

# sleeplab

MAGAZINE

JUL/AUG 2023

FOR SLEEP PROFESSIONALS

VOL. 4 NUM. 4

## ENDO PHENOTYPES

THE KEY TO UNLOCKING PRECISION MEDICINE FOR OSA



LOW  
RESPIRATORY  
AROUSAL  
THRESHOLD

IMPAIRED  
AIRWAY  
ANATOMY

INADEQUATE  
PHARYNGEAL  
DILATOR  
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IS AHI THE BEST  
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WAKE UP  
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SLEEP APNEA  
TREATMENT  
FOR VETERANS  
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BACK TO SCHOOL:  
OPTIMIZING SLEEP  
HEALTH IN CHILDREN

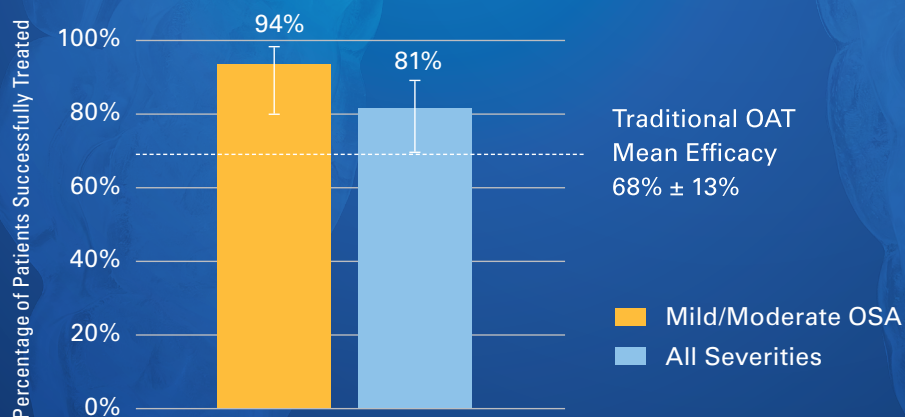
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A recent independent, prospective clinical study published in the *Journal of Clinical Sleep Medicine*<sup>1</sup> reported:

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<sup>1</sup>Mosca 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.

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

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

<sup>4</sup>Murphy 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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## New Perspectives in Sleep Health: Expert Insights and Partnerships

In this issue, we will explore several related topics. As we learn more and more about sleep apnea and the endo-phenotypes contributing to this condition, we are also considering whether the apnea-hypopnea index is the best measurement. As discussed, used as a metric by many insurers to initiate treatment, this single parameter may be missing the mark, and many patients

may go untreated. Recently there has been more and more debate in the field that this metric might need to be modified to capture all of the nuances of the various layers of sleep apnea complexity. These issues, in turn, bring us to consider emerging options for sleep apnea treatment. It is exciting to think about the research and product development that is going on in our field. Dr. Danny Eckert, Dr. Kingman Strohl, and Snorri Helgason from Nox Medical contributed perspectives on these topics.

Well, it's also back to school time again! For many parents, it's a time of anxiety and relief! In this issue, we will tackle some of the common problems related to sleep and how to combat the summer sleep schedule as school approaches. We know that sleepy kids abound, and sleep is essential for them to achieve their potential. It's also beneficial for the parents!

Dr. Afolabi-Brown provides tips for parents and strategies for promoting healthy sleep in schools. This topic is an excellent opportunity for the sleep health community to provide this information to teachers and administrators in their local school districts.

The article on post-traumatic stress disorder in the veteran population was a very insightful read for me and gave me pause to think about things we might take for granted. It is always good to see these perspectives.

We also have our regular columns from the American Academy of Dental Sleep Medicine, the Board of Registered Polysomnographic Technologists, and a column on home sleep testing. We also welcome our newest partnership with Wake Up Narcolepsy and look forward to their future contributions.

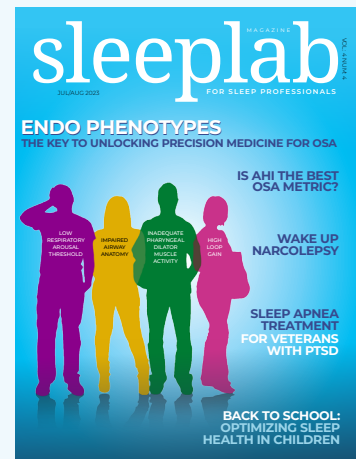
As always, I would like to thank the many people who have contributed their time, expertise, and knowledge to provide you with a stellar edition. We hope you will enjoy their insights and apply them in your world.

Make Sleep Inquiry an ALWAYS event!

Robyn Woidtke  
[robyn@sleeplabmagazine.com](mailto:robyn@sleeplabmagazine.com)



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### ABOUT THE COVER:

The application of OSA endo-phenotyping is opening up new avenues for new therapies and tailored treatment approaches.

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# Sleep Apnea Treatment for Veterans with PTSD: TRUST THEN COMPLIANCE

Boyd Goodson, MBA; Chelsae Avila, RRT  
and Jason Goodson, Ph.D.

For most of us, visiting a Target store is a benign, likely mundane experience. There is momentary alarm if a toddler screams in a passing shopping cart or even frustration caused by a line five-deep at the checkout. But for sufferers of post-traumatic stress disorder (PTSD)—especially combat veterans—the same experience can conjure such a strong reaction that looking for exits, watching other shoppers for warning signs, scanning for threats, and desperately wanting to leave the store as soon as possible can all be expected responses to the same environment.

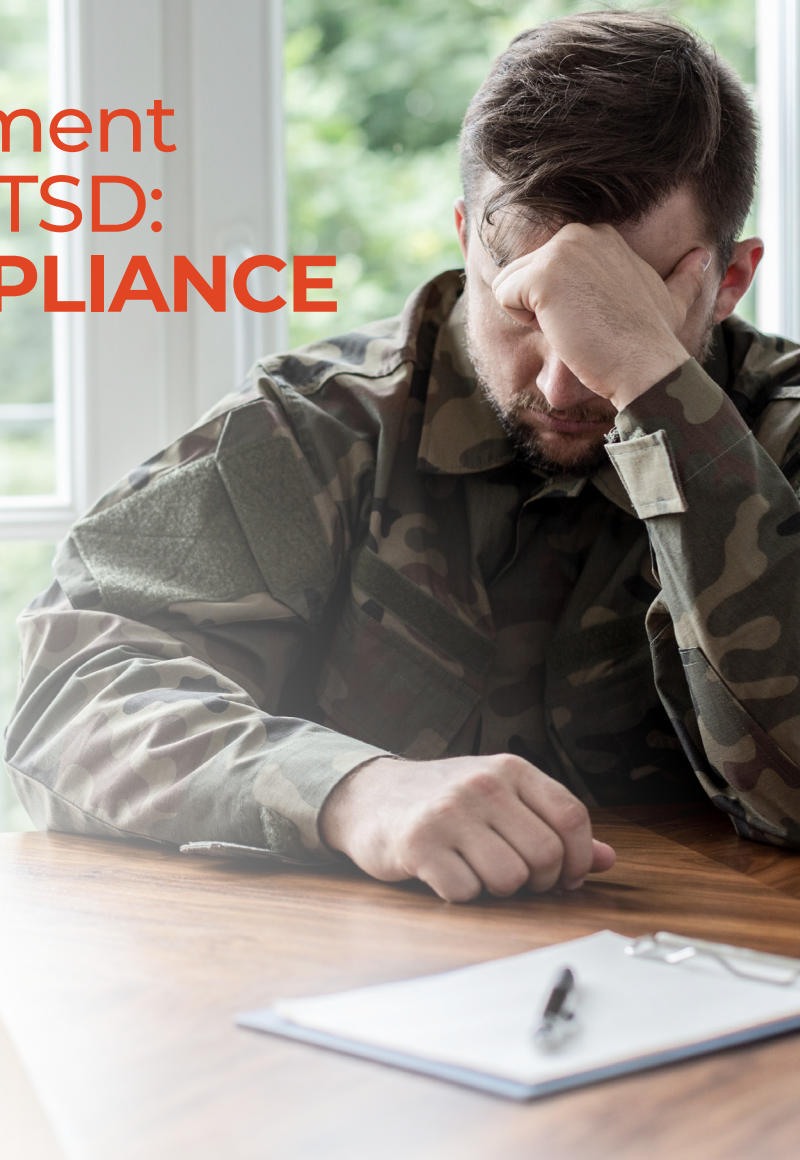
PTSD is a mental health problem that can affect anyone but was first used to describe the combat veteran's enduring and distressed response to experiencing or witnessing a traumatic event. Experienced as a sense of ongoing threat, the trauma gets reinforced in the repetition of one or more behavior patterns, including intrusive memories, hyper-vigilance, and avoidant activity. These actions effectively perpetuate the sense of threat. And for combat veterans with PTSD, those behaviors are ubiquitously accompanied by sleep problems.

A 2021 study by Veteran's Affairs found that veterans are four times as likely to suffer from obstructive sleep apnea (OSA) than the rest of the population. Prevalent among young vets as well, OSA tends to multiply right alongside PTSD. One study showed a 40% increase in the probability of developing OSA as the severity of PTSD increased.

There are currently more than 16.5 million combat veterans in the U.S. More than half have sleep apnea, and that number is only increasing as vets of the Iraq and Afghanistan wars inhabit middle age. This means respiratory therapists (RTs) and sleep technologists who work well beyond the walls of VA hospitals are being called upon to treat veterans in ever greater numbers, many of whom will be presenting with combat-related PTSD.

## Service-related disability: the treatment conundrum

Veterans can wait years to get support for service-related disabilities through Veteran Affairs (VA), and there is a real chance the process will end in a denial of coverage if no correlation is found that ties their OSA to a service-connected condition. Many with severe OSA are not willing to wait that long or take that chance. As a result, growing numbers of veterans are looking to cash-pay sleep clinics for support with OSA and other prevalent sleep disorders such as insomnia.



