



AWAKE sleep apnea

Raising our voices for progress in treatment and care



RAISING VOICES FOR PROGRESS IN TREATMENT AND CARE:

**Report of the Patient-Focused Medical
Product Development Meeting on
Obstructive Sleep Apnea**

ASAA Board of Directors & Staff

Only patients and established patient advocates serve on the Board of Directors. The Board ensures that ASAA maintains the highest standards of performance, governance, accountability, transparency and cost-to-fundraising ratios. Additionally, the Board ensures that the patient's voice is reflected in all major decisions and program implementation. All board members contribute financially to the organization. Staff include patients diagnosed with sleep disorders, patient-advocates, and researchers. The highly qualified staff works to advance the ASAA's mission through research, program development and implementation, fundraising, networking, marketing, and administration.

For a listing of members of the ASAA's Board and Staff, please see page 68.

About the American Sleep Apnea Association

Founded in 1990, the American Sleep Apnea Association (ASAA) is a patient-led, nonprofit organization dedicated to the promotion of sleep health through research, advocacy, and education. Each year ASAA responds to thousands of requests for information and provides answers to a multitude of questions about the diagnosis of and treatment options for sleep apnea. ASAA works collaboratively with non-profit organizations and professional societies to further its mission.

The ASAA engages patients, physicians, and the public through several programs and research related activities. Its key initiatives include: the CPAP Assistance Program (CAP); a national patient engagement network called Alert, Well and Keeping Energetic (A.W.A.K.E); a closed A.W.A.K.E Facebook page for patients; monthly webinars; a Sleep Health app (available at no cost on iTunes); and a month-long awareness campaign conducted in September called SleepSeptember.

The ASAA is currently involved in four primary sleep-related research projects: (1) the SleepHealth Mobile App Study; (2) the COPD and OSA O2VERLAP Study; (3) a project on the development and prioritization of sleep-related comparative effectiveness research questions; and (4) a CPAP pressure adjustment study.

For more information,
visit ASAA online:



sleepapnea.org and
awakesleepapnea.org



[facebook.com/
sleepapneaorg/](https://facebook.com/sleepapneaorg/)



[@sleepapneaorg](https://twitter.com/sleepapneaorg)



[youtube.com/channel/
UCbk8jK9zCu8XuMT6UTtro-Q](https://youtube.com/channel/UCbk8jK9zCu8XuMT6UTtro-Q)





TABLE OF CONTENTS

RAISING OUR VOICES FOR PROGRESS IN TREATMENT AND CARE: An Introduction to the AWAKE Sleep Apnea Meeting & Initiative	4
SECTION 1: Symptoms, Diagnosis & Life Impacts of Sleep Apnea	10
SECTION 2: Treating Sleep Apnea	22
SECTION 3: Treatment Barriers	32
SECTION 4: Unmet Needs	40
SECTION 5: Results of the Patient & Caregiver Survey	52
ACKNOWLEDGMENTS	68
APPENDIX:	
AWAKE Sleep Apnea Meeting Agenda	70
AWAKE Sleep Apnea Patient & Caregiver Survey Instrument	71
SIDEBARS:	
About the American Sleep Apnea Association	2
About AWAKE Sleep Apnea	5
FDA's Expanding Commitment to Enlisting Patients As Partners	6
About Obstructive Sleep Apnea	9
Most Problematic Symptoms	12
Clinical Features of Sleep Apnea	14
Life Impacts of Sleep Apnea	17
Detecting and Diagnosing Sleep Apnea in Children	18
What Have You Found Helps the Condition the Most? Survey responses	25
Caregiver Perspectives on CPAP Therapy	28
Medicare Coverage Policy for CPAP Therapy	30
Summary of Barriers to Treatment	36
Making Tradeoffs	39
Challenges Revealed by the AWAKE Sleep Apnea Initiative	44

RAISING OUR VOICES FOR PROGRESS IN TREATMENT AND CARE:

AN INTRODUCTION TO THE AWAKE SLEEP APNEA MEETING & INITIATIVE



***“This is a monumental day
for our community.”***

*Adam Amdur,
Chief Patient Officer,
American Sleep Apnea Association
(ASAA)*

Vivid orange banners signaled the meeting location to participants arriving at the College Park Marriott Conference Center near Washington, D.C. The meeting room itself was lined with larger-than-life portraits of women and men living with sleep apnea, a fitting invitation to the dozens of patients who would soon gather to share their journeys, hopes, and expectations. A sophisticated video recording system had been assembled to broadcast the meeting (with live captioning) to hundreds of participants via the web, YouTube, and Facebook Live. The stage was set — literally and figuratively — to showcase panelists’ experiences in recognizing symptoms, seeking a diagnosis, making treatment decisions, accessing informed care, and living their lives in the face of sleep apnea. It was the morning of June 8, 2018, and the American Association for Sleep Apnea’s patient-focused medical product meeting was about to begin.

Adam Amdur, chief patient officer of the American Sleep Apnea Association (ASAA), welcomed fellow patients, patients’ family members, patient advocates, health care professionals, federal agency representatives, and industry partners. “This is a monumental day for our community. This AWAKE Sleep Apnea meeting marks the first public forum, with representatives from the U.S. Food and Drug Administration (FDA) intently listening, for us to share first-hand testimonials about the way we are trying to manage sleep apnea and the comorbidities that can come with it. It is the first time we’re collectively looking at devices, drugs, and all the other approaches we use, often in combination. It’s the first time to highlight what we as patients have learned, that if you don’t have your sleep under control, you don’t have your health under control.”



Adam identified himself as a patient, a son of a patient, a brother of a patient, a father of a patient, and a husband of a patient. He shared a bit of his own story, and made a forecast: “I expect today you’ll hear good, successful stories and outcomes. You’re going to hear some of the bad news, too. And I think you’ll also hear a lot of the ugly, as far as obstacles and barriers that patients face.”

He reviewed the day’s agenda and highlighted clinical overviews that would begin the morning and afternoon sessions. “We have chosen a clinician, Dr. Shelley Berson, rather than a researcher to provide this information. We wanted someone who actually sees patients in a clinical care setting every day to give these brief talks. She is a board certified ear, nose, and throat doctor, an allergist, and a sleep doctor. Dr. Berson will help describe the whole picture — what’s going on with the structure of face and jaw, within the body, in the air around us that we breathe — and how all of it affects how well we sleep.”

Pointing out several ASAA board members in the room, Adam called attention to patient support programs the organization provides and invited those in the room and watching via the webcast to spread the word about the availability of these support services. He thanked the FDA and sponsors for making the meeting possible, for providing this forum to dispel myths and lend a helping hand. “The stereotype for sleep apnea has been the obese Caucasian man, but I think you’ll learn today — as we have over the years and through thousands of responses to our AWAKE Sleep Apnea Patient & Caregiver survey — that sleep apnea does not discriminate. We have an array of individuals who will speak on two panels today and dozens of others in the room who will take part in discussion. Our panelists have made it ‘out the other side’ and want to give back to their community. As you’re told you at the beginning of an airline flight, ‘Put your own mask on first, then help others around you.’ We would not be able to help others unless we had helped ourselves first. That’s what we’re here to do today,” Adam affirmed.



AWAKE Sleep Apnea is a strategic initiative of the American Sleep Apnea Association (ASAA) conducted in collaboration with the U.S. Food & Drug Administration (FDA) and with support from several life science companies and non-profit organizations. (See page 69 for a listing of sponsors and partners.) It is the first-of-its-kind initiative to accelerate progress in patient-focused medical product development for and patient-centered care of sleep apnea.

FDA's Commitment to Patients

The U.S. Food and Drug Administration (FDA) has placed a high priority on hearing directly from individuals with lived experience about what it's like to live with medical conditions. To bring this important information to FDA leaders and review staff, FDA created the Patient-Focused Drug Development (PFDD) initiative within the Center for Drug Evaluation and Research (CDER)¹. More than 40 PFDD meetings have been held since 2013, focusing on a wide range of prevalent and rare diseases where there is substantial unmet medical need. Twenty-six of these meetings were hosted by FDA and the balance have been externally led by patient organizations working in close collaboration with FDA, as was the case with the AWAKE Sleep Apnea meeting.

In 2013, FDA's Center for Devices and Radiologic Health (CDRH) launched the Patient Preference Initiative to develop methods of understanding patients' expectations for benefits and tolerance for harms and risks related to interventions that involve medical devices. In 2016, CDRH established "partnering with patients" as one of three strategic priorities and CDRH director Dr. Jeffrey Shuren set aggressive goals to measure progress. In 2017, it convened a Patient Engagement Advisory Committee to guide the agency's continued interactions with patients and patient organizations.

These programs and others established by FDA have created new opportunities for patient perspectives to inform decisions about clinical trials and regulation of medical products.

In Collaboration With FDA

The AWAKE Sleep Apnea meeting is part of a meeting series initiated by FDA in 2013 designed to more systematically obtain the patient perspective on specific diseases and their treatment. ASAA applied to FDA's patient-focused drug development (PFDD) program in November 2017, proposing to host a meeting focused on the full range of treatment approaches used by people with sleep apnea, including medications, medical devices, and a range of other approaches. The AWAKE Sleep Apnea meeting was the culmination of a collaborative effort with FDA to involve staff and reviewers from two centers — the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH), making it the first in the series of approximately 40 meetings identified as a Patient-Focused Medical Product Development (PFMPD) meeting.

Attending the meeting were 11 staff members from FDA review divisions, including Dr. Tiffany Farchione, deputy director of CDER's division of psychiatric products (responsible for reviewing drugs to treat sleep apnea and other sleep disorders), and programs that focus on creating opportunities for patient perspectives to inform regulatory decisions. **Kathryn (Katie) O'Callaghan**, assistant director for CDRH's Strategic Programs, spoke at the meeting about ways in which the FDA has benefited from its enhanced focus on understanding patient perspectives. She began, "I believe all of us at the FDA have been humbled to really recognize that patients and their family members are truly experts in the diseases and conditions they face. We are learning a lot from the patient community, as we have already today."

Katie polled the audience members to find out by a show of hands whether they were a patient, family caregiver, healthcare professional, researcher, regulator, or life science industry representative. "I do that to highlight that people see things from different points of view. It also highlights that whichever stakeholder group you represent, you have come today with a shared goal of improving the lives and quality of life for patients. That's what we have in common. And that journey begins by listening to patients and learning from patients and families about what they've encountered and how they've improved over the time they have lived with this condition. We are benefiting from their lived wisdom."

She described the purpose of FDA's more intense focus on understanding patient perspectives when they review medical products, including devices (like continuous positive airway pressure, or CPAP, machines) and pharmaceutical drugs. "We are looking at whether the benefits of using a medical product outweigh the risks. We do that in consideration of the impacts on patients of the untreated or undertreated condition and in consideration of the evolution of the state of the scientific understanding of the condition, as well as the state of technology. We are starting to be able to incorporate the patient perspective more substantially into that weighing of benefits and risks." Katie elaborated on three ways in which FDA is seeking to take a more patient-focused view, summarized below:

¹FDA's External Resources or Information Related to Patients' Perspectives archive, available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm579132.htm> (accessed July 21, 2018)

- **Understanding:** Through meetings such as the AWAKE Sleep Apnea meeting, FDA is listening to patients describe the period before diagnosis; obstacles to getting diagnosed; treatment decisions they have been presented with; benefits they derive(d) from treatments and care; side effects, harms, adverse events, and risks they faced; treatment effects of highest priority; unmet medical needs; and barriers to sticking with therapy or obtaining services.
- **Advancing a science of patient input:** FDA and others are developing and improving science-based methods and tools to enhance the ability to translate patients' experiences into evidence that can "stand alongside" clinical studies and other technical information that the agency considers when evaluating the extent of meaningful benefit and the potential for harm and negative outcomes. This assessment is essential to ensuring that medical products are safe and effective before they are approved for widespread use.
- **Recognition of patients and patient-based organizations:** While there has been a long history of involvement of individuals and nonprofits in raising funds and awareness, increasingly they are involved directly in medical product innovation and development. This has shifted expectations from patients being *passive subjects* in research to patients being *active partners* in research.

Katie closed her comments with this call to action: "It is critical to have patients involved in innovation, research, and development because it's a team sport. We're working with patients as partners to improve the state of affairs for everyone involved. One of the most promising opportunities from FDA's perspective is to move from a 'peep hole view' that we get from information gathered at a clinical visit to a much bigger picture view of the impact of a condition by seeing the full scale of the patient's life. That will help us identify and overcome some of the barriers. There are opportunities to bring patients, citizen scientists, patient-innovators, and people who have experience with the business of healthcare and all of the other parts of the ecosystem together as a team to tackle these barriers. Thank you for allowing me and other FDA folks to be part of your discussion today."

A Broader Initiative

To provide FDA and others with quantified evidence in addition to the valuable testimonies collected at the meeting, ASAA launched the AWAKE Sleep Apnea Patient & Caregiver Survey on April 24, 2018. Partner organizations and several of the Initiative's sponsors (listed on page 69) helped promote the survey and encourage participation. The survey attracted responses from 5,241 individuals by the June 8th meeting. Evidation Health deployed the survey within its consumer health Achievement platform to contribute 44 percent of the total responses collected. In total, the survey closed on July 18, 2018 with a total of 5,630 responses, making it the largest survey conducted in connection with a PFDD/PFMPD meeting.

Information from the survey helped to shape discussion questions and audience polls used by meeting moderator Kim McCleary, Founder and CEO of the Kith Collective. She also drew from survey responses to reinforce or



"It is critical to have patients involved in innovation, research, and development because it's a team sport."

*Kathryn (Katie) O'Callaghan,
Assistant Director,
Strategic Programs, CDRH, FDA*

“I hope that this is the first of many, many important gatherings of our community together with different stakeholders in an inclusive, collaborative manner so we can start making a greater difference in people’s lives.”

*Adam Amdur,
Chief Patient Officer,
American Sleep Apnea
Association (ASAA)*



AWAKE Sleep Apnea Initiative by the Numbers

465 participants at the
AWAKE Sleep Apnea Meeting —
87 in person
378 by live webcast

8 corporate sponsors

12 partner organizations

5,380 views of the webcast
on YouTube and Facebook

5,630 responses to the
AWAKE Sleep Apnea Patient &
Caregiver Survey

155,339 words in open
text survey responses

complement viewpoints offered by those participating in the room. Responses from the survey are woven throughout this report and are presented in Section 5, beginning on page 52, which also describes the methods for survey development and deployment. Under the direction of its chief science officer, Carl Stepnowsky, PhD, ASAA plans to prepare several manuscripts for publication based on the survey data. This will help build scientific knowledge that reflects patients’ experiences and expectations.

Individuals participating in two panel discussions were identified through the meeting registration process inviting willing individuals to volunteer more information about their journeys through a confidential screening questionnaire. Others came to ASAA’s attention through its CPAP Assistance Program that helps individuals in need obtain CPAP equipment and supplies. Finally, ASAA reached out through traditional and social media to solicit volunteers. In addition to panelists, every meeting participant was welcomed to take part in the discussion periods and a wide range of perspectives were shared, as detailed in the next four sections of this report. Travel support was provided by ASAA to panelists with demonstrated need.

During the AWAKE meeting, ASAA took the opportunity to record one-on-one interviews with patients and patient advocates about their experiences for future awareness and education campaigns. Artist Gilles Frydman photographed patient-volunteers to expand the portrait gallery on display in the meeting room. These portraits too will be used by ASAA in awareness and education activities; several appear in this report.

Monthly meetings with FDA’s Meghana Chalasani, operations research analyst in FDA-CDER’s Office of Strategic Programs, helped shape meeting plans within the general guidelines FDA has used throughout the PFDD series. This report, one of the key deliverables to FDA, will be submitted to the agency’s FDA’s online repository for patient experience information as an evergreen resource for FDA review teams, medical product sponsors, the patient community, and the public.

Elucidating Unmet Needs

In all, the outreach for the AWAKE Sleep Apnea initiative, the regular dialogue with FDA staff about the initiative, the valuable information contained within survey responses, the meeting discussion, and the community’s response to it served to bring into sharper focus a wide range of unmet needs for people living with sleep apnea, identified in Section 4 of this report. ASAA’s objective in hosting the AWAKE Sleep Apnea Initiative was to mobilize the community to share its experiences and make its successes, challenges, and needs known. It will now endeavor to enlist partners and resources to better meet those needs.

Adam concluded the day with a reminder that while the meeting was ending, the ASAA’s commitment was not. “I hope that this is the first of many, many important gatherings of our community together with different stakeholders in an inclusive, collaborative manner so we can start making a greater difference in people’s lives and we can begin to wipe out sleep apnea and its comorbidities in a generation or so. If we start together now, the benefits for society will be immeasurable. Thank you to all who participated so far and who gave of themselves in doing so. I don’t know where we’d be without you.”



About Obstructive Sleep Apnea

The Greek word “apnea” literally means “without breath.” Sleep apnea is an involuntary cessation of breathing that occurs while the patient is asleep. There are three types of sleep apnea: obstructive, central, and mixed. Of the three, obstructive sleep apnea (OSA) is the most common. Despite the difference in the root cause of each type, all three — if left untreated — cause people to stop breathing repeatedly during their sleep, sometimes hundreds of times during the night and often for a minute or longer. In most cases the sleeper is unaware of these breath stoppages because they don’t trigger a full awakening. Left untreated, sleep apnea can have serious and life-shortening consequences: high blood pressure, heart disease, stroke, automobile accidents caused by falling asleep at the wheel, diabetes, depression, and other ailments.

Sleep apnea is seen more frequently among men than among women, particularly African-American and Hispanic men. A major symptom is extremely loud snoring and gasping/ snorting noises after periods of not breathing. Sometimes the sounds of these symptoms are so loud that bed partners find it intolerable. Other indications that sleep apnea may be present are obesity, persistent and severe fatigue and daytime sleepiness, bouts of awakening out of breath during the night, and frequently waking in the morning with a dry mouth or a headache. But it can be possible that at times none of these symptoms are present. Physical features associated with sleep apnea include a narrow jaw, recessed chin, crowded upper airway, and large neck circumference. Only a sleep study in a sleep laboratory or a home sleep study can show definitively that sleep apnea is present and how severe it is.

Obstructive sleep apnea is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. In central sleep apnea, the airway

is not blocked but the brain fails to signal the muscles to breathe. Mixed sleep apnea, as the name implies, is a combination of the two. With each apnea event, the brain rouses the sleeper, usually only partially, to signal breathing to resume. As a result, the patient’s sleep is extremely fragmented and of poor quality.

The Apnea-Hypopnea Index (AHI) is used to indicate the severity of sleep apnea, represented by the number of pauses in breathing per hour of sleep. To be counted as an apnea event, each one must last for at least 10 seconds and be associated with a decrease in blood oxygenation. Combining AHI and oxygen desaturation gives an overall sleep apnea severity score that evaluates both the number of sleep disruptions and the degree of oxygen desaturation (low oxygen level in the blood).²

Sleep apnea is very common — as common as type 2 diabetes — and researchers estimate that it affects more than 18 million Americans. Risk factors include being male,

overweight, and over the age of 40, but sleep apnea can affect males and females of any body type, at any age, even children. Lack of awareness by the public and health care professionals leaves the vast majority of sleep apnea patients undiagnosed and therefore untreated, despite the fact that this serious disorder can have significant consequences.

Untreated, sleep apnea can cause high blood pressure and other cardiovascular disease, memory problems, weight gain, impotence, headaches, and premature death. Moreover, untreated sleep apnea may be responsible for job impairment and motor vehicle crashes. Fortunately, sleep apnea can be diagnosed and treated. Several treatment options exist, and research into additional options continues.

The patient journey with sleep apnea is described in detail in this report.

²https://en.wikipedia.org/wiki/Apnea%E2%80%93hypopnea_index

SECTION 1:

SYMPTOMS, DIAGNOSIS & LIFE IMPACTS OF SLEEP APNEA



“My mother had a saying — ‘El sueño es vida’ or ‘Sleep is life.’ I didn’t realize how true this was until March 20, 2018, the day I was diagnosed with sleep apnea.”

*San Juanita Sanchez, Panelist
San Juan, TX*

“My mother had a saying — ‘El sueño es vida’ or ‘Sleep is life.’ I didn’t realize how true this was until March 20, 2018, the day I was diagnosed with sleep apnea and the day I began to realize how much this condition has affected me, for a lot longer than I ever imagined,” stated panelist **San Juanita Sanchez**, an attorney and former mayor from San Juan, Texas, and the AWAKE meeting’s most recently diagnosed participant.

After her term as mayor ended, San Juanita found she had a bit more time for herself and she began to pay attention to how she was feeling. “I realized how tired I was, that I’d fall asleep when our family prayed together. I had to have coffee as soon as I woke up and maybe sleep for another hour after that before I could get my day going. I was starting to come home at lunch for two-hour naps. I recognized that I was falling asleep while interviewing clients and that I wasn’t able to remember what they had just told me. In court, I couldn’t recall the name of an objection. It was definitely affecting my practice.” One day while driving home, she fell asleep at a stop light and started to dream. When she woke, she had no idea how long she’d been there. “I told my sister, ‘I’m dying.’ It was just an instinct because at the time I was only being treated for high blood pressure, which was improving with medication. But I knew there was something else going on.”

A family member who is a physician suggested sleep apnea as a possibility, made a doctor appointment for her, and paid for the office visit and a home sleep test. “A couple days after my home sleep test the doctor told me, ‘You’re very severe. You had 83 apnea episodes in one hour for an average of 19 seconds each. We need to do something for you.’” An overnight sleep study

confirmed the diagnosis. As an attorney in solo practice, San Juanita was uninsured and feared having to wait until she could afford to purchase the continuous positive airway pressure (CPAP) machine her doctor prescribed. Fortunately, she was able to obtain one right away through the American Sleep Apnea Association's CPAP Assistance Program. "It's really incredible. You don't know that you're not sleeping well until you do sleep well. The very next day I didn't need a nap. I was able to sit through a client interview without them looking at me like, 'What is going on with you?' I am still learning and trying to figure out what my new normal is, but I hope my story helps others realize there is something going on that they need to take care of," San Juanita concluded.

Erin Taylor of Colorado Springs is another participant who had been diagnosed within the last year, although her symptoms began eight years earlier, following the birth of her first child and gestational diabetes during that pregnancy. "I was having chronic pain and spasms in my back. I was extremely fatigued, but I chalked that up to being up with the baby. I was having memory and concentration problems at work and caught every cold or flu that went around. I was snoring badly — something I had never done before. I didn't know these things could be connected or have a root cause," she recalled.

Years later, Erin's parents were both diagnosed with sleep apnea. She didn't connect their diagnosis to her health issues until her symptoms became much worse in the summer of 2017. Her parents shared more of their experience getting diagnosed and treated and Erin decided to pursue the possibility. "I have a wonderful primary care physician, so I mentioned it to her. She gave me the Epworth Sleepiness Survey³ in the office and I scored very high, so she referred me for an overnight sleep study. It took about six weeks to get in. Halfway through the night, after I had stopped breathing 50 times an hour with the longest apnea being 40 seconds, they put a CPAP mask on me. I felt remarkable after using it for just a few hours. It took more than a month to get my own machine, but I've had a lot of success with it so far." Erin also shared some of the challenges she's encountered with the fit and seal of the mask and insurance coverage, problems others expressed throughout the day that are covered later in this report.

