

January 25, 2022

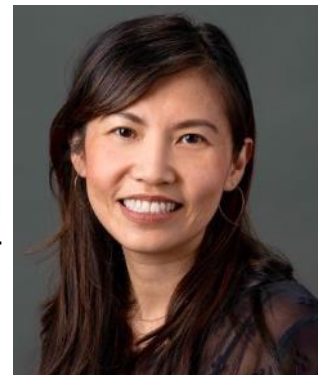


CTS INSPIRATIONS

CTS NEWS

President's Message

As president for 2022, I am thrilled to lead CTS into its 81st year! I first became acquainted with CTS as a faculty speaker for the southern California educational conference in San Diego, and soon after, became deeply involved and served as the Chair of Education Committee and the annual northern California educational conference. I then accepted a position on the Executive Committee. What a wonderful journey it has been, and it is with such pride and honor that I serve as president of CTS. My commitment to CTS is to advance our mission by promoting California lung health through advocacy, education, and to advancing the science and practice of pulmonary, critical care, and sleep medicine. As one of the oldest and largest ATS chapters, CTS continues to lead the respiratory community in innovation, education, inclusion, and diversity. An important goal as president is to engage young faculty and medical providers to become active members and to join the CTS family. CTS provides networking, sponsorship, and mentorship for new and returning members. It is an amazing resource and venue for young clinical faculty striving to pursue academic achievements outside of their respective institutions.



The year of 2022 continues to be a challenging year with COVID-19 still infiltrating our daily professional and personal lives. Our much-anticipated annual northern California educational conference is scheduled for March 11-12 in the beautiful city of Monterey. We are continuing to closely monitor the "Omicron" situation and will update our members and community as the situation evolves. It is my sincere hope to be able to meet our attendees, including returning and new members in person and extend a warm welcome to each of you.

Sincerely

A handwritten signature in black ink that reads "Michelle Cao". The signature is fluid and cursive, with a long, sweeping underline.

Michelle Cao, DO
Stanford University

EDITOR'S NOTE

I love this photo. It was taken in JAN 2019, during CTS' last in person conference at the end of a hugely successful poster symposium. There were fellows and faculty from all over the state. Everyone looks so *happy*.

Come join us in March. The Education Committee puts a lot of effort into designing clinically relevant, stimulating sessions with engaging speakers. What makes CTS special is not just our community, our love of science and education, or dedication to excellence, it's our shared passion for making other people's lives better.



It is more important to question than to agree. (Paul Quinton, PhD)

Hypoglossal Nerve Stimulation

Christopher N. Schmickl MD, PhD; Brandon Nokes MD; Andrew Vahabzadeh-Hagh MD
University of California, San Diego

Background

At least 10% of the US population has obstructive sleep apnea (OSA),¹ which is characterized by a recurrent collapse of the upper airway during sleep causing arousals and drops in oxygen saturation, which can ultimately lead to severe neurocognitive (e.g., excessive sleepiness, memory issues, car accidents) and cardio-vascular (e.g., high blood pressure, heart attack, stroke) sequelae.² The first-line therapy is continuous positive airway pressure (CPAP), which stents open the upper airway by providing pressurized air via a nasal or oro-nasal interface. CPAP is highly efficacious, but up to 50% of patients are unable to tolerate it long-term.³ Alternative therapy options are limited, and it is a clinical reality that many patients remain untreated.

In 2014, the US Food and Drug Administration (FDA) approved the first—and so far the only—hypoglossal nerve stimulation (HNS) device as a novel treatment for select patients with OSA who refuse/fail CPAP and meet the criteria in **Table 1**.⁴ Criteria include an AHI > 15. HNS is normally not paid for in persons with a BMI > 32. The HNS device is produced by Inspire Systems Inc (Maple Grove, MN) and is similar to a cardiac pacemaker. It is implanted in a pocket under the skin located in the right upper chest (**Figure 1**). The device is off during the day but can be switched on by the patient at bedtime via a remote control. It consists of a pulse generator and two leads: One lead senses when the patient breathes in, enabling the pulse generator to stimulate the distal branch of the hypoglossal nerve selectively via the second lead during each inspiration. The result is the activation of tongue protrusors leading to a forward movement of the tongue and the soft palate (due to palatoglossal coupling), thus preventing upper airway collapse during sleep.