Along with being treated for sleep disorders by service-related compensation organizations like the VA comes the fear of losing disability due to improvements in the condition. A reassuring layer of anonymity and confidentiality comes with the private, non-traditional company model of diagnosis and treatment. When veterans arrive at cash-pay sleep clinics, there is often relief and a notable determination to give CPAP therapy their best shot.

Compared to the general populace, veterans are relatively educated about sleep apnea, but challenges to treatment remain many and complex. Veterans with PTSD often arrive at private sleep clinics sick, worn-down, and frustrated, either nudged at the behest of partners and spouses or due to an event that scares them into action, such as falling asleep behind the wheel.

For RTs and sleep technologists, the influx means working to treat sleep disorders with veterans who are also experiencing PTSD. The confluence of factors makes therapy success hard, especially in the beginning.

## So, what is different about treating combat veterans?

Keep in mind that veterans with PTSD already have an extra hard time dealing with the day-to-day. Support for this group requires additional sensitivity to their challenges and, at times, accommodations with treatment. A little extra knowledge goes a long way to increase the



chance of success. The presence of PTSD can amplify the inherent challenges of CPAP treatment experienced by most patients. It requires additional focus on the tenets of excellent care.

### **CPAP success predicated on soft skills**

Veterans with PTSD are more likely to thrive when RTs and sleep technologists pay attention to a few interpersonal basics. It is harder to treat someone for OSA who is struggling with numerous sleep challenges, such as insomnia with an underlying anxiety disorder, as is the case for many veterans. Frustration is often high because the person can't sleep long enough to get an accurate test result. In the case of at-home testing, it can take multiple rounds of sending a device out to get the diagnosis.

Beyond the technical challenges, in order to increase the odds of long-term success with this group, there are a few modifications and considerations that go beyond finding the right mask and the technical aspects of treatment.

### **Realistic expectation and practice**

Lofta clinical services manager and respiratory therapist Chelsae Avila is a veteran who works with many ex-military looking to the sleep company for diagnosis and treatment. She notes that veterans can be defensive in the beginning, even a little aggressive. Avila points out that most have been through a lot.

Given that PTSD is a stress disorder, donning the CPAP mask is in and of itself a big challenge

for many combat survivors. But they are ready and will likely give treatment a huge effort. There needs to be additional space for time to adjust, equipment, fears, and the very real prospect that the process will trigger intrusive thoughts and other PTSD symptoms.

### **Trust, patience, respect**

The first step is to build trust—the foundation of all healthy communication and the cornerstone for working with veterans with combat-related PTSD. Trust isn't won easily, but treatment progression depends entirely on building a solid relationship, preferably with one therapist or technologist. Deep listening is essential. Be wary of coming across as judgmental or condescending. Sounds simple, but this self-aware approach in initial meetings will dictate the outcome and compliance.

Second, dissolve expectations of fast compliance. With PTSD-affected veterans, the reality is that the chance of long-term success is low if expectations of short-term compliance remain the goal. Avila also recommends not jumping into intervention mode. The primary aim is to create comfort with the process and with the device. In those critical first stages, there is no goal beyond this except to build trust. It's not about optimal therapy. Sometimes, it's about trying on the mask while watching TV for a few minutes at a time.

Keep in mind that many people with PTSD have trouble being in a small room or feel claustrophobic before the additional pressure of placing a mask on their face. The process is challenging for anybody but even more so for someone with combat-related PTSD. Wherever possible, set realistic expectations focused on the goal of developing comfort rather than time spent in compliance.

Veterans can arrive closed off and withdrawn. Avila stresses that patience is paramount working with this group. Military culture trains in detachment, and given that PTSD is an anxiety disorder, working through a CPAP setup with someone with a PTSD diagnosis requires clear and regular communication based on trust. Moving from a place of little personalized support to opening up about the impact of wearing a mask on one's face and well-being is difficult. Compliance is even more of an issue than with other clients. But working with the same therapist or technologist and keeping low expectations are imperatives for long-term therapy compliance.

### **Respect**

From first contact, be respectful and polite and avoid phrases like, "thank you for your service." Generic phrases can be annoying or even taken negatively. Having said that, being authentically appreciative is always well-received.

Avila leads her calls with, "I'm not here to judge you; I'm not your teacher. I just want to help. And if you're not using the CPAP, it's because there's a problem. And that's what I'm here for. Let's try something different."

### **The right kind of support**

The good news is that the military veteran network is broad and full of support groups. Compared to the more traumatic conversation topics between veterans, bad sleep and how to manage it is considered one of the more neutral topics. This openness also extends to awareness about sleep apnea being a major issue.

Lastly, virtual care is proving just as helpful to veterans as in-person treatment. The current combination of new technology that allows at-home testing, diagnosis, and telehealth access to respiratory and sleep care is opening up options for veterans across America.

For more information about veteran-related PTSD, visit the National Center for PTSD: [www.ptsd.va.gov](http://www.ptsd.va.gov). ■



*Boyd Goodson serves as general manager at Lofta. He has an MBA from the Stanford Graduate School of Business and a B.A. in Economics from Brigham Young University.*

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# IS AHI THE BEST OSA METRIC?

Snorri Helgason

Sleep apnea has been identified as a serious health issue for most countries. It exerts a substantial influence on individuals' physical and mental health, impairing daily functioning and overall quality of life if left untreated. Moreover, sleep apnea imposes a substantial burden on society, leading to extensive healthcare costs, absenteeism, presenteeism, reduced productivity, heightened personnel risks, and an increased likelihood of motor vehicle accidents and injuries.

Since sleep apnea was defined in the 1970s as a disease, the definition of the disease and how to measure its severity has been categorized through the application of the apnea index, then later the apnea-hypopnea index (AHI).<sup>1</sup> Over the years, sleep medicine has established its diagnostic approach for sleep apnea predominantly using the AHI.<sup>1,2</sup> This metric holds significant influence as regulatory bodies, payors, and providers rely on it to make crucial patient diagnostic decisions. The AHI plays a pivotal role in categorizing patients according to the severity of their condition and determining whether they receive treatment for obstructive sleep apnea (OSA).

However, throughout the years, the question has been raised by many in the field: Is the AHI truly the optimal metric for these purposes?

## UNDERSTANDING THE AHI

Per the AASM manual, obstructive apneas involve complete upper airway collapse with a 90% or more drop in airflow for at least 10 seconds, accompanied by continued respiratory effort. Central apneas lack respiratory effort throughout the event, while mixed apneas start with no respiratory effort but resume despite absent airflow. The American Academy of Sleep Medicine (AASM) recommends that hypopneas be identified using a definition that is based on a  $\geq 30\%$  decrease in airflow associated with a  $\geq 3\%$  reduction in the oxygen saturation or an arousal (H3A) for diagnosis of obstructive sleep apnea (OSA) in adults.<sup>3</sup>

The severity of sleep apnea is defined by the AHI, a ratio of the sum of all respiratory events divided by the total hours of sleep. Currently, AHI is the sole indicator of OSA severity recognized by scientific societies. By this convention, an AHI of 5 to 15 per hour defines mild sleep apnea, an AHI of 15 to 30 per hour is moderate sleep apnea, and an AHI of 30 or more per hour is severe sleep apnea.<sup>4,5</sup> Historically, the AHI has been favored for its simplicity in calculation and objective measurement of events like apnea and hypopnea,<sup>6</sup> helping physicians to classify the severity of the disease.

## LIMITATIONS OF THE AHI

The correlation between the AHI and clinical outcomes has been found to be inadequate.<sup>1,2,6,7</sup> Since the AHI threshold is based on population averages, it fails to account for the unique characteristics of individual patients. This means that symptomatic patients may exhibit a low AHI, while asymptomatic individuals may be diagnosed with a high AHI. In such cases, healthcare providers face a challenge in determin-

ing the appropriate course of action.

Furthermore, the usefulness of the AHI as a metric in clinical settings is called into question when it is not strongly linked to symptoms or the risk of developing comorbid chronic diseases, such as cardiovascular disease, and does not provide information on the severity of the single events as they occur,<sup>8</sup> presence of significant oxygen desaturation, ECG abnormalities, and sympathetic activation, that may imply more significant pathology than the AHI alone.<sup>6,7</sup>

Over time, there have been changes in the definition of the AHI, including notable modifications in how oxygen saturation and breathing cessation are defined, as well as the inclusion of arousals with hypopnea events.

The AHI alone cannot help evaluate symptoms like cognitive impairment, daytime sleepiness, or cardiovascular complications. Additionally, the methods employed in deriving the AHI can vary significantly in clinical practice. The measurement and scoring techniques used to calculate the AHI differ among sleep laboratories and devices, resulting in potential inconsistencies and inter-laboratory variability. These variations can compromise the accuracy and reliability of the AHI as a metric, making it challenging to draw direct comparisons between studies and treatment outcomes.<sup>8,9</sup>

## ALTERNATIVE METRICS

To truly understand individual risks and predict treatment outcomes, it is crucial to delve deeper into the intricacies of this condition. Achieving a comprehensive understanding of the complexity of OSA is imperative for advancing precision medicine and personalized care within this field.<sup>7,10-14</sup>

As a response to this enlightened understanding, new, advanced polysomnographic metrics are starting to be developed, like hypoxic burden (HB),<sup>14</sup> pulse wave amplitude drop (PWAD),<sup>15</sup> adjusted AHI (a-AHI), and others, to characterize the full impact of the disease.