Common Symptoms

As San Juanita and Erin described, the symptoms often cited by meeting participants and survey respondents as having the most significant impact are severe fatigue and daytime sleepiness. One survey respondent wrote, "I am basically a shut-in due to the fatigue. I no longer participate in my prior activities. I go to the doctor and occasionally to the store and I seldom spend time with family."

Cognitive issues were cited frequently at the meeting and in survey responses. Erin elaborated on the impact she experienced, "For me, difficulty thinking and with memory was one of the scariest aspects of sleep apnea. I had difficulty recalling words. I was very forgetful about bringing things with me



"Difficulty thinking and with memory was one of the scariest aspects of sleep apnea. I had difficulty recalling words. I was very forgetful about bringing things with me places or what my children had just asked me to do with them. Losing my cognitive ability was one of the things that prompted me to seek out treatment."

*Erin Taylor, Panelist
Colorado Springs, CO*

³Epworth Sleepiness Survey, viewable at www.sleepapnea.org/assets/files/pdf/ESS%20PDF%201990-97.pdf

Most Problematic Symptoms

Survey respondents rated the following symptoms as being of “severe” or “moderate” impact (in order):

- Fatigue
- Daytime sleepiness
- Unrefreshing sleep
- Loud, habitual snoring
- Dry mouth in the morning
- Cognitive difficulties (including “feeling in a fog,” forgetfulness, memory loss, short-term memory problems, and poor concentration)
- Irritability
- Depressed mood
- Awakening with breath-holding
- Frequent nighttime limb movements
- Anxiety
- Nasal congestion
- Nighttime bladder control issues
- Morning headaches

Severe impact indicates major limitation on daily activity.

Moderate impact refers to some limitation of daily activities.

See bar graph on page 64

places or what my children had just asked me to do with them. If I didn’t do it immediately, I would forget that they asked it all. Losing my cognitive ability was one of the things that prompted me to seek out treatment.”

Dry mouth, sore throat, air hunger (dyspnea), and nighttime bladder issues were mentioned by several participants and in open text comments in the survey. Patients reported allergies, sinus problems, recurrent upper respiratory infections, and gastrointestinal distress. Mood issues came up frequently too, including depression, irritability, anger, and feeling anxious. Weight gain was another problem raised; some tied it to decreased physical activity due to fatigue, but others indicated it was unrelated or disproportionate to changes in diet or activities levels.

For some, the interplay of these symptoms was hard to tease apart. “My self-esteem is impacted by the cognitive issues and this contributes to my depression. It has also affected my professional life in that I don’t feel I can perform at the level that I should and I am afraid to advance my career. I don’t drive because of the fatigue and I can’t begin to fathom being in a romantic relationship and having a family. I only have the energy to care for myself and barely that,” wrote one female survey respondent.

Attention Grabbers

For 39 percent of survey respondents, symptoms became so problematic that they sought medical attention as San Juanita and Erin described. For about half of survey respondents, the primary push came from someone else — a family member, an overnight traveling companion, a house guest, or a medical professional. Loud snoring and nighttime breath-holding were the symptoms that most often drew others’ attention. Some survey respondents noted these symptoms coming to attention during hospital stays for other procedures, like childbirth or orthopedic surgery to replace a hip or knee. For others, new romantic relationships revealed these symptoms.

Panelist **Rick Gordon** of Upland, California, described the morning after he and his wife first spent the night together in 1983. “She was sitting on the bed with a look of horror on her face and I asked, ‘It wasn’t that bad, was it?’ She told me she thought I was going to die, that I had stopped breathing. She said I was choking and snoring and thrashing around all night. I told her that’s just the way it was.” Ten years later she read a magazine article in the dentist’s office waiting room. “She handed it to me and said, ‘Here. They wrote a story about you.’ The article was about sleep apnea and it *was* about me,” Rick recounted.

Paul Zuccarini of Key Biscayne, Florida, heard for years about his snoring and breath-holding from camping buddies, his wife, and later, after his divorce, from his girlfriend. “I felt bad that I was keeping people awake, but I didn’t do anything about it. Finally a friend convinced me to get a doctor to refer me for a sleep study. After the test they told me I had 56 somethings, which I didn’t understand. But I did understand that it was bad and it helped me recognize that for years sleep apnea had been impacting me.”



About eight percent of survey respondents indicated a moderate or high chance of dozing while driving.

Fatigue and bouts of daytime sleepiness had some dramatic consequences, with several panelists and survey respondents noting a tendency to doze off while waiting at traffic lights or even while driving. About eight percent of survey respondents indicated a moderate or high chance of dozing while driving.

One panelist, **John Andrews** of Virginia Beach, fell asleep while flying a Navy plane. “I’ve probably had sleep apnea most of my life. I had issues falling asleep in high school and used to dread chemistry class, but I didn’t deal with the symptoms until I was deployed and there came times when I was so tired I was falling asleep in

the airplane. Thank God for autopilot,” John said, only half-joking. The flight surgeon gave me stimulants and that’s what I used throughout my flight career. It wasn’t until I was being sent to Iraq with the Army that the doctor giving me a physical exam noticed redness in the back of my throat. ‘Dang! Do you snore?’ he asked. I said I’d been told that I do and he recommended I get checked for sleep apnea. I did that when I got back from that tour of duty and, sure enough, I had it.”

Peter Stein’s diagnosis came after a crisis that was preceded by many years of poor sleep, insomnia, and high levels of stress. “After earning my PhD from MIT in 1986 in a highly specialized technical field, I started a small business. I married a woman I met when I was 20. Over the years she would tell me that I held my breath at night and that I didn’t sleep well. It got worse as I got older, but I didn’t do anything about it. My company developed technology used to help protect national security. I had a top secret security clearance and was under an incredible amount of stress with many sleepless nights. I believe the combination of sleep apnea and stress is deadly. You hold your breath and it wakes you up. Then you can’t go back to sleep because your mind starts turning. Eventually you don’t sleep at all. For weeks, months I wasn’t sleeping at all. I started having these ‘microsleeps’⁴ where everything in my body would just droop for a minute and in that moment I was asleep.”

Peter continued, “Then my mind broke. I had a full-blown manic episode. My family got me to doctors and psychiatrists. They put me through all kinds of tests but nobody thought of sleep apnea. My security clearance was pulled. I was losing control and everything was collapsing around me, just crumbling. That created even more stress and made me feel even more mentally ill. It got worse and worse and worse.

“I was driving to a stress test on a winding road through Maine. I was running late, going about 60 miles per hour around a curve. I felt sleepy and had just

“I’ve probably had sleep apnea most of my life. I had issues falling asleep in high school and used to dread chemistry class, but I didn’t deal with the symptoms until I was deployed and there came times when I was so tired I was falling asleep in the airplane. Thank God for autopilot.”

*John Andrews, Panelist,
Virginia Beach, VA*



⁴Microsleeps are brief, unintended episodes of loss of attention associated with events such as a blank stare, head snapping, and prolonged eye closure which may occur when a person is fatigued but trying to stay awake to perform a monotonous task like driving a car or watching a computer screen. Reference: <https://www.tuck.com/microsleep/>



Clinical Features of Sleep Apnea

Dr. Shelley Berson, a triple-board-certified sleep specialist, provided an overview of sleep apnea and its diagnosis to provide context for the morning discussion. She made reference to two mnemonics she uses to help detect sleep apnea and describe its impact to her patients.

STOP-Bang Questionnaire⁵

- S**NORE
- T**IRE
- O**BSTRUCTIVE APNEA
OBSERVATION
- HYP**ERTENSION
- B**MI GREATER THAN 35
- A**GE GREATER THAN 50
- N**ECK CIRCUMFERENCE GREATER
THAN 15 INCHES FOR FEMALES
AND 17 INCHES FOR MALES
- G**ENDER MALE

Refer for sleep study if
more than 5 criteria are met

PITZA

(also used to help establish diagnostic codes that can support referral for a sleep study for insurance purposes)

- P** pee (urinary frequency), pain, parents (family history), pills (use of meds to help with sleep or wakefulness), pulse (atrial fibrillation)
- I** eyes (vision problems, glaucoma, cataracts), indigestion (GERD, reflux), insulin (diabetes, insulin resistance), insomnia, irritability (mood, depression)
- T** temporomandibular joint disorder (TMJ, teeth grinding), timing of work (night shift worker), travel (jet lag and different time zones)
- Zzz** naps, bizarre dreams, kicking (and other limb movement) during sleep
- A** allergies, addictions to caffeine and sugar, auto accidents, apple body shape

⁵Chung F, et al. STOP-Bang Questionnaire: A Practical Approach to Screen for Obstructive Sleep Apnea, Chest, 2016 Mar;149(3):631-8

told myself that I needed to stop and take a nap, because I'd frequently do that. But I didn't stop. The next thing I heard was 'BANG!' I had hit a minivan that was coming around the curve, also at 60 miles per hour. Fortunately, we just clipped sides and everybody walked away. The fireman who responded to the scene said he rarely saw it come out that good. That woke everybody up." Peter's doctor scheduled an emergency sleep study which confirmed sleep apnea.

Diagnostic Odysseys

Such dramatic events were the primary motivating factor for approximately five percent of survey respondents. Others, like television producer and director **Joelle Dobrow** of Los Angeles, had a long road with many diagnoses and treatment regimens along the way to a diagnosis of sleep apnea. She described the active lifestyle she led in her early career, "80-hour work weeks were normal. I was extremely physically fit and I regularly hiked, took dance lessons, did yoga, and walked every day. In my 20s I had terrible insomnia and weeks would go by without sleep. I had a Rolls Royce-type health plan and everything was covered, so I was sent from one doctor to another — gynecologists, endocrinologists, ear-nose-and-throat specialists, and a psychiatrist. They all prescribed pills and I was a compliant patient, so I took whatever was prescribed. But I still wasn't sleeping well, and I also woke every morning feeling groggy and foggy-headed. I was irritable and uncomfortable. It affected my work performance and I went through a period when I got fired, constantly. I had the chance to direct two pilots — in the 1970s when women weren't given those opportunities — but I just didn't have the stamina. They flopped and it spelled the end of my directing career."

Joelle described how years went by like this. With each job change, she had different insurance coverage. In her 50s, she was enrolled in an HMO and a physician sent her home with a machine to monitor her sleep. The test revealed sleep apnea and she was prescribed CPAP treatment. She attributes this long journey to her atypical presentation, as a young, thin, physically fit woman. "I didn't meet any of the standard criteria," she said.

By the time he was 5 or 6 years old, Adam Amdur's brothers wouldn't share a room with him because his snoring was so loud; however, it took 30 years for him to get diagnosed. He saw a therapist for depression in elementary school and got through middle school by drinking coffee. In his teens and 20s, he wrecked more cars than he could count. "I fell asleep at the wheel going 60 miles per hour. I drove through a gas station and barely missed hitting a light pole. It's a wonder I am alive today. I was young and skinny and my doctors missed the signs."

Adam's father had serious heart disease, including a triple bypass surgery when Adam was two, and multiple stents before he developed vascular dementia and died at age 62. Both his grandfathers had heart disease and one died at age 61 from a sudden heart attack. This family history prompted Adam to get attention from a cardiologist in his 20s. By then he had already developed fibromyalgia, vision problems, constant irritability, and depression.



Joelle Dobrow of Los Angeles had a long road with many diagnoses and treatment regimens along the way to a diagnosis of sleep apnea. She attributes this long journey to her atypical presentation, as a young, thin, physically fit woman. "I didn't meet any of the standard criteria."



“Instead of being a social worker providing for others, I ended up in the social system myself. Finally, I found out sleep apnea was the root of all that evil. Now I have atrial fibrillation, congestive heart failure, degenerative bone disease, and immunoglobulin G deficiency. I live off a disability check and in supportive housing. It’s a hell of an ending for a fighter and an ambitious person like me.”

*Eugena Brooks, Panelist
Brooklyn, NY*

The cardiologist recommended Adam take a statin drug for preventative purposes. “I developed rhabdomyolysis as a result of an allergic reaction to the statins, but my doctors were at a loss. They didn’t make the connection that my fatigued and oxygen-depleted muscles could not properly react with the drug.” Finally, years later at age 35, he was seen by a renowned sleep specialist and during the overnight sleep study, 150 apneas were recorded in a single hour. “That night, due to the severity of my condition, I was given CPAP treatment in the clinic. When I woke at 5:36 a.m., I felt like I had gone back in time and was reborn. My brain felt like it was 10 years old,” he exclaimed. “Years of questions about my health and behaviors were answered with this diagnosis, but at the same time, it opened up a new world of frightening realities and frustrating misconceptions.”

Eugena Brooks, of Brooklyn, NY, had it tough as she was coming up. Her mother’s death at age 18 left her with three younger siblings to raise. She married at 20 and was a widow and single parent at age 28 after her husband died of cancer. Through it all she pursued musical talents, played sports, and furthered her education, earning a Master’s of Public Administration and becoming a social worker.

At age 37 she experienced bouts of sinus problems and bronchitis. “It got worse instead of better,” she said. “By the time I was 43, one doctor noticed all the redness in the back of my throat and recommended surgery. They removed my uvula and tonsils. I thought that was the end of the rainbow and I took a new position. Out of nowhere, I started to rapidly gain weight. I couldn’t breathe; I was falling asleep on the job and behind the wheel. Six months later I sounded like Darth Vader and I was in the worst physical condition of my life. They had to let me go from my job. I lost my home, my car, everything. Instead of being a social worker providing for others, I ended up in the social system myself. Finally, I found out sleep apnea was the root of all that evil. And now I have atrial fibrillation, congestive heart failure, degenerative bone disease, and immunoglobulin G deficiency. I live off a disability check and in supportive housing. It’s a hell of an ending for a fighter and an ambitious person like me.”

Comorbidities

Joelle, Adam, and Eugena’s experiences illustrate the frequent reports that multiple health conditions either precede, accompany, or follow the diagnosis of sleep apnea. Among survey respondents, hypertension (high blood pressure), gastroesophageal reflux disease (GERD), diabetes, and depression occurred at much higher rates than are reported for the U.S. population as a whole, as shown in the figure on page 58. ASAA and the Chronic Obstructive Pulmonary Disease (COPD) Foundation are collaborating on a study funded by the Patient-Centered Outcomes Research Institute (PCORI) to better understand, from a patient perspective, the overlap between the two disorders.⁶ Study coordinators recruited at the AWAKE meeting.

Other sleep disorders can be present with sleep apnea, too. Two participants described co-occurring parasomnia, unusual and/or violent behaviors during

⁶For more information, please visit:
www.o2verlap.org

sleep. **Deb McCall** of Murrieta, California, said it was this violence during sleep that prompted her husband to seek medical attention. “I live with three sleep apnea patients and there’s a lot of snoring in my house. My husband was one of those breath-holding types; I knew it when we started dating but it took him years to get a sleep study. One night while he was sleeping, he picked me up and threw me across the room. Because he had hurt me, he decided to get a sleep study and it detected sleep apnea, parasomnia, and somnambulism, or sleep walking.”

Paul Foxworth of Chicago reported, “My parasomnia causes me to move during sleep like I’m kicking a soccer ball and swatting at an opponent. It seems like my brain is supplying a dream during REM sleep so that I will move and then I will breathe.”

Narcolepsy Network’s **Melissa Patterson** described the immediate and longer term challenges for kids with both narcolepsy and sleep apnea. “There is more recognition of narcolepsy as an adolescent condition, but with sleep apnea there is a perception that only happens to older adult men. But we hear from kids who have sleep apnea and narcolepsy. When you diagnose and treat only narcolepsy, you’re only hitting part of the problem. So these kids are still sleeping through algebra. They’re failing a grade. This leads to more educational complications, to a life not fulfilled. We need to get better at diagnosing the entire spectrum of the problem, whether that comorbidity is diabetes and sleep apnea or narcolepsy and sleep apnea.”


Several meeting participants made reference to depression. A survey respondent with bipolar disorder elaborated on her experience, “I think depression and sleep apnea make each other worse. When I’m more depressed, I don’t sleep well. When I’m tired, I make poor lifestyle choices, such as eating and drinking too much and I don’t exercise. That makes me more depressed, which makes me so tired that I don’t sleep well. It’s a vicious cycle, and it seems impossible to break.” Another woman responding to the survey shared how serious the impact can be, “I have episodes when I cannot get out of bed because of fatigue, mental impairment, and severe depression. I often feel hopeless because I cannot function physically and/or mentally for a period of time. I have been suicidal at times because of this and have attempted suicide three times.”

Cardiovascular issues, including hypertension and atrial fibrillation, were common to many. Survey respondents wrote about having had cardiac arrests, coronary bypass surgery, congestive heart failure, an enlarged heart, valve disease, strokes, implanted pacemakers, edema, palpitations, and fluttering in the chest. For one family member who completed the survey, the coroner’s report of sleep apnea after her brother’s sudden death from cardiac arrest at age 36 prompted her other brother to seek medical attention. “Sleep apnea and heart dysrhythmia were diagnosed in the overnight sleep lab. For our other brother it was too late. We had no clue until the autopsy. I wish we had known more about sleep apnea, talked more about it, and checked into it for him.”

Life Impacts of Sleep Apnea

Survey respondents rated impacts related to sleep quality highest among the activities they can’t do at all or as fully as they like due to sleep apnea. However, the condition’s impact on education, profession and career, and relationships were evident in the open text comments and at the meeting through panelists’ presentations and during discussion periods. These are some of the areas of life impacted by the condition itself:

- **Overall health, well-being, and lifespan** (e.g., general unwellness, life-ending or -shortening consequences of sleep apnea and comorbidities, loss of physical fitness and weight gain, etc.)
- **Academic performance or attainment** (e.g., grades that did not represent ability, challenges pursuing higher education or graduate studies due to symptoms, etc.)
- **Educational program** (e.g., selection of alternative schooling to accommodate later starting time or behavioral issues related to sleep apnea, etc.)
- **Choice of profession, employer, or position(s)** (e.g., pursuit or choice of work and/or workplace that allowed flexibility for later starting time or naps, did not require long commuting distance, or provided other accommodations, etc.)
- **Professional advancement** (e.g., interruptions in career progression, inability to fulfill performance expectations due to symptom severity, need for reduced schedule, etc.)
- **Finances** (e.g., reduced earning potential including full-time disability status, increased out-of-pocket medical costs and insurance premiums, expenses related to vehicle accidents, etc.)
- **Family responsibilities** (e.g., diminished engagement in child care, meal preparation, household repairs and maintenance, etc.)
- **Family, spousal, and romantic relationships and friendships** (e.g., negative consequences of fatigue and mood, time/availability to accommodate additional sleep or naps, sexual dysfunction, separate sleeping arrangements, etc.)
- **Self-image and self-care** (e.g., loss of professional identity, stigmatization, body image, loss of libido, loss of interest or ability for self-care due to lack of energy, general feeling of unwellness, financial strain, etc.)



At her overnight test, Mia (age 2) stopped breathing an estimated 27 times per hour.

Detecting and Diagnosing Sleep Apnea in Children

There has been growing awareness that sleep apnea can occur in children and distinct diagnostic criteria have been established to reflect the different presentation from adults. Numerous panelists and survey participants responded that while their own diagnosis wasn't made until adulthood, they recognized signs and symptoms dating back to childhood, supporting the need for greater awareness among health professionals and parents.

Sleep apnea in children is characterized by the following behaviors during sleep: snoring, breath-holding, labored breathing, bed-wetting, frequent movements and arousals, and paradoxical chest movement. During the daytime, children may have fatigue, excessive daytime sleepiness, hyperactivity, aggressive behavior, slow rate of growth, morning headaches.⁷ Sleep testing is required to confirm the diagnosis; any apneas or arousals are considered abnormal in children.

Adam Amdur described how he and wife Justine recognized symptoms in their daughter, Mia, when she was just two years old:

"One early sign we overlooked was that Mia was sick a lot as a baby and toddler with skin rashes, colds, and ear infections. As new parents, my wife and I thought this was typical. Mia would sleep in 'child's pose' — on her belly, head down, butt in the air. It may look cute, but child's pose is actually a protective posture where the tongue falls forward and the body engages the diaphragm to get more oxygen to the brain. Then I witnessed an apnea event as Mia slept; she held her breath for several seconds and slightly roused to get a breath.

Determined not to let Mia suffer the same fate as me and so many in our family, I relentlessly sought help. Justine and I faced a dismissive attitude from her pediatrician and the general medical community. Sleep apnea is not widely discussed or known in the pediatric circles and insisting our daughter had sleep apnea made us seem like overactive parents prone to hypochondria. In hindsight, it was easy for me to recognize crucial moments where I should have advocated better for my own health. I was not going to let that happen to my daughter.

I took Mia to the Stanford Sleep Medical Clinic and insisted on a sleep study. Finally, her diagnosis was confirmed. Mia and I both have adenoidal faces with recessed chins, genetically predisposing us to sleep apnea. At her overnight test, Mia stopped breathing an estimated 27 times per hour."

⁷Berry, Richard. "Fundamentals of Sleep Medicine." Elsevier. 2012. Pages 251-252.

Barriers To Diagnosis

As so many of the stories illuminated, there is frequently a gap — sometimes a very long one — between awareness of symptoms and the diagnosis of sleep apnea. For panelist **Celeste James**, a retired postal worker and community organizer from St. Albans, New York, the diagnosis came as quite a shock due to a lack of awareness about sleep apnea and accommodation of her symptoms as being normal for her as a busy and active girl and woman. “It never occurred to me, honestly. I had never heard the term ‘sleep apnea,’” Celeste emphasized as she recounted the events that transpired when in 2015 she was helping with a community health fair at her church. “I wanted everyone to feel comfortable speaking with the health professionals who had come, so I was having my blood pressure checked, and my eyes checked, you know? The NYU School of Medicine asked questions about sleep difficulties, which I answered just to show attendees that nothing at the fair was going to hurt them. That’s when the professional giving the sleep survey asked if he could follow up with me about my answers. ‘Sure, you can follow up,’ I said. ‘Nothing here is going to hurt you!’ I said to other attendees nearby.”

In the follow-up visit, Celeste was given a device to monitor her sleep at home for a night. Shortly after that she had a sleep study in the clinic and sleep apnea was diagnosed. “I had no idea about how long I was experiencing sleep deprivation until I got involved with this program. Now I’m finally understanding the way that things going back to childhood were connected. I was always doing things at school, with sports, at church. I never knew I was tired. This was just my normal. And for women, because we wear an ‘S’ on our chests, we always have three things going on at once. I slept only four hours a night and I’d have these periods that I called ‘fall down or lie down,’ but I didn’t know that was connected to anything medically. Now I understand that long-term sleep deprivation is linked to my diabetes, migraines, and cataracts.” The state of not recognizing the contribution of poor quality sleep to other symptoms or experiences was repeated by many survey respondents in their written comments.