Potential Risks and Benefits

Published efficacy and safety data are primarily based on two studies. First, the STAR trial^{5,6} supported the Inspire HNS device approval by the FDA. The industry-sponsored prospective multicenter study included 126 patients who were followed for up to five years after HNS implantation. In a subgroup of 46 responders, therapy was randomly withdrawn for one week to verify a causal effect. Second, the ADHERE registry⁷ is a multicenter, prospective cohort study with published outcome data for up to one year after HNS implantation in 382 patients.

Overall, the Inspire HNS device reduced OSA severity as measured by the apnea-hypopnea index (AHI) on average by ~70%. Secondary outcomes such as subjective daytime sleepiness, sleep-related quality of life, and partner-reported snoring were similarly improved. Importantly, these benefits were maintained during the 5-year follow up period. Furthermore, >90% of patients in the ADHERE registry report being satisfied with HNS therapy, and objectively measured treatment adherence was 5.7 h per night. Of note, low/no CPAP usage is one of the eligibility criteria for HNS therapy.

Serious adverse events requiring revision/removal of HNS device were relatively infrequent ($\leq 6\%$ over 5 years). Reasons included lead dislodgements, device failures, discomfort or attempts to improve stimulation by changing the lead placement. Non-serious events during the post-operative period included temporary discomfort related to the incisions and device implantation as well as short-term tongue weakness in some patients. Similarly, some patients experienced discomfort and tongue abrasions during the titration period, which tended to disappear with device adjustments in most patients over time.

Logistics

As summarized in **Figure 2**, HNS therapy is usually based on an interdisciplinary approach. Typically, preoperative drug-induced sleep endoscopy is used to rule out a complete concentric velopharyngeal

collapse (a contraindication for HNS therapy – see Table 1) and to implant the HNS device. Both are performed by an Otolaryngologist / Head and Neck surgeon, while the device activation, titration and long-term management are performed by a sleep physician. Following these steps, ~70% of patients achieve satisfactory control of their sleep apnea within 4 months after HNS implantation, while up to 30% require additional steps to optimize therapy (e.g., repeat titrations and/or awake endoscopies to inform further device adjustments). Thus, in addition to close cooperation between the otolaryngologist and sleep specialist, the keys for successful therapy with HNS are rigorous patient selection and ensuring that patients have a good understanding of the process, alternative therapy options, as well as realistic expectations.

Limitations and Future Directions

Some studies suggest that female sex, older age, and lower body mass index predict a favorable response to Inspire HNS therapy, but results have been mixed. Further, long-term data beyond 5 years and data on hard (cardiovascular) outcomes are lacking but subject of ongoing investigations (NCT03359096). Other areas of active research include the search for reliable predictors of response⁸, validation in pediatric/special populations (NCT04801771), exploration of hybrid therapies in patients with incomplete response,^{9,10} and assessments of alternative neurostimulator devices for OSA (NCT02263859).^{11,12}

Summary

For select patients with OSA who are unable to tolerate CPAP therapy, the Inspire HNS may be a good treatment alternative and referral to a qualified sleep and/or otolaryngologist for further evaluation and discussion of all available treatment options should be offered.

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Table 1. Key Eligibility Criteria for Inspire HNS Therapy Based on the Approval by the US Food and Drug Administration. Note, the body mass index (BMI) is not part of the eligibility criteria set forth by the FDA, but the pivotal STAR trial excluded patients with a BMI >32 kg/m² and most insurances will deny therapy for patients with a BMI >32-35kg/m² (a higher BMI may be a negative predictor of response).

Indications
Age >21 years ^a
AHI 15 to 65 ^b events/hour
PAP failure ^c or intolerance ^c
Contraindications
Central + mixed apnea >25% of total AHI
Complete concentric collapse (CCC) during drug-induced sleep endoscopy (DISE)
Any issues that compromise upper airway stimulation
Pregnancy (now or planned)
Requiring magnetic resonance imaging (MRI) other than what is specified in the MR conditional labeling ^e
Another implanted device that may interact with the Inspire device
<p>a In April 2020 the FDA also approved Inspire for patients between 18-21y who meet all of the criteria listed <u>and</u> are not able to undergo, or not effectively treated by, an adenotonsillectomy</p> <p>b Upper AHI limit is based on the eligibility criteria in the STAR trial, but in practice patients with an AHI>65/h are still being considered for therapy</p> <p>c AHI >15 events/hour despite PAP usage</p> <p>d Inability to use PAP for >4h/night on >5nights/week or unwillingness to use PAP</p> <p>e with the newest generation device MRIs excluding the torso are generally possible (for details see the "MRI Guide-</p>

Figure 1. Key parts and location of the Inspire HNS Device (from Inspire HNS Patient Manual, available at <https://manuals.inspiresleep.com/>; reprinted with permission.)