The HB aims to capture the total amount of respiratory event-related hypoxemia over the sleep period. The HB is defined as the total area under the respiratory event-related desaturation curve.<sup>15</sup> The HB has a better association with cardiovascular disease than the AHI.<sup>16</sup>

The PWADs are typically observed concomitantly with cortical arousals, which occur spontaneously or after nocturnal events such as sleep apneas/hypopneas and leg movements. The PWAD events reflect transient vasoconstriction followed by vasodilation that occurs in response



to surges in sympathetic activity. This is then followed by a compensatory parasympathetic response.<sup>18</sup> PWA drops associated with respiratory events were correlated to cortical activity, suggesting that PWA drops could be used to indicate the brain's response to respiratory events.<sup>20, 21</sup>

The a-AHI adds an obstruction severity parameter that includes durations of each individual apnea and hypopnea and areas of related desaturation normalized for total time analyzed and provides valuable additional information to the AHI, potentially enhancing the identification of patients with obstructive sleep apnea (OSA) who are at the greatest risk of mortality or cardiovascular complications.<sup>14</sup>

Utilizing these newly derived metrics, extracted from extensive information obtained through polysomnography (PSG), will significantly bolster our ability to identify various obstructive sleep apnea subtypes (OSA). Additionally, these metrics will facilitate the exploration of the underlying mechanisms of the disease in relation to specific comorbidities, leading to the discovery of improved treatments for OSA.

## CONCLUSION

To comprehensively address the patient journey of individuals with sleep apnea and enhance their outcomes, it is imperative to identify more effective tools for personalizing the treatment pathway. It is crucial to reevaluate the approach of condensing an entire night's sleep into a single numerical value, particularly when this value, such as the AHI, exhibits weak correlations with symptoms and clinical outcomes.

While the sleep field has made significant strides in making sleep diagnostic studies more accessible, relying solely on the AHI and even employing various approaches to calculate the AHI raises valid concerns (e.g., using derived, indirect signals that correlate with AHI but do not measure airflow or effort directly). In some cases, the ease and accessibility offered by simplified or oversimplified tests may come at the expense of more detailed and thorough diagnostic assessments.

Though these tests can provide initial screening or basic insights into sleep disorders, they may not capture the intricacies needed for accurate diagnosis and personalized treatment planning. A broader perspective is needed to ensure that sleep apnea care and diagnosis are approached holistically, considering a range of factors beyond a single metric to achieve better patient outcomes.



Snorri Helgason is the Director of Market Access at Nox Medical in Reykjavik, Iceland.

## Interesting reading

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# Endo-phenotypes:

The key to unlocking precision medicine for obstructive sleep apnea

Danny J. Eckert, BAppl Sc, BSc (Hons), PhD, FAASM



LOW  
RESPIRATORY  
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In June 2006, after working and studying for five years with Professors Doug McEvoy and Peter Catcheside at the Adelaide Institute for Sleep Health in South Australia, I completed my Ph.D. thesis in sleep and respiratory physiology. My Ph.D., conducted through the University of Adelaide, focused on the effects of hypoxia on respiratory sensation and reflexes. One day after my thesis submission, I packed my suitcases (and favourite bike as I am an avid cyclist) and headed for Adelaide airport, bound for Salt Lake City, to attend the SLEEP meeting. Thankfully, Doug was traveling with me, so I managed to leverage his baggage allowance to avoid excess baggage fees for my bike and two bags because following the SLEEP meeting, after a brief detour to Bryce Canyon and Zion, I was headed further east to commence my postdoctoral studies in Professor David White's sleep and breathing laboratory at the Brigham and Women's Hospital in Boston.

Dr. White had just received RO1 NIH funding to commence a 4-year project to define the key pathophysiological phenotypes that contribute to obstructive sleep apnea (OSA). I had initially committed to two years in Boston to work on this project. However, as my fellow co-workers, Drs. Andrew Wellman and Amy Jordan, and I soon realised this was no ordinary project, and two years was never going to cut it. Indeed, it was clear that this challenging project that involved performing very detailed physiology measurements to carefully characterize the key anatomical and non-anatomical causes of OSA in approximately one hundred people had the potential to unlock new targets for novel therapies and potentially change the field.

Along with now Professor Amy Jordan, my role in the project was to perform the detailed upper airway physiology measurements of upper airway collapsibility (or the critical closing pressure of the upper airway- Pcrit – pioneered by the Hopkins team), respiratory arousal threshold via the use of an epiglottic pressure sensor and finally, upper airway electromyographic recordings of the pharyngeal dilator muscles using fine-wire intramuscular electrodes that I had learnt how to perform during my Ph.D. studies (see Figure 1).

On a separate night, Andrew Wellman performed measurements of respiratory control, or loop gain, on the cohort using techniques he refined and developed inspired by prior work by Professor Magdy Younes. Five and a half years quickly disappeared when finally, we completed data collection for what felt like a mammoth study.

It was at this point, with another Boston winter looming, that I had the opportunity to return to sunny Australia to develop an OSA respiratory phenotyping sleep research program at Neuroscience Research Australia (NeuRA) in Sydney, where I

spent the first six months analyzing the physiology data that I collected in Boston and writing up what became known as the "OSA phenotyping study."<sup>1</sup>

It has been approximately ten years since our initial discovery paper was published, which has been cited nearly 1000 times. This project opened up multiple new lines of investigation, shaped my research career agenda, and created a lifetime of future work.

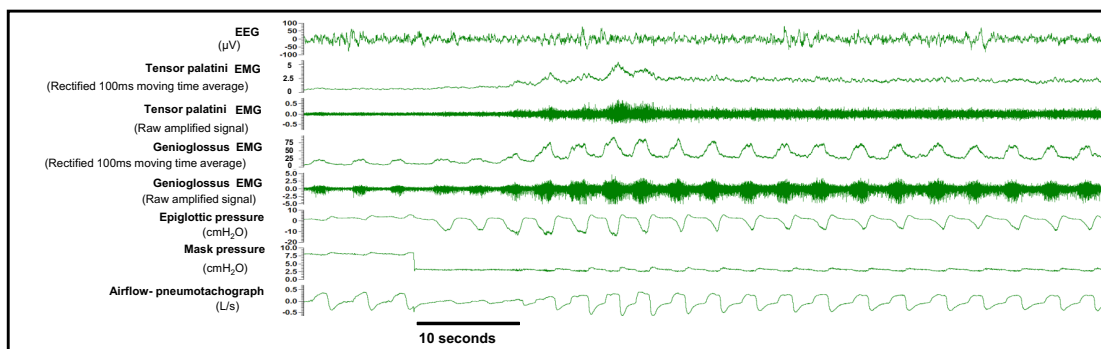
In this piece, ten years on from

the initial discovery paper, I outline the latest knowledge on OSA endo-phenotyping and how these concepts can be applied to realign the diagnostic and therapeutic agenda for OSA towards an individualised, precision medicine approach rather than the current one-size-fits-all, trial, and error model.

## OSA ENDO-PHENOTYPING

When I entered the field nearly 25 years ago, OSA was largely considered an upper airway anatomical problem, although there was a general appreciation that the combined interaction between impaired airway anatomy and inadequate pharyngeal dilator muscle activity underpinned OSA pathogenesis. While this, of course, remains fundamentally very true, we now know that the magnitude of upper airway anatomical impairment in people with OSA varies markedly between individuals (Pcrit ranges between -5 to in excess of +10cmH<sub>2</sub>O).

Indeed, 20% of people with OSA have the same degree of upper airway anatomical impairment as many people who do not have OSA.<sup>1</sup> Furthermore, 70% of people with OSA also have problems with one or more of three non-anatomical contributors to OSA. More than 30% of people with OSA are unable to activate their pharyngeal dilator muscles during sleep. Similarly, in excess of a third, wake up too easily to minor pharyngeal airway narrowing episodes (low respiratory arousal threshold) which further limits the ability to build up enough respiratory stimuli (i.e., CO<sub>2</sub>, hypoxia and negative airway pressure) to recruit the pharyngeal dilator muscles, limits the ability to reach deeper, more stable sleep and the repetitive awakenings triggered by a low arousal threshold feed into the final non-anatomical contributor—respiratory control instability, or high loop gain. High loop gain is also present in about a third of people with OSA. High loop gain is essentially charac-



**FIGURE 1.** Picture of the fine wire intramuscular electrodes used to record genioglossus and tensor palatini electromyographic (EMG) muscle activity during sleep and examples of the recordings captured using this technique and other key physiology signals including electroencephalography (EEG), airflow, mask, and epiglottic pressures.

terized by a respiratory control system that is too sensitive or overreactive to small changes in CO<sub>2</sub>, which leads to destabilization of breathing and feeds the repetitive cycle of OSA.<sup>1</sup>

## APPLICATION OF OSA ENDO-PHENOTYPING TO DEVELOP NEW THERAPIES AND TAILORED TREATMENTS

Identification of each of these mechanistic traits or “OSA endotypes” has not only advanced our understanding of the underlying pathophysiology, but it has also opened new avenues for the development of new therapies and tailored treatment approaches. Application of the Pcrit, Arousal threshold, Loop gain, Muscle response, or PALM scale concept<sup>1,2</sup> aims to apply this physiological model to improve success rates with existing therapies, most of which are directed towards the anatomical cause of OSA.

For example, identifying the individual breakdown of the four OSA endotypes can increase treatment success rates for oral appliance therapy<sup>3</sup> and upper airway surgery.<sup>4</sup> In addition, people with a low arousal threshold endotype are more likely to fail CPAP therapy.<sup>5</sup> OSA endotyping can also help predict patients who respond to newer and emerging therapies that target the impaired pharyngeal muscle endotype, such as hypoglossal nerve stimulation<sup>6</sup> and novel pharmacotherapy, including drug repurposing approaches<sup>7</sup> and the development of new agents.<sup>8</sup> While these proof-of-concept trials have laid the foundation for precision medicine for OSA, the ability to easily and accurately estimate these endotypes in a clinical setting remains a major challenge. However, as highlighted, with the evolution of non-invasive new home monitoring solutions, signal processing, and machine learning techniques, we are getting closer to reaching this goal.