For others, barriers to diagnosis included medical professionals who were unaware of sleep apnea or missed the signs in patients who fell outside the stereotypical presentation of an older, overweight man with a large neck circumference, narrow jaw, and overbite, as we heard from Joelle and Adam. Panelist Paul Zuccarini had been a lifelong champion athlete; he held records in decathlon, played soccer in college, and was nationally ranked in triathlon. In his panel comments he explained the reference to his sports achievements, “I bring them up to let you know that sleep apnea can affect anyone, whether you’re physically fit or not.” Paul added that he could hold his breath for five minutes, noting, “I’m not sure that’s good for you, but a doctor friend once remarked, ‘No wonder you can hold your breath so long; you’ve been training in your sleep!’”

While 86 percent of survey respondents have been diagnosed by a physician, the lack of access to knowledgeable professionals was reported by 13 percent of survey respondents to be a barrier. One wrote, “I had asked my doctor in

“When you have sleep apnea you’re not in a good, mentally strong position to be strong advocate for yourself.”

*Erin Taylor, Panelist
Colorado Springs, CO*



Panelist Paul Zuccarini had been a lifelong champion athlete; he held records in decathlon, played soccer in college, and was nationally ranked in triathlon. “Sleep apnea can affect anyone, whether you’re physically fit or not,” he stated.



“The established definitions and cut-off points for sleep apnea are somewhat arbitrary and may not catch everyone who is experiencing disturbed sleep.”

Dr. Shelley Berson

previous years about my very loud snoring and had hinted about sleep apnea concerns. It wasn't until this year that my wife noticed me stopping breathing a few times while I was asleep and I found I was waking up during the night with a rapid heartbeat. I pushed for the sleep study and was just recently diagnosed.”

A lack of resources kept others from seeking a diagnosis or care. As one respondent stated, “I was in my 30s when I noticed I stopped breathing at night. I was raising two kids by myself, so I just lived with it. There was no time or money for doctors for me, only for my kids. I was finally diagnosed five years ago at age 60 and I have a CPAP machine now.” Several people reported challenges getting insurance plans to cover the sleep test. One man wrote, “Convincing the insurance company to authorize a sleep test was a real battle, but my doctor persisted and I got a diagnosis and treatment.”

Erin Taylor got caught in a dispute between her doctor and the insurance company over her overnight in-clinic sleep test. “They’re trying to charge me the full amount for the sleep study. Apparently it was supposed to be preapproved between the employer, the insurance company, and the sleep center. They thought I should have a home sleep test instead of being sent to a clinic study first; I’m not exactly sure where the confusion arose. When you have sleep apnea and have fatigue, depression, and cognitive problems, you’re not in a good, mentally strong position to be a strong advocate for yourself or to do the research to find out you should be doing a home study first. The very symptoms of this condition make it hard to be an informed consumer.”

Erin’s comments prompted discussion about the appropriate role of home testing by sleep technicians in attendance. **Allen Boone** described their intended use, “Industry brought home sleep testing (HST) to bear to help contain costs. HST was designed for somebody they thought had a simple apnea. If they have comorbidities such as diabetes, hypertension, other maladies, those folks are actually supposed to go straight to the sleep laboratory for testing.” Given the severe consequences of undetected and untreated sleep apnea, several people noted the cost to the health care system and the individual being many times greater than either a home sleep test or an overnight polysomnography study. Still, insurance coverage policies vary greatly.

Access to clinic-based polysomnography testing can be challenge itself, especially in geographic areas with no or overtaxed sleep clinics, with long waits to get on the schedule. San Juanita experienced this. “I remember going home after the visit when I was told my apnea [as shown on the HST] was very severe, but I wasn’t told what else to do. My overnight sleep study was going to be about six weeks later. As a good lawyer, I went straight to my computer and sent a message to my doctor that said, ‘Okay, you’ve just diagnosed me and I am very severe, but no one has told me what happens. Can you tell me what we need to do to prevent a mishap in the meantime?’ Fifteen minutes later, I received a call from his office that there was a cancellation and I could come in that night. But how many patients know to do that? How many don’t know what to ask?” she asked.

Although the overnight test is more comprehensive and sensitive, several people noted how uncomfortable an experience it is, with the many leads attached from the monitors to all parts of the body, a sticky adhesive used to attach the leads to the skin and scalp, and the experience of being watched all night in an unfamiliar setting. Peter Stein drew laughter and head nods with his description. “The sleep study is a miserable experience. There must be a far easier way to tell whether somebody is holding their breath in their sleep. It’s like spending a night in the tool closet. I had to go through it a second time so they could determine the settings for my CPAP machine, but I went home after 20 minutes. It’s just miserable,” he said with a shrug.

In addition to the expense, inconvenience, and discomfort of the test, it is not foolproof. A woman responding to the survey shared her frustrating experience. “I lived in three different states and had seen many doctors, each trying to figure out why I was tired and couldn’t stay awake. After I fell asleep at the wheel, my primary care provider set up a sleep study. It came back that nothing was wrong. My condition continued to get worse and I was falling asleep standing up. I got more frustrated every day. Finally, I found an excellent neurologist who specializes in sleep disorders. It turned out I needed 18 hours sleep to be diagnosed and that my shallow breathing made it more difficult to for the technology to pick up my breathing pauses. My sleep apnea is mild with 9.6 apneas per hour and I have severe narcolepsy. The sleep apnea makes the narcolepsy worse. Now we also know that my partner and my two oldest boys have sleep apnea too.”

In the overview of sleep apnea provided at the beginning of the meeting, Dr. Shelley Berson pointed out that the established definitions and cut-off points for an episode of apnea and the thresholds for mild, moderate, and severe sleep apnea are somewhat arbitrary and may not catch everyone who is experiencing disturbed sleep. “Apnea is defined as holding your breath for 10 seconds, but a normal breath lasts 3-6 seconds. What about something that is 9.5 seconds? There are also occurrences called respiratory effort-related arousals, or RERAs. They’re not severe enough to be hypopneas or apneas, but they cause your brain to wake up from whatever stage of sleep it’s in. As I learned when I was studying for my board exams, these things are considered ‘almosts,’ meaning they don’t count. I think there are some people who are ‘almost sick’ out there who aren’t getting all the data reported in their sleep tests.”

The stigma of the diagnosis and treatment with CPAP kept some from pursuing care sooner. For one woman who responded to the survey, her attempts to find answers to her fatigue, daytime sleepiness, aches, and loud snoring were discouraged by her physician. “My primary doctor said that I wouldn’t want to have to deal with ‘those machines.’ I happened to change doctors a few years ago and she referred me to sleep specialist. Now I have CPAP and my symptoms are much better with treatment.” Another didn’t recognize the potential severity of the condition at first. He wrote, “I was first told of my snoring and apnea episodes when I was in my early 30s. I was formally diagnosed in my mid-50s. Education and learning of the increased risk of stroke, death, and other bad outcomes led me to get a test and then CPAP.”



“The sleep study is a miserable experience. There must be a far easier way to tell whether somebody is holding their breath in their sleep. It’s like spending a night in the tool closet.”

*Peter Stein, Panelist
Portland, ME*

SECTION 2:

TREATING SLEEP APNEA

“What we, as specialists in sleep medicine, try to do is customize a treatment plan that recognizes how the body works, how each body is shaped, and how we can use medications, devices, surgery, and lifestyle adjustments to get you the best sleep and daytime functioning possible.”

Dr. Shelley Berson

Dr. Shelly Berson opened the afternoon session of the meeting with an overview of treatment approaches and stumbling blocks that patients and health care professionals may encounter in getting satisfactory results. She underscored that the multiple contributing factors to sleep apnea called for a multi-pronged plan for managing the condition. “What we, as specialists in sleep medicine, try to do is customize a treatment plan that recognizes how the body works, how each body is shaped, and how we can use medications, devices, surgery, and lifestyle adjustments to get you the best sleep and daytime functioning possible.”

Among both AWAKE meeting participants and survey respondents, there was a great deal of improvement reported with whatever current therapy was being used, as shown on page 63. However, there remained considerable unmet medical need in terms of persisting symptoms and the burdens related to treatment. In this section, we will review how patients were managing their condition and the successes and challenges they faced.

Positive Airway Pressure Devices

The mainstay of sleep apnea treatment is noninvasive ventilation using a motorized device that draws air from the room, pressurizes it, and delivers it via tubing and a facial mask to the user. This pressurized air keeps the upper airway from closing during sleep. There are different ways of delivering pressurized air including continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), and automatic positive airway pressure (APAP). CPAP is the most common of these therapies for obstructive sleep apnea and for ease of reference, CPAP will be used to refer to all modes of

delivering noninvasive ventilation. However, it is critical to note that patients experience challenges getting the most effective type of device and differences between them are clinically important. In some cases, CPAP is supplemented with concentrated oxygen and/or a humidifier.

In the survey, 69 percent of respondents were currently using CPAP, 12 percent had used it in the past (but not at present), and 17 percent had never tried CPAP. Among the meeting participants who volunteered their experience with CPAP, most were still using it. **Rick Gordon** was one of the most enthusiastic long-term users. He described being seen in a brand new sleep clinic that opened in his town in 1992. “I consider myself very fortunate because the clinic was so new and it was run by an outstanding doctor with an outstanding staff. They spent time talking to me, telling me what to expect with the sleep test, and what was going to happen after that. They showed me a videotape of what the CPAP machine was. In those days it was huge — the size of a toaster oven — with a separate humidifier and hoses going from here to there and to my face,” Rick said, as he stretched his arms wide. “I never thought I’d be able to use it.”

Rick’s sleep test did, in fact, document sleep apnea and they treated him with CPAP for part of the night. “At age 36, I was the youngest and the most severe patient they had seen at that time and I ended up becoming a case study for the clinic. It was the best night of sleep I’d had in my whole life. I was amazed at what a good night’s sleep felt like. With their encouragement, education, and training ahead of time, I was able to use CPAP at home just fine, from the very first night. And I’ve used it almost every night since then,” he reported. Rick’s experience echoed that of other panelists who derived great benefits from using CPAP, as well as survey respondents who most often cited CPAP in open text replies to the question, “What have you found that helps the condition the most?” (See listing of responses on page 25.)

Meeting participants and survey respondents reported that CPAP therapy helped resolve some concomitant conditions and other symptoms too. One man wrote, “I had a number of heart issues: chest pain, racing pulse, shortness of breath. I was hospitalized half a dozen times and had no energy. Since CPAP, no heart issues. Now I run five miles 2-3 times a week and last year I rode more than 1,000 miles on a bike trip with my daughter.”

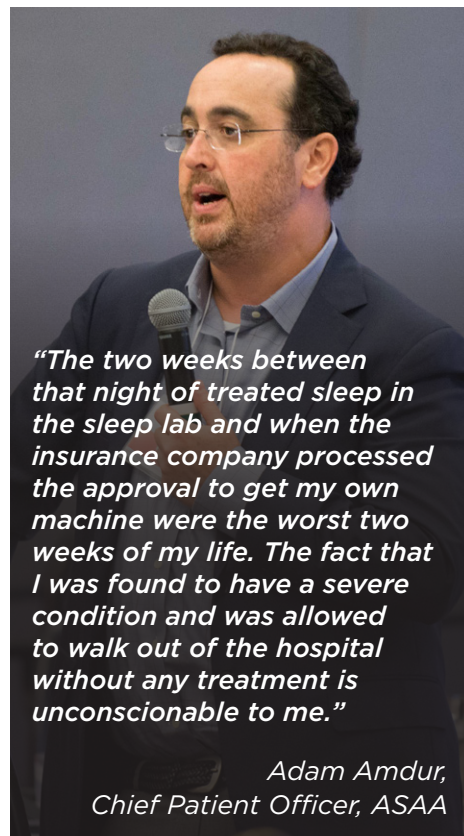
Some people indicated that the time between successful treatment with CPAP in the sleep lab and getting their own machine was a particularly stressful period. **Adam Amdur** was one of them. “The two weeks between that night of treated sleep in the sleep lab (described on page 16) and when the insurance company processed the approval to get my own machine were the worst two weeks of my life. The fact that I was found to have a severe condition and was allowed to walk out of the hospital without any treatment is unconscionable to me.”

For others, CPAP was hard to adjust to: the pressure settings, the fit and seal of the mask, the feeling of the mask on their face, the placement of the hose, the way it looked on them, and most of all, the sound of it. These challenges and others are explored in Section 3.



“It was the best night of sleep I’d had in my whole life. I was amazed at what a good night’s sleep felt like.”

*Rick Gordon, Panelist
Upland, California*



“The two weeks between that night of treated sleep in the sleep lab and when the insurance company processed the approval to get my own machine were the worst two weeks of my life. The fact that I was found to have a severe condition and was allowed to walk out of the hospital without any treatment is unconscionable to me.”

*Adam Amdur,
Chief Patient Officer, ASAA*

Other Ventilation and Airway-Related Therapies

A much smaller group of patients — seven percent of survey respondents — reported improvement using an oral appliance to either reposition the jaw (bringing the lower jaw forward) or hold the tongue in place to keep the airway open. There are many different types of appliances, including custom-made appliances that are fitted and fabricated by dentists and ear-nose-and-throat physicians, and commercially available splints that may require the user to heat and then bite into to form. This online guide⁸ illustrates the wide variety of models. For some patients, they are prescribed to treat mild to moderate sleep apnea; they can also be used in combination with CPAP therapy. One woman responding to the survey wrote, “The positional therapy and dental device I’m using seem to have eliminated the symptoms, including loud snoring, cognitive problems, and unrefreshing sleep.” She reported going from moderate symptom impact to mild impact with this intervention.

For others, like retired Navy pilot **John Andrews**, they are a first line therapy. “It was pretty effective to prevent the snoring but it didn’t really resolve the sleep issues and I was still tired all the time.” He fell asleep during an important meeting, sitting next to a four-star admiral, and snored loudly. John recounted, “Nobody was happy with that and I walked out of there telling myself, ‘I gotta do something else.’” He had another sleep study and was prescribed CPAP, but his wife didn’t like it and he went back to using his oral appliance.

A survey respondent shared her experience using an appliance as an alternative to CPAP after a long period of being undiagnosed and untreated. “As a teen I thought my nighttime panic attacks were related to hormones and stress. As a young adult, I thought they were due to stress. While pregnant and raising babies, I was told they were due to hormones and fatigue. It wasn’t until I was 43 years old that my primary care provider thought to send me for a sleep test that confirmed sleep apnea. I tried CPAP and could not tolerate it and an oral appliance has been a fantastic solution to my apnea. I now sleep well, my spouse isn’t disturbed by a fitful sleep partner, and my nighttime panic attacks are gone.”

Others reported using oral devices as a back-up treatment when traveling, when upper respiratory infections or other acute illness made it difficult to use the mask, or during power failures. Professional societies, including the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM), recommend oral appliances over no treatment at all for those who may require but cannot use CPAP.

Surgical treatments are also used as a first-line therapy, an adjunct to CPAP, and/or an alternative to it. Surgery may be performed at different sites to open an airway that is obstructed. The most common type of surgery is uvulopalatopharyngoplasty, or UPPP, which may include removing the tonsils, the adenoids, and/or remodeling the uvula, soft palate, and/or nearby tissues. These procedures are sometimes performed in a series with other surgeries to reposition the jaw, shorten the tongue, remove excess tongue tissue, release a “tongue tie” or ankyloglossia, repair a deviated septum, or reduce enlarged

⁸<http://a360-wp-uploads.s3.amazonaws.com/wp-content/uploads/sleeprev/2015/09/OralAppliancesGuide082015.pdf?a3137e>

What Have You Found That Helps The Condition The Most?


Survey respondents share their experiences via open text comments

The most frequent response was treatment with positive airway pressure (CPAP, BiPAP, APAP) devices. Many responses noted the importance of using the device all night, every night, and during naps. Persistence was required to find the right machine and optimal settings, a well-fitting mask, and a good seal. For some, there were additional benefits from having humidifier- and supplemental oxygen-equipped machines. Having a properly cleaned machine and frequently replaced filters were noted as being critical, too.


Other top treatments included:

- Oral appliances and positioning devices (including chin strap)
- Inspire upper airway stimulation implant
- Tonsillectomy
- Bariatric surgery
- Prescription Medications: Nuvigil and Provigil; Adderall and other stimulants; Flonase; decongestants; antihistamines; allergy medicines and shots; Xanax, Buspar, and other anti-anxiety medications; Ambien; corticosteroids; trazadone, amitriptyline, Remeron, and other antidepressants; gabapentin; Mirapex
- Over-the-counter decongestants, allergy and pain medicines, sleep aids
- Melatonin and magnesium supplements
- Marijuana and THC edibles
- Getting longer hours of sleep by going to bed earlier, waking later, and/or taking naps
- Naps to deal with excessive daytime sleepiness when possible
- Sleeping on the side (using wedge pillows or a tennis ball in the nightshirt) and/or with head elevated (including sleeping in a recliner chair)
- Following good sleep hygiene practices: cool, dark sleeping area used only for sleep; following a bedtime routine that begins at the same time every night; waking at the same time every day regardless of schedule; no blue-light devices used in the sleeping area
- Comfortable bed and/or pillow
- Physical activity and/or exercise
- Weight loss (or maintaining a healthy weight)
- Eating a healthy, nutritious diet (with mention of specific diets, such as all-organic, dairy-free, gluten-free, low-carb, plant-based, etc.)
- Drinking lots of water
- Restricting (or eliminating) caffeine, alcohol, spicy foods (all noted especially within 4-6 hours of bedtime)
- Increased caffeine intake
- Increased alcohol intake
- Reducing nasal congestion through use of medications, regular nasal passage rinsing, and/or nasal strips
- Myofunctional therapy
- Massage
- Acupressure and acupuncture
- Meditation and mindfulness
- Yoga and tai chi
- Stress reduction and relaxation techniques
- Positive attitude

Many respondents commented that nothing seemed to help, or that nothing seemed to deliver sustained help.



Many respondents commented that nothing seemed to help, or that nothing seemed to deliver sustained help.

A photograph of a man with glasses, wearing a light-colored checkered shirt, speaking into a microphone. He is standing in front of a large presentation screen displaying a bar chart. The scene is dimly lit, with the screen providing the main light source. The background shows the silhouettes of other people in the audience.

"I started with surgery. I went on to an oral appliance. Now, I'm a CPAP user and a very adherent one. I think everyone knows - you'll get sick if you don't take care of this condition."

Will Headapohl, ASAA Board Member (Chairman Emeritus)

"It's like Whack-A-Mole. You think you've got it swatted down and something else pops up over here."

*Paul Foxworth,
Chicago, IL*

turbinates, which may also be done as stand-alone procedures. Bariatric surgery used to treat obesity can sometimes result in relief from or reduced severity of sleep apnea.

The most extreme — and effective — surgery is a tracheostomy, where a hole is created in the windpipe through the neck. As Dr. Berson stated, "While it fixes all upper airway obstructive sleep apnea, nobody wants a trach." One-half of one percent of survey respondents reported having had a tracheostomy. One survey respondent reported having had 45 surgeries to correct jaw issues, reconstruct sinuses, address lip and tongue interference with the airway, and finally, a tracheostomy. "Sleep apnea issues have totally turned my life upside down. Resources, including time and money and MY sleep, must be allocated to medical care," he wrote.

A woman responding to the survey reported her experience after getting surgery to remove her tonsils and adenoids. "The recovery period was awful but since the surgery, my sleep apnea has been non-existent." For others, the outcome was not as durable or successful. Wrote one man whose symptoms have returned after UPPP surgery and correction of a deviated septum, "I don't have a current treatment plan other than staying in good shape. I cannot tolerate CPAP and I'm considering a custom mouth appliance, but I don't have \$2,500 to get tested again due to the high deductible on my health plan."

Eugena Brooks spoke to worsening of symptoms following surgical removal of her uvula in panel comments (see page 16). **Paul Foxworth's** septum and turbinate surgery wasn't the whole answer for him either. "Much as I'd like to be the poster boy for surgery and tell you, 'It's all good after that,' I can't. It's like Whack-A-Mole. You think you've got it swatted down and something else pops

up over here.” Paul continued, “So, surgery, I recommend. Yes. CPAP – which I couldn’t use – can be good, but there are other things, too. It may be that the oral device I’m being fitted for turns out to be the best thing yet for me. We’ll see.”

This experience of trying multiple successive approaches was echoed by **Will Headapohl**. “I started with a tonsillectomy, then they went in to correct a deviated septum, and then I had another surgery. There was no way I was going to use a CPAP, so I went on to an oral appliance. Now, eventually, I’m a CPAP user and a very adherent one. I know — I think everyone knows — you’ll get sick if you don’t take care of this condition,” Will counseled.

When surgical corrections or CPAP fail to be effective or not possible, a surgically implanted device can be used to treat sleep apnea. Electrodes are implanted in the diaphragm or airway, along with a receiver device placed under the skin. A male survey respondent shared his positive experience with a recent upper airway stimulation implant. “I didn’t know what I had and my symptoms were getting worse. My hands went numb and I felt drunk most of the day. When I went in for a sleep study, I was diagnosed with severe sleep apnea. I had throat surgery, my tonsils out, and a broken septum repaired to get obstructions removed, but I still needed more treatment. CPAP made my breathing issues 10 times worse. The implant was the next step and it is just amazing. It took me out of the fatal zone of nightly sleep apneas.” A woman who also had multiple surgeries and could not tolerate CPAP or oral devices was suffering severe symptoms until getting the implant. “My health was declining. I woke every day with a migraine headache and did not have a clear mind. I couldn’t stay awake at work or while driving. My diabetes was out of control because I didn’t have enough energy to exercise or make proper meals. I don’t know if I’d be alive today without the implant,” she expressed.

Medications

In addition to appropriate treatment of comorbid medical and mental health conditions, medications are often prescribed to address a number of issues related to sleep apnea. In the survey, the most often used medications were decongestants and nasal corticosteroids to improve the function of nasal passages and aid breathing. Medications used for control of allergies, asthma, and gastric reflux were also reported to have positive effects on sleep. Various treatments for pain and mood disorders such as muscle relaxants, anti-epileptics, and selective serotonin-reuptake inhibitors were used for both those conditions and to aid sleep.

Survey respondents described the use of medications and supplements to aid sleep initiation and maintenance and deal with insomnia, including prescription sedatives and muscle relaxants, over-the-counter antihistamines, nighttime formulations of anti-inflammatory pain medications, and melatonin. Some people reported turning to these to help them comply with CPAP therapy. As one woman wrote in the open text on her survey response, “I fall asleep best when lying on my stomach. I can’t do that with my mask on, so taking





Caregiver Perspectives on CPAP Therapy

At the AWAKE meeting and via open text responses in the Patient & Caregiver Survey, caregivers shared differing viewpoints about CPAP therapy. A few are provided here to reflect the range of experiences.

