient's nares (not shown is the IV bag/tubing into the Airvo chamber).

temperature. We ended up trialing disposable polyvinylidene fluoride (PVDF) sensors (**Figure 5**). This one-time-use single sensor can generate up to three waveforms depending on the airflow filtration module used—apneas, hypopneas, and snoring. It is plugged directly into the sleep system where the thermistor and pressure transducer are currently plugged in. The PVDF airflow sensors were ideal for use with HHHF due to their size and flatness fitting perfectly underneath the HHHF cannula. This allowed for a better patient experience during the HHHF titration. As you can see in **Figure 5**, the PVDF sensor gave a very readable signal for the airflow and pressure from the patient using HHHF during the entire titration polysomnogram.

OTHER EQUIPMENT AND SUPPLIES

Since our pediatric sleep center is directly located in the hospital, these supplies (**Figure 6**) were easy to obtain, including IV poles and bags of distilled water, as HHHF was also being used in the neonatal intensive care unit. Although the Fisher & Paykel Airvo 2 has a water chamber, a bag of distilled water is needed to ensure enough water is available throughout the sleep study. The IV pole is used to hang the bag of water to gravity feed into the water chamber, which reduces the need for the sleep technologist to stop the titration to refill the water chamber and restart the titration. The IV pole should be on wheels and adjustable in height so it can be moved and positioned as needed.

EQUIPMENT AND SUPPLY LIST

- Airvo 2 Nasal High Flow System (Fisher & Paykel)
- MR290 Auto-Fill Humidification Chamber for Airvo 2 (Fisher & Paykel)
- Airvo 2 AirSpiral Heated Breathing Tube (Fisher & Paykel)
- Optiflow High-Flow Nasal Cannula (Fisher & Paykel), appropriate size for patient's nares
- OPT016 T-Valve (Fisher & Paykel), if only using a traditional pressure transducer and not the Dymedix equipment
- IV pole
- Bag or bottle of distilled water
- TriplePlay Airflow Sensor (Dymedix), appropriately sized to the patient
- TriplePlay FM4 Airflow Filtration Module (Dymedix)

F&P myAirvo 2

Evidence suggests that humidified high flow therapy improves outcomes for patients with COPD.



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DISCUSSION

Granted, the patient presented in the case study was younger than age 2 and went straight to HHHF instead of the induction of PAP. Typically, patients who are older than 2 years of age and who are using PAP have gone through several visits with the sleep medicine provider and sleep educator before making this transition. Before transitioning patients from PAP to HHHF, we want to ensure we do everything possible to make patients comfortable and compliant with PAP therapy, often making several changes in masks, PAP pressure, and expiratory pressure relief. In addition, patients and parents often meet with the sleep psychologist as well.

The policy and procedure for doing HHHF in the sleep center were written similarly to our CPAP titration policy and procedure. Titrations of the HHHF followed the pediatric recommendations from the AASM on when to increase CPAP. Similarly, we increased HHHF for snoring, apneas, and hypopneas.⁷ When titrating, HHHF was increased by 5.0 lpm at a time instead of 1.0 lpm, so there was time to reach an optimal HHHF pressure or until the maximum of 25 lpm was reached. HHHF can go above 25 lpm, but the policy was written not to go over 25 lpm since this was a new alternative for the sleep center, and we wanted to keep the pressure comfortable for the patients.

In those patients where we did reach the maximum of 25 lpm and patients were still having sleep-disordered breathing, it was noticed that the OAI was decreased from their baseline studies, but the OHI increased at the maximum flow of the titration of HHHF policy. This finding suggests that HHHF was converting the obstructive apneas to obstructive hypopneas and raised a question that we haven't explored yet: If we had allowed the HHHF to go higher than 25 lpm, could HHHF have been able to eliminate the obstructive hypopneas?

INSURANCE CONSIDERATION

It is important to reiterate that CPAP was not used on the case study patient and went straight to HHHF due to being under two years of age. After the titration was completed and it was demonstrated that the therapy would benefit the patient, obtaining the Fisher & Paykel equipment and supplies for the patient took longer than a CPAP delivery and setup. It was very important to find the right durable medical equipment (DME) company to work closely with, as the DME had to collaborate with the insurance companies and the sleep center for reimbursement. Communication was key from the DME provider, so that all the proper documentation was sent to the insurance company. All HHHF requests to the insurance companies were initially denied and required a letter of medical necessity. Once the insurance companies received and reviewed the letter of medical necessity, all HHHF orders were approved.

It is important to note the key points the insurance companies were asking for in the letter of medical necessity were:

- Patient comorbidities
- AHI of the baseline sleep study
- At least a 50% reduction in HHHF titration AHI
- What was done to help the patient be compliant with PAP therapy?
 - List of dates the patient was seen by provider or sleep technologist.
 - List of different PAP masks that were tried.
 - List of pressure changes made.
 - Any notes or printouts of CPAP compliance.

Creating a form letter within the electronic medical record (EMR) is the best way to ensure that all the needed information is captured for all orders of HHHF. This process may require working with your IT staff and EMR vendor. Staff within the sleep center filled out the needed information and forwarded the letter to the provider for approval and signature. On average, the process from when the order was submitted to the DME to when insurance was approved took between six to eight weeks. This meant a delay in treatment. Hopefully, this will improve with time. It may be advantageous to send the letter of medical necessity along with baseline and HHHF titration polysomnogram results, provider consult notes, patient demographics, and HHHF order.

CONCLUSION

Our prior research showed that the Fisher & Paykel Airvo 2 is a viable alternative to PAP in noncompliant patients or those too young for PAP, as opposed to just using low-flow oxygen or no treatment at all. Once staff became accustomed to using HHHF, there were no differences seen in the time it took for sleep technologists to set up the equipment or perform titration, and patient acclimation between HHHF and PAP was similar.