## TRANSLATION OF ENDO-PHENOTYPING INTO THE CLINIC-THE FUTURE OF PRECISION SLEEP MEDICINE FOR OSA

The invasive physiology techniques outlined above that we used to define the different OSA endotypes that contribute to OSA are not feasible for routine clinical use. However, we routinely collect clinical phenotype information that may help guide treatment selection decisions, such as levels of obesity and obesity patterns, age, sex, maxillo-facial structure, symptomology such as sleepiness and insomnia symptoms, and associated disease risk factors such as hypertension.

The use of non-invasive home monitoring technology such as under-mattress sensors has also allowed us to identify new clinical phenotypes, such as high night-to-night variability in OSA severity, which is associated with hypertension.<sup>9</sup> Combining simple clinical phenotypes such as age and BMI with standard outputs from overnight diagnostic polysomnography such as the apnea/hypopnea index, oxygen and arousal parameters, etc. into machine learning models can allow for accurate estimation of OSA endotypes<sup>10</sup> and better prediction or oral appliance therapy treatment response (from 60-100% depending on the outcome definition).<sup>11</sup>

Signal processing techniques<sup>12</sup> from the airflow signal of a diagnostic sleep study can also be used to accurately estimate the endotypes. These technological advances,<sup>13</sup> including smarter use of the existing diagnostic information that we already collect and new clinically feasible endo-phenotyping approaches, show considerable potential

to revolutionize OSA diagnostics and precision medicine-based care for OSA,<sup>14</sup> including combination therapy.<sup>15</sup> Thus, there is considerable hope that scalable clinical implementation of precision medicine for OSA is not too far away from becoming a reality.



Danny Eckert is a Matthew Flinders Professor and Director of the Adelaide Institute for Sleep Health/ Flinders Health and Medical Research Institute Sleep Health, College of Medicine and Public Health, Flinders University, Adelaide, Australia.

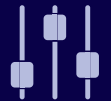
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**AWAKENINGS** from Wake Up Narcolepsy

# Wake Up Narcolepsy - Partnership & Conference

Cara Weaver

**W**ake Up Narcolepsy is excited for the opportunity to partner with BreakAway Media Group! "This new alliance presents an opportunity to provide a regularly appearing column in Sleep Lab Magazine reaching a broader audience and creating more exposure and awareness about narcolepsy," says Monica Gow, Founder and Executive Director of Wake Up Narcolepsy.

Wake Up Narcolepsy (WUN) is a 501(c)(3) nonprofit organization dedicated to driving narcolepsy awareness, education, and research toward improved treatments and a cure. Narcolepsy is a lifelong disorder of the central nervous system, characterized by the brain's inability to control sleep-wake cycles.

Wake Up Narcolepsy's 2023 National Conference & Patient Summit will take place on September 9th, 2023, in Rochester, Minnesota!

## WHAT IS IT?

Our national conference & patient summit is an annual meeting that includes leading speakers in the field, opportunities to form connections, and a separate "teen track" for younger attendees!

## WHO CAN ATTEND?

All attendees are welcome, whether you're a person with narcolepsy



(PWN), a loved one of a PWN, a physician or medical professional or just someone who wants to learn more about the frequently misunderstood disorder!

## WHAT DOES IT COST?

Our event is FREE! Breakfast, lunch, snacks, and parking are also included. The only thing you're responsible for is the planning and cost regarding transportation to the event and booking a hotel room. Visit [tinyurl.com/2023WUNBookRoom](http://tinyurl.com/2023WUNBookRoom) or click here to reserve your room at the hotel!

## WHAT IS THE SCHEDULE?

We're glad you asked! The schedule is being updated as we get closer to the event, but the current one can be seen below.

## WHAT IF I CAN'T MAKE IT TO MINNESOTA?

Don't worry! We know not everyone is in the area, so we're offering remote options for attendance as well. The option for this will be available at the registration link.

We hope to see you there! In the meantime, check out our website and connect with us on social media! Search "Wake Up Narcolepsy" on Instagram, Facebook, Twitter, LinkedIn, YouTube, or Threads! ■



Cara Weaver is the Marketing & Communications Coordinator at Wake Up Narcolepsy and is also a person with Narcolepsy Type 2.

**WAKE UP NARCOLEPSY 2023 CONFERENCE & PATIENT SUMMIT**  
September 9th - The Kahler Grand Hotel, Rochester, MN

<p><b>KEYNOTE SPEAKER</b> 9:05 - 9:50 AM Medications for Narcolepsy: Present &amp; Future <b>MICHAEL H. SILBER, M.B., CH.B</b></p> <p><b>SPEAKER 1</b> 9:50 - 10:35 AM Narcolepsy Symptoms &amp; Diagnosis <b>MITHRI JUNNA, MD</b></p> <p><b>SPEAKER 2</b> 10:45 - 11:30 AM Person with Narcolepsy Panel <b>NICOLE JERAY, THOMAS HECKMASTER</b></p> <p><b>BREAKOUT SESSION 1</b> 12:30 - 1:30 PM Transition of Care from Pediatrics to Adult <b>JULIE BAUGHN, MD</b> Pregnancy, Parenting with Narcolepsy <b>MELISSA LIPFORD, MD</b> Patient Perspective <b>EMILY ROBINSON</b></p>	<p><b>BREAKOUT SESSION 2</b> 1:40 - 2:40 PM Mental Health &amp; Narcolepsy <b>BHANUPRAKASH KOLLA, MD</b> Medical Comorbidities &amp; Narcolepsy <b>DIEGO Z. CARVALHO, MD, MS</b> Comorbid Sleep Disorders &amp; Narcolepsy <b>ERIK ST. LOUIS, MD</b></p> <p><b>INDUSTRY SPEAKERS</b> 2:50 - 3:20 PM</p> <p><b>WUN BREAKOUT SESSION</b> 3:25 - 4:30 PM Youth Breakout <b>HERO ANDERSON</b> Person w/ Narcolepsy Breakout <b>TBA</b> Parents, Loved Ones Breakout <b>ANNE SAMARAWICKRAMA</b></p> <p><b>FREE HYBRID EVENT - JOIN US: IN PERSON OR VIRTUAL</b> BREAKFAST, LUNCH &amp; PARKING INCLUDED</p> <p>THANK YOU TO OUR SPONSORS</p> <p>Avadel Jazz Pharmaceuticals H3 Oxsome Takeda CENTESSA</p> 
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# When to Avoid Recommending Home Sleep Apnea Tests

Joseph Krainin, MD

It will come as no surprise to sleep clinicians that the majority of sleep studies are now being performed at home.<sup>1</sup> The home sleep apnea test (HSAT) revolution has had a paradigm-changing effect on sleep diagnostics. Nevertheless, not all patients are good candidates for HSATs. In this article, I will review considerations for when to refer for an in-lab polysomnogram (PSG) instead of an HSAT.

## HISTORICAL CONSIDERATIONS: ARE THEY STILL VALID?

When the American Academy of Sleep Medicine published the Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea in 2017, the following was written: regarding contraindications for HSATs,

“We recommend that PSG [attended in-laboratory polysomnography], rather than HSAT, be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.”<sup>2</sup>

Interestingly, this is a “STRONG” recommendation despite the quality of evidence indicated as “very weak,” which is curious. To understand the context of this language, one needs to consider that this practice guideline essentially signified the AASM “opening the floodgates” for home sleep testing. In this author’s opinion, concessions to sleep laboratory-owning stakeholders may have trumped the evidence in shaping these contraindications to HSATs.

Furthermore, advances in HSAT technology since 2017 have further mitigated concerns about HSATs in the above populations. For instance, devices like the WatchPAT and NightOwl use an accelerometer-based algorithm to accurately determine sleep time. WatchPAT boasts an 89% correlation between its AHI and that of the gold-standard in-lab PSG.<sup>3</sup> This ability to measure “True Sleep Time,” as Zoll/Itamar calls it, should remove the basis for the insomnia contraindication. With regard to more traditional type 3 HSAT device recordings, through pattern recognition, astute clinicians may discern telltale signs of wakefulness in the raw data, such as irregular RIP belt signal indicative of body movements. Excluding these epochs from analysis increases the accuracy of the report’s respiratory event index (REI), compared with an REI derived by including all hours of recording time in the denominator of the REI calculation as has traditionally been recommended.

Hypoventilation in adults may be demonstrated on HSATs by prolonged periods of continuous, abnormally low oxygen saturation, similar to in-lab PSGs, so there does not seem to be a diagnostic advantage for in-lab sleep studies in this clinical scenario. Fears about central sleep apnea (CSA) can also be allayed. In my experience, traditional type 3

devices like the Philips Alice NightOne and ResMed ApneaLink typically provide excellent clarity on the phenotype of respiratory events. There is a theoretical risk that with type 3 devices, the patient could improperly apply the RIP belt; if it is too loose, the study could over-represent the number of central events. A reasonable approach is to perform a subsequent in-lab PSG if significant CSA is seen on an HST and RIP belt signal is of questionable quality. Newer iterations of the WatchPAT now have an additional sensor to detect chest movement and differentiate between obstructive and central respiratory events.

## COGNITIVE DISORDERS

If the patient has a cognitive disorder like dementia and is unlikely to be able to successfully complete the HSAT, an in-lab sleep study is suggested. However, if the patient has a caregiver to help them set up and perform the test, HSATs may still be an option. An important consideration for performing HSATs in patients with impaired cognition is the possible advantage of using a device type that offers multi-night testing capabilities and the ability to determine if sufficient data was obtained remotely (without physically returning the device to obtain the data) in case the first attempt results in an unsuccessful study. A possible advantage of HSATs in patients with dementia is that these individuals often have irregular sleep schedules due to circadian rhythm degradation from their underlying disease, which can pose a problem when trying to conform to a sleep lab’s typical testing hours.