AWAKE panelist Rick Gordon recalled this conversation with his daughter, reflecting back on the time before and after Rick was treated with CPAP: “She said to me, ‘Pop, don’t you know that all of us remember the day you started using your CPAP machine?’ I asked, ‘Why? Because the house was quieter?’ to which she replied, ‘No, Pop, because the house was nicer.’ That caught me off-guard — my my children were young at the time — so she explained, ‘When you started using your machine you were a changed person. You didn’t come home

tired and grumpy. You were no longer yelling at us all the time and falling asleep on the couch. Now you were spending time with us. You had patience; you read to us, rode bikes with us, played with us. The CPAP machine didn’t change only your life; it changed all our lives.’”

A survey respondent echoed these sentiments in her comments about her husband’s CPAP therapy, “He wakes up refreshed and ‘human.’” Another stated, “Treatment has made a drastic improvement to his sleep quality and in his daily energy level. He used to have to take a nap during his lunch break just to make it through the day; now he does not.” Another survey respondent indicated, “Without the use of a CPAP machine, my boyfriend wakes up still drowsy and with headaches that fade in and out throughout the day after non-use.” Finally, this happy spouse wrote, “God bless the person who invented the CPAP. Now we BOTH sleep better!”

Not all experiences were positive, however. Phyllis Foxworth shared this experience about her husband’s CPAP treatment: “When my husband first got his CPAP, initially I was thrilled. I was well aware of the sleep issues he was having and I was quite frightened about it. I didn’t want to be a widow at such a young age. But his CPAP was so disturbing that I suddenly developed sleep issues. I don’t mean that in a light manner. I went to on-line communities to find out what other spouses were doing to cope and was stunned by the amount of negativity towards the caregiver. ‘How dare you?’, they asked. ‘Your spouse is finally getting some sleep and you’re complaining?’ After seeing these kinds of comments, I just read, and didn’t post my own question. What they didn’t understand was that I was no longer getting any sleep. To help, Paul bought me industrial grade ear muffs. Those made it so I could only sleep on my back and I couldn’t roll over. We used to joke that it was like Darth Vader and Princess Leia sleeping at night, but it wasn’t a joking matter. I want to point out CPAP sometimes has a negative consequence to the caregiver.”

This perspective was reflected by several survey respondents, as well. “As a bedmate, the CPAP and mask can make my sleep much more difficult at times. I hope the treatment helps with my partner’s health issues,” wrote one person whose loved one had not yet experienced much treatment benefit. Another described that his bed partner’s poor CPAP mask seal led to a whistling noise that kept him awake and caused him to move to another room. Another said she missed the chance to cuddle at night and to be heard by her partner due to the machine’s noise. Twenty-three percent of caregivers whose loved one was treated with CPAP indicated that the ability to share a room with their partner was impacted.

One parent of a teenager with sleep apnea who was being treated with CPAP related this experience: “Being a tween, my daughter hates having a CPAP. She does not want to have friends for sleepovers, or go to their houses for overnight stays. She doesn’t want to take it on vacation, to summer camp, or on school trips. The mask also causes acne. All of these are significant issues at her age. She constantly asks if she will have to use it forever. She wants a pill developed that she can take instead, or to have something smaller and unnoticeable.”

A survey respondent offered this final lament in his or her comments, “The extent of my partner’s sleep apnea was not known until after his sudden, unexpected death. He had quit wearing his CPAP for approximately a year and I didn’t know he was having problems.”

Ambien helps me fall asleep with the CPAP.” Another woman indicated, “I am claustrophobic, so wearing the full face mask causes me to panic. I have to take Ambien or Ativan to stay relaxed enough to fall asleep.”

To combat fatigue and daytime sleepiness, some participants and survey respondents reported using stimulants and wakefulness-promoting agents. Many, including some of the AWAKE meeting panelists like Joelle and John, reported use of these types of medications prior to getting a correct diagnosis with sleep apnea. As one survey respondent stated, “I couldn’t drive, sit in a meeting, or go to class for more than 20 minutes without taking strong drugs to stay awake. Over time, even high levels of amphetamines and constant caffeine didn’t help, and I hated taking them because of how hard they are on the heart. I just wish I had gotten treatment earlier in life. I feel I lost so many years, or decades even — my kids’ younger years, my career. I try not to be angry at all the doctors that said because I was not fat, I did not have sleep apnea.”

Many others relied on these medications in addition to other treatment approaches, including CPAP. In fact, rates of fatigue and daytime sleepiness among survey respondents were very similar in groups of CPAP users and non-CPAP users. Retired IT professional **Paul Blumstein** of Annandale, Virginia, spoke at the meeting about his experience using a BiPAP machine successfully for years, yet he still had one looming difficulty. “The biggest problem I’m having, post-diagnosis is that mid morning on most days, I start feeling tired. The doctor said that’s known as excessive daytime sleepiness or EDS. So, I do one of two things — either I take a power nap of between one and two hours, but I’m not always in a position to do that. In that case, I take Nuvigil, a [wakefulness] medicine used to treat narcolepsy. However, it has a side effect that if you take it regularly, you can start experiencing insomnia. I try not to take the Nuvigil if I don’t have to. On days when I have to make a judgment call, I sometimes weigh whether I can take half a pill.” A survey respondent offered a similar experience, “According to the data, my sleep apnea is well-controlled by the CPAP, but I still have severe daytime fatigue. I take both Nuvigil and Adderall just to wake up.”

Comments both at the meeting and in the open text fields of the survey reflected a degree of ambivalence about using medications. All medications have side effects and some can interfere with getting restorative sleep, even if they address other aspects of the sleep disorder. Other people reported that appropriate treatment of their sleep apnea reduced reliance on medications of all types. Adam related his experience early in the period following his diagnosis. “I was on more pharmaceuticals, both prescribed and self medicating, than I can count over a long period of time. My sleep was so bad that my sympathetic nervous system was firing all the time and I was in a lot of pain. Bottom line is, once I finally got hold of my sleep and started treating it the right way, my fibromyalgia, my chronic pain, disappeared. Once the sleep was stabilized, my body reset and what I needed to do as far as medication management of it was just night and day.”

“I just wish I had gotten treatment earlier in life. I try not to be angry at all the doctors that said because I was not fat, I did not have sleep apnea.”

Survey Respondent



“The biggest problem I’m having, post-diagnosis is that mid morning on most days, I start feeling tired. The doctor said that’s known as excessive daytime sleepiness or EDS. I do one of two things — either I take a power nap of between one and two hours, I take Nuvigil, a [wakefulness] medicine.”

*Paul Blumstein, Panelist
Annandale, VA*

Medicare Coverage Policy For CPAP Therapy

There were numerous references to Medicare's coverage policy for CPAP therapy. Some expressed gratitude for access to therapy provided under Medicare, while others found the agency's policies difficult to understand and follow. For purposes of clarifying the current policy, key provisions are listed below. More information is available at <https://www.medicare.gov/coverage/sleep-apnea-and-cpap-devices-and-accessories.html>.

- A three-month trial of CPAP is covered if a Medicare beneficiary has been diagnosed with obstructive sleep apnea. The trial may be extended if the doctor meets with the patient in person and documents that CPAP therapy is helping. The doctor must also document adherence with CPAP therapy, defined as "at least 4 hours per night on 70 percent of nights during a consecutive 30 days anytime during the first three months of initial usage."⁹
- If CPAP therapy began before a person was covered by Medicare, a replacement machine and supplies may be covered if certain criteria are met.
- Medicare-covered patients are required to pay 20% of the Medicare-approved amount of the machine rental, plus replacement supplies (like tubing and masks). Part B deductibles apply.
- Medicare will pay the CPAP supplier for the machine rental for 13 months if used without interruption. After a 13-month rental period, the user owns the machine. Failure to demonstrate continued compliance may result in repossession of CPAP equipment.
- In certain areas of the country, machine rentals and supply purchases must be handled through a competitive bidding program among Medicare-approved suppliers.

Information on Medicare's website states, "Your doctor or other health care provider may recommend you get services more often than Medicare covers. Or, they may recommend services that Medicare doesn't cover. If this happens, you may have to pay some or all of the costs. Ask questions so you understand why your doctor is recommending certain services and whether Medicare will pay for them."¹⁰



Supportive and Non-Medical Management Strategies

As Dr. Berson described in her treatment overview, addressing sleep apnea and getting healthy, restorative sleep often requires multiple approaches — at any given time and over time. In addition to the medical interventions discussed above, meeting participants and survey respondents alike endorsed a wide range of complementary, lifestyle, behavioral, and cognitive approaches to getting better sleep and living better in the face of sleep apnea. For those with little access to care, either because of a shortage in their area or lack of insurance or resources, these might be their primary treatment. As one survey respondent put it, "You call these things supportive; I call them my main strategies: losing weight, tongue/throat exercises, and cardio exercise."

Two-thirds of survey respondents also used weight loss as a primary or supportive strategy, either at present or in the past. Comments revealed a combination of diet, exercise, and, in some cases, bariatric surgery. Many spoke to the challenge of losing weight when energy levels are low, making it hard to exercise and prepare nutritious meals. There was also frustration expressed with medical professionals and family members who pushed weight loss as being the simple answer. Said one, "None of these things [in this survey] have ever been suggested to me before. Doctors just keep telling me I should lose weight." While many people spoke to the direct and overall benefits of weight loss, others who reported substantial weight loss (of 50 pounds or more) didn't find it relieved their sleep apnea symptoms as much as they had hoped. Even significant body weight loss doesn't reduce tissue mass in the tongue, leaving a primary cause of airway obstruction unchanged. Others experienced weight gain with use of the CPAP, possibly because they were sleeping more soundly and not burning as many calories during the nighttime hours.

Participants at the AWAKE meeting addressed the challenges of achieving and maintaining a healthy body weight too. **Celeste James** explained how she was addressing it. "I didn't understand that there was a certain amount of weight gain with this malady, so I changed the way I ate. I worked with a nutritionist to help me identify what was important to have in my diet, working with the diabetes. When I wake in the morning I try to do a few minutes of cardio to raise my heart rate. I'm active during the day and I walk regularly and do a little kick boxing. Just a little, you know, because I don't want to hurt nobody," she said with a chuckle.

Sleep positioning was used by about one-third of survey respondents at present, with most of the comments indicating that sleeping on their side and/or with their head elevated was helpful. To help with this, people suggested using wedge-shaped pillows, positioning belts or devices, inserting tennis balls into a pocket sewn into the back of a nightshirt, getting an adjustable bed, or sleeping in a recliner. Dr. Berson added that people with a deviated septum in the nose should lie with the "bad side" down — a direction that can be determined by closing off one nostril at a time to determine which side has more difficulty pushing air through it.

In terms of current strategies being used, survey respondents cited alcohol avoidance next most often, with slightly less than one-third currently



employing this strategy. Comments ranged from complete abstinence to reduced quantities, to cutting alcohol intake within a certain number of hours of bedtime. A few outliers cited alcohol as beneficial. Caffeine was the most contested substance; 22 percent of survey respondents indicated they were currently using increased levels of caffeine to help combat symptoms, with 11 percent more having done so in the past. However, there were numerous written comments about the importance of eliminating caffeine, reducing it, or curtailing its use within a certain number of hours before bed to improve sleep quality.

Extending the total number of hours slept by taking naps, waking at a later time, and/or going to bed earlier was next most popular, with about 28 percent of survey respondents using this approach at present. Naps, in particular, were often cited as a means of dealing with persistent fatigue and daytime sleepiness even with adequate treatment using other therapies. For others, naps were a vestige of the past, prior to diagnosis and even moderately effective treatment. Good sleep hygiene practices came up frequently in the comments, including such things as listed in the ASAA's "10 Commandments of Healthy Sleep,"⁹ referenced by Rick Gordon at the meeting. (See also the text box on page 25.)

Seventeen percent of survey respondents used one or more strategies to relieve or reduce nasal congestion and/or allergies, including nasal rinsing with saline solution (or netti pot), nasal strips, running a humidifier in the bedroom, and/or taking a hot shower or steam before bedtime. Dr. Berson emphasized the importance of addressing household allergens that may reside in bedding, carpeting, clothes hampers, etc. to improve the sleeping environment.

Meeting participants shared a few other personal favorite "hacks." Paul Foxworth offered one: "Here's my low tech, low-expense therapy. I tape my mouth shut with a Band Aid. The reason I use a Band Aid is because it has gauze in the center that goes over the lips so it won't peel skin off my lips. I take meds that create dry mouth and I probably would breathe through my mouth every night, part of the night, if I didn't do this." Paul Blumstein had a fix for dry mouth too, a problem identified by many others, "There's an over-the-counter product available in any drugstore called Biotene. It's next to the mouthwashes. If you rinse with it before you go to sleep, it will keep your mouth moisturized for hours." Similarly, one of the survey respondents recommended nasal gels to keep nasal passages open and moist. Another person said they used a chin strap to keep their mouth closed at night.

In addition to these suggestions, others added smoking cessation, soothing music at bedtime, and becoming more self-educated by attending a sleep apnea support group as part of their therapeutic approach. Replies to the survey question, "What have you found that helps the most?" based on respondents' open text answers are listed on page 25. One person's response highlighted the importance of keeping at it, stating what helped most was, "stubbornness. I have refused to give up. It took a while to find a good sleep doctor, but I did. He is supportive and innovative and he is also stubborn and hasn't given up on me."

Two-thirds of survey respondents also used weight loss as a primary or supportive strategy at present or in the past. Many spoke to the challenge of losing weight when energy levels are low, making it hard to exercise and prepare nutritious meals. There was also frustration expressed with medical professionals and family members who pushed weight loss as being the simple answer.

"I have refused to give up. It took a while to find a good sleep doctor, but I did. He is supportive and innovative and he is also stubborn and hasn't given up on me."

Survey Respondent

⁹"Positive Airway Pressure (PAP) Devices: Complying with Documentation & Coverage Requirements," Centers for Medicare and Medicaid Services, October 2016.

¹⁰<https://www.medicare.gov/coverage/sleep-apnea-and-cpap-devices-and-accessories.html>, (accessed July 14, 2018)

¹¹<https://www.sleephealth.org/sleep-health/ten-commandments-of-healthy-sleep/>

SECTION 3:

TREATMENT BARRIERS

In planning for the AWAKE meeting, FDA staff asked ASAA to explore with patients and caregivers some of the barriers to treatment and things that keep them from following through on treatment recommendations. The meeting discussion and survey results uncovered a large number of factors occurring before diagnosis, immediately after diagnosis, and over long-term experience living with sleep apnea. The more common of these are described below.

Stigma surrounding the condition and the therapy, a lack of understanding about the potential serious health consequences of untreated sleep apnea, and financial barriers were cited as reasons for inaction.

Failing to meet established cut-offs for diagnosis can also get in the way of treatment.

Getting Appropriate Medical Attention

Prior to diagnosis, challenges with awareness, attitudes, and access can lead to delays in seeking or receiving appropriate medical attention. **Celeste James'** experience not having ever heard the term "sleep apnea" before leading a community health fair, at which her symptoms were linked to possible sleep apnea by a university-based clinic-exhibitor (as described on page 19), contributed to her living most of her life without appropriate care. "I can tell you that I never thought I had a sleep disorder. I felt the way that I felt, but it was normal to feel the way I felt because of the active life that I lived. From an early age I was always busy, so yes, I've always been tired. It never occurred to me that I might have a sleep disorder." Other meeting participants and survey respondents expressed this same surprise upon learning that there was a medical condition at the root of their experiences and health problems. Said one, "I never knew what it was until I saw a dentist who made oral appliances. He sent me on to a sleep specialist who did surgery on my nose and prescribed positive airway pressure. I tried several devices before finding one that eliminated my apneas."

A lack of awareness — or unwillingness to address sleep issues — among physicians also contributed to delays in diagnosis, as Joelle and other AWAKE participants recounted (see pages 15-16). As one recently diagnosed survey respondent reported, “I had been experiencing exhaustion, even after sleeping 12 hours. I would nap and feel worse when I woke up. My doctor told me to exercise or take a walk. When I did, I found I needed a nap. Finally, after four years of these conversations with my doctor, he referred me to a pulmonologist who evaluated me and then sent me for a sleep study. Thank goodness now I know why I’m tired all the time; I have sleep apnea.” Another woman commented on how her atypical presentation delayed appropriate attention from her doctor. “My doctor wouldn’t order a sleep study because I didn’t fit the criteria and didn’t report falling asleep at stop lights or in waiting rooms [on the Epworth Sleepiness Scale]. I was waking up gasping for air, but that wasn’t part of the criteria my doctor used. Finally, I developed congestive heart failure and got attention. I’m in year four on CPAP and no more heart failure, thank God!”

Misdiagnosis can also play a role, as this survey respondent stated, “It took me a long, long time to be diagnosed since I was misdiagnosed with adrenal fatigue and treated for the wrong thing for a long time. This led to a worsening, of course, over time and I felt like I was dying.” Another commented, “I was diagnosed with postpartum depression in 1999, but it was actually sleep apnea and, finally in 2014 I got treatment for that. I was on antidepressants all those years for no reason.”

Failing to meet established cut-offs for diagnosis can also get in the way. “I had two studies done with a borderline diagnosis, so no machine was prescribed. I was hospitalized a couple times and nurses would be terrified when I stopped breathing overnight. A couple years ago my uncle passed away during his sleep study so I asked for another test and this time it was really bad. They were surprised I wasn’t already on CPAP,” wrote one woman. Another person indicated that the testing conditions made it hard to get a good reading. “I had at least six sleep studies that all used very cumbersome wiring harnesses that made getting any real sleep of more than 45 minutes impossible for me. I knew I had severe sleep apnea but it wasn’t confirmed by testing until I had a test with less cumbersome monitoring equipment,” he reported.

Problems also arise with established diagnostic thresholds for Medicare patients trying to access treatment. The American Academy for Sleep Medicine (AASM) updated its diagnostic criteria for sleep apnea in 2012, stating that oxygen desaturation is no longer required for a diagnosis of obstructive sleep apnea. However, the Centers for Medicare and Medicaid Services (CMS) did not revise its guidelines, sticking by the 2005 criteria that require oxygen desaturation. For Medicare beneficiaries who otherwise meet sleep apnea criteria but do not have evidence of oxygen desaturation, CPAP therapy may not be covered.¹²

Patients’ attitudes can sometimes get in the way of a prompt diagnosis, as Dr. Berson pointed out in her treatment overview and as this survey respondent admitted. She writes, “I was diagnosed three years ago. Before that, I was



“From an early age I was always busy, so yes, I’ve always been tired. It never occurred to me that I might have a sleep disorder.”

*Celeste James, Panelist
St. Albans, NY*

For Medicare beneficiaries who otherwise meet sleep apnea criteria but do not have evidence of oxygen desaturation, CPAP therapy may not be covered.¹²

¹²Meskill, G. “Medicare regulations are driving a wedge between obstructive sleep apnea patients and their providers.” *Huffington Post*. January 11, 2017.



told for years, by several doctors, to have a full sleep study, but I didn't follow through." Another woman made a similar acknowledgment, "I would wake up numerous times struggling to breathe, but I waited about three years to get a formal diagnosis." Stigma surrounding the condition and the therapy, a lack of understanding about the potential serious health consequences of untreated sleep apnea, and financial barriers were cited as reasons for inaction.

The lack of a well-established medical profession dedicated to sleep made navigating to a knowledgeable provider difficult for some. A shortage of sleep clinics delayed others from getting attention, including AWAKE panelist **Erin Taylor**. "It took me about six weeks to get into a sleep center. That was the first barrier I faced in that I wanted to get a resolution immediately once my doctor and I recognized the possibility of sleep apnea. It was hard to get into that first sleep study because they were just overbooked." San Juanita would have had to wait six weeks for her overnight sleep test had she not pressed her doctor for a more immediate appointment after a home test pointed to sleep apnea. (See page 20.)

Financial and Coverage-Related Challenges

The cost of testing keeps some people from getting the medical attention their symptoms warrant. Out-of-pocket expenses pose barriers for insured patients and uninsured patients alike. A survey respondent highlighted this in her comments, urging creation of a fund to help people get tested. "If you can't afford the cost of a sleep study, then you do without the help you desperately need. If you can't get the help you need, this condition can eventually cause you to have a heart attack or stroke," she pleaded. Financial issues posed a barrier for slightly more than one-third of survey respondents.

In the period immediately following diagnosis, some of the above challenges persist and new ones emerge. After sleep apnea is confirmed and a CPAP device is prescribed, there can be a delay in actually getting the device arising from the processing of insurance coverage approvals or problems with the availability of specific equipment. This can be a particularly anxious period for the newly diagnosed patient who is now acutely aware of the severity of their condition and the need for treatment. Erin Taylor is one who experienced this after getting half a night's sleep with CPAP as part of the overnight sleep study. "I was really excited to go home and start using my CPAP any day. But it took longer than I expected. My sleep study was on October 6 and I finally got my CPAP on November 8. So I went a month knowing there was a solution out there for me and knowing that I could be getting better sleep, but not having it yet," she remarked.

Public and private payers may restrict choice among the machine models available on the market, potentially limiting patients to older models with fewer features. One man expressed his frustration on this point, “Insurance and therapy has become too bureaucratic. Give me the equipment and I’ll use it. But don’t restrict my choices to fixed pressure or no-data machines!” Others lamented that their insurance companies wouldn’t cover quieter, lighter, more portable models, or the equipment to help clean the device. As one indicated, “I worry that long-term, just washing my mask and tubing may not keep it clean enough. I already seem more prone to respiratory problems, but the devices that disinfect the machines are so expensive and they are not covered by my insurance plan.” Panelist **Eugena Brooks** viewed some of the coverage policies and decision made by payers as short-sighted. She observed, “It’s like they’re operating on the penny wise and pound foolish model. They want you to have the cheaper, home version of a sleep test first, rather than pay for the more expensive in-clinic study because they’re not thinking about the fact that it’s going to cost more in the long run.” She saw policies that restricted or withhold treatments the same way. “They don’t get it. They’re so focused on saving a dime right now. Never mind the thousands of dollars that dime saved is going to cost them later on,” she said shaking her head.

There were also many comments about the challenge of getting coverage, or competitive pricing, for consumable supplies because of requirements to use a particular supplier. Others echoed this sentiment, “I wish I could just buy the supplies I want and be reimbursed by my insurance, but the whole process is confusing and I can’t find my options spelled out anywhere. I see better pricing and options online but feel tied to the durable medical equipment (DME) distributor because that’s who my insurance requires me to buy them from.” On a positive note, one woman’s insurer helped her get effective treatment, “Thankfully, I have insurance that has helped me obtain the CPAP machine I now own. My insurance helps greatly to continue to get needed supplies, masks, nasal pillows, tanks, hoses, etc. I use my machine every night.”

Several people commented that their insurance policy would not cover the cost of wakefulness medications or that the out-of-pocket costs for these prescriptions put them out of reach. “I NEED a daytime stimulant to manage the sleep attacks, but insurance won’t cover it,” wrote one individual.

Equipment Instruction, Support, and Service

Numerous speakers at the meeting addressed the lack of information provided to them about proper use of CPAP, either by the prescribing physician, the sleep technician who conducted the polysomnography test, or the equipment supplier. **Joelle Dobrow** described her experience, which drew head nods across the room. “Once I had a diagnosis and CPAP prescription, they sent me into a room with eight other people so I could get trained on my machine. I was the only woman in the room. Every one of us had a different machine and a different mask. The representative from the durable medical equipment (DME) supplier played a video and didn’t really answer our questions. So when I got the machine home, it didn’t make sense to me. I didn’t know where to turn with



“They’re operating on the penny wise and pound foolish model.”