The FDA indications for the use of the Fisher and Paykel product used here do not specifically mention OSA. Thus, this is an off-label use. However, the indications for use detailed in the K131895 510(k) Premarket Notification do not exclude pediatric patients.⁷ Using medical devices off-label is not unusual in the pediatric population, as most medical devices have not received either clearance or approval for their use in pediatrics.⁸ ■

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High-Tech Help for Harried Docs

Drew Copeland, RPSGT, CCSH

Hey everyone! Let's say we did all that stuff we talked about in the last article (link). A doc still needs to order the test. And this is where we oftentimes have a Fatberg-sized bottleneck in the patient journey. I've worked for sleep clinics where patients had to wait weeks or months to get an appointment. So, let's explore some ideas on how some cool current and future tech can help our busy clinicians bust that fatberg (yes, I just wanted another excuse to say "fatberg." And yes, I did it again).

Importance of Enhanced Patient-Clinician Interaction

You work in sleep medicine. That means you've seen folks around - on the subway, at a PTA meeting, or in your local big box store - who you'd bet \$100 are suffering from untreated sleep apnea. You **know** they have it just by looking at them. But you can't actually diagnose them in the cereal aisle; They still need the complete medical check-up and validated testing. But many of them will have to wait ages to see a jam-packed provider before testing. This is where technology can step in, not to take over but to give our docs a helping hand. Let's dive into what that might look like.

Utilization of Advanced Questionnaires in Evaluation

First up, let's talk about snazzy digital questionnaires. They could be AI-powered or run on some smart algorithms, helping us get the low-down on symptoms, sleep habits, and the lifestyle stuff that matters for OSA. Raise your hand if you've ever filled out a pre-visit questionnaire asking for information you *know* is in your chart and up to date. Ok, you can all put your hands down now.

Instead, imagine your EHR doing its thing, checking out the patient's history, firing off a tailored pre-visit questionnaire directly to the patient, and then dropping a neat summary into pre-charting (pending provider approval). This would put the important stuff front and center, freeing up our docs to focus on the person, not just their chart.

Role of Data Analytics in Clinical Decision-Making

Next, the patient pops into the office. The docs have all the pre-charting info and can make the most of the visit. With all this extra data, plus what they learn during the visit, we can use some clever analytics to [determine the best tests to run](#), how severe the OSA might be, and even what treatment could work best.

With the right messaging, this can help set more accurate expectations for the patient (e.g., "thousands of patients with a similar medical history to you were able to treat their OSA with an oral appliance. We still need to confirm that, but you might not have to use the CPAP mask that your husband has had so much trouble getting used to.") And that's before an order for a sleep test is even written.

To be clear, this absolutely does not remove the need for testing. But Big Data is pretty powerful. If we see that tens of thousands of patients

with the same OSA severity had similar pre-test physiology, comorbidities, and symptoms, we have a predictive value that can be trusted at least enough to better inform pre-testing our patient education.

Streamlining Pre-Authorization Processes

Now, let's talk insurance - not the most fun topic, I know. Getting tests approved can be a real headache. What if docs had real-time AI help to ensure their notes tick all the boxes for insurance? Picture a little on-screen tip popping up, saying something like, "Hey doc, for this test, you might want to add a bit more here to keep the insurance folks happy." It would not in any way overrule their educated medical knowledge or clinical reasoning--it would simply let them know what rules they were playing by for that patient.

Imagine if a great team knew the opposing team's full game plan. It's possible that the great team could win without it, but the additional foresight could help them avoid unnecessary mistakes. That'd be a game-changer (ba-dum ching)!

Patient Education and Care Plans

[Did you know patients remember as little as 40% of what they hear in the doc's office?](#) That's why after-visit summaries exist. But what if these could be more than just generic printouts? We're talking custom, interactive summaries sent to their phone, detailing what they need to know and do next when they exit the clinic. Plus, with the right integrations between systems, they could get real-time updates on their prior auth status, out-of-pocket responsibility, and test scheduling.

This would mean that the well-trained sleep techs could stop calling patients to tell them their authorization was approved and instead focus on higher yield tasks like remotely monitoring patients' PAP use to provide timely interventions. As my old construction foreman used to say, "right tool for the right job." And no, I am not saying sleep techs are tools. I meant it . . . nevermind. It's just a phrase. Please don't be offended.

Conclusion

Even if we find ways to identify potential patients, getting that golden ticket for a sleep test is still fairly intricate and labor-intensive. But mix in some advanced questionnaires, smart data analysis, and AI-powered admin tools, and we've got ourselves a slick, effective way to get to the proper tests faster. It's all about making things smoother for the doc and patients. You may say I'm a dreamer . . . but I'm not the only one. ■



Drew Copeland, RPSGT, is a 20-year veteran in the field of sleep medicine and resides in Brooklyn, New York. He possesses a penchant for technology and knows just enough to get himself into trouble.

Integrating OAT in Atrial Fibrillation Management for OSA Patients

Maria Sokolina, DDS

As the prevalence of atrial fibrillation (AF) continues to rise, particularly among the aging population, its connection with obstructive sleep apnea (OSA) has become increasingly evident.¹ Patients with AF seeking treatment for OSA often present with a complex medical history that includes a number of comorbidities, such as hypertension, acid reflux, and asthma, which contributes to the overall complexity of their care.² This article will delve into the intricate relationship between AF and OSA, emphasizing the need for comprehensive management strategies and shedding light on the potential benefits of oral appliance therapy (OAT).

UNDERSTANDING ATRIAL FIBRILLATION

AF, characterized by an irregular and often rapid heart rhythm originating from the atria, has become the most common persistent heart rhythm disorder in adults. Recent epidemiological data reveals a 2.0% occurrence in a random population sample, with prevalence increasing with age—from 0.2% in those ages 45–54 to 8.0% in those ages 75 and older.