## SPECIFIC DEVICE CONSIDERATIONS

Some newer HSAT technologies have specific warnings:

The following are listed as WatchPAT “precautions”:

- Use of one of the following medications: alpha blockers, short-acting nitrates (less than 3 hours before the study).
- Permanent pacemaker: atrial pacing or VVI without sinus rhythm.
- Sustained non-sinus cardiac arrhythmias. In the setting of sustained arrhythmia, the WatchPAT’s automated algorithm might exclude some periods of time, resulting in a reduced valid sleep time. A minimum valid sleep time of 90 minutes is required for automated report generation.<sup>4</sup>
- Note: presumably, the NightOwl device, which is also based on PAT technology, has similar contraindications, although no specific information could be found on the parent company’s (ResMed) website.

Sunrise. The following groups should not use the device

- Bearded individuals
- Conditions affecting the rotation of the condyle in the temporomandibular joint.<sup>5</sup>

SleepImage:

- Although there are no signal-specific contraindications, certain conditions such as cardiovascular disease and arterial stiffness can reflect signal-specific differences that can cause variability where it is normal to expect  $\pm 10\%$  differences that can be greater for certain patients based on disease conditions.<sup>6</sup>

## WHEN TO CONDUCT IN-LAB PSG: OTHER SLEEP DISORDERS

If there is an indication to test for another sleep disorder, such as,

- nocturnal seizures
- periodic limb movement disorder (PLMD)
- parasomnias
- central hypersomnias like narcolepsy and idiopathic hypersomnia then HSAT would not be recommended, and an in-lab sleep study is required:

There has been a great leap in HSAT technological innovation since the 2017 AASM practice parameter, and some of the contraindications in that document must be seen in the context of that time and are not necessarily relevant to today's practice. Novel technologies will continue to emerge, offering faster, cheaper, and easier home diagnosis of sleep apnea. It will be important for clinicians to familiarize themselves with the limitations of the individual devices for proper patient selection. The HSAT devices discussed thus far in this article are limited to diagnosing sleep apnea by definition.

In the future, it is likely that something closer to a full PSG can be performed in a home environment. Indeed, the Onera STA (sleep testing

system) has been FDA-cleared<sup>7</sup> after being found to be substantially equivalent to an in-lab testing system. Based on these trends, I predict that in the near future, almost all sleep diagnostics will be performed at home.



*Dr. Joseph Krainin is a board-certified sleep physician and the founder of Singular Sleep (a OneCare Media company), the first-ever online sleep center.*

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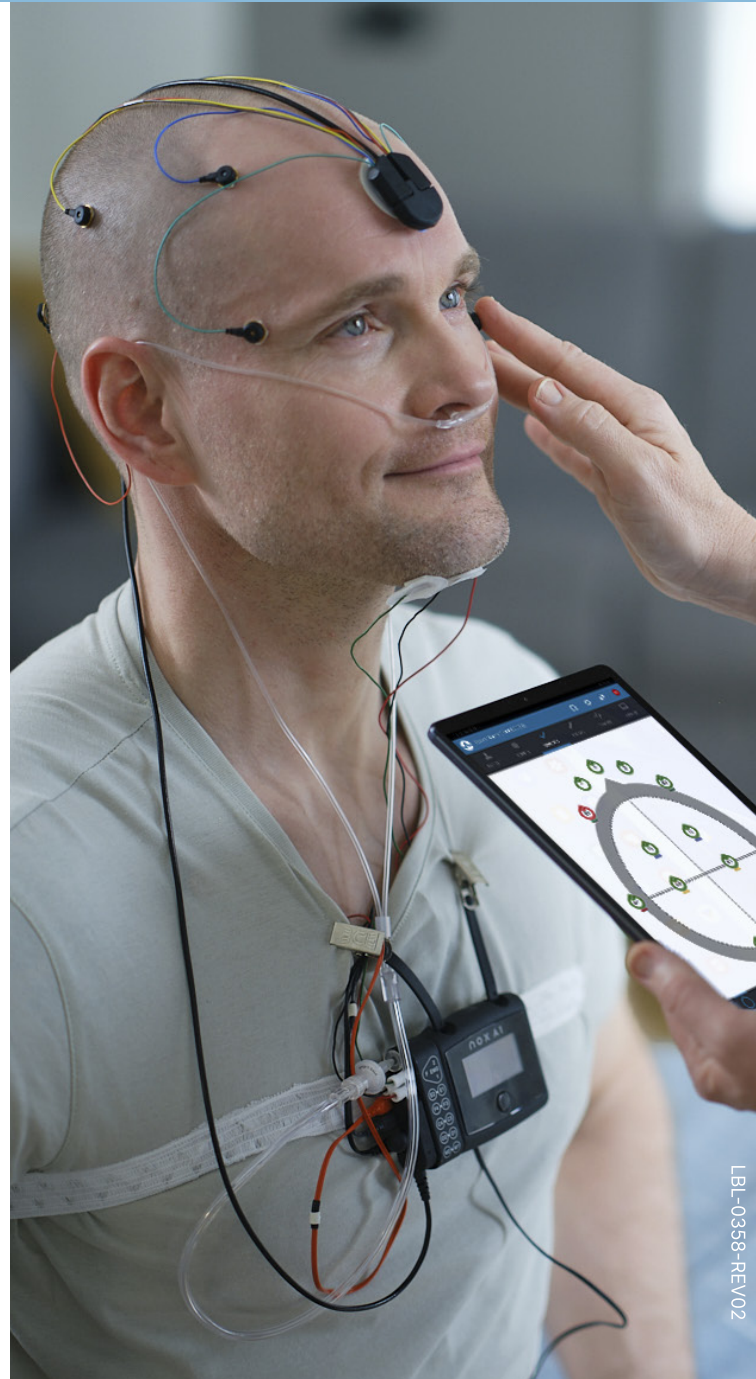
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Evaluation of the feasibility and preference of Nox-A1 type 2 ambulatory device for unattended home sleep test: a randomized crossover study. Sleep Biol. Rhythms 17, 2929 7-304 (2019)



# Back to School: Optimizing Sleep Health in Children

Funke Afolabi-Brown, MD

In children, the benefits of sleep extend beyond their mental and emotional health and are critical to their cognitive function and academic performance.<sup>1</sup> Studies have shown that irregular sleep-wake patterns have been associated with poorer academic performance and delayed circadian timing.<sup>2</sup>

With the demands of modern society, children have become more prone to poor or insufficient sleep. Several factors play a role in negatively impacting children's sleep health, understanding the physical, social, and psychological causes of sleep problems is fundamental to addressing these issues. For example, the use of electronic devices among children across all ages of life, busy schedules, and academic and extracurricular responsibilities can affect the quality and quantity of sleep.<sup>3</sup> Short sleep duration and late sleep onset have been associated with an increased risk of obesity in children and adolescents. Other adverse consequences of poor sleep include inattention and cognitive deficits.<sup>4</sup>

During the school break in the summer and with transitions back to school in the fall, the effects of changing sleep schedules may become more apparent.<sup>5</sup> While a relaxed summer schedule may support increased sleep time overall, these changes may contribute to later bedtimes and short sleep, particularly in younger children who may remain early risers. Adolescents, on the other hand, may have later bedtimes and wake-up times that align with their normal delayed circadian rhythm, but this could subsequently become more extreme, resulting in difficulties adjusting to the school schedules in the fall. Various camps and other activities influence the sleep schedule changes in the summertime. Unfortunately, low-income minority children may not have access to these structured programs due to financial and logistical barriers. A study of sleep patterns of 60 minority school-age children (ages 10 to 14 years) showed that 30–50% of low-income, urban, African American, and Latina girls slept for less time than is optimal for their age during the summertime months.<sup>6</sup>

To optimize sleep in children, we should focus on strategies like ensuring adequate sleep hygiene, consistent sleep routines, sufficient sleep quantity and timing, and promptly identifying and treating various sleep disorders. In this review, we discuss the importance of optimizing sleep health in school-age children and getting them ready for school.

## UNDERSTANDING SLEEP HEALTH

### Definition and Components of Sleep Health

Sleep health in children refers to the overall quality, duration, and regularity of sleep essential for their physical, cognitive, and emotional well-being.<sup>7</sup> The interplay of the various components contributes to optimal sleep. Firstly, sleep duration refers to the total amount of

sleep a child gets in a 24-hour period, which varies depending on age. For instance, infants typically require around 14-17 hours of sleep, school-aged children may need 9-11 hours, and adolescents require 8-10 hours.<sup>8</sup> Sleep quality refers to the uninterrupted, restorative nature of sleep and can be influenced by factors such as the sleep environment, physical, behavioral, and psychological factors. Finally, sleep regularity involves establishing consistent sleep-wake schedules, promoting a predictable routine that aligns with a child's natural circadian rhythm. Optimizing these components will ensure adequate sleep in school-age children.

## ROLE OF SLEEP IN COGNITIVE FUNCTION AND LEARNING

Sleep plays a crucial role in cognitive function and learning. During sleep, the brain consolidates and processes information acquired throughout the day, allowing for optimal learning and memory formation. Sleep is an active process as it is while we sleep that the brain goes through different stages, including nonrapid eye movement (NREM) and rapid eye movement (REM) sleep, each contributing to distinct cognitive processes. NREM sleep is further divided into Stages 1 to 3 (N1, N2, N3). During NREM sleep, researchers have postulated that memory consolidation occurs, facilitating the transfer of information from short-term to long-term memory. NREM sleep is also responsible for physical and mental restoration, hormone regulation, metabolism, and overall well-being. For instance, during this stage of sleep, growth hormone is also released, which promotes tissue growth, repair, regeneration, and a strengthened immune system.

REM sleep, a stage of increased brain activity, has been associated with integrating new information into existing neural networks. REM sleep is also associated with emotional regulation and processing and plays a crucial role in brain development and growth.