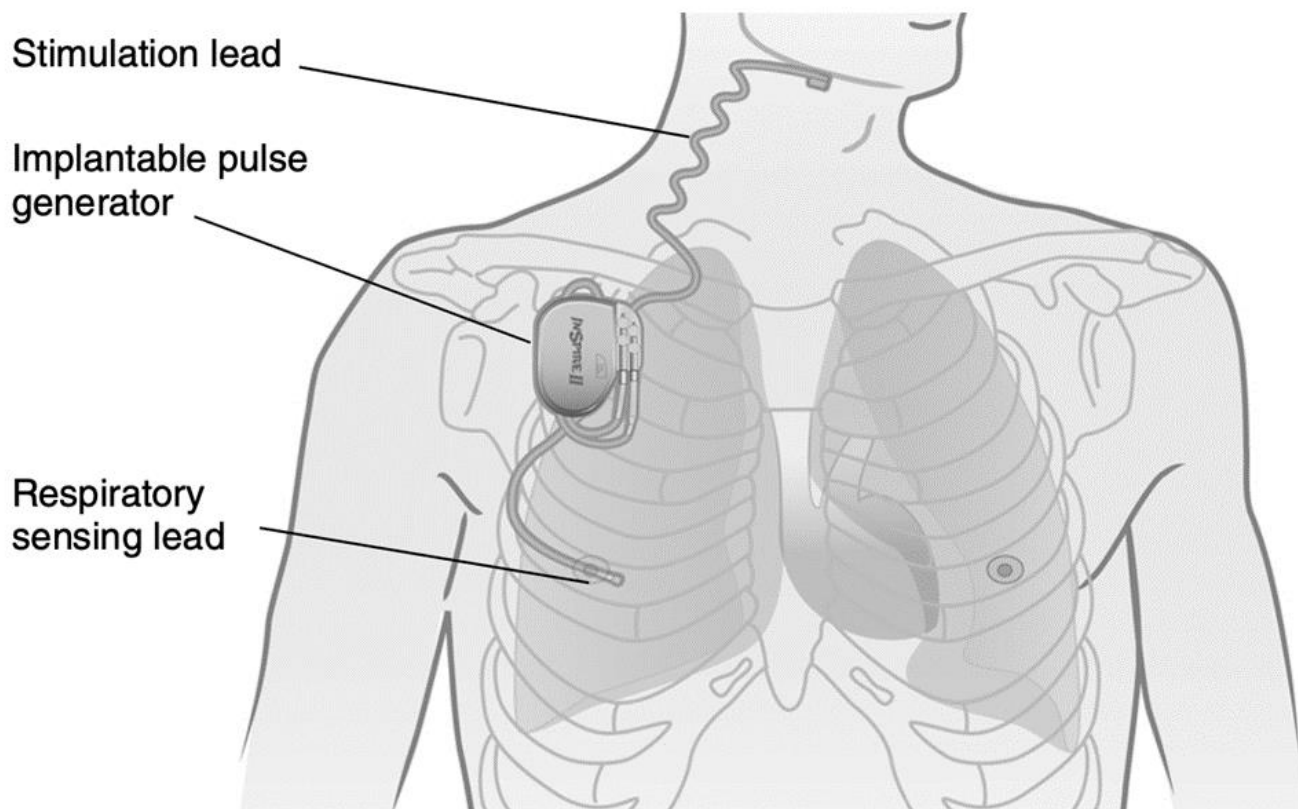
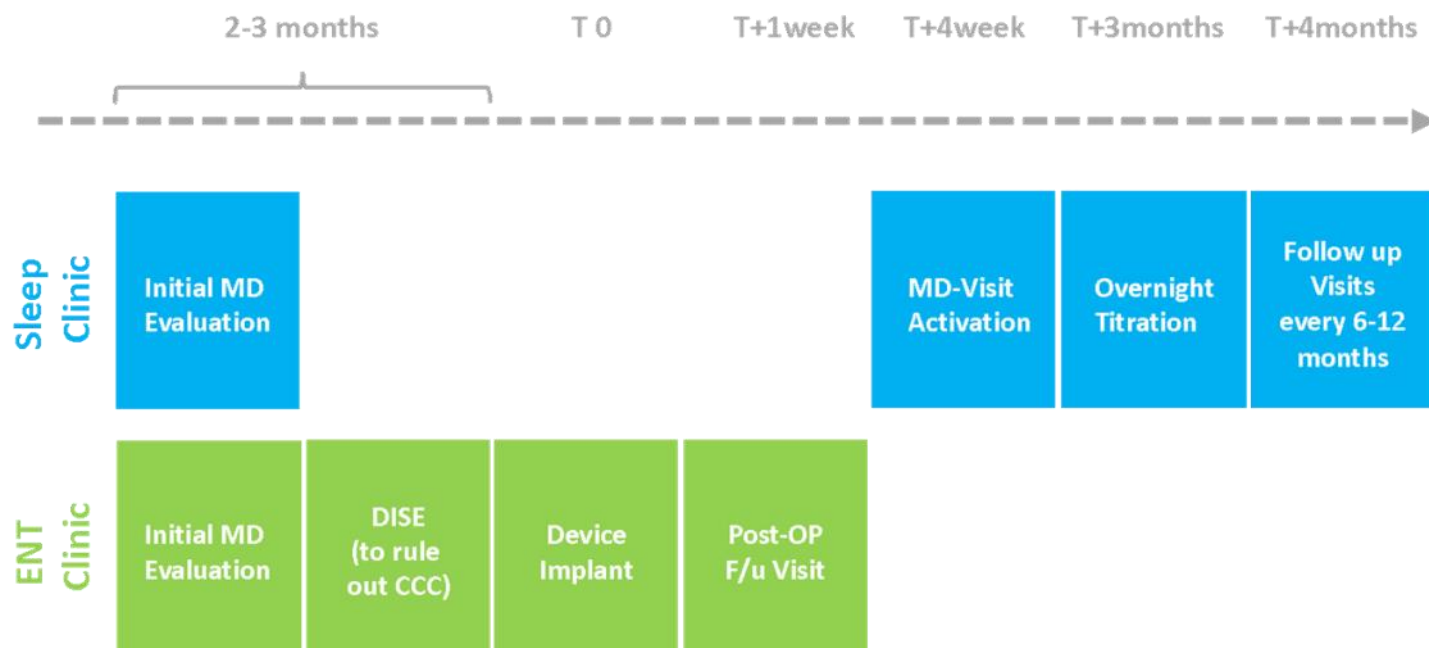