*Eugena Brooks, Panelist
Brooklyn, NY*

“I NEED a daytime stimulant to manage the sleep attacks, but insurance won’t cover it.”

Survey Respondent



Summary of Barriers to Effective Treatment or Sticking with Therapy

- Awareness and full understanding of sleep apnea — its signs, symptoms, and consequences
- Attitudes about sleep apnea and its treatment
- Access to knowledgeable healthcare professionals, equipment suppliers, and services (including sleep testing and support for proper use of therapies)
- Not fully meeting established criteria or thresholds for mild, moderate, and/or severe sleep apnea
- Misdiagnosis
- Insurance coverage for sleep testing, therapies, full-featured equipment, supplies (such as masks, tubing, cleaning materials), patient education, and support
- Lack of financial resources for out-of-pocket expenses (including unreimbursed expenses)
- Treatment delays due to administrative processes or shortages of testing facilities, equipment, or supplies
- Discomfort with or challenges tolerating treatment
- Side effects or negative impacts of treatment use (including physical, emotional, psychological, social, or interpersonal effects)
- Medical complications
- Power outages, lack of access to sufficient electrical current, and other electrical power-related issues
- Insufficient perceived benefit relative to the burden of treatment

my questions. Two or three years later I found that I had been issued an out-of-date machine model no longer being manufactured. I also learned from online reviews that the DME company had poor ratings and didn't help anybody use their machines. I learned later that I needed a CPAP machine with a humidifier. Two years later, a machine that had a humidifier that was heated. All of this came in steps, 2-3 years apart from one another.” Joelle related that it wasn't until she had reached her seventh sleep specialist that she found someone familiar with the equipment. “He had no fear of touching the equipment; no other doctor would touch or discuss the equipment with me,” she said.

Properly setting the machine was another frequent complaint, one that Celeste James experienced. “When I first got my machine, I couldn't get any sleep because the air was coming at me like a wind tunnel. The doctor had to change the prescription and then someone [at the DME supply company] had to program it remotely. I had no control over it, whatsoever.” A survey respondent had to discontinue use while waiting to get his machine recalibrated. “I have been trying to get it done for almost 90 days and it has been very, very difficult waiting. My symptoms have returned with a vengeance,” he reported.



Like Joelle and others who weighed in at the meeting and via the survey, many people experienced high frustration with slow or no response and a general lack of customer service from DME representatives. One person summed it up with this statement: “The DME is not as knowledgeable as I am. I have to argue with them as they always send the wrong supplies or incomplete orders that take a long time to get. The excuse they use is always, ‘It’s on back order.’”

Problems understanding proper use of CPAP equipment and having tools to adjust settings and otherwise make it more comfortable and effective are compounded by the hammer of strict compliance requirements for payment coverage. Instead of addressing interruptions in use with offers for assistance and patient education as is provided by some providers and payers to patients with diabetes, patients struggling with CPAP therapy can have machines repossessed. Another sleep test is required to start the treatment process anew, compounding barriers to treatment, rather than resolving them.¹³

Some patients, including Australian computer programmer Mark Watkins or “JediMark” as he is known by users of his SleepyHead software, have taken matters into their own hands. Using programs like his, they explore the raw data generated by their CPAP machines, identifying correlations that help them detect the need to adjust or change masks, request (or make) changes to pressure settings, take their machines in for service, or return to the physician for help when new symptoms or complications aren’t otherwise explained or easy to manage another way.

Instead of addressing interruptions in use with offers for assistance and patient education as is provided to patients with diabetes, patients struggling with CPAP therapy can have machines repossessed.

Poor Fit, Discomfort, and Inconvenience

While the majority of survey respondents currently using a CPAP reported using it seven days a week, six to eight hours each night, there were many, many comments about the discomfort of the mask and equipment itself being a barrier. Among all survey respondents, “Uncomfortable” was the top barrier with 53 percent of all respondents; among 1,478 SurveyMonkey respondents currently using CPAP, 56 percent of them cited “uncomfortable” as a barrier to sticking with treatment, compared with 75 percent of past CPAP users (n=151). One respondent wrote, “I’m a mouth-breather when asleep and wearing a full face mask causes severe cervical pain and discomfort, insomnia, and frequent waking from pain and dry mouth. Teeth grinding also causes pain and problems maintaining a good seal on the mask.”

There were dozens of comments that contained elements of this person’s feedback, “The CPAP mask makes a lot of sounds that wake me up, like the tube rattling or hitting things, parts of the mask getting pinched and whistling, etc. Also, I usually have to readjust the mask at least once per night because the straps have shifted.” And these problems were frequently mentioned as

¹³Meskill, G., *op cit.*

**“I HAVE A LOVE/
HATE RELATIONSHIP
WITH MY CPAP!”**

well: “The forceful blowing of air is horrible. My stomach gets so full of air it is difficult to eat breakfast in the morning and I’m burping it out for hours. My throat feels like it has been blown apart every a.m.”

People also noted the following problems: getting tangled in the hosing; thin or sensitive skin being irritated by the mask; feeling hot, claustrophobic, or suffocated while wearing the mask; straps and headgear put pressure on face and head, are itchy, and leave marks on skin; usage contributing to sinus congestion, sore throat, hoarse voice, and/or dry mouth; and the sound of the machine motor being problematic. This woman summed up a lot of the input received via the survey and at the meeting: “I have a love/hate relationship with my CPAP!”



“I currently am not doing any treatment as I do not have insurance and I cannot afford insurance or a new sleep study, a new CPAP machine, or a mask. I know that I am a danger to myself as well as others if my condition does not improve.”

Survey Respondent

Spouses and bed partners can find these treatments uncomfortable, too, as described on page 28. One woman wrote, “My husband hates my CPAP machine and thinks it is a scam.” There were several comments related to the lack of family and general support for sleep apnea and its treatment that contributed to low satisfaction with available approaches, like this one: “There is a general lack of understanding for the severity of the condition and its consequences from family and friends that keeps me from doing more to treat it. I feel alone sometimes.”

Oral appliance users also cited discomfort as being a key barrier to use and sticking with therapy. “My bite changes with my use of the oral appliance which creates continuous jaw and joint pain,” wrote one woman. Another expressed concern with long-term use of her positioning appliance, “I worry about the effect it will have on my teeth, my bite, and my gums over time.” Recent dental work caused panelist **John Andrews** to stop using his 10-year-old appliance. “My dentist put a crown on a tooth and now the appliance doesn’t fit. Insurance is in the way of me getting a new one so I’m not doing any treatment right now and I feel it. I’m going to see if I can dig out my old CPAP machine.”

Emergent and Persisting Complications

As other acute and persistent medical conditions arise, individuals expressed new challenges sticking with their therapy or achieving effective results. One woman reported that surgery to treat breast cancer made it impossible to continue with CPAP therapy. Phobias, dementia, or skin allergies/sensitivities interfered with treatment, according to several comments. Persistent sinus or other upper respiratory infections were cited by numerous people as requiring temporary or permanent suspension of CPAP treatment. As one person shared, “I used CPAP for three years after diagnosis, then I developed such a bad cough I could not use it. I had bronchoscopy and many other tests, but there was no cure for or control of my cough. Fungal lung infection is part of the problem.” Dr. Berson mentioned at the meeting that she has seen some nasty lung infections as a result of inadequate or improper CPAP machine cleaning and/or maintenance.

Practical issues, like power outages or lack of access to electricity can also interrupt treatment. At the meeting, Florida resident **Paul Zuccarini** mentioned the challenge of frequent power outages caused by hurricanes and storms as being a threat to him and others who rely on CPAP. He also recounted the time he was forced to move out of his condo while it was being treated for termites and forgot to pack his machine. “I was stunned how much that three days without it impacted me, so I went to my doctor and said, ‘I need a prescription today!’ I paid cash to buy another machine online. You have to be prepared for those types of events as you go through your life facing sleep apnea.” People who travel a lot commented on the shortage of outlets near beds in hotel rooms and overnight accommodations booked through private rental sites being a challenge. This long-haul trucker shared his challenge with being compliant while working on the road, “The anti-idling legislation gets in the way of my treatment. I can’t run my CPAP without idling the truck motor on my sleeper berth-equipped truck unless I purchase a \$10,000 auxiliary power unit.”

Over time, equipment wears out and must be replaced. Machines operated at higher pressures experience more wear and tear and need to be replaced more often. Medicare and many insurance plans require another sleep test before approving a new machine. This poses barriers similar to those encountered during the diagnostic process, as well as added frustration of knowing that symptoms may return or comorbidities may worsen in the meantime. “I need a new machine but it’s not covered by my insurance and no provider will write a prescription for a new machine unless I take another sleep study, which my insurance won’t cover. I don’t have the thousands of dollars available for this; I’m still in thousands of dollars of debt for past medical bills. It’s pretty sad it’s so expensive when it is so vital to be able to use CPAP for relief,” wrote one exasperated survey respondent. Another shared his perilous status, “I currently am not doing any treatment as I do not have insurance and I cannot afford insurance or a new sleep study, a new CPAP machine, or a mask. I took this survey as I am looking for help. I know that I am a danger to myself as well as others if my condition does not improve. Sleep apnea controls my life. I cannot function without thinking about how tired I might be, or wondering what I need to do to fall asleep. This has caused me to lose two very lucrative jobs and now has financially ruined me. It has completely ruined my life.”



Making Tradeoffs

For some, these treatment burdens made them question whether the benefits were worth the tradeoffs. Calculations were highly individual, but this person’s resigned comments had elements of other perspectives shared: “I dread going to sleep because I hate my CPAP. I hate the idea of not having my CPAP because I know I need it so I don’t die in my sleep. It is a complete and total turnoff sexually and it has affected my life in that area, which makes me sad. I need surgery, but that scares me because of the risk involved. I know someone who almost bled to death after the surgery. Overall, I have adjusted, but I still hate it.”

The following success story illustrates the many positive outcomes that were shared: “I was diagnosed with severe sleep apnea in 2012 and used CPAP faithfully for five years. When I requested a new machine, Medicare insisted I be re-evaluated with a sleep study. I had lost 40 pounds since the original diagnosis and the new sleep study results showed that I no longer met diagnostic criteria for even mild sleep apnea. My husband, who also has sleep apnea, requested a new study for himself after losing 60 pounds. He was found to have gone from moderate apnea requiring CPAP to mild apnea, now successfully treated with an oral appliance.”

SECTION 4:

ADDRESSING UNMET NEEDS

Throughout the meeting, participants raised issues that represent unmet needs. Survey responses surfaced many of the same topics that warrant attention. Below is a summary of the most common topics, presented as they may be encountered along the patient journey.

Lack of Preemptive Action: In general, current messaging around prevention of sleep apnea focuses on maintaining a healthy lifestyle and a healthy body weight, paying attention to diet, physical activity, and avoiding smoking and alcohol. While beneficial guidance in general, many individuals develop sleep apnea even though they follow these practices. For those who may be at greater risk for developing sleep apnea due to physical features that form a vulnerable airway, family history, disruption of natural diurnal rhythms (as with night shift workers), safety-sensitive occupations (such as truck drivers, bus drivers, or rail operators), and/or other factors that may increase chances that they will suffer its consequences (or where its presence could have potentially catastrophic effects), more proactive measures to monitor for early warning signs and address emerging sleep apnea in a milder state might prevent progression and/or serious and costly consequences. There is also little understanding about ways to prevent progression from mild sleep apnea to moderate and severe forms. Potential links between sleep apnea and sudden infant death syndrome merit more research attention and elucidation.

“I’m a thin and healthy guy at 5’9” and 160. A family member expressed concern about me choking and gasping for breath during sleep. I sought diagnosis and apparently my sleep apnea is due to my jaw structure and bad genetics. Who knew?”

— Survey respondent



"I knew my father, uncle, and cousins had it but I really didn't want to deal with the mask since I have anxiety about things on my face so I didn't tell my doctors. I also didn't know all the symptoms or possible bad things that could happen or I would have told my doctor five years earlier."

— Female survey respondent

Low Awareness: Meeting testimony highlighted the need for greater awareness of sleep apnea among the general public and within the healthcare community. Awareness campaigns are needed to improve recognition and understanding of the risk factors that contribute to sleep apnea, its presenting signs and common symptoms, the potential benefits of effective therapy, and potential risks and consequences of non-treatment. Special efforts should be taken to improve recognition that sleep apnea occurs in children, in women, and in people of all body types to erode the persisting stereotype that sleep apnea occurs only in overweight middle-aged and older men.

"I've wondered for many years whether I had sleep apnea. My husband, a physician, told me many times, 'There's no way you have sleep apnea; you're not obese.' Well, guess who has severe obstructive sleep apnea?"

— Female survey respondent

"I did not know about sleep apnea or the dangers of it before I was diagnosed. Looking back, my mother probably passed away earlier than she should have. We just thought she surely did snore loudly. No physician ever mentioned sleep apnea as a possible cause of that."

— Female survey respondent

Special efforts should be taken to improve recognition that sleep apnea occurs in children, in women, and in people of all body types to erode the persisting stereotype that sleep apnea occurs only in overweight middle-aged and older men.



The importance of healthy sleep and better detection of sleep disorders warrants more attention in medical school curricula and training of professionals in all health care settings, a need made even more urgent as several leading sleep specialists are approaching retirement.

¹⁴Final Recommendation Statement: Obstructive Sleep Apnea in Adults: Screening. U.S. Preventive Services Task Force. January 2017. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/obstructive-sleep-apnea-in-adults-screening> (accessed July 24, 2018)

¹⁵Mold, JW. Identification by primary care clinicians of patients with obstructive sleep apnea: a practice-based research network (PBRN) study. *Journal of the American Board of Family Medicine*. 2011 Mar-Apr;24(2):138-45

"After being formally diagnosed with sleep apnea and learning more about its signs and symptoms, it's likely I have been suffering with the condition for the majority of my life. Other people with whom I have been close over the years can confirm the presence of certain signs of sleep apnea going back many years, but no one ever raised it with me."

— Male survey respondent

Poor Detection: The number of stories recounted about tragedies or near-tragedies prompting individuals to seek care underscores the need for evidenced-based screening programs in addition to better awareness (addressed above). A 2017 statement from the U.S. Preventive Services Task Force highlights the need for screening tools in current use (including the Epworth Sleepiness Scale and the STOP-BANG questionnaire, see page 14) be validated in primary practice settings as a first step in establishing the evidence for a net benefit of widespread screening of asymptomatic individuals or individuals with unrecognized symptoms for sleep apnea.¹⁴

The importance of healthy sleep and better detection of sleep disorders warrants more attention in medical school curricula and training of professionals in all health care settings, a need made even more urgent as several leading sleep specialists are approaching retirement. More attention to sleep in the review of systems as part of routine care would help to improve upon the relatively low rate of 20 percent of patients who spontaneously report sleep-related issues to their physician.¹⁵ Better coordination of care and referrals across settings (primary and specialty medical, dentistry, and mental health) would also help to better detect and address sleep disorders early, before they become severe and/or lead to catastrophic outcomes. This is especially true in children, where symptoms and behaviors may be mis-identified as attention disorders, with opportunities for effective management delayed or missed entirely.

"I asked my doctors about whether I might have sleep apnea, but they brushed me aside because I'm thin. It was finally diagnosed in the intensive care unit after I had suffered a heart attack."

— Male survey respondent

"The average amount of time spent educating a medical student about sleep is 18 minutes. The average medical resident gets three hours of instruction about sleep. So we need to do a better job as a nation on sleep education. It is one-third of our lives."

— Melissa Patterson, patient advocate

"There's one thing I beg of the entire healthcare community — before any child is written a prescription for any attention deficit disorder medication, refer them for a sleep work-up. It's not the child's fault that they're bouncing off the walls. It's not the child's fault they are wetting the bed. Those are the body's way of waking them up. We have to teach all the moms and dads and grandmas and grandpas about this."

— Adam Amdur, ASAA's chief patient officer

Family members and other caring individuals around the person who may have undiagnosed or inadequately treated sleep apnea need resources to help them relate their observations and engage in productive dialogue about their concerns and possible action steps to investigate the observed signs and symptoms.

“My husband had a home sleep test but has never gone to see a doctor about the results and diagnosis. He has very high blood pressure and is on four medications and we’re both worried about him having a stroke but he won’t ask about his sleep results. It’s hard to get someone to get diagnosed and treated if they’re not willing. I feel I have to respect his autonomy and self-agency, even though I know there is a problem.”

— Female survey respondent

“My ex-husband had a lot of the symptoms and, like a typical male, hated doctors. He had a heart attack and finally got a sleep test, was diagnosed with sleep apnea, and got treatment. Now my 10-year-old son has some of the signs and symptoms, with anxiety being the most disruptive to his life. My fiancé also shows signs, but he doesn’t like doctors either. It’s a lot to take on.”

— Female survey respondent

“My husband was diagnosed with sleep apnea shortly after we married, when his snoring and gaps in breathing were startling me awake and I insisted he talk to a doctor. His symptom level was becoming intolerable for me, and the poor sleep quality was adversely affecting his cognitive ability and mood. It also affected our relationship. I’ve become a lighter sleeper because I’m constantly listening to his breathing to make sure he’s not choking or stopping breathing. Even with CPAP treatment he still snores, and the machine itself is loud. So I’m still getting lower quality sleep because of it. I’m not sure what else to do.”

— Survey respondent

Burdensome Diagnosis: Numerous unmet needs along the path to diagnosis were revealed by AWAKE meeting participants. While home sleep tests (HSTs) were developed to provide a less expensive, more convenient, and more immediate alternative to clinic-based overnight polysomnography, there were reported shortcomings too. Integrating patient perspectives in utilization policies may help to refine practices so that a wider range of short-term and long-term benefits and tradeoffs are considered. The experience of clinic-based tests warrants attention and innovation to become more patient-centered, much as the settings and procedures for childbirth have changed in response to women asserting their needs and expectations. Criteria for sleep apnea and other conditions of sleep disordered breathing necessitate making considerations for borderline findings and sleeping abnormalities that may not be easily measured in a single night of sleep, under unfamiliar and observed conditions. In circumstances where CPAP therapy is delivered as part of the testing protocol with immediate benefits to the patient, there need to be expedited means of providing a device for home use to prevent treatment delays and potential negative consequences that can occur during the waiting period.



Family members and other caring individuals around the person who may have undiagnosed or inadequately treated sleep apnea need resources to help them relate.

Challenges Revealed by the AWAKE Sleep Apnea Initiative

- Lack of pre-emptive action
- Low awareness
- Poor detection
- Burdensome diagnosis
- Inadequate treatment
- Insufficient patient education and support
- Inaccessible patient-generated data
- Stalled innovation
- Dissatisfactory DME customer experience
- Inadequate coverage policies
- Undefined national research agenda



"I do not feel my first sleep study was done properly. I had almost no REM. I could not order a retest myself so I was put off for several years until I had another study which showed severe sleep apnea."

— Male survey respondent

"As a rape victim, the sleep lab was very triggering and was not dealt with appropriately by the technician. Hopefully this will become a part of training. I can't imagine this is something new for people with sleep issues and trauma."

— Male survey respondent

"I have been exhausted my entire life and it was blamed on my lupus. A previous sleep study 10 years ago did not diagnose the apnea and even when another did, it didn't capture the severity of it. It has taken a year of turning up the pressure on my machine to get it under control."

— Female survey respondent

"I complained of symptoms as far back as 2003, but doctors kept saying I was 'just depressed.' I told them I was really tired all the time. In 2008, I asked again and was told I was just depressed. A rheumatologist diagnosed me with fibromyalgia but didn't tell me that. In 2010 he ran out of things he could prescribe for my sleep problems so he sent for a sleep study and I got diagnosed with sleep apnea."

— Female survey respondent

Inadequate Treatment: In spite of the array of treatment options, there remain many untreated or undertreated individuals. The top unmet medical need identified by the AWAKE Initiative is for effective treatment of fatigue and excessive daytime sleepiness that, based on survey data, persists even in the setting of adherent CPAP usage. There is a need to expand sources of support to help individuals overcome financial barriers to treatment, as evidenced by patient testimony and the 17,000 calls for help received each year by ASAA's CPAP Assistance Program. Better understanding the impacts on sleep and sleep apnea of the source of weight gain in CPAP treatment, contradictory experience with abstinence from or use of caffeine and alcohol, various diets, and medications used to treat symptoms or concurrent conditions would help to refine treatment recommendations and could improve patient satisfaction, adherence, and health outcomes.

"From this meeting we've all gained a better appreciation for the daytime symptoms that patients experience. One of the things we're hearing is, 'I've had daytime sleepiness and effects of long-term sleep deprivation.' Chronic sleep deprivation takes a toll and starts to break down the body. We have to do a better job of appreciating and managing that."

— Carl Stepnowsky, ASAA's chief science officer

"Sleep apnea has affected my overall health in so many ways. It contributed to erratic blood sugar levels and ultimately diabetes. It contributed to difficulty losing weight. The worst though is the exhaustion. It is so overwhelming and all consuming. I use my APAP machine 7 hours a night and 7 nights a week, but I'm still exhausted."

— Female survey respondent

The top unmet medical need identified by the AWAKE Initiative is for effective treatment of fatigue and excessive daytime sleepiness that, based on survey data, persists even in the setting of adherent CPAP usage.

“APAP has reduced my AHI from a home study index of 72 to under 20. I need a more advanced machine for any hope to be adequately treated. My underlying disordered breathing is not treated by APAP.”

— Survey respondent

“No matter how much I work out or restrict food intake, the weight does not come off. It sucks when you were once 175 pounds; I have not been below 230 pounds in 15 years.”

— Male survey respondent using CPAP therapy

Greater ongoing patient education and support at the point of care and in home and community settings is needed to improve both patient satisfaction and treatment outcomes.

Insufficient Patient Education, Training, and Support: At the point of diagnosis of sleep apnea, a dialogue of shared decision-making should begin. Ideally, this exchange between provider and patient would yield adequate information about various treatment options and approaches that incorporate appropriate medical devices, medications, and surgical and supportive strategies, incorporating bed partners in the assessment of treatment benefits and burdens and reassessing regularly and as new considerations arise and additional options are introduced.

Greater ongoing patient education and support at the point of care and in home and community settings is needed to improve both patient satisfaction and treatment outcomes. The model of accredited diabetes patient educators is worthwhile to examine for parallels, including providing for coverage and reimbursement for these services as a part of total patient care. Greater use of telehealth technologies could help scale these services in a cost-effective manner.

The importance of the family caregiver(s) in getting effective treatment and maintaining adherence to treatment affirms the need to engage them in ongoing decision-making and education about treatment. More formalized peer support programs can also help to bridge gaps in care and improve the individual's ability and confidence to navigate an increasingly complex healthcare system.

“Adequate OSA treatment MUST include patient teaching/understanding/preparation, as about 98% of treatment for this condition is performed by the patient/caregiver in the home.”