Potential Complications of Atrial Fibrillation

Beyond the symptoms of fatigue or shortness of breath, AF poses an elevated risk of stroke, emphasizing the importance of preventive measures.³ The risk of stroke in AF patients is estimated between 1% and 20% annually, making the prevention of such episodes a key focus in treatment.

Treatment Options for Atrial Fibrillation

AF management strategies involve antiplatelet or anticoagulant therapy; medication to control heart rate; and interventions such as cardioversion and ablation. Recurrent AF after ablation is not uncommon, leading to repeat procedures in a significant percentage of patients.⁴ Complications of AF contribute to substantial healthcare costs, with patients incurring approximately \$28,000 in additional annual healthcare costs compared to those without AF.⁴

The Interplay Between Sleep Apnea and Atrial Fibrillation

The correlation between OSA and AF is well known, with AF occurring in 5% of patients experiencing OSA. OSA is not only a risk factor for the onset and progression of AF but also diminishes the efficacy of antiarrhythmic drugs, electric cardioversion, and catheter ablation in AF. The prevalence of OSA is notably high in AF patients, ranging from 50% to 80%, surpassing the 30% to 60% observed in control groups.⁵

How OSA Contributes to Atrial Fibrillation

OSA and AF exhibit a robust association, as seen in animal and hu-

man studies. In animals, OSA-induced hypoxia and hypercapnia contribute to imbalances in the autonomic nervous system, potentially leading to atrial electrical changes and promoting AF. Studies in rats highlight that intrathoracic pressure fluctuations during OSA can result in structural remodeling in the heart, characterized by increased left atrial dilatation and fibrosis.

OSA's impact on cardiac function and structure is significant. The repetitive struggle to breathe against a closed airway induces negative intrathoracic pressure, increasing cardiac afterload and resulting in atrial remodeling. This remodeling, marked by enlarged atria and elevated wall stress, creates a predisposition to arrhythmias. Additionally, severe intermittent hypoxemia, acidosis, and hypercapnia associated with OSA can lead to autonomic dysfunction, characterized by sympathetic activation, elevated heart rate, and blood pressure fluctuations, persisting into the daytime despite normal oxygen levels.

The release of vasoactive substances like endothelin during hypoxemia can contribute to long-term vascular damage, increasing the likelihood of hypertension. OSA-related hypoxemia also triggers inflammation, evidenced by elevated markers such as C-reactive protein. Autonomic stimulation, inflammation, oxidative stress, and involvement of the renin-angiotensin-aldosterone system collectively heighten susceptibility to arrhythmias.

The Role of Oral Appliance Therapy

Acknowledging the intimate connection between AF and OSA, the American Heart Association recommends screening all AF patients for OSA. Treatment options include continuous positive airway pressure (CPAP) for severe cases and oral appliances for those with mild to moderate OSA or CPAP-intolerant patients. Continuous follow-up sleep testing is essential to assess the effectiveness of treatment.

Research shows that important health outcomes, including quality of life, reduced daytime sleepiness, lowered blood pressure, heightened energy levels, and enhanced cognitive abilities, were similar after one month of optimal use of mandibular advancement devices (MAD) and CPAP treatment in patients with moderate-severe OSA.

The results may be explained by the greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in similar effectiveness, known as mean disease alleviation.⁶ Both CPAP and MAD may be equally effective therapies in reducing the risk of fatal cardiovascular events in patients with severe OSA.⁷⁻⁸

CASE STUDY INTRODUCTION

Patient M's case provides a compelling narrative that underscores the complexities of managing AF, especially when coupled with OSA. This case study illuminates the challenges patients face, explores var-



FIGURE 1. Front view: Significant loss of tooth structure of anterior bottom teeth.

ious treatment modalities, and emphasizes the potential benefits of OAT in AF management.

PATIENT BACKGROUND

Patient M, a 68-year-old male, initially sought treatment for mild OSA, characterized by nocturnal disruptions and confirmed AF episodes. Despite undergoing two ablation procedures and a Watchman FLX™ device insertion to mitigate stroke risk, AF persisted at an alarming frequency.

Clinical Profile

Weight: 320 pounds; BMI: 48.7
 Blood pressure: 144/75
 Resting pulse: 50-60 bpm; During AF event: 100-130 bpm
 Nocturnal disruptions confirmed via FibriCheck app
 SnoreLab app score: 31 (indicating snoring)
 Dry mouth, frequent nocturnal awakenings (three times per night)
 Visible dental attrition and temporomandibular joint (TMJ) attrition on 3-D X-ray. The teeth and the jaw joint show evidence of grinding or clenching, which can impact dental health and is usually associated with OSA (**Figures 1-6**).

Medications: Wegovy® (semaglutide) 2.4 mg injection; Ozempic® (semaglutide) injection (prescribed by the patient's primary care physician for weight loss to reduce BMI and promote a healthier



FIGURE 2. Occlusal view of upper jaw: Loss of tooth structure of anterior upper teeth, fracture lines.

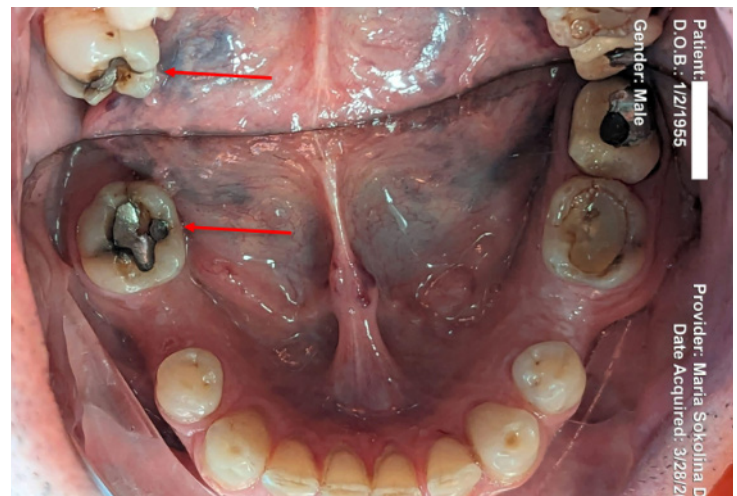


FIGURE 3. Occlusal view: Lower teeth, attrition, and fractures line (arrows).