Poor sleep is associated with impaired attention, concentration, problem-solving, and decision-making abilities, highlighting the importance of sleep in these crucial learning processes. In addition, children with poor sleep are more likely to exhibit behavioral problems and emotion dysregulation, impaired immune function, and develop excessive weight gain and obesity. Insufficient sleep in children can also increase accident risk, risk-taking behaviors, and suicidality.<sup>9</sup>

## FACTORS INFLUENCING SLEEP HEALTH IN STUDENTS

Factors influencing sleep health in students can be classified into biological, environmental, and behavioral.

### Biological Factors





A systematic review of studies examining associations of neighborhood socioeconomic, social, and physical characteristics with sleep outcomes (e.g., duration, quality, variability, timing, problems, diagnoses) among children and adolescents demonstrated that poor neighborhood environments were associated with worse sleep outcomes.<sup>12</sup>

### Behavioral/ Social Factors

1. The two-process model of sleep: Two processes regulate the sleep-wake cycle; the circadian rhythm (Process C) and the homeostatic process (Process S).<sup>10</sup> The circadian rhythm refers to the internal biological clock that regulates various bodily functions, including the sleep-wake cycle. In children, this rhythm undergoes significant development and maturation with an erratic polyphasic sleep-wake schedule in early infancy, and sleep consolidates with age as their circadian rhythm and melatonin production stabilize. The homeostatic drive (Process S) represents the body's internal system that controls the need for sleep based on the duration and quality of prior wakefulness. As the day progresses, this sleep drive intensifies, eventually leading to sleepiness. Factors, such as light exposure, mealtimes, physical activity, daily routines, and social interactions, influence our sleep-wake cycle. School schedules contribute to these processes significantly. For instance, early school start times in teenagers, waking at a time unaligned with their circadian rhythms, coupled with the burden of schoolwork and other responsibilities, will lead to insufficient sleep.

2. Puberty and Hormonal Changes: During puberty, the body undergoes various physiological and hormonal transitions, which can disrupt sleep-wake cycles. Adolescents often experience a shift in their circadian rhythm, resulting in a natural tendency to stay up later at night and wake up later in the morning.<sup>11</sup> This delayed sleep onset can clash with societal demands, such as early school start times, leading to insufficient sleep. Hormonal fluctuations, particularly increased sex hormones like estrogen and testosterone, can also affect sleep by causing disruptions in sleep architecture, resulting in difficulties falling asleep, more frequent awakenings, and a decrease in deep, restorative sleep.

### Environmental Factors

**Bedroom Environment and Sleep Hygiene:** Optimal bedroom environments can impact sleep quality significantly. For example, comfortable mattresses and pillows and cool temperatures, and dark room environments can enhance sleep. External light and noise pollution, such as living in a noisy neighborhood, can lead to sleep fragmentation and poor-quality sleep.<sup>12</sup>

2. Homework and academic pressure: The burden of excessive homework and academic expectations can create a cycle of stress and sleep deprivation. When children are overwhelmed with assignments and study obligations, they often sacrifice their sleep to meet deadlines, disrupting sleep schedules. Insufficient sleep negatively affects their cognitive function, memory consolidation, and attention span. It can also lead to increased irritability, reduced motivation, and diminished academic performance.

3. School schedules: During the school year, most children, particularly teenagers, may experience sleep deprivation due to busy schedules and early school times. During the summer, their sleep tends to change, with many contributory factors, including a more laid-back routine.<sup>5</sup> These changes make it more challenging to adjust to the school schedule in the fall, and most children need help returning to their routines.

### Back to School Transition and Sleep Health

The transitions from summer break – when children typically have more relaxed schedules and later wake-up times – to the demanding pace of the school year can pose a challenge. Waiting till the end of summer break before readjusting their sleep may result in a more stressful transition. A plan of action before starting the school year will promote an easier transition.

### Sleep Schedule Adjustments

1. Start with a conversation: Our kids, especially older ones, need buy-in regarding changes in their sleep habits. Before making changes, it is essential to have discussions with them about the importance of sleep and the amount of sleep they need.

2. Gradually transition to the school schedule: Adjust their sleep schedule gradually a week or two before school starts. Shift their bedtime and wake-up time by 15 minutes every few days until they reach their desired schedule. Young elementary school children may not require significant adjustments, and as such, this transition may only take a few days, while adolescents may need up to two weeks.

3. Light exposure in the morning: Early morning exposure to light

will help facilitate circadian shifts. Spending some moments outdoors and opening the blinds to natural light will accomplish this.

4. **Consistency:** Once the schedule transition is complete, consistency is key. Maintain a consistent bedtime and wake-up time, even on weekends, to help regulate your children's internal body clock while ensuring adequate sleep.

5. **Be patient:** Parents should understand that it takes time for children to adjust to the new sleep schedule. Be patient and understanding during this transition period.

## STRATEGIES FOR PROMOTING HEALTHY SLEEP HABITS

Getting the kids ready for back to school is vital, but equally important is to keep them sleeping well throughout the year. Below are suggestions to help.

1. **Consistent bedtime routines:** Establishing a consistent bedtime routine helps signal time to wind down and prepare for sleep.<sup>14</sup> This routine can include taking a warm bath, reading a book, or listening to calming music.

2. **Create a sleep-friendly bedroom environment:** Ensure the bedroom is cool, dark, and noise free. Warmer temperatures, background noise, and light can contribute to restless and nonrestorative sleep. Since early in the school year, it gets dark later and lighter much earlier, consider adding blackout shades to their bedroom to avoid any light pollution, as this could send wakefulness signals and suppress melatonin production.

3. **Limiting technology use before bedtime:** Due to the impact of electronic devices on sleep, including blue light suppressing effect and increased cognitive arousal, limit screen time about an hour before bed. Devices should be kept out of the room in a central location for charging.

4. **Avoid caffeine use:** Caffeine is a stimulant that can disrupt sleep and prolong sleep onset. Limit caffeinated beverages, including coffee, tea, sodas, and energy drinks.

5. **Recognize if sleep disorders play a role:** For children with difficulties adjusting to these schedule changes or experiencing unrefreshing sleep despite adequate sleep opportunities, this may raise concerns for sleep disorders such as sleep apnea, restless legs syndrome, insomnia or narcolepsy.

### Recognizing and detecting sleep disorders

Sleep problems in children are often multifactorial and can contribute to poor sleep, excessive daytime sleepiness, behavioral and mood changes as well as poor academic performance. Pediatric sleep issues can range from frequent nighttime awakenings to insomnia, sleep-related breathing disorders, parasomnias, circadian rhythm disorders, and sleep-related movement disorders. The reported prevalence of sleep disorders in children is as high as 25%.<sup>15</sup> Commonly recognized sleep disorders based on the third edition of The International Classification of Sleep Disorders include:

1. **Insomnia:** Characterized by difficulty falling asleep, staying asleep, or experiencing non-restorative sleep, leading to daytime impairment or distress. It is the most common sleep disorder in children, with a reported prevalence of 10 to 25% of the pediatric population.

2. **Obstructive sleep apnea (OSA):** OSA refers to difficulties breathing due to the collapse of the upper airway. In children, the etiology of

OSA is multifactorial, including enlarged tonsils and adenoids, obesity, craniofacial abnormalities, and genetic factors like trisomy 21.

3. **Restless legs syndrome:** Also known as Willis-Ekbom disease, is a neurological condition characterized by an irresistible urge to move the legs, often accompanied by uncomfortable or unpleasant sensations and can prolong sleep onset.

4. **Narcolepsy:** This is a neurological disorder characterized by an uncontrollable urge to sleep and includes other symptoms like cataplexy, sleep paralysis, hypnagogic hallucinations, and fragmented sleep. The diagnosis of narcolepsy is often delayed due to the variable presentation, lack of familiarity with the symptoms as well as limited access to appropriate testing.<sup>16</sup>

5. **Delayed sleep-wake phase syndrome (DSPS):** This condition is frequently seen in adolescents and is characterized by a persistent and significant delay in the timing of the major sleep period. People with DSPS tend to fall asleep and wake at a time not considered typical for the general population.

6. **Parasomnias:** Parasomnias are sleep disorders that involve abnormal behaviors, movements, or experiences during sleep. These disorders are common in children and can affect their sleep quality and overall well-being. Examples include sleepwalking, sleep terrors, sleep-related eating disorders, and confusional arousals.

### Strategies for promoting sleep health in Schools

Promoting sleep health is a collective effort involving parents, educators, and the broader community. By prioritizing sleep, schools can create an environment that supports children's well-being and enhances their learning experiences. A few ways by which schools and educators can help optimize sleep health include.

1. **Advocate for delayed school start times:** Sleep deprivation is prevalent in adolescents, and one of the contributors is early school start times. Robust research demonstrates that later school start times increase adolescent sleep duration, which is associated with better health, executive function, and performance. While some school districts have adopted later school start times, there has been resistance to this intervention in various regions in the US. There is a need to continue advocating for delayed school start times as it will ensure adolescents get sufficient sleep and decrease known morbidity and burden of sleep loss.<sup>17</sup> (Afolabi-Brown et al. 2022).

2. **Incorporate sleep health as part of the school curriculum:** Providing sleep health education to teachers, administrators, and students is essential in raising awareness on this important topic and its relationship to student health and performance.

3. **Balanced homework and assignments in a way that gives students ample sleep opportunities.**

4. **Encourage and promote increased physical and outdoor time to promote better sleep.**

5. **Communicate resources, tips, and research articles to parents to help support their children's sleep health.**

## CONCLUSION

Optimizing sleep in school-age children is a fundamental aspect of their overall well-being and academic success. By recognizing the importance of sleep and implementing appropriate strategies, we can help optimize their health and empower them to reach their full potential. Promoting sleep health among school-age children will re-



quire a collaborative effort with various stakeholders, including parents, educators, and policymakers.