— Survey respondent

“Knowledgeable healthcare is a big need. CPAP is a great treatment if the patient is taught properly to use it, which means the healthcare provider really needs to know how the machines work and how best to set them up for each individual. A patient can't simply be told, 'Here's your machine and a mask, read the user manual, and off you go!' Care should be taken to have the patient try several masks that have been properly fitted to their own face using sizing guides and try-ons. Regular follow-up should be provided more frequently than every few months to ensure the patient doesn't get so frustrated with the adjustment to this life alteration that they give up. There are many tweaks and strategies to optimize the treatment and patients need to have attentive healthcare providers who can support them through the adjustment period and beyond.”

— Female survey respondent



The importance of the family caregiver(s) in getting effective treatment and maintaining adherence to treatment affirms the need to engage them in ongoing decision-making and education about treatment.

Inaccessible Patient-Generated Data: Consumer and patient expectations are rapidly changing and calls for direct access to patient-generated data from medical devices of all types is intensifying, as is the demand for more autonomy to control home care devices. While current practice still limits the amount of CPAP data exposed to patients along with their ability to adjust machine settings, one can envision a near-term future where these restrictions are lifted under certain conditions. The FDA's August 2017 approval of an expanded indication for a home hemodialysis machine so that it could be used without a care partner being present is one example of such a change reshaping the environment.

More device-connected mobile applications (apps) to equip patients with easy means of recording and making sense of patterns in diet, physical activity, sleep quality, stressors, symptoms, and treatment outcomes would also serve to inform and fine-tune therapeutic and lifestyle decisions and practices.

"Not only are you entitled to your data, it is your data. It is our data, whether we're talking about sleep apnea patients with CPAP machines, cardiac patients with pacemakers, we are now seeing a big movement with type 1 diabetes patients using the hashtag #wearenotwaiting. We don't have 90 days to wait to get to see a clinician to figure out what's going on. We have to start making this data and this technology work for us. We need to start using it with our doctors in shared decision making."

— Adam Amdur, ASAA's chief patient officer

Stalled Innovation: There were also many calls for true innovation in the approaches to treating and caring for sleep apnea, as well as the manner in which care is delivered. Patients have benefitted from incremental progress in making CPAP devices smaller, quieter, and less obtrusive, but the high rates of stated discomfort, inconvenience, and aversion to therapy options leaves much room for improvement. New technologies such as 3-D printing and computer modeling are potential sources of creating more customized approaches to some therapeutic options.

"I get frustrated with the status of treatment options today which have stagnated for some reason. I talk with a lot of patients and they'd like other kinds of alternatives to come along. So far, it's been a very incremental thing. I don't know what has driven innovation out of this



Among the most universally expressed needs was for better technical and customer service training for representatives of durable medical equipment (DME) suppliers.

field and I realize it's going to take time to get more things in the pipeline, but I'm hopeful. While I'm hopeful, I'm still using my CPAP machine."

— Will Headapohl, ASAA board member

Dissatisfactory DME Customer Experience: Among the most universally expressed needs was for better technical and customer service training for representatives of durable medical equipment (DME) suppliers. Transforming this key role from being an obstacle to effective treatment to being an active facilitator of it has the potential to transform the patient journey and the morbidity of the condition itself for those who interact with DMEs.

"I went through 26 different mask styles. I kept a spreadsheet so we wouldn't duplicate one I had already tried. I also had nine DME companies because my insurance changed often and none of them helped either. Finally, I landed with a DME technician who also had sleep apnea. He taught me all these things to do — to ask the doctor to prescribe a specific machine, how to clean it differently, and more. It was radical and everything changed for me then. I've been a compliant patient ever since."

— Panelist Joelle Dobrow

Inadequate Coverage Policies: It is essential to evolve medical coverage, reimbursement, and utilization policies to support effective patient care, rather than punish non-compliance or create additional obstacles to maintaining effective therapy.

"I find it terribly ironic that an insurance company would fight paying for a sleep study when it could save them literally tens of thousands or hundreds of thousands of dollars in treatment costs down the line."

— Panelist Erin Taylor

"When I got my CPAP machine at home, the pressure was so strong that I could not sleep because the air was coming at me, blowing up my nose and making me gag. I tried to tell my doctor that I couldn't function this way. I was told, 'You have to use the machine at least six hours a night or we're going to take it away from you and you may not get another one.'"

— Panelist Celeste James

"My doctor prescribed a CPAP machine for me but my insurance wouldn't pay for it so I have had to do without it for years. I'm just praying every night that I will wake up the next morning."

— Survey respondent

"My insurance company stopped covering my CPAP equipment at 100% and I can no longer replace parts as they wear out because it is prohibitively expensive. My apnea used to be well managed with minimal side effects when I had functioning equipment; now many of my symptoms prior to treatment have returned."

— Female survey respondent

"We have to work hard with insurance companies to get sleep tests they periodically require. When the sleep apnea is responding to regular use of CPAP, the incidence of apnea is reduced, making it appear less chronic. Then they threaten to stop paying for treatment."

— Male survey respondent

Undefined National Research Agenda: In 2011, the U.S. Agency for Healthcare Research and Quality (AHRQ) recognized that "methods for diagnosing and treating obstructive sleep apnea (OSA) are cumbersome, resource-intensive, and often inconvenient for the patient."¹⁶ The agency commissioned a systematic comparative effectiveness review of published research to evaluate the strength of the evidence for methods used to diagnose and treat sleep apnea and to identify knowledge gaps. A total of 234 studies were included in the review and there were numerous limitations, including, "Very few trials evaluated objective clinical outcomes. Data were meager for many specific questions. Studies were generally of moderate to poor quality, and often had short follow-ups, high dropout rates, and poor analyses, and reporting."¹⁶ The review made the following conclusions:

"Portable monitors and questionnaires may be effective screening tools, but assessments with clinical outcomes are necessary to prove their value over polysomnography. CPAP is highly effective in minimizing AHI and improving sleepiness. Oral devices are also effective, although not as effective as CPAP. Other interventions, including those to improve compliance, have not been adequately tested."¹⁶

However, the review could not answer many of the key questions it set out to address because of insufficient or poor quality evidence. A 2017 review by the U.S. Preventive Services Task Force (USPSTF) ran into similar problems in evaluating evidence for widespread screening of asymptomatic individuals.

In 2012, several Tufts University-based authors of the AHRQ review convened stakeholders from a variety of areas relevant to sleep apnea to submit and prioritize research topics to advance the state of diagnosing and treating sleep apnea. One patient and one representative of a patient advocacy organization were included; industry was invited to submit research topics for consideration, but was not permitted to participate in the prioritization task.

"My insurance company stopped covering my CPAP equipment at 100%."

"My doctor prescribed a CPAP machine for me but my insurance wouldn't pay for it."

"We have to work hard with insurance companies to get sleep tests they periodically require."

¹⁶Balk EM, Moorthy D, Obadan NO, Patel K, Ip S, Chung M, Bannuru RR, Kitsios GD, Sen S, Iovin RC, Gaylor JM, D'Ambrosio C, Lau J. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-100551). AHRQ Publication No. 11- EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2011. Accessed at <https://effectivehealthcare.ahrq.gov/topics/sleep-apnea/> on July 21, 2018*



In general, the stakeholders agreed that, “OSA patients, their healthcare providers, and society at large would benefit from refocusing research efforts into the prioritized research questions and away from simple comparisons of short-term outcomes between specific interventions.”

Thirty-seven topics were discussed and prioritized. The nine highest ranked topics¹⁷ included:

- Cost-effectiveness of management strategies
- Defining age- and sex-specific criteria for OSA
- Evaluating routine preoperative screening for OSA
- Evaluating involvement of a sleep medicine specialist in diagnosis of OSA
- Evaluating clinical prediction rules
- Assessing the effect of treating sleep disordered breathing and long-term clinical outcomes
- Comparing treatments for patients who do not tolerate positive airway pressure
- Evaluating strategies to improve treatment compliance
- Evaluating the association between sleep apnea severity and long-term clinical outcomes.

In general, the stakeholders agreed that, “OSA patients, their healthcare providers, and society at large would benefit from refocusing research efforts into the prioritized research questions and away from simple comparisons of short-term outcomes between specific interventions.” It is important to note that this group did not consider novel or theoretical markers or interventions among potential future research needs. This need for more innovation was identified that same year, 2012, by a task force convened by the Board of Directors of the American Academy of Sleep Medicine (AASM) to examine the future of sleep medicine in the care of adult patients.¹⁷ The publication of results of the Tufts-led ranking exercise is the last reference in the published literature to an effort to create a strategic research plan for sleep apnea.

In 2017, the USPSTF identified the following research gaps and needs:

“The identification of valid and reliable clinical prediction tools that could accurately determine which asymptomatic persons (or persons with unrecognized symptoms) would benefit from further evaluation and testing for OSA is needed. In addition, studies that evaluate the effect of OSA treatments or interventions on health outcomes (e.g., all-cause and cardiovascular mortality, cardiovascular disease and cerebrovascular events, motor vehicle crashes, and cognitive impairment) that are adequately powered and have an appropriate length of follow-up are needed. Studies are also needed to evaluate whether improvement in AHI (for mild to severe OSA) leads to improvement in health outcomes. These represent critical gaps in the current evidence base. The USPSTF has identified the need for further research on the effect on health outcomes of screening for OSA among asymptomatic persons in the general population, as well as the role of sleepiness in determining health outcomes. More data on the natural history of mild OSA are also needed, in particular the rates of progression from mild to severe OSA, the length of duration before progression, and the magnitude of benefit if OSA is identified and treated earlier.”¹⁸

¹⁷Patel, K, Moorthy D, Chan JA, et al. High Priority Future Research Needs for Obstructive Sleep Apnea Diagnosis and Treatment. *Journal of Clinical Sleep Medicine*. 2013 Apr 15; 9(4): 395–402.

¹⁸USPSTF, January 2017

Patient-centered evidence accumulated through the AWAKE Sleep Apnea initiative affirms that the 2011 state of diagnosing and treating obstructive sleep apnea that triggered the initial AHRQ review remains the same in 2018. As was heard at the June 8th meeting and through 5,630 survey responses, diagnosing sleep apnea remains “cumbersome, resource-intensive, and often inconvenient for the patient.” Moreover, there is significant opportunity to partner with patients to explore these and other research questions. The AWAKE Sleep Apnea Patient & Caregiver Survey found that while 33 percent of survey respondents indicated an interest in participating in research, only five percent had ever taken part in a sleep apnea study.

In light of the high prevalence of sleep apnea, its considerable morbidity and large economic impact, and the often serious effect across the lifespan and on mortality, a multistakeholder process is warranted to develop a national research agenda. It should bring together participants from the patient community, government, industry, academia, relevant medical specialties, private foundations, and payers to formulate an integrated multidisciplinary research agenda that fosters innovation, accelerates development of better diagnostics and new therapeutic options, care delivery, and payment models, and leads to precision medicine for the successful treatment and prevention of sleep apnea. There are many existing models that could be used to shape the process, including the National Plan to Address Alzheimer’s.¹⁹

The U.S. Centers for Disease Control has reported that, as a nation, we are not getting enough sleep for optimal health, with significant negatives effects on physical, cognitive, and emotional functioning.²⁰ A report issued by the Institute of Medicine in 2006 states,

*“Some of the most devastating human and environmental health disasters have been partially attributed to sleep loss and night shift work-related performance failures, including the tragedy at the Bhopal, India, chemical plant; the nuclear reactor meltdowns at Three Mile Island and Chernobyl; as well as the grounding of the Star Princess cruise ship and the Exxon Valdez oil tanker. Each of these incidents not only cost millions of dollars to clean up, but also had significant impact on the environment and the health of local communities.”*²¹

Research has shown that persons with severe obstructive sleep disorder die at twice the rate of controls.²² Thus, the consequences of chronic deprivation of restorative sleep for people living with sleep apnea are even greater and warrant considerably more intense attention and ongoing research than they currently receive.

For, as San Juanita Sanchez stated at the beginning of the AWAKE Sleep Apnea meeting,

“El sueño es vida” — “Sleep is life.”

¹⁹<https://aspe.hhs.gov/national-plans-address-alzheimers-disease>, accessed July 23, 2018

²⁰Liu Y, Wheaton AG, Chapman DP, Cunningham TJ, Lu H, Croft JB. Prevalence of healthy sleep duration among adults — United States, 2014. *MMWR Morb Mortal Wkly Rep.* 2016;65(6):137–141. Free full text article: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6506a1.htm>, accessed July 23, 2018.

²¹*Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem.* Committee on Sleep Medicine and Research, Board on Health Sciences Policy. Institute of Medicine of the National Academies. 2006. Page 138.

²²Jonas DE, Amick HR, Feltner C, Weber RP, Arvanitis M, Stine A, Lux L, Middleton JC, Voisin C, Harris RP. Screening for Obstructive Sleep Apnea in Adults: An Evidence Review for the U.S. Preventive Services Task Force. *Evidence Syntheses*, No. 146.



SECTION 5:

RESULTS OF THE AWAKE SLEEP APNEA PATIENT & CAREGIVER SURVEY



The 32-item survey attracted responses from a total of 5,630 individuals, 85 percent of whom are patients

In preparation for the June 8, 2018 AWAKE Sleep Apnea meeting, ASAA fielded a Patient & Caregiver Survey to capture a broad set of patient experiences and inform the discussion at the meeting. The survey was launched on April 24, 2018 and accepted its last response on July 18, 2018. The 32-item survey attracted responses from a total of 5,630 individuals, 85 percent of whom are patients; the balance were family members and caregivers. Described below are the methods of developing and deploying the survey, as well as a preliminary analysis of data. ASAA intends to undertake additional analyses of these valuable data under direction of Chief Science Officer **Carl Stepnowsky, PhD**.

Methods

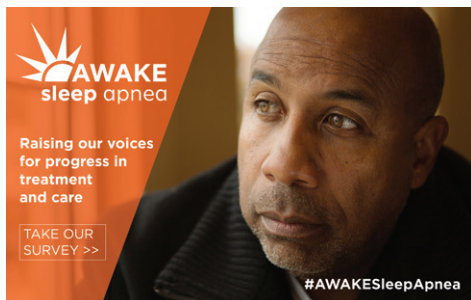
The survey was developed as a fit-for-purpose instrument for use in conjunction with the FDA's Patient-Focused Drug Development (PFDD) initiative. **Kim McCleary**, founder and CEO of the Kith Collective, was the primary author of the survey. Its format and style were based on PFDD-related surveys used for other disease conditions, including myalgic encephalomyelitis/CFS, narcolepsy, and lupus. Questions delved into patients' experience of symptoms, impact and severity of symptoms, treatments used in the past and at present, barriers to diagnosis and treatment, and outcomes of greatest interest. A literature review and consultation with ASAA staff, including Dr. Stepnowsky, informed development of the multiple choice answers. Only the first question, "Which of the following best describes your (primary) relationship to sleep apnea?" was required to advance through the survey. Six of the 32 items were questions inviting open-ended text responses only. In addition, 20 of the 26 multiple choice questions invited additional open text

comments. The survey was tested with project staff and then by volunteers diagnosed with sleep apnea. Input from the test groups helped refine the instrument prior to its public launch on April 24, 2018.

No personally identifying information was collected and all survey respondents were and remain anonymous. Respondents spent an average of 17 minutes completing the survey. The voluntary nature of each of the 31 questions after the first resulted in a varying number of responses to each question; results are reported in both raw numbers and as a percentage of those who completed the question. The survey instrument is included in the Appendix.

SurveyMonkey: ASAA utilized the SurveyMonkey platform to collect responses from patients and caregivers reached through outreach conducted by ASAA and 12 partner organizations (see page 69 for a listing of partners), primarily through social media and e-newsletters. Press releases issued on April 24, 2018 and May 29, 2018 helped to raise visibility of the survey. ASAA dedicated \$1,572 to boost and promote Facebook posts about the AWAKE survey and meeting to reach more of its followers and others interested in sleep health. No login or password was required to access the survey; only one response per device was permitted. Respondents could change answers on any survey page until they completed the survey.

ASAA and 12 partner organizations used social media posts to promote the AWAKE survey and meeting.



The survey closed on July 18, 2018 with 3,130 responses collected via the SurveyMonkey platform. Ninety-three percent were from people identifying as having sleep apnea and an additional four percent of respondents identified as having a close family or personal relationship to a sleep apnea patient. 102 (3%) of initial respondents were individuals who either identified primarily as healthcare providers or not having a close relationship to someone with sleep apnea; based on the nature of the survey being limited to patients and caregivers, these respondents were exited from the survey and are not included in the analysis. Most survey responses were submitted prior to the June 8 meeting, with 242 received in April; 2,188 responses were received in May; 691 were received in June; and nine were received in July.

Evidation: ASAA also partnered with Evidation Health, San Mateo, California, to deploy the survey within Evidation's consumer health "Achievement" platform. Achievement is a consumer technology platform that allows members to share behavior and patient-reported outcome (PRO) data in exchange for points for participation in health-related activities. Members connect smartphone applications (e.g., Fitbit, Garmin, Apple Health, food tracking, etc.) and

evidation

93% of respondents via SurveyMonkey had been diagnosed by a physician, compared to 78% of those responding via Evidation.

complete PROs to support population labeling. Achievement members who self-reported sleep apnea or being connected to someone with sleep apnea were invited to take the AWAKE Patient & Caregiver Survey. A total of 2,500 responses collected on the Achievement platform between May 25, 2018 and June 1, 2018 were provided to ASAA in support of the AWAKE Sleep Apnea Initiative. Responses received from Evidation account for 44 percent of the total number of survey responses reported in this analysis.

Demographics

As a whole, 85 percent of respondents self-identified as patients and 14 percent indicated they were family members and/or close to a person with sleep apnea. A higher percentage of responses collected via SurveyMonkey were from patients compared to those collected via Evidation's Achievement platform. Seventy-four percent of Evidation responses came from individuals self-reporting as having sleep apnea; 26 percent were submitted by individuals close to someone with sleep apnea. Respondents via SurveyMonkey were more likely to have been diagnosed by a physician than those responding via Evidation's platform – 93 percent compared to 78 percent, respectively.

SURVEY RESPONDENT PROFILE

	Combined (n=5,630) ²³	Survey Monkey (n=3,130) ²³	Evidation (n=2,500) ²³
Patients	4769 (85%)	2,917 (93%)	1,852 (74%)
Caregivers	760 (14%)	112 (4%)	648 (26%)
Male	2,274 (41%)	1,145 (37%)	1,129 (45%)
Female	3,224 (57%)	1,914 (61%)	1,310 (52%)
Diagnosed by physician	4,827 (86%)**	2,905 (93%)**	1,922 (78%) ²⁴
Diagnosed within 12 mos. of onset	2,389 (45%)	1,547 (53%)	842 (34%)
Diagnosed 10 yrs or more after onset	375 (7%)	259 (9%)	116 (5%)
Diagnosed within past 12 months	346 (6%)	183 (6%)	163 (7%)
Diagnosed more than 10 years ago	1,648 (30%)	1,125 (36%)	523 (21%)
Onset before age 18	392 (7%)	151 (5%)	241 (10%)
Current age: 25-44	1,652 (30%)	396 (13%)	1,256 (51%)
Current age: 55 or older	2,510 (45%)	2,047 (65%)	463 (18%)

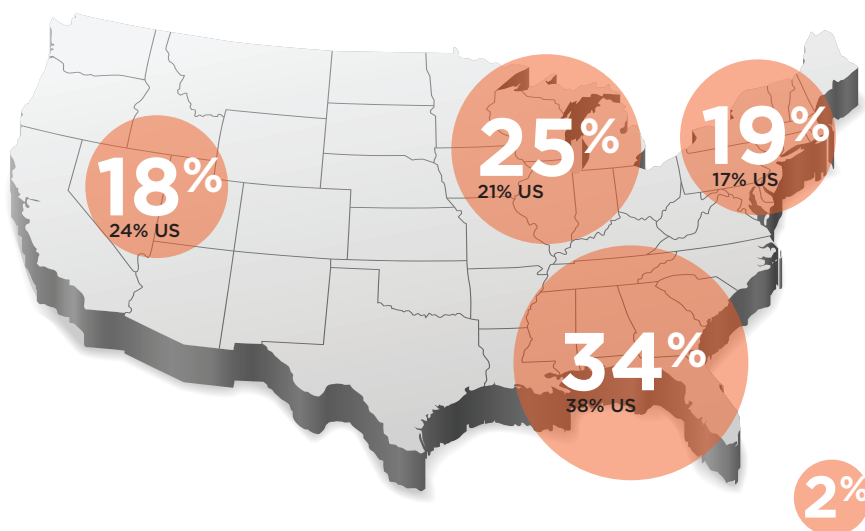
²³Total number of respondents. The number of responses to each survey question varies. Percentages are stated in relation to the number of responses received to that question.

²⁴Includes reports from caregivers on behalf of person with sleep apnea, so may approach or exceed number of patients.

²⁵Lin CM, et al. Gender Differences in Obstructive Sleep Apnea and Treatment Implications. *Sleep Medicine Reviews*. 2008 Dec; 12(6): 481-496.

Fifty-seven percent of total survey respondents were responding on behalf of a patient identifying as being female and 41 percent were responding on behalf of a male patient. This is notable because men are considered to be at higher risk for sleep apnea, with a study of gender differences in sleep apnea studies describing the estimated male-to-female ratio as between 3:1 to 5:1 in the general population and 8:1 to 10:1 in some clinical populations.²⁵

Responses came from across the United States and two percent (2%) from other countries. Compared to population distribution reported by the U.S. Census Bureau, there was slight overrepresentation from the northeast and midwest regions, and the south and west were underrepresented among the total respondents.