FIGURE 4. Anterior view: Loss of tooth structure, mild fracturing of the incisors.

lifestyle).

Epworth Score: 4; Fatigue Score: 9

Patient reported CPAP intolerance due to claustrophobia.

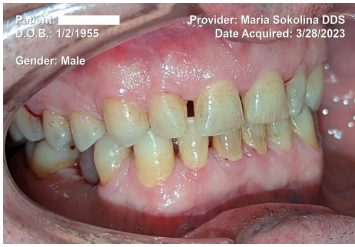


FIGURE 5. Right side of the anterior view of dentition. **Figure 6.** Left side anterior view of dentition.

Initial reluctance to exercise and low desire for physical activity.

Treatment Journey OAT (Figure 7)

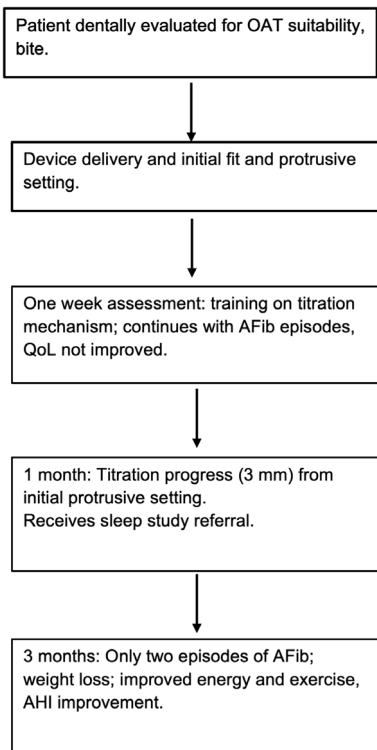


FIGURE 7. Patient's Therapeutic Journey
 with AF. (See **Table 1** for results.)

Follow-Up and Lifestyle Changes

The patient returned after three months, reporting only two AF episodes during that period. Subsequent long-term evaluation revealed a weight loss of 22 pounds (BMI 45.3).

The patient established a regular walking and daily exercise routine. (OAT contributes to increased daytime energy levels by promoting uninterrupted sleep. As a result, patients often find themselves more motivated to engage in regular exercise.)

The patient reported improved sleep quality with a blood pressure reading of 126/59.

CONCLUSION

Patient M's case exemplifies the potential of a personalized, multi-modal approach in AF management. Integrating Wegovy, Ozempic, and OAT into the patient's care contributed to weight loss, im-

Re-evaluation after one week using Herbst® Appliance (DynaFlex): Initial appliance fabrication did not alleviate AF episodes or encourage exercise (Figures 8-10).

Introduction of self-titration (eight turns every other day equals 0.5 mm) and diary recording. Patient received direction to stop upon reaching 3 mm advancement from initial protrusive setting.

Titration Progress

Follow up and re-evaluation: One month of use revealed that the 3 mm titration led to improved sleep, reduced awakenings, and a notable decrease in AF episodes.

Sleep Study Referral

Referral for polysomnography (PSG) to evaluate sleep apnea severity and its correlation with AF.



FIGURE 8. Anterior view with Herbst-type appliance with elastic to improve mouth closure.

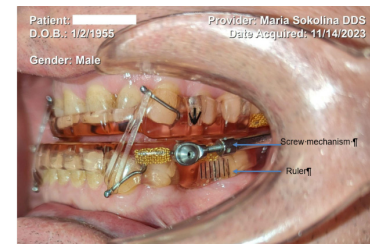
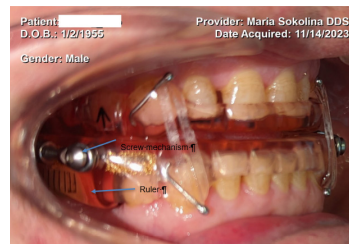


FIGURE 9. Right side with Herbst-type appliance; titrated 3 mm forward from 50% protrusive position. Red ruler showing 3 mm advancement of the screw mechanism. **FIGURE 10.** Left side with appliance titrated 3 mm forward from initial 50% protrusive position; ruler and screw mechanism.

proved sleep, and reduced AF episodes. The case highlights the need for ongoing research to uncover specific benefits of OAT as an adjunct in AF treatment, offering hope for patients who may be reluctant to adhere to traditional CPAP treatment.

This nuanced approach acknowledges the individuality of each patient, emphasizing the importance of tailored strategies for optimal AF care.⁹

In titrating oral appliances for OSA and AF, regular nocturnal monitoring using wearables or smartphone apps proves invaluable. This continuous monitoring at various titration points allows for nuanced adjustments, optimizing the patient's experience. The American Academy of Sleep Medicine provides guidance with regard to the use of consumer wearables in clinical practice.¹⁰⁻¹¹

Frequent communication between the patient and the cardiologist further refines the treatment approach, ensuring a tailored strategy. The positive impact is evident as patients express gratitude for uninterrupted sleep without AF episodes.

Crucially, follow-up overnight PSG with the appliance in place is pivotal at the most effective protrusion to maximize the airway. This step is essential to assess the appliance's effectiveness in mitigating OSA and AF, providing critical insights for further adjustments and personalized care.