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## WEBINAR:

# Transforming OSA Compliance with TherapistAssist™ Jeanie

**WHEN: September 12, 2023  
2:00 PM – 3:00 PM EST**

**WHERE: Virtual**

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# Avoiding Bad Impressions: The Critical Role of Qualified Dentists

Mitchell Levine, DMD, MS

For patients diagnosed with obstructive sleep apnea (OSA), there are more therapeutic options available than ever before. Having a variety of treatment options is normally optimal for patient-centered care. However, some sleep apnea treatment options minimize the role of healthcare providers and ultimately put patients at risk.

There has been an emergence of sleep apnea care models that use at-home impression kits to make oral appliances. These models promise increased convenience and symptom relief but remove a trained clinician from the equation. Patients may be enticed by convenience or cost and believe that these treatment options— even under the guidance of telemedicine or teledentistry— meet the standard of care for apnea symptom abatement.

However, proper oral appliance therapy (OAT) occurs through the collaboration between a patient and a Qualified Dentist to achieve an appropriate standard of care. A critical in-person evaluation allows the clinician to review the patient's health history, take accurate impressions, then develop a custom-fit device and a personalized treatment plan.

## THE CRITICAL ROLE OF A QUALIFIED DENTIST IN ORAL APPLIANCE OUTCOMES

To best serve their patients, it's important for providers to openly discuss the reasons why patients may want to self-treat—or not treat—their apnea and help them understand the complexities involved in managing the disorder and the positive impact of well-tolerated and well-executed treatment.

While hundreds of different oral devices are available to manage mild to moderate sleep apnea, only a handful are best suited for any given patient. Qualified Dentists have the training to evaluate a patient's dentition, oral tissues, and structures to identify all possible contraindications and determine which appliance is the most appropriate.

There are numerous decision-making events that occur in the design, fabrication, delivery, calibration, and ongoing maintenance of a device for sleep apnea over time. Patients alone simply cannot manage the calibration schedule or discern appropriate remedies for resultant side effects. Further, without a Qualified Dentist managing the process at follow-up visits, no one is informed when patients abandon treatment, subjecting them to ongoing apnea risks.

## THE IMPORTANCE OF MAKING A GOOD IMPRESSION

Accurate impressions are essential to a properly fitted and effective oral appliance for OSA treatment. A compromised impression—

whether taken by an adjunct healthcare provider unfamiliar with the technique or by the patient themselves—can miss important dental structures that are essential to proper appliance fitting and functioning of the appliance. Patients simply do not have the necessary training to take impressions and measurements to ensure the accurate fit and necessary comfort of a custom-fabricated oral appliance.

A lack of precision at the impression stage significantly increases the risk of side effects for the patient, such as tissue ulceration, unintended tooth mobility, tooth loss, pain, discomfort, and temporomandibular joint problems.

## INCREASING REGULATIONS FOR CLINICIANS

As new models of care that utilize do-it-yourself impressions increase in popularity, regulations have begun to follow suit. In fact, many states have implemented regulations that allow only a dentist to take impressions for an oral appliance; in some states, even a dental assistant working under the supervision of a dentist is restricted from taking impressions.

States are also recognizing the significance of having a relationship with a patient prior to the use of teledentistry. For example, Nevada recently wrote into law that dentists cannot use teledentistry unless they have had specific training and have previously conducted an in-person exam. The exceptions to this regulation would be in the event of an emergency, a public health initiative, or to diagnose an orthodontic issue prior to an in-person exam.

## THE CRITICAL ROLE OF QUALIFIED DENTISTS IN ORAL APPLIANCE OUTCOMES

Neither retailers nor manufacturers in the do-it-yourself dental impressions industry are responsible for patient outcomes, leaving patients at risk for serious health issues. That's why proper multidisciplinary management for sleep apnea is key. From impressions through maintenance— OAT for OSA is best left to the qualified professionals. ■



*Mitchell Levine, DMD, MS, is the president of the American Academy of Dental Sleep Medicine and a diplomate of the American Board of Dental Sleep Medicine. Dr. Levine is also an associate professor of orthodontics at St. Louis University.*

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# It's Not All Negative for OSA with Negative Pressure

Kingman Strohl, MD

**O**bststructive sleep apnea (OSA) is effectively managed by positive airway pressure (PAP), applied to the nose and/or mouth. The principle of PAP is to inflate the critical region of closure in the upper airway, usually at the base of the tongue or the uvula. The effective property of the airway is the elasticity of the tube. This important property permits us to eat, talk and sing while awake, but a detriment if all you want to do is keep the airway open at night. Those in the sleep laboratory who titrate PAP see the effectiveness of changes of increasing pressure during a titration. The pharyngeal airway during sleep is mechanically acting like a collapsible tube within a rigid box, such that providing a positive internal pressure stabilizes some part of the collapsible airway.

However, if this is true, then negative pressure surrounding the airway in this rigid box might be useful as an alternative option to open the airway

in those who snore or have sleep apnea. The practicality of this approach was demonstrated in two studies. In one study in 1990, vacuum pressure was applied eternally to the neck in spontaneously breathing anesthetized dogs.<sup>1</sup> Upper airway resistance was measured using a cuirass applied from the jaw to the chest to provide negative pressure (-2 to -20). This range resulted in a progressive, although not linear, fall in resistance without causing a change in respiratory drive or timing.

The first demonstration in humans using negative external pressure to the submental region was done under anesthesia to record the collapsibility of the passive pharynx and also addressed the potential influence of obesity.<sup>2</sup> Submental negative pressure in ten obese and ten nonobese adult women was measured under general anesthesia and induced paralysis. Negative pressure was applied through the use of a silicone collar covering the entire submental region and a vacuum

pump. Submental negative pressure decreased observed collapsibility at the retropalatal and retroglottal airway but only in the nonobese group. No such changes were found in obese subjects.

Now that the feasibility of a negative pressure produced in a collar around the human neck could be effective in reducing obstruction, at least in some individuals, attention turned to other examples of where it could be demonstrated. One device currently marketed (aerFree, Sommetrics, Rancho Bernardo CA, DEN140024) lessens respiratory impairment during screening colonoscopy.<sup>3</sup> In patients placed on the device -35cmH<sub>2</sub>O could reduce the decline from baseline of >4% in oxygen saturation, and/or apnea lasting ≥20 seconds. During screening colonoscopy, sedation-related respiratory impairment is significantly reduced by continuous negative external pressure (cNEP) (ClinicalTrials.gov NCT01895062).

Sommetrics, who developed the collar for use in moderate anesthesia subsequently developed a collar for providing cNEP with the intent of testing whether this approach might be effective in treating OSA.<sup>4</sup> In a prospective, open-label pilot study in 15 subjects fitted with a first-generation device, 87% were responders to and nine had an excellent response in reducing their apnea hypopnea index (AHI) <5 per hour, and four had a partial response (AHI <50% baseline and <15 events/h). The range of AHI and BMI were limited but feasibility was demonstrated for this application. Three minor, self-limited adverse events occurred, which appeared related to contact pressure of the collar on the skin.

A recently published prospective, open-label pilot study<sup>5</sup> included 28 people with moderate OSA AHI 15 events/h ≤ AHI ≤30 events/h and each participant tested at least two of six available cNEP devices which could vary the negative pressure from -10 to -35cmH<sub>2</sub>O during sleep periods of at least 2 hours (NCT04718142). Approximately 71% responded to therapy with half of those having an AHI ≤5/h, and 21% showing an AHI ≤50% baseline. For the 20 responders, the therapy reduced the portion of total sleep time when peripheral oxygen saturation <90% and improved minimum pulse oximetry oxygen saturation to above 90%. Six patients experienced a minor, self-limited adverse event. Twenty-six participants (93%) stated that they would use cNEP nightly.

There is currently an on-going pivotal trial on the use of a second-generation collar called Study Using Negative Pressure to Reduce Apnea (SUPRA). For this trial, Sommetrics designed an improved collar, in three sizes, to deploy a standardized protocol developed in collaboration with the United States Food and Drug Administration (FDA) (NCT04861038). It is designed to rigorously test the safety, efficacy, and durability of an aerSleep II system in subjects who had a prior diagnosis of OSA and would not or did not tolerate CPAP. Other requirements are a BMI <42, age >18 years, and AHI at baseline of 15-50/hr. as measured over two nights of home sleep testing (Nox T3s, Nox Medical). This is the first OSA therapy study to address the unpredictability of the pandemic era by trying to minimize person-to-person contact by limiting in-person visits to collar demonstration, fit and download of use, as well as internet deployment of virtual visits, staff coaching, and electronic patient-reported outcome measurements (ePRO). Two-night home sleep testing was performed to document effectiveness and durability of the response. One to two weeks after collar fitting, and then at 12 and 24 weeks. The primary endpoint is AHI, with a change from baseline to <5 or at least 50% to a value less than 20/hr.

Subjects will be enrolled at up to fifteen study sites in the United

States to ensure that approximately 79 subjects who are termed initial responders can be evaluated after 24 weeks of home use with the aerSleep II device. After a 1–2 week period of acclimation, subjects will have a second HST (HST #2). Initial responders with a ≥50% reduction in AHI from baseline with an AHI <20/hour will be continued on home treatment. Non-responders will be discontinued from the study.

The primary endpoints are a sustained response in a majority of those on aerSleep II therapy at 24 weeks, as defined as a change of at least 50% of their baseline AHI with an AHI rate less than 20 per hour at the final home sleep test at 24 weeks. Primary safety items related to adverse device effects. Secondary endpoints are the change in ODI, the AHI change from baseline for all subjects that acclimate to the aerSleep II device, the proportion of subjects that acclimate to the device that exhibit a change in AHI after 24 weeks of home use with the aerSleep II device, the change in self-reported sleep disturbance from baseline as measured by Patient-Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance and Sleep Disturbance 8b questionnaires, and perceived change from baseline as measured by the Patient Global Impression Scale questionnaire.