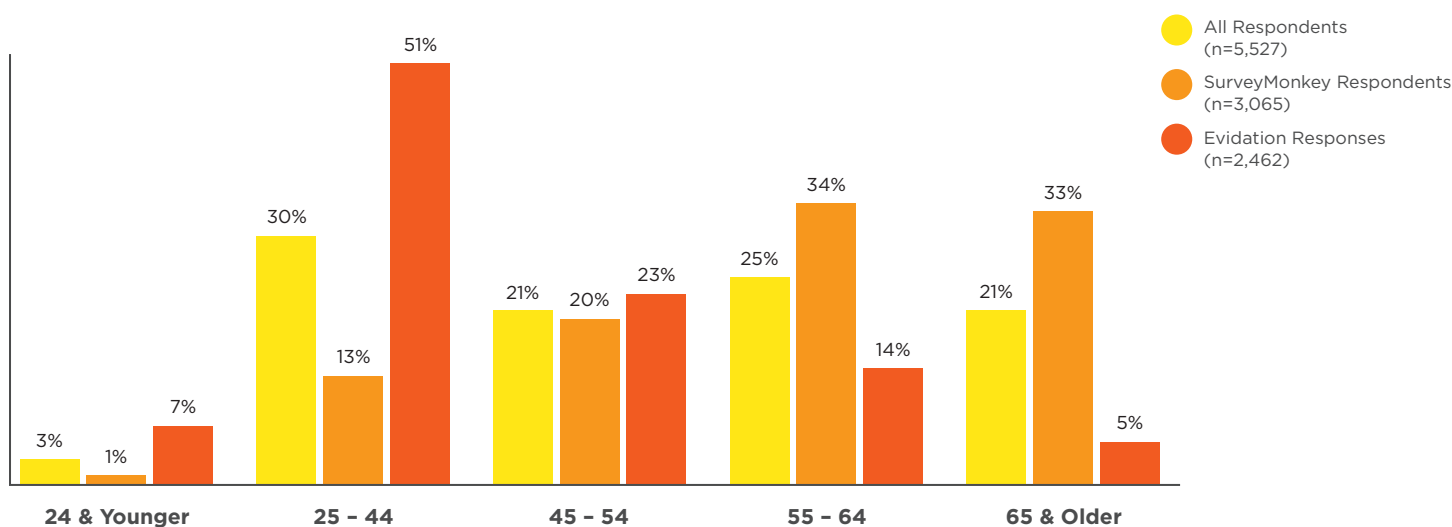
GEOGRAPHIC DISTRIBUTION

PRIMARY RESIDENCE	ALL RESPONSES	U.S. POPULATION ²⁶
Northeastern U.S.	586 (19%)	17%
Midwest U.S.	783 (25%)	21%
Southern U.S.	1,001 (34%)	38%
Western U.S.	552 (18%)	24%
Outside U.S.	64 (2%)	N/A
Prefer not to answer	52 (2%)	N/A

There was a notable difference in the current age of respondents by collection platform. As a whole, 45 percent of respondents are currently age 55 or older. However, 65 percent of responses collected via SurveyMonkey came from individuals age 55 or older, while just 18 percent of responses collected by Evidation were in this age group. A slight majority (51%) of Evidation responders are currently age 25-44, while just 13 percent of the responses collected via SurveyMonkey were from the same age group.

²⁶<https://www.census.gov/geo/reference/webatlas/regions.html>

RESPONDENTS BY CURRENT AGE



Age of onset of sleep apnea peaked in the years between ages 45-54, with 23 percent of overall responses. Overall, seven percent of respondents indicated that onset occurred before age 18. Six percent of total responses were made by individuals diagnosed within the past 12 months; 30 percent had been diagnosed 10 or more years ago.

No information about race, ethnicity, or relationship status was collected; some respondents volunteered such information in the context of open text comments but it is not included in this analysis.

Diagnosis

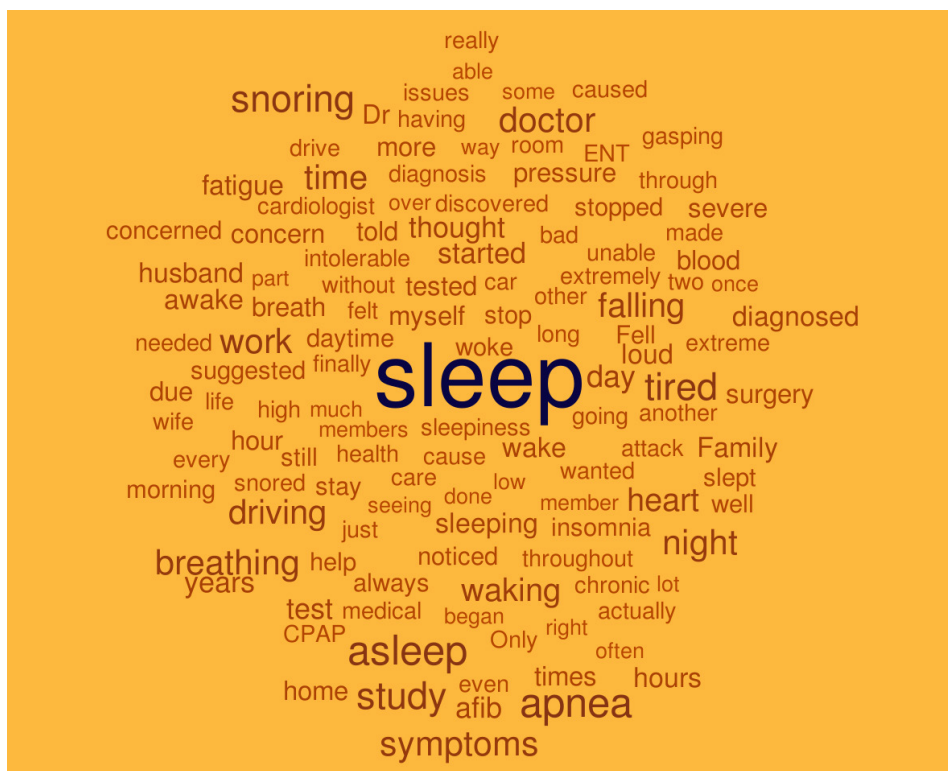
The primary motivating factor for pursuing a formal diagnosis was symptoms becoming bothersome or intolerable (39%), followed by concern expressed by a family member or friend (28%). Those responding by SurveyMonkey were more likely to have been motivated by a health care professional's concern (24%) compared to those responding by Evidation (14%). For five percent, a diagnosis was sought following an episode where their own life or someone else's was put in jeopardy by sleep apnea.

PRIMARY MOTIVATING FACTOR TO SEEK FORMAL DIAGNOSIS

	Combined (n=5,363)	SurveyMonkey (n=2,908)	Evidation (n=2,455)
Symptom level bothersome or intolerable	2,104 (39%)	1,176 (40%)	928 (37%)
Family member or friend expressed concern	1,496 (28%)	726 (25%)	777 (31%)
Medical professional expressed concern	1,049 (20%)	688 (24%)	361 (14%)
Episode where patient's life or another's life in jeopardy	239 (5%)	177 (6%)	62 (3%)

When asked how long it took to get diagnosed, slightly fewer than half of respondents overall (45%) indicated within a year of recognizing symptoms, with 53 percent of those responding via SurveyMonkey in this group and just 34 percent of the Evidation responders getting diagnosed this fast. The other half were split relatively evenly between 1-2 years, 3-5 years, and more than six years after recognition of symptoms. In open text comments many respondents stated that in retrospect they may have had sleep apnea far longer than initially perceived, as is described in Section 1 of this report.

An overnight sleep study was involved in diagnosing sleep apnea for 76 percent of all respondents, with 85 percent of those responding via SurveyMonkey having had attended polysomnography compared to 65 percent of the Evidation responders. A home sleep study was involved for 26 percent, with some individuals reporting having had both types of testing. A higher percentage of Evidation respondents (15%) had not been formally diagnosed than those responding by SurveyMonkey (1%). Overall, eight percent had not been formally diagnosed.



WHAT WAS THE PRIMARY MOTIVATING FACTOR FOR PURSUING A FORMAL DIAGNOSIS?

From open text survey responses — word size reflects frequency of use by respondents.

There is a tremendous amount to be learned from the extensive open comments submitted by survey respondents, which total 155,339 words.

SLEEP TESTING USED FOR FORMAL DIAGNOSIS

	Combined (n=5,369)	SurveyMonkey (n=2,966)	Evidation (n=2,403)
Overnight sleep study in a sleep lab (“attended polysomnography”)	4,091 (76%)	2,524 (85%)	1,567 (65%)
Home sleep test	1,381 (26%)	771 (26%)	610 (25%)

Comorbidities

Consistent with the published literature about sleep apnea, survey respondents reported a large number of current co-morbid conditions. Hypertension (high blood pressure) was reported by 45 percent of respondents overall, reflecting a rate much higher than the estimated U.S. prevalence of 33 percent. Gastroesophogael reflux disease (GERD), acid reflux, and/or silent reflux was reported by 30 percent, also considerably higher than the estimated U.S. prevalence of 18 percent. Twenty percent of respondents reported having diabetes, more than twice the U.S. rate of nine percent. Major depression was reported by 15 percent of respondents, more than double the U.S. prevalence of 6-7 percent. U.S prevalence estimates for various conditions were obtained from publicly available reports from authoritative sources including the National Institutes of Health, U.S. Centers for Disease Control and Prevention, and academic research centers.

Respondents also reported significant comorbidities with allergic rhinitis (allergies) of 26 percent, restless leg syndrome or periodic limb movement among 19 percent, and 17 percent having chronic pain and/or fibromyalgia, all of which were higher than estimates for U.S. prevalence.

Differences between the two cohorts by platform collector were notable for rates of hypertension, GERD/reflux, diabetes, atrial fibrillation, and chronic obstructive pulmonary disease, all of which were higher among the generally older, more severely affected individuals responding via SurveyMonkey.

More respondents via SurveyMonkey were motivated to pursue diagnosis by a health care professional’s concern (24%), while Evidation responders were more likely to have been prompted by a family member or friend’s concern (31%).

High rates of serious comorbid conditions were reflected in survey respondents' rating of "potential long-term consequences on health and lifespan" as their top concern about living with sleep apnea.

PREVALENCE OF COMMON CO-OCCURRING CONDITIONS

Condition	Combined (n=5,295)	Survey Monkey (n=2,921)	Evidation (n=2,374)	U.S. prevalence (estimated)
High blood pressure	2,403 (45%)	1,625 (56%)	776 (33%)	33%
GERD	1,567 (30%)	988 (34%)	580 (24%)	~18%
Allergic rhinitis or allergies	1,355 (26%)	784 (27%)	571 (24%)	8%
Diabetes	1,059 (20%)	695 (24%)	362 (15%)	9%
Restless leg syndrome or periodic limb movement	983 (19%)	597 (20%)	386 (16%)	2-8%
Chronic pain or fibromyalgia	891 (17%)	570 (20%)	321 (14%)	11%
Major depression	812 (15%)	432 (15%)	378 (16%)	~10%
ADD/ADHD	458 (9%)	227 (8%)	231 (10%)	11%
Atrial fibrillation	450 (8%)	350 (12%)	100 (4%)	2-9% ²⁷
Chronic obstructive pulmonary disease	394 (7%)	306 (10%)	88 (4%)	4-12% ²⁸

Impacts On Daily Living

Topping the list of symptoms that have a severe or moderate impact on daily activities are fatigue (80%), daytime sleepiness (78%), unrefreshing sleep (69%), dry mouth in the morning (47%), and cognitive difficulties (40%). The first three of these did not differ significantly by platform; SurveyMonkey respondents reported more severe impact of dry mouth in the morning and cognitive difficulties compared to Evidation responders.

Of particular interest is the finding that rates of severe to moderate fatigue, daytime sleepiness, unrefreshing sleep, and cognitive problems were higher among those being current treated with CPAP compared to individuals not currently using CPAP or not having ever been treated with CPAP (combined as "All Non-CPAP Users"). As described below, CPAP was reported to be used a mean of 6.4 nights per week for a mean of 6.4 hours per night — a threshold considered fully adherent by most criteria. Fatigue, daytime sleepiness, unrefreshing sleep, and cognitive difficulties also topped the list when respondents were asked which 1-3 symptoms had the most significant impact on their lives.

²⁷Varies by age group with increasing prevalence across the lifespan.

²⁸Varies by state, with low of 4% (Utah) and high of 12% (West Virginia).

SYMPTOM SEVERITY (see bar graphs, page 63)

WITHOUT CURRENT TREATMENT

	Mild	Moderate	Severe
Combined (n=4,968)	949 (19%)	2,197 (44%)	1,822 (37%)
Survey Monkey (n=2,566)	316 (12%)	957 (37%)	1,293 (50%)
Evidation (n=2,402)	633 (25%)	1,240 (50%)	529 (21%)

Rates of severe to moderate fatigue, daytime sleepiness, unrefreshing sleep, and cognitive problems were higher among those being current treated with CPAP.

WITH CURRENT TREATMENT

	Mild	Moderate	Severe
Combined (n=4,538)	3,030 (67%)	1,304 (29%)	204 (5%)
Survey Monkey (n=2,526)	1,635 (65%)	743 (29%)	148 (6%)
Evidation (n=2,012)	1,395 (69%)	561 (22%)	56 (2%)

Respondents longed to awaken feeling refreshed (71%), sleep through the night (59%), perform as they'd like to at work or at school (32%), and get through the day without falling asleep (30%). Evidation responders more often cited the first three of these desired outcomes than did responders via SurveyMonkey.

PRIORITY ACTIVITIES THAT CAN'T BE DONE AT ALL OR AS FULLY AS WOULD LIKE

	Combined (n=4,723)	SurveyMonkey (n=2,507)	Evidation (n=2,216)
Awaken feeling rested, ready to start the day	3,331 (71%)	1,644 (66%)	1,687 (76%)
Sleep through the night	2,806 (59%)	1,400 (56%)	1,406 (63%)
Perform as I'd like to at work or at school	1,515 (32%)	759 (30%)	756 (34%)
Get through the day without falling asleep	1,397 (30%)	762 (30%)	635 (29%)

Asked to identify just one or two top concerns, those living with sleep apnea identified the potential long-term consequences on health and lifespan (53%) and the effect of symptoms on physical and/or mental performance (48%). There were differences by collection platform, with the younger, less severely affected respondents reached via Evidation citing the effect of symptoms on physical and/or mental performance as their top concern, with close rankings among the top three answers. There was stronger concern about long-term health consequences of sleep apnea among those responding by SurveyMonkey.

53% of respondents identified the potential long-term consequences on health and lifespan as their top concern.

TOP CONCERNS ABOUT LIVING WITH SLEEP APNEA
(limit of 1-2)

	Combined (n=4,830)	Survey Monkey (n=2,491)	Evidation (n=2,339)
Potential long-term consequences on health and lifespan	2,546 (53%)	1,508 (61%)	1,038 (44%)
Effect of symptoms on physical and/or mental performance	2,342 (48%)	1,175 (47%)	1,167 (50%)
Impact of symptoms on daily activities	1,914 (40%)	882 (35%)	1,032 (44%)
Impact of symptoms on relationships and well-being	1,087 (23%)	470 (19%)	617 (26%)
Burden of treating sleep apnea	840 (17%)	489 (19%)	351 (15%)
Risk of having or causing an accident while driving or at work	578 (12%)	296 (12%)	282 (12%)

Nearly two-thirds of respondents reported that their sleep apnea is more stable and better managed than when symptoms first became evident. Just six percent report that it is worse and 13 percent indicate that it is about the same.

Overall, CPAP users reported high rates of adherence, with mean use of 6.4 nights per week and mean use of 6.4 hours per night.

Management

A large majority of total respondents, 69 percent, were currently using positive airway pressure (including CPAP, BiPAP, and APAP) to manage their sleep apnea. The percentage of individuals currently using PAP responding via SurveyMonkey was considerably higher (88%) compared to Evidation responders (47%). Respondents using PAP reported using it 0-7 nights per week with 82 percent of respondents indicating use seven nights per week and four percent using PAP six nights per week with a mean usage of 6.4 nights a week. Nightly, 74 percent reported use of their PAP device of six hours or more and a mean use of 6.4 hours per night.

There was much less utilization of oral appliances, with more respondents indicating past use (11%) than current use (7%), and a much lower rate of utilization (3 nights per week on average) compared to PAP. Among oral appliance users, respondents reported using their appliance 0-7 nights per week with 59 percent using the appliance zero nights per week and 28 percent using the appliance all seven nights per week, with a mean of 2.4 nights per week. Nightly use ranged from 0-12 hours per night with 58 percent using the appliance for zero hours and 29 percent using it for 6-8 hours per night, with a mean of 2.7 hours per night.

TREATMENTS REPORTED: VENTILATION AND AIRWAY-RELATED THERAPIES

	Combined (n=4,593)	Survey Monkey (n=2,235)	Evidation (n=2,358)
CURRENT Positive airway pressure (CPAP, APAP, BiPAP)	3,132 (69%)	1,963 (88%)	1,177 (47%)
PAST Positive airway pressure (CPAP, APAP, BiPAP)	549 (12%)	176 (8%)	375 (15%)
CURRENT Oral appliances	287 (7%)	142 (8%)	146 (6%)
PAST Oral appliances	446 (11%)	223 (12%)	228 (9%)
CURRENT Nasal expiratory resistance device	127 (3%)	55 (3%)	72 (3%)
PAST Nasal expiratory resistance device	250 (6%)	75 (4%)	175 (7%)
CURRENT Upper airway stimulation	127 (3%)	81 (4%)	46 (2%)
PAST Upper airway stimulation	77 (2%)	12 (1%)	65 (3%)

88% of SurveyMonkey respondents reported using positive airway pressure (PAP), compared to 47% of Evidation respondents.

Medication use included a wide array of pharmacologic agents, both currently and in the past, with serotonin reuptake inhibitors (SSRIs) being the most utilized at present by 23 percent of total respondents, followed by nasal corticosteroids (23%), and decongestants (20%). For all medication types listed in the survey, current use was higher among SurveyMonkey respondents compared to Evidation respondents.

TREATMENTS REPORTED: CURRENT MEDICATIONS

	Combined (n=4,482)	Survey Monkey (n=2,162)	Evidation (n=2,320)
Selective serotonin-reuptake inhibitors (Prozac, Zoloft, Cymbalta, etc.)	1,003 (23%)	565 (27%)	441 (18%)
Nasal corticosteroids	990 (23%)	550 (26%)	441 (18%)
Decongestants	851 (20%)	414 (20%)	440 (18%)
Anticonvulsants (Neurotin, Klonopin, Ativan, etc.)	495 (11%)	262 (14%)	213 (9%)
Anti-anxiety agents (BuSpar, Vistaril)	397 (9%)	197 (10%)	201 (8%)
Leukotrein inhibitors (Singulair, Accolate)	319 (7%)	197 (10%)	123 (5%)
Hypnotics (Ambien, Lunesta)	252 (6%)	143 (7%)	110 (4%)
Prescription stimulants (Concerta, Adderall)	209 (5%)	111 (6%)	98 (4%)
Wakefulness-promoting agents (Nuvigil, Provigil)	164 (4%)	107 (5%)	57 (2%)

For all medication types, current use was higher among SurveyMonkey respondents compared to those responding via Evidation.

There were relatively few respondents who had undergone surgery to treat sleep apnea; among those who did, tonsillectomy and/or adenoidectomy was the most reported surgical procedure with nine percent overall. Upper airway surgery (4%) and bariatric surgery (3%) were the next most often cited surgical approaches having been used. Nineteen survey respondents had tracheostomies, with slightly more of them 11 (0.7%) responding via Evidation than SurveyMonkey, eight (0.3%). Surgical repair of a deviated septum or enlarged turbinates were not specifically queried, although several respondents mentioned these in open text comments.

TREATMENTS REPORTED: SURGICAL INTERVENTIONS

	Combined (n=3,808)	Survey Monkey (n=2,120)	Evidation (n=1,688)
Tonsillectomy and/or adenoidectomy	355 (9%)	193 (9%)	162 (10%)
Upper airway surgery	143 (4%)	75 (4%)	68 (4%)
Uvulopalatopharyngoplasty (UPPP)	90 (2%)	59 (3%)	31 (2%)
Bariatric and/or obesity surgery	112 (3%)	46 (2%)	66 (4%)
Laser-assisted uvuloplasty (LAUP)	36 (1%)	16 (1%)	20 (1%)
Tracheostomy	19 (0.5%)	8 (0.3%)	11 (0.7%)

More than half (51%) of all respondents indicated they were using weight loss through diet and/or activity as a supportive strategy to manage their sleep apnea, with a slightly higher percentage of Evidation respondents (55%) pursuing this approach. One-third reported using sleep position as a support. Alcohol avoidance and extending sleep time (using naps or earlier bedtime/later waking time) were reported by 29 percent and 28 percent of all respondents, respectively.

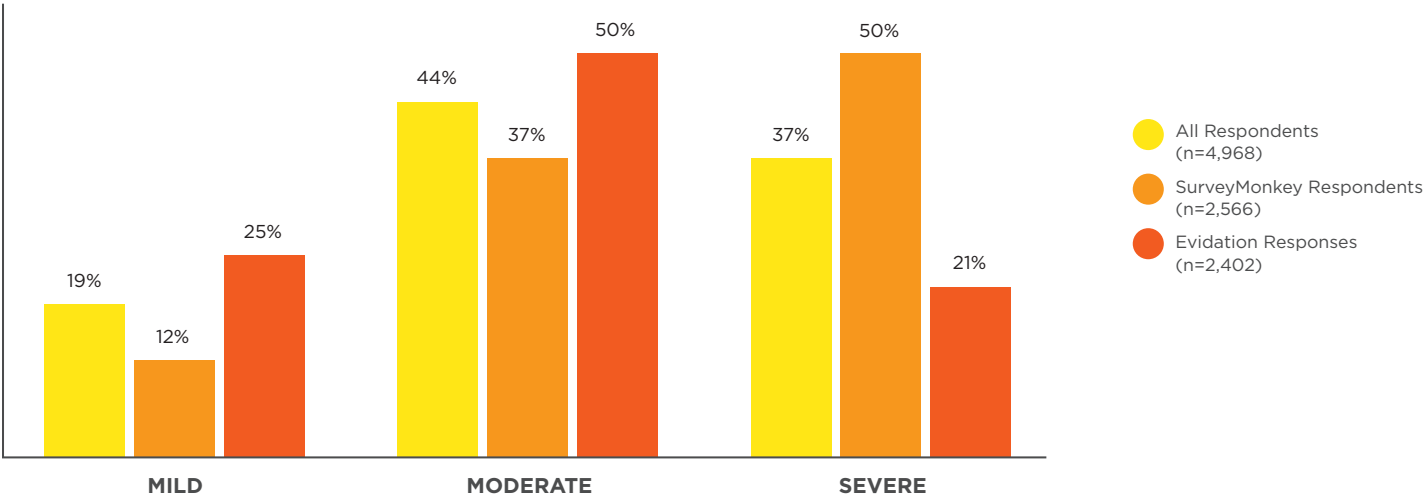
TREATMENTS REPORTED: CURRENT SUPPORTIVE STRATEGIES

	Combined (n=4,436)	Survey Monkey (n=2,108)	Evidation (n=2,328)
Weight loss (through diet & activity)	2,249 (51%)	975 (47%)	1,274 (55%)
Sleep positioning	1,448 (33%)	710 (34%)	738 (30%)
Alcohol avoidance	1,269 (29%)	648 (32%)	621 (27%)
Extending sleeping time (naps, earlier bedtime, later waking time)	1,214 (28%)	634 (31%)	580 (25%)
Increased caffeine intake	968 (22%)	406 (20%)	560 (22%)
Relief of nasal congestion with nasal strips, nettie pot, and/or other non-medical approaches	751 (17%)	417 (20%)	334 (14%)
Meditation and/or mindfulness	699 (16%)	319 (16%)	380 (16%)

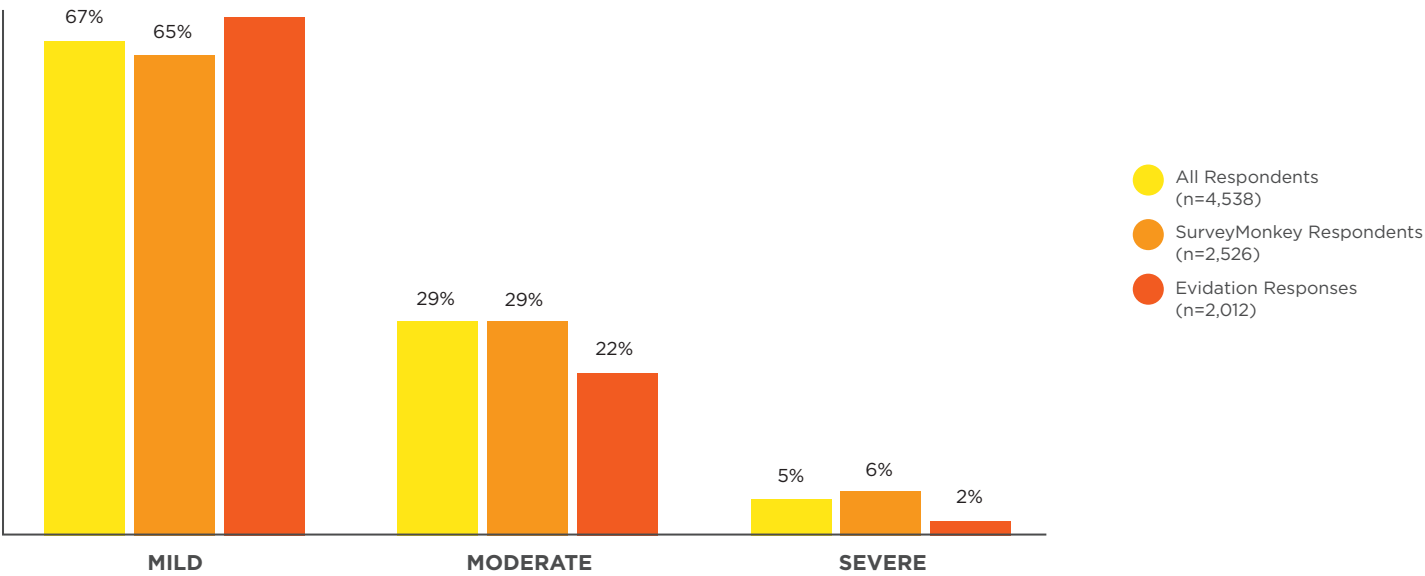
In describing the impact of sleep apnea symptoms as currently treated compared to not treated, respondents shifted from 37 percent reporting “severe” impact (significantly impacts daily activities) when not treated to

just five percent (5%) reporting “severe” impact when treated. Comparing the responses by collection platform, individuals responding via SurveyMonkey rated their untreated condition as having more severe impact than did those responding by Evidation, with 50 percent of SurveyMonkey respondents indicating “severe” untreated impact and 50 percent of Evidation respondents indicating “moderate” untreated impact. With treatment, a slightly lower percentage of SurveyMonkey respondents rated the impact as being “mild” (65%) compared to 69 percent of Evidation respondents indicating mild impact with current treatment.