Understanding OSA and its intricate relationship with AF is key in ensuring the long-term success of interventions like catheter ablation.¹²⁻¹³ Despite the numerous opportunities that cardiologists and arrhythmia specialists have in managing AF, systematic screening for OSA is yet to be universally established. This gap in awareness is compounded by the underestimation of OSA's negative prognostic impact.¹⁴

Undiagnosed OSA stands out as a modifiable risk factor, necessitating appropriate therapeutic interventions to optimize the efficacy of AF treatments, including catheter ablation. The advent of smartphone applications and mobile devices for self-screening of OSA presents a

TABLE 1. COMPARISON WITH THE OAT IN PLACE DURING THE PSG RECORDING AT ONE MONTH

	Baseline results	After active treatment phase
AHI	5.85	0.2
RDI	19.5	10.4
Supine AHI	11.0	0.0
Supine RDI	28.0	
REM AHI	13.1	0.0
REM RDI	26.0	
Non Supine AHI	0.2	0.2
Nadir Oxygen	86	88

promising avenue, offering a convenient tool for preliminary and ongoing assessments. While clinical diagnoses based solely on these devices warrant caution, the evolving technology holds the potential for streamlining OSA screening processes.

The formation of a comprehensive OSA care team, fostering collaboration between sleep disorder specialists and cardiologists, is advocated for efficient diagnosis and treatment. OSA emerges as a costly risk factor in both the screening and treatment phases of AF, emphasizing the economic burden associated with untreated OSA.

In response to the growing need for insights into the impact of oral appliances on cardiovascular health, the Oral Appliance Network on Global Effectiveness (ORANGE) study, supported by the American Academy of Dental Sleep Medicine, is underway. This multinational effort aims to evaluate the long-term effectiveness of OAT in OSA patients, shedding light on its potential implications for cardiovascular outcomes. As of November 2022, the study has enrolled 163 patients from four research centers.¹⁵⁻¹⁶

It is evident that untreated sleep apnea poses a significant risk, leading to costly complications such as AF. The ongoing ORANGE study represents a step toward addressing this gap in knowledge, offering a platform to explore the potential benefits of OAT on AF and cardiovascular health.¹⁶

Public education becomes a cornerstone in this context, empowering individuals to utilize phone apps for health monitoring. Educating the public about the intricate link between sleep apnea, AF, and the role of innovative technologies fosters proactive health management. As we advance in research and technology, prospective clinical trials are anticipated to unveil the impact of OSA, the effectiveness of its treatment, and the cost-effectiveness of routine screening, contributing to a more informed and engaged public in the realm of AF care. ■



Maria Sokolina, DDS, is a diplomate of the American Academy of Dental Sleep Medicine and serves on their board. She is actively involved in dental sleep medicine, seeking solutions for sleep apnea through dental appliances and myofunctional therapy.

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The Basics of Narcolepsy Knowledge Starting Off Simple in the New Year

Cara Weaver

Happy 2024 from Wake Up Narcolepsy (WUN)! This coming year, we are working to continue our mission of driving narcolepsy awareness, education, and research toward improved treatment and a cure.

In this issue, we're bringing you breakdowns of terms associated with narcolepsy to help you understand the basics. Knowing these terms will make learning much easier and help prepare you to spread narcolepsy awareness and education to others!

What Does That Mean? is a WUN series that breaks down terms in easy-to-understand ways, allowing anyone to learn more no matter where they are in their journey with the disorder.

Remember, narcolepsy is a complex disorder that looks different for everyone who experiences it. These terms are meant to serve as guides, but some issues/concerns may not be present in each individual. We encourage you to ask questions and listen to people telling their stories whenever possible to learn more.

Narcolepsy is a lifelong disorder of the central nervous system, characterized by the brain's inability to control sleep-wake cycles.

The five main symptoms of narcolepsy are **cataplexy**, **excessive daytime sleepiness (EDS)**, **sleep disruption**, **sleep paralysis**, and **hallucinations**.

Narcolepsy type 1 (NT1) is also known as narcolepsy with cataplexy and is caused by low levels of orexin/hypocretin in the brain.

- Diagnostic criteria¹:
- Sleepiness
- At least one of the following:
 - Cataplexy and a positive Multiple Sleep Latency Test (MSLT)
 - Low orexin-A level in spinal fluid

Narcolepsy type 2 (NT2) is also known as narcolepsy without cataplexy. Individuals with NT2 have normal orexin/hypocretin levels in the brain.

- Diagnostic criteria²
- Sleepiness
- Positive MSLT

In the MSLT, "a person is given 4-5 opportunities to sleep every two hours during normal wake times. The specialist uses the test to measure the extent of daytime sleepiness (how fast the patient falls asleep in each nap, also called sleep latency) and how quickly REM sleep begins."³

"Positive MSLT = mean sleep latency of less than or equal to eight minutes and two or more REM onset periods

-REM sleep latency less than 15 minutes on the preceding nocturnal sleep cycle may be included in the tally."⁴

Orexins, also known as **hypocretins**, are "key brain chemicals that help sustain alertness and prevent REM sleep from occurring at the wrong times."⁵

-Narcolepsy with cataplexy (type 1) is caused by a lack of

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orexin/hypocretin

-There are no other known conditions that cause a decrease in the orexin/hypocretin levels

-A Lumbar Puncture is used to test the level of orexin/hypocretin-1 in the cerebrospinal fluid

Rapid Eye Movement (REM) Sleep is the stage of sleep where most dreams take place and brain activity is highest. In people with narcolepsy (PWN), aspects of REM sleep intrude on wakefulness, and wakefulness intrudes on their sleep.

-PWN may quickly enter REM sleep without first experiencing non-rapid eye movement (NREM) sleep.

-During the diagnostic process, one indication of narcolepsy is when individuals fall asleep quickly and enter REM sleep during naps, as determined by the MSLT.