Figure 2. Typical logistics of HNS therapy. Abbreviations: DISE drug induced sleep endoscopy, CCC complete concentric collapse.





Professionalism • Advocacy
Commitment • Excellence

40 years of Respiratory Care Licensure

By Krystal Craddock MSRC, RRT, RRT-NPS, AE-C, CCM



The practice of respiratory care has been around for quite some time, dating back to the 1940's. This was during this time that 'on the job' training for respiratory care began to address post-surgical patients. For several decades, respiratory care did not require a professional license and relied exclusively on on-the-job training. California was the first state to implement licensing for respiratory care practitioners, with the bill being signed in 1982, 40 years ago. However, the advocacy and legislative work began years before. It all began with a caring young RT and a worried parent.

41 years ago, an 18-month-old patient was being prepared to undergo a cleft palate repair at UC Davis Medical Center. There was a young respiratory therapist, named Mark Goldstein, who provided comfort and reassurance to the child's parents who were so scared for their first born. Their little daughter was getting prepped to go under general anesthesia. Mark told them that their daughter would be okay, and she was. As the father got to know Mark, he found out that RT's were not licensed and were trained on the job. This made the father even more appreciative of Mark, since Mark had to hand ventilate his daughter in the operating room, given the limitations of medicine at that time. Her life, at that moment, was in Mark's hands.

The father was Aaron Read, CEO of Aaron Read and Associates, a Legislative Advocacy Agency. This started the journey that would improve the lives of millions of patients and establish the respiratory care profession and the critical role we play today in patient care. Aaron Read worked with RT's to overcome many obstacles and get the respiratory care licensing requirement signed into law. They weaved in and out of all the obstacles, made great arguments, and fought hard to pass this bill. This was all accomplished without a Political Action Committee (PAC), meaning no PAC money. Per Mr. Read "We argued it is to protect the public, to ensure a basic level of competence, a way to require continued education. And we won. The rest is, as they say, history!". Aaron Read and Associates continues to lobby and advocate for RT's in California to this day, so that we can further our profession and keep Californians in need of respiratory care safe.

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Payer Coverage of Valley Fever Diagnostic Tests	Pulmonary	Grace Rose CE	2021	23	6	155-61	12/11/21
A Summary of Outpatient Recommendations for COVID-19 Patients and Providers December 9, 2021	Pulmonary	Robbins RA	2021	23	6	151-4	12/10/21
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