Alternatives in the treatment of OSA continue to evolve from the first use of PAP as an alternative to tracheostomy and then uvulopalatopharyngoplasty. New technologies such as hypoglossal nerve stimulation and improvements on oral appliance therapy have a place in the therapeutic regimen.

The recognition that OSA is common, serious and chronic condition is becoming more accepted. It is so common as to justify investment in improved therapy and patient management. The “care that fits” model will continue to evolve and reach clinical use through such pathways of identifying the underlying physiology and improved understanding of the mechanisms of therapy. OSA is more complicated than we think, and no one approach will work or be acceptable for treating this chronic disorder.



Kingman Strohl, MD, is a pulmonary/sleep physician and Professor of Medicine, at University Hospitals Cleveland Medical Center, and the Director of the Case Sleep Fellowship at Case Western Reserve University.

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# CPAP Alternative: Oral Negative Pressure Device

Nathan Costiuc, MSN, APRN, FNP-BC

To provide as many avenues for obstructive sleep apnea (OSA) therapy as possible, the clinical sleep community has begun considering using negative pressure therapy for OSA treatment. Standard treatment for moderate to severe OSA is, of course, positive airway pressure (PAP). PAP can also be used with mild OSA with other symptoms such as excessive sleepiness and hypertension. But PAP adherence rates are not always favorable.

As a result, alternative treatment options, such as hypoglossal nerve stimulation (HGNS) and oral appliance therapy (OAT), have been explored. However, all these have pros and cons, leading to a greater and greater need for various therapeutic devices that support a plethora of unique patient profiles. The iNAP® Sleep Therapy System, a newly developed intraoral pressure gradient therapy (IPGT) device, presents itself as a promising alternative treatment for OSA.

## The iNAP Sleep Therapy System

The iNAP device is an intraoral pressure gradient therapy system designed to stabilize the upper airway during sleep by introducing negative pressure. The system consists of an oral interface that fits into the oral cavity, a tube set that terminates in a saliva container, and a negative pressure console. During sleep, negative pressure is applied through the oral interface, pulling the tongue, soft palate, and uvula forward to maintain airway stability.

The device has a set negative pressure between a range of -27 cmH<sub>2</sub>O to -122 cmH<sub>2</sub>O. The pressure setting can be remotely adjusted for better comfort and efficiency based on the patient's response. Once the target pressure is achieved, the suction pump stops, making the device totally silent and energy efficient, allowing the device to only run on battery power. The initial FDA (Class II) clearance was received in May 2020, and an extension to enable pressure changes was received in June 2023.

"The iNAP One Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment choice" (K220907) and has a companion app for providers and patients to have a direct view to review adherence information. It is cleared for all levels of OSA severity.

## Research

Somnics lists the iNAP system as "featured in more than 35 publications in peer-reviewed journals." One Taiwan-based study with a sample size of 32 patients with moderate to severe obstructive sleep apnea revealed a reduction in the baseline apnea-hypopnea index (AHI) from 32.0 events/h to 8.7 events/h while demonstrating superior comfort compared to previous oral pressure therapy devices.<sup>1</sup>

Another study, including nine patients (five males and four females) with mild to moderate OSA, showed a decrease in AHI from 17.2 events per hour to 12.7 events per hour during iNAP treatment ( $p < 0.01$ ). Furthermore, the iNAP device showed a significant reduction in wakefulness after sleep onset (WASO) on the initial treatment night compared to the baseline.<sup>2</sup>

## Options for the Future

The iNAP® Sleep Therapy System, an intraoral pressure gradient therapy device, has established its potential as an alternative treatment for OSA patients to improve OSA severity effectively. Although cleared for all levels of OSA, patient selection criteria for this form of therapy are not yet solidified. Still, the existence of negative oral pressure therapy offers a new and exciting opportunity for patients and providers.

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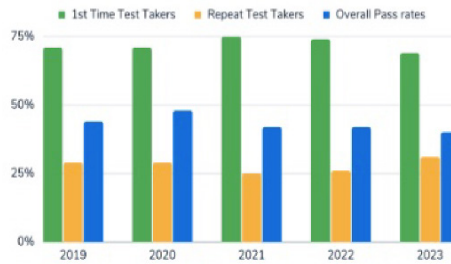
# Explaining The RPSGT Exam Pass Rate

Andrea Ramberg, MS, CCSH, RPSGT, and Michael McLeland, Ph.D., RPSGT

A question the BRPT is often asked is, "What is the RPSGT exam pass rate?" Well, it depends, and it is complicated. In first-time test-takers, the average pass rate is 72 percent, and the average pass rate for repeat test-takers is 28 percent, which significantly impacts the overall pass rate, bringing it down to 43 percent. According to our team of psychometric analysts at Pearson VUE, our test development partner, individuals who take any exam and fail three or more times fall into a pass-rate range as low as the bottom 10%.

Unfortunately, a low pass rate can paint a very skewed picture of the overall difficulty of an exam. Regarding the difficulty of the RPSGT exam, we have both board members and staff who have been a part of the five-year National Commission for Certifying Agencies (NCCA) reaccreditation cycle two to three times. We've analyzed the post-test data and found that the exam has not changed in difficulty to any notable degree in the past 10-15

RPSGT PASS RATES



1st Time Test Takers Average  
72%

Repeat Test Takers Average  
28%

Overall Pass Rate Average  
43%

years. **Figure 1** compares other exam-type pass rates for first-time and repeat test takers.<sup>1-3</sup>

The RPSGT credential is the only internationally recognized credential for sleep technologists that is accredited by the NCCA. The RPSGT exam pass rate challenge is a fairly complex issue to navi-





gate and has been much debated over the years by multiple organizations. The methodology used for setting the passing score for a credentialing exam is based on very rigorous standards set by the NCCA that the BRPT and its Exam Development Committee must strictly follow, or we risk losing accreditation. Therefore, the exam standard-setting process and determination of the "cut score" (the minimum score required to pass the exam) follow well-established best practices and NCCA standards.

Even if it were permissible and statistically valid, arbitrarily lowering the cut score in an effort to increase the overall pass rate percentage would allow individuals into the field who are not minimally competent. Patients – and the entire sleep care team – as well as our credentialed colleagues, deserve better than that.

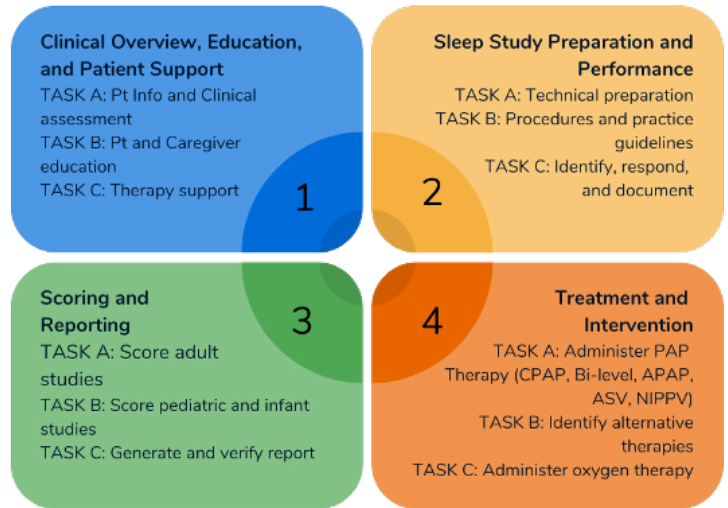
Further, once the NCCA accredits the RPSGT credential, the standards are routinely monitored, and the BRPT is required to submit a Quality Assurance (QA) plan that proves that the BRPT continues to remain in compliance.

## UNDERSTANDING THE ROLE OF THE PSG EDUCATIONAL PROGRAMS

All educational programs designed specifically for sleep technologists – STAR designated, CAAHEP, and CoARC – follow their own standards and reporting requirements. The BRPT has been told on multiple occasions that the schools and programs rightfully do not "teach to the RPSGT exam." They have the latitude to develop their own curriculum, independent of the BRPT and the exam we offer. Further, per NCCA requirements, the BRPT is prohibited from involvement with education programs that lead toward certification. In other words, there is a "firewall" standard that NCCA enforces to ensure the certification organization is not exerting undue influence over education programs that lead to certification.

It is also important to note that the total number of exam candidates who graduate from a PSG program each year who actually sit for the RPSGT exam is fairly small. However, the BRPT provides these programs with data on the exam domains in which their students are struggling, and if programs choose, they may alter their curriculum to better focus on those areas. We also advise anyone who did not pass the exam on their first attempt to refrain from applying for another retake right away but to instead focus on their performance within each domain and to study accordingly. **(Figure 3)**

The BRPT, and the like-minded organizations we partner with, care very much about getting qualified sleep technologists into the



field. For example, we are working with the AAST and the AASM on a "Choose Sleep" initiative to help draw more talent to the field. We also work closely with Health Occupations Students of America (HOSA), a global student-led organization whose mission is to promote career opportunities in the healthcare industry.

Finally, while the BRPT is not an educational entity, it is deeply committed to offering resources and guidance to RPSGT candidates that will position them for success on the exam. In doing so, we offer a number of tools to help candidates prepare for the RPSGT exam, including a comprehensive candidate handbook and study guide, an online practice exam, study and exam test-taking tips, and a list of primary reference materials to assist applicants sitting for the exam. ■

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# Understanding NCCA Accreditation

The National Commission For Certifying Agencies (NCCA) was created in 1987 by the Institute for Credentialing Excellence (ICE) – formerly the National Organization for Competency Assurance (NOCA) – to help ensure the health, welfare, and safety of the public through the accreditation of a variety of certification programs/organizations that assess professional competence. NCCA accredits over 200 of the leading credentialing examinations in the United States, including exams in many of the nursing and other allied health disciplines.

In the professional credentialing industry, NCCA accreditation represents compliance with best credentialing industry practices. Every five years, the BRPT must apply to have the RPSGT credential reaccredited. In 2022, the RPSGT credential received its accreditation for the next five years.



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