Cataplexy is a symptom of narcolepsy type 1 and can be defined as a sudden and uncontrollable, brief loss of muscle tone. In PWN, this is often caused by experiencing strong or intense emotions. Cataplexy is experienced in different ways and to varying degrees in each individual. Examples include:

- Slurred speech
- Weakness of face, limbs and trunk
- Slumping to the ground unable to move or talk

Excessive Daytime Sleepiness (EDS) isn't just falling asleep

during the day and can present in many forms and create obstacles for daily life, such as:

- Poor memory
- Difficulty following a conversation

Automatic behaviors (automatic behaviors are when an individual continues engaging in whatever habitual activities they are doing but in a semiautomatic way without conscious awareness). These can be unsettling experiences for individuals and sometimes put them in harm's way. Automatic behaviors lead to psycho-social impairments and affect relationships, academic performance, professional success, and leisure activities. Examples of automatic behaviors include:

- Eating
- Talking
- Driving a familiar route

-Brain Fog is the foggy feeling of PWN's head and mind. This can lead to:

- Difficulty thinking, concentrating, and/or forming thoughts
- Being more forgetful, forgetting things you usually wouldn't
- Trouble focusing on, following, and/or carrying on conversations

Sleep Disruption is the breaking up of sleep by frequent awakenings, also known as fragmented sleep. PWN often transition quickly to REM sleep but then awaken often, causing many more transitions from deep sleep into light sleep or wake.

Sleep Paralysis is the temporary inability to move or speak while falling asleep or waking up. It is frequently accompanied by hallucinations, such as someone standing over you or in the corner of your room. It can also cause physical sensations, like pressure on your chest. Anyone can experience sleep paralysis, but it can be more common in people with sleep disorders or panic disorders. Sleep paralysis can resemble cataplexy, except it occurs at the edges of sleep.


Hypnagogic & Hypnopompic Hallucinations are vivid dream-like hallucinations that PWNs may experience while falling asleep or waking up. They are often accompanied by sleep paralysis.

- Hypnagogic: Hallucinations while falling asleep
- Hypnopompic: Hallucinations while waking up

Sleep Attack is the strong urge to sleep, often followed by a period of sleep. These are considered uncontrollable⁶ and may happen to some PWN. Attacks can last between a few seconds and a few minutes. If these attacks happen to a person with narcolepsy type 1, they may also experience cataplexy during it. These may happen after eating or in situations such as while talking to someone, but they can also occur while the person is driving or doing other activities where falling asleep is dangerous.

-These episodes **DO NOT** happen to everyone with narcolepsy and vary from person to person with the level of control. Certain medications can lessen the prominence of sleep attacks. Because of the considerable misrepresentation of narcolepsy in the media, it is essential to listen to people's experiences rather than making assumptions.

Microsleep is a period of sleep that lasts 15 seconds or less, during which people lose conscious control of what they are doing. Even if someone has their eyes open or seems awake during a microsleep, their brain isn't processing information in the usual way. Although more common in people with sleep disorders, anyone can experience microsleep after sleep deprivation. Microsleeps usually happen when performing tasks considered monotonous, such as driving.⁷



2024 WAKE UP NARCOLEPSY NATIONAL SUMMIT

April 27th - Seattle Marriott Redmond, WA

**All times are in Pacific Daylight Time (PDT)*

9:00 - 9:45 AM Keynote Speaker EMMANUEL MIGNOT MD, PHD	1:45 - 2:30 PM Sleep Inequities & Inclusion Panel TONY BENNAE RICHARD, TATIANA MARIA CORBITT MODERATOR: MICHAEL GRANDNER, PHD, MTR, CBSM, FAASM
10:00 - 11:15 AM People with Narcolepsy Perspectives Panel KATY SCRUTON, BRIAN MAHN, STEPHANIE MANULI, TRE BURGE MODERATOR: NICOLE JERAY	3:00 - 3:45 PM Breakout Sessions: Navigating Parenting & Family Life with Narcolepsy EMILY ROBINSON, ELISA WIRKALA, TIM STROUD MODERATOR: ANNE MARIE MORSE, DO What to Know about Narcolepsy NICOLE JERAY, EMMANUEL MIGNOT, MD, PHD
12:15 - 1:00 PM Managing your Mental Health MICHAEL GRANDNER PHD, MTR, CBSM, FAASM	3:45 - 5:00 PM Support Groups: People with Narcolepsy Loved Ones Teens

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If you're looking for more opportunities to connect with the community and learn about narcolepsy, make sure you check out our:

HYBRID SUMMIT

Join us in Seattle, Washington, on April 27th, 2024, for our [National Summit!](#) This opportunity is offered at no cost in a hybrid format to unite the community. We believe that cost and location shouldn't be barriers keeping the community apart, and we work hard to make sure we can offer something for everyone.

We've recently released the schedule and hope you'll find it as exciting as we do! Our speakers and panelists will cover an array of topics, so there is something for everyone!

Make sure to [register now!](#) If you're attending in-person, you can also take advantage of our group rate when [booking your hotel room!](#)

ASK THE EXPERTS

Throughout 2024, WUN has scheduled eight Brown Bag Webinars on hot topics surrounding narcolepsy. These no-cost webinars connect the community with experts and allow them to ask questions about the content with a live Q&A after the event. All webinars are recorded and uploaded to our [YouTube channel](#) for anyone unable to attend.

We are excited to announce that our first webinar will be on February 8th, 2:00 - 3:00 PM EDT, and will feature Thomas Scammell, MD, speaking on the topic of "Narcolepsy 101!" If you're looking for an overview of the important details regarding this often misunderstood disorder, this is the perfect place to start! [Register now!](#)

CME CREDIT COURSE

["Restoring the Balance: Recognizing and Addressing Disrupted Sleep-Wake Cycles in Narcolepsy"](#) is a new CME-certified, on-demand webinar provided by Paradigm Medical Communications in collaboration with Wake Up Narcolepsy!

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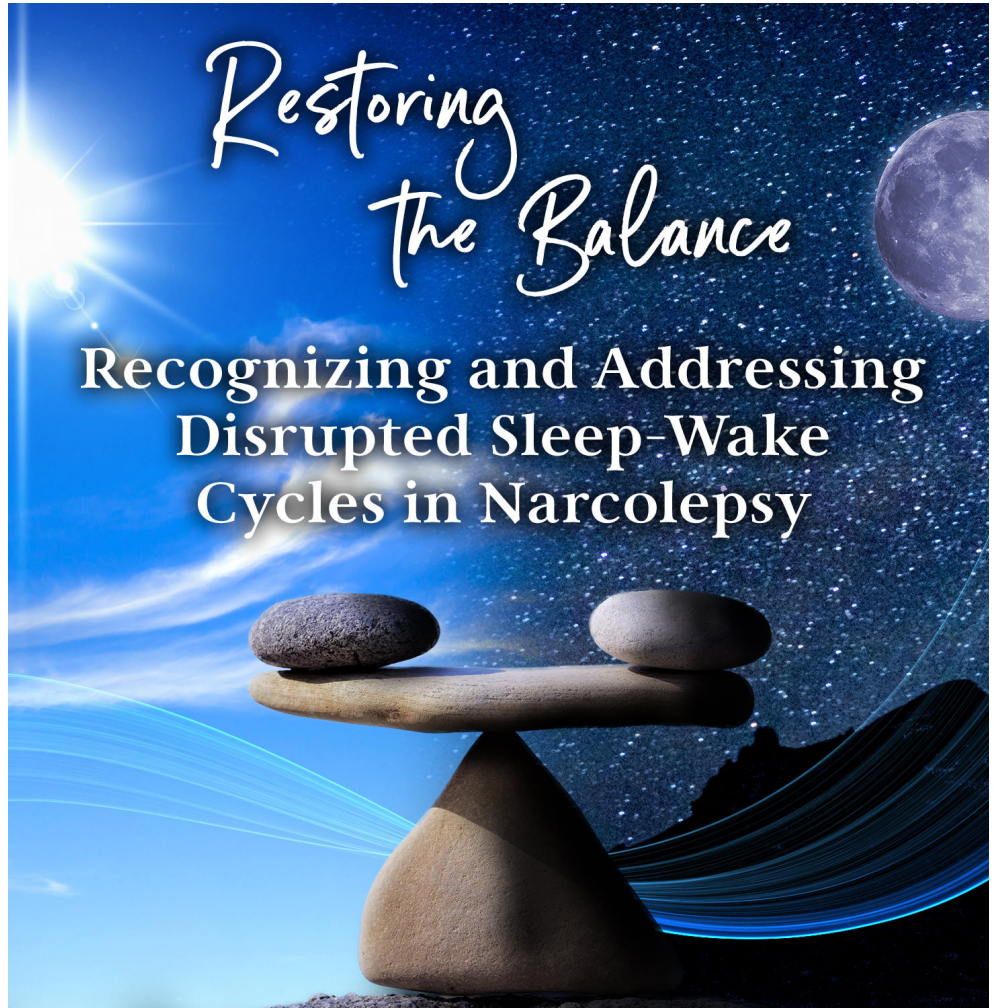
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Cara Weaver is the marketing and communications coordinator at Wake Up Narcolepsy and is also a person with narcolepsy type 2.

Wake Up Narcolepsy (WUN) is a 501(c)(3) nonprofit organization dedicated to driving Narcolepsy awareness, education and research towards improved treatments and a cure ■

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Sleep Pharmaceutical Update

SleepWorld Magazine Staff

AXSOME THERAPEUTICS PRELIMINARY FOURTH QUARTER AND FULL YEAR 2023 NET REVENUE AND 2024 ANTICIPATED MILESTONES

Axsome Therapeutics, Inc. has announced preliminary net product revenue for the fourth quarter and full year ending December 31, 2023.

Dr. Herriot Tabuteau, Chief Executive Officer of Axsome, stated, "In 2023, Axsome successfully completed its inaugural year as a commercial entity, impacting approximately 100,000 unique patients. Our flagship medications, Auvelity and Sunosi, garnered a combined total of over 236,000 and 139,000 prescriptions, respectively, throughout the year. As we look forward to 2024, we anticipate a dynamic year marked by an expanded field force effort to bolster our robust commercial execution for Auvelity and Sunosi. Additionally, Axsome foresees pivotal clinical and regulatory milestones across its leading neuroscience portfolio in 2024."

Preliminary unaudited financial information indicates total product revenue expectations of approximately \$71 million and \$204 million for the fourth quarter and full year of 2023, respectively. Auvelity® net product sales are anticipated to reach approximately \$49 million and \$130 million for the fourth quarter and full year, respectively, while Sunosi® net product revenue is projected to be \$22 million and \$74 million for the same periods. It is noteworthy that these figures exclude \$66 million in license revenue recognized in the first quarter of 2023.

It is important to highlight that these figures are preliminary estimates and subject to the completion of Axsome's financial closing procedures. The final financial results will be released upon the completion of these procedures and may differ from the preliminary estimates provided.

Axsome's 2024 development pipeline includes five late-stage product candidates addressing ten serious conditions affecting more than 150 million people in the U.S. alone. Key anticipated milestones for the pipeline programs in 2024 include regulatory submissions for AXS-07 for migraine and AXS-14 for fibromyalgia, as well as clinical trial topline results for AXS-12 in narcolepsy, AXS-05 for Alzheimer's disease agitation, and solriamfetol in attention deficit hyperactivity disorder (ADHD) in adults. Clinical trial initiations are also expected for solriamfetol in major depressive disorder (MDD), binge eating disorder (BED), and shift work disorder (SWD). Furthermore, a pivotal Phase 2/3 trial of AXS-05 for smoking cessation is anticipated in 2024.

AVADEL PHARMACEUTICALS ANNOUNCES STRONG LUMRYZ LAUNCH PERFORMANCE AND PRELIMINARY 2023 FINANCIAL HIGHLIGHTS

Avadel Pharmaceuticals plc has provided a comprehensive business update, offering preliminary estimates for fourth-quarter and full-year net revenue, along with details on its financial standing and the progress of its flagship product, LUMRYZ.

Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals, high-

lighted the transformative nature of 2023 for the company, marked by substantial growth and the achievement of key milestones. The FDA approval and the subsequent receipt of Orphan Drug Exclusivity for LUMRYZ were significant accomplishments, setting the stage for a successful launch.

Divis expressed satisfaction with the LUMRYZ launch, citing robust demand and positive feedback from the narcolepsy community, health-care providers, and payers. Looking ahead to 2024, the company anticipates the continued impact of LUMRYZ on the narcolepsy community.

Key developments in the launch progress through December 31, 2023, include more than 1,900 patients enrolled in Avadel's RYZUP patient support services, with over 1,000 patients initiating therapy. The majority of enrollments and current LUMRYZ patients are those who switched from first-generation oxybates. Avadel also secured contracts with all three Pharmacy Benefit Manager (PBM) owned Group Purchasing Organizations (GPOs), and LUMRYZ achieved preferred status within CVS commercial formularies and Optum Select as of January 1, 2024. Additionally, nearly 1,800 healthcare providers have completed the LUMRYZ REMS certification process.

In terms of financial highlights, preliminary estimates indicate approximately \$19 million and \$28 million of net product revenue for the quarter and year ended December 31, 2023, respectively. As of December 31, 2023, Avadel reports approximately \$105 million in cash, cash equivalents, and marketable securities.

The company provided a pipeline update, revealing that the Supplemental New Drug Application (sNDA) for LUMRYZ in the pediatric narcolepsy population has been accepted by the FDA. This development holds the potential to alleviate the burden on families and caregivers of children with narcolepsy.

HARMONY BIOSCIENCES REPORTS PRELIMINARY UNAUDITED 2023 FINANCIALS, REVENUE INCREASES 30%

Harmony Biosciences Holdings, Inc. has reported robust preliminary, unaudited net product revenue growth of more than 30 percent for the fourth quarter and full year of 2023. Additionally, the company has provided a forward-looking net product revenue guidance for 2024, projecting a range of \$700 to \$720 million.

Jeffrey M. Dayno, MD, Harmony President and CEO, commented on the company's achievements in 2023, emphasizing the advancement of clinical development programs and portfolio diversification. He highlighted the impressive net revenue of approximately \$582 million for the year and expressed confidence in the potential to generate up to \$720 million in net revenue for 2024. Dr. Dayno outlined the company's strategic focus on the one billion dollar plus opportunity for WAKIX in adult narcolepsy, leveraging their strong cash position and expertise in clinical development and commercial execution to build a robust pipeline.

Preliminary, unaudited net product revenue for the fourth quarter of 2023 reached approximately \$168 million, reflecting a notable growth of approximately 31% compared to the same period in 2022. ■

A Milestone Year Ahead

By Jim Magruder, BRPT Chief Executive Officer

In January, the BRPT welcomed its new President, Amber Allen, BA, AAS, RPS-GT, RST, CCSH. Amber has been an integral part of the BRPT Board since 2017, serving on the public relations and marketing committee and chair of the education and CSTE committees. She has been in the sleep field since 2008 and currently serves as the Program Director of the CAAHEP-accredited Polysomnographic Technology Program at Collin College in McKinney, TX where she was instrumental in developing and building the program from the ground up.

"I begin my term as President humbled and honored to serve the BRPT, after working alongside – and learning from – our previous President Andrea Ramberg, MS, CCSH, RPSGT," said Amber. "My goals are to build on the great work of my predecessors who thoughtfully drove the organization forward, and to assure the BRPT credentials continue to have an impact on the next generation of clinical sleep health professionals."

2024 is also a big year for the BRPT as



Fun Fact

In 2021, Amber Allen graduated summa cum laude with an AAS degree in Cybersecurity and hopes to bridge this education into sleep medicine and other areas of healthcare to make facilities and patient information more secure.

it celebrates its 45th anniversary. Since the first credentialing exam administration in 1979, the BRPT has credentialed over 25,000 RPSGTs in the United States, Canada, and 32 countries overseas. In addition to marking this important milestone, the year ahead is busy and active on multiple fronts from collaborating with like-minded organizations to upgrading internal systems.

The BRPT is an active member of the AASM's Sleep Technologist Shortage Presidential Committee that is currently examining the sleep technologist shortage. The Committee's mandate is to uncover factors contributing to the sleep technologist shortage, build awareness around the problem, and recommend solutions to correct the shortage. We're excited to be a part of this important initiative.

And the BRPT's Executive Office team is in the process of implementing a new Contact Management System (CMS) technology platform to better support its credential holders.

Stay tuned and watch www.brpt.org for updates throughout the year. ■

(continued from page 4)

6. Often, establishing a closer relationship and validating the sleep concerns reveals key clues in how a patient can make the necessary behavioral changes to improve sleep hygiene.

7. When in doubt about purported claims regarding sleep hygiene, take the opportunity to strengthen the patient relationship.

So much of sleep hygiene is subjective. Remember, a habit only becomes ingrained in our minds when we prioritize it. Sometimes the best clinical treatment we can offer patients struggling with sleep is to engage in meaningful conversation and talk through the problem. The solution, more often than not, will reveal itself in time. As the progenitor of modern medicine, Sir William Osler once wrote: "Listen to your patient; he (or she) is telling you the diagnosis."

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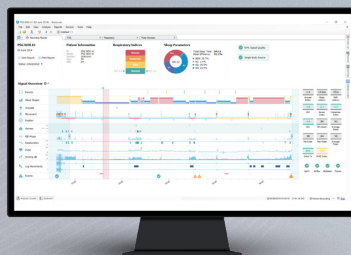
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