SYMPTOM SEVERITY: WITHOUT TREATMENT

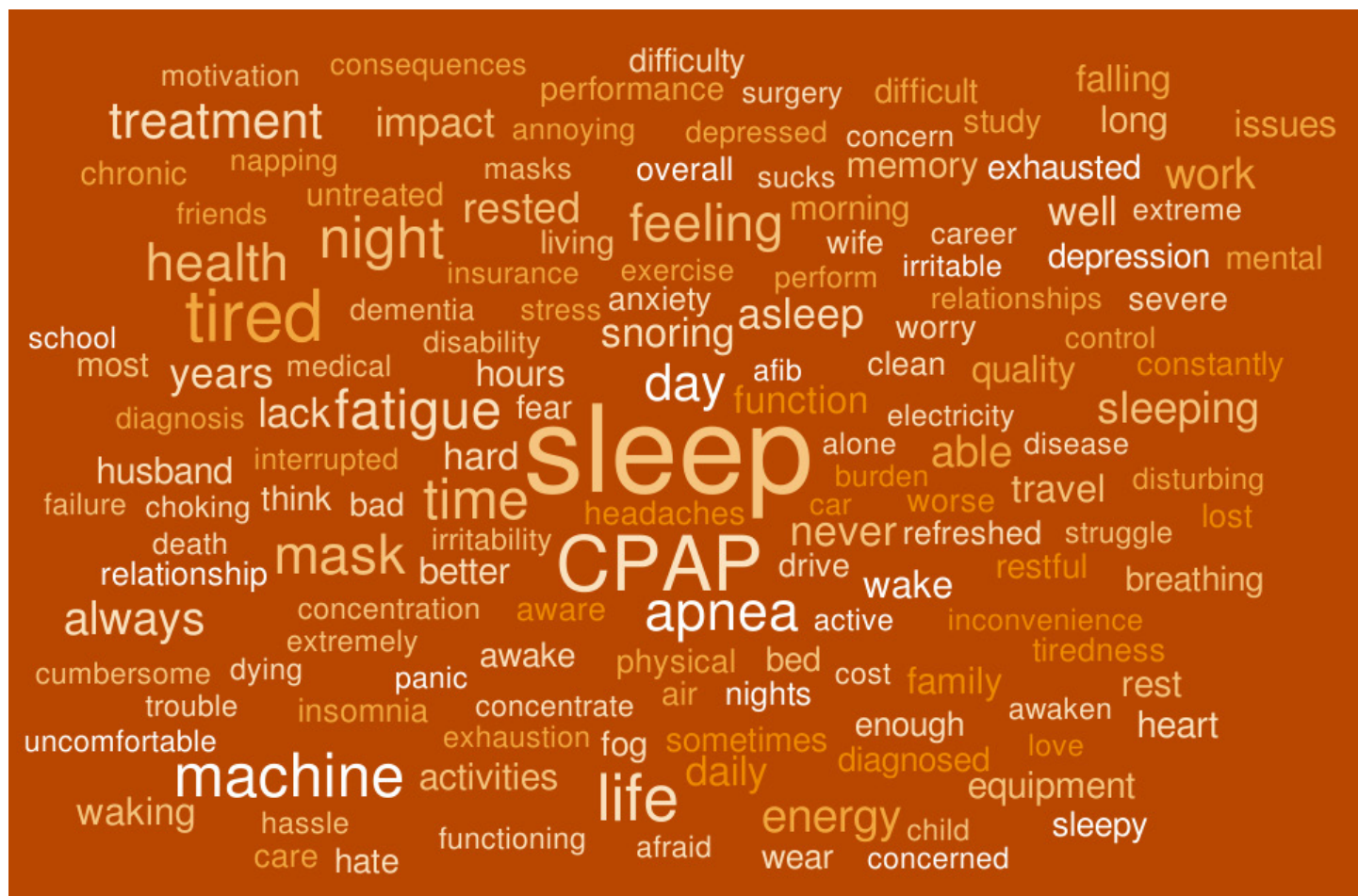


SYMPTOM SEVERITY: WITH TREATMENT

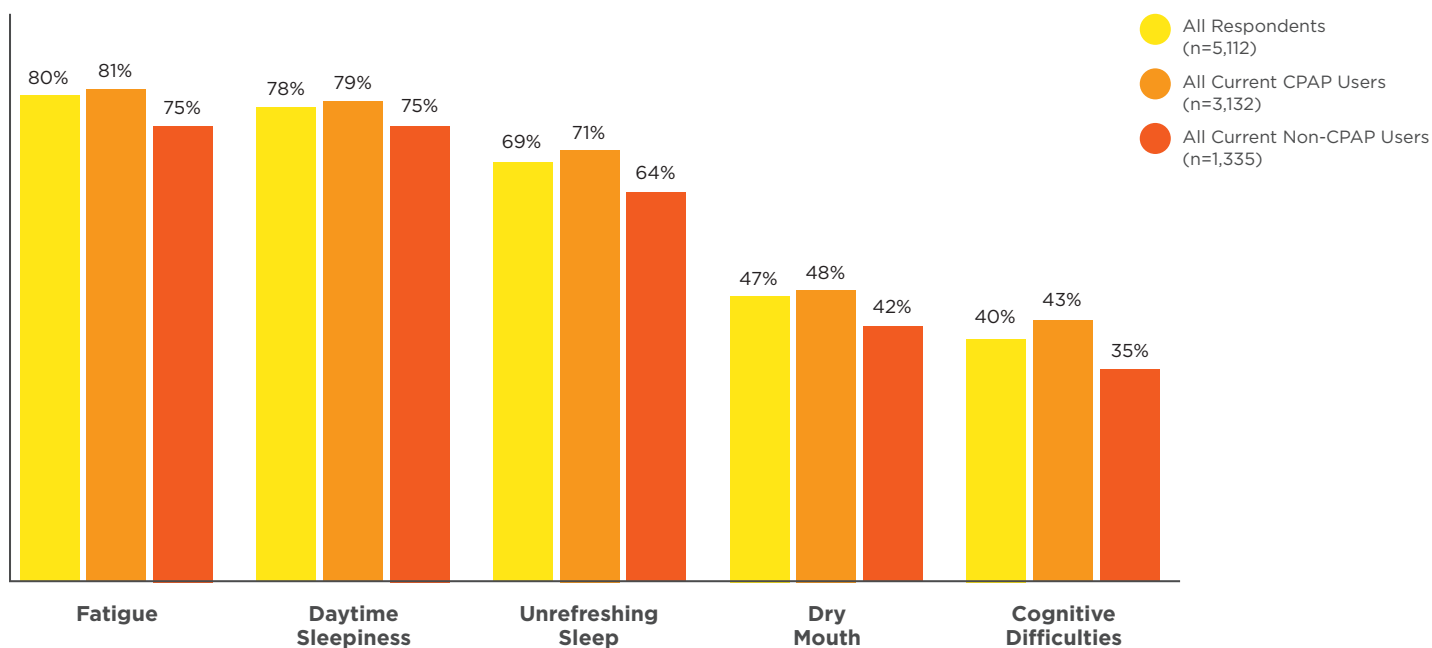


From open text survey responses — word size reflects frequency of use by respondents.

From open text survey responses — word size reflects frequency of use by respondents.



TOP SYMPTOMS WITH SEVERE OR MODERATE IMPACT



Barriers To Treatment

Barriers survey respondents encounter in either starting or sticking with therapy include therapies that are “uncomfortable” (53%) or “inconvenient” (48%), or there being financial barriers (34%), including lack of insurance, lack of coverage, or high out-of-pocket costs. Many of the free text responses focused on finding well-fitting equipment, getting good service from equipment suppliers, and accessing new models not covered by insurance plans. There were also multiple comments about challenges that arose in relationships with bed partners, including being self-conscious about the way masks made them look, and general stigma and embarrassment attached to sleep apnea and its treatment. See Section 3 of this report for detailed accounts.

CHALLENGES/BARRIERS TO STICKING WITH OR SEEKING OUT TREATMENT

	Combined (n=4,015)	Survey Monkey (n=1,692)	Evidation (n=2,323)
Uncomfortable	2,109 (53%)	972 (57%)	1,137 (49%)
Inconvenient	1,921 (48%)	811 (48%)	1,110 (48%)
Financial issues (including lack of insurance, lack of coverage, high out of pocket expenses)	1,382 (34%)	611 (36%)	771 (33%)
Concerns about long-term use	589 (15%)	270 (16%)	319 (14%)
Lack of access to healthcare or knowledgeable healthcare	532 (13%)	286 (17%)	246 (11%)
Side effects	488 (12%)	193 (11%)	295 (13%)
Stigmatizing	356 (9%)	155 (9%)	201 (9%)
Other conditions make it hard to follow treatment plan	333 (8%)	167 (10%)	166 (7%)

Desired Treatment Outcomes & Research Participation

The most important result that a treatment could provide was to help the person “feel better and go about daily life more easily” for 46 percent of respondents. Another 20 percent sought to experience a significant improvement of the symptoms that present the biggest problem for them. Slightly more of the respondents via SurveyMonkey prioritized having fewer long-term health problems (18%) compared to those responding via Evidation (12%), possibly due to the significant age difference in the two groups.

Across both platforms, respondents agreed that the ability “to feel better and go about life more easily” was the most important treatment benefit sought.

ASSUMING NO CURE, MOST IMPORTANT RESULT FROM A TREATMENT (1 choice)

	Combined (n=4,443)	Survey Monkey (n=2,149)	Evidation (n=2,294)
Feel better and go about daily life more easily	2,049 (46%)	936 (44%)	1,113 (45%)
Experience a significant improvement of symptoms that present the biggest problems for me	897 (20%)	416 (19%)	481 (19%)
Fewer long-term health problems	676 (15%)	377 (18%)	299 (12%)
Longer life expectancy	469 (11%)	249 (12%)	220 (9%)
Overall treatment plan is easier (fewer meds, fewer routines to follow, fewer doctor/hospital visits)	208 (5%)	101 (5%)	107 (4%)
Overall treatment plan costs less	144 (3%)	70 (3%)	74 (3%)

Slightly more than one-third expressed interest in participating in research. Only five percent had ever participated in a sleep apnea study; an overwhelming majority — 76% — had never been asked to participate in research.

EXPERIENCE PARTICIPATING IN SLEEP APNEA RESEARCH

	Combined (n=4,475)	Survey Monkey (n=2,176)	Evidation (n=2,299)
I have never been asked to participate in a research study	3,416 (76%)	1,725 (79%)	1,691 (74%)
I am interested in learning about research opportunities	1,473 (33%)	754 (35%)	719 (31%)
I have participated in one or more research studies for sleep apnea	204 (5%)	99 (5%)	105 (5%)
I have participated in one or more research studies for another condition I have	144 (3%)	66 (3%)	78 (3%)
I am not interested in participating in research at this time	378 (8%)	176 (8%)	202 (9%)

Conclusion

There was remarkable concordance between patient and caregiver experience communicated through the survey and first-person testimony provided at the June 8 AWAKE meeting. The large total number of respondents to this survey provides confidence that these findings reflect a wide continuum of the sleep-apnea-aware community. In particular, the two sampling methods — using community-based recruitment through SurveyMonkey and a data technology company's consumer health platform — yielded important insights about subgroups within the broader community of people living with sleep apnea. This survey did not attempt to reach individuals who lack internet access or who are unaware of sleep apnea and results of the survey cannot be generalized to those important populations.

In general, results from survey responses collected through SurveyMonkey describe a patient group that is more diagnostically “certain,” is more severely affected (when untreated), has more co-morbidities, and is more concerned about long-term consequences of sleep apnea on their health. People responding via Evidation are younger, less likely to have been referred for a sleep work-up by a health care professional and/or diagnosed by a physician, and are less likely to be using CPAP, oral appliances, or pharmaceutical drugs to manage their condition. These individuals are slightly more concerned about the impact of symptoms on daily activities, relationships, and overall well-being. In spite of these differences, there was strong agreement on the symptoms that most significantly impact daily life being fatigue, daytime sleepiness, and cognitive problems. There was also strong agreement that individuals sought to awaken feeling rested and ready to start the day, to sleep through the night, and feel better and go about daily life more easily. The burdens of the condition and its current treatments as described throughout this report were widely endorsed by both groups of respondents.

Future data analyses planned by ASAA may delve deeper into differences by age (current age and age at onset), sex, and treatment experience. There is also a tremendous amount to be learned from the extensive open text comments submitted by respondents, which total 155,339 words.

In general, results from survey responses collected through SurveyMonkey describe a patient group that is more diagnostically “certain,” is more severely affected (when untreated), has more co-morbidities, and is more concerned about long-term consequences of sleep apnea on their health.



Future publications based on this rich data set will help build scientific knowledge that reflects patients' experiences and expectations, for the benefit of patient-focused medical product development and addressing the wide range of unmet needs described in this report.

ACKNOWLEDGMENTS



The American Sleep Apnea Association gratefully acknowledges the many contributions made by all the AWAKE Sleep Apnea participants and extends special thanks to the following individuals and organizations:

- *The 465 people who attended the June 8, 2018 meeting*
- *The 5,630 people who responded to the Patient & Caregiver survey*

Professionals who provided services to the AWAKE Sleep Apnea Initiative

John Dudley, president of Dudley Digital Works, for video and broadcast services to make the AWAKE meeting accessible to a wide audience.

Gilles Frydman at @notadrawing for capturing the portraits of individuals living with sleep apnea featured in the gallery at the meeting and in this report.

Kim McCleary, CEO & founder of the Kith Collective, for strategic counsel about patient-focused medical product development, program management of the AWAKE initiative, and authorship and production of the AWAKE Sleep Apnea report.

Julie Rathjens, of Hello Brand, for design and creative services for the AWAKE initiative, including design and layout of the AWAKE Sleep Apnea report.

Erin Scott for photographing the AWAKE meeting.

Members of the American Sleep Apnea Association's Board of Directors and Professional Staff

Board:

Adam Amdur – Chairman
Joe Borelli, MD
Rich Bren
Bill Clark
Will Headapohl – Chairman Emeritus
Paul Jannace
Andy Mendoza – Secretary
Zack Miller
Theresa Shumard
Carl Stepnowsky, PhD – Chief Science Officer

Staff:

Adam Amdur – Chief Patient Officer
Justine Amdur – Program Coordinator
Kevin Bradley – Community Engagement
Valerie Danielson – CAP Program Manager
Sean Deering – Information Technology
Megan Gramstad – CAP Program Coordinator
Elizabeth Johnson – Finance Manager
Sergio Martinez – Research Assistant
Tina Piazza – Community Reporting & Analytics
Theresa Shumard – Community Leader
Carl Stepnowsky, PhD – Chief Science Officer
Erin Taylor – Grant Writer
Tania Zamora – Relationship Coordinator

Corporate sponsors of the AWAKE Sleep Apnea initiative for unrestricted educational grants and in-kind donations that helped make the meeting and survey possible:

Platinum: Jazz Pharmaceuticals

Silver: ResMed

Bronze: Fisher & Paykel Healthcare

Bronze: Philips

Friends of AWAKE: CMB Solutions; Evidation Health; RemZzzs; RT Sleep World



Partners of the AWAKE Sleep Apnea initiative for assistance with community outreach and education about the meeting and survey:

American Academy of Sleep Medicine

American Academy of Sleep Technologists

American Brain Foundation

Celiac Disease Foundation

COPD Foundation

Depression and Bipolar Support Alliance

Medical Device Innovation Consortium

Paralyzed Veterans of America

Parrish Sleep Center

Project Sleep

Savvy Cooperative

StopAfib.org



APPENDIX: AGENDA

Patient-Focused Medical Product Development Meeting

AGENDA | June 8, 2018

9:00-10:00 AM	Registration & Networking
10:00-10:05	Welcome & Agenda Overview Kim McCleary, Moderator, Founder & CEO, The Kith Collective
10:05-10:15	Welcome & Opening Remarks Adam Amdur, Chief Patient Officer, American Sleep Apnea Association
10:15-10:25	Overview of Sleep Apnea and Its Diagnosis Shelley R. Berson, MD, FACS, FAASM, FAAOA, Founder, ZZenter
10:25-10:35	Overview of Discussion Format & Polling Instructions Kim McCleary, Moderator
10:35-11:00	Panel 1: Patient Perspectives on Symptoms and Impacts on Daily Living Eugena Brooks; Brooklyn, NY Joelle Dobrow; Los Angeles, CA San Juanita Sanchez; San Juan, TX Peter Stein; Portland, ME Paul Zuccarini; Key Biscayne, FL
11:00-12:00	Polling & Facilitated Discussion Among Patients & Caregivers Kim McCleary, Moderator
12:00-12:45 PM	Lunch Break
12:45-1:00	Overview of Treatment of Sleep Apnea and Therapy Challenges Shelley R. Berson, MD, FACS, FAASM, FAAOA
1:00-1:25	Panel 2: Patient Perspectives on Current Approaches to Managing Sleep Apnea John Andrews; Virginia Beach, VA Paul Blumstein; Annandale, VA Rick Gordon; Upland, CA Celeste James; St. Albans, NY Erin Taylor; Colorado Springs, CO
1:25-2:25	Polling & Facilitated Discussion on Managing Sleep Apnea Kim McCleary, Moderator
2:25-2:45	Break
2:45-3:30	Polling & Focused Discussion of Challenges Adhering to Therapy Kim McCleary, Moderator
3:30-3:50	Summary of Day's Discussion by FDA Kathryn O'Callaghan, CDRH Assistant Director, Strategic Programs
3:50-4:00	Wrap Up and Closing Remarks ASAA Board Members Adam Amdur & Carl Stepnowsky, PhD
4:00	Adjourn

APPENDIX: PATIENT/CAREGIVER SURVEY

1. Welcome to the AWAKE Sleep Apnea Survey

Thank you for taking time to respond to this survey. We value your experience and the time you'll dedicate to this project.

The U.S. Food and Drug Administration (FDA) has placed a high priority on hearing directly from individuals with lived experience about what it's like to live with medical conditions. On June 8, 2018, the American Sleep Apnea Association (ASAA), working with several other organizations, will host the AWAKE Sleep Apnea meeting so that FDA can hear directly from people living with sleep apnea and their family members about their experiences.

This survey provides a way for members of the sleep apnea community to share their experiences with FDA, researchers, and ASAA. It is designed to collect information about symptoms, impacts on daily life, and how individuals are managing their condition with medical and supportive treatment approaches. These are the topics that FDA is most interested in, to help them understand patient and family/caregiver perspectives as new medical products (medications, medical devices, etc.) are being developed and evaluated for safety and effectiveness.

Here is some additional information to keep in mind as you work through this survey:

- If you are a person with sleep apnea (diagnosed or not) or a family member, partner, or caregiver (someone in close, regular contact with the person living with sleep apnea), we welcome you to participate in this survey and the June 8 meeting - in-person or by live webcast. (You can find more information about it at www.awakesleepapnea.org.) For most questions, respond on behalf of the person in your life who has sleep apnea. A few questions ask about your own point of view.
- Answer questions to the best of your ability. Only the first question requires an answer to proceed; the rest are optional.
- You can work on the survey a bit at a time and your answers will be saved as you move from page to page.
- You may learn new information about sleep apnea, its diagnosis and treatment from this survey.
- There are 6 sections of this survey. Depending on how much information you choose to share in the open comment fields, the survey may take 12-18 minutes to complete. Please pace yourself!
- You can leave the survey and come back to it if you use the same link to re-enter. Your answers will be saved at the end of each page.
- All the responses are anonymous and completely confidential.

We will provide some interim results of the survey at the June 8 meeting and will include a final analysis in the meeting report that will be made publicly available later this summer. Demographic information is requested to help identify patient subgroups and help document the full breadth of experience across the sleep apnea community.

We greatly value your perspective and the time and energy you'll invest. Please feel free to share the survey link with others whose lives are affected by sleep apnea, including family members and caregivers.

Click the "NEXT" button to proceed with the survey!

THANK YOU!

2. Getting acquainted

Tell us a bit about yourself and your experience.

1 Which of the following best describes your (primary) relationship to sleep apnea?

- ☐ I have sleep apnea
- ☐ I am a spouse, parent, partner, family member, and/or primary caregiver for someone who has sleep apnea.
(Note - please think about the person who has sleep apnea as you respond to questions in this survey. We will use the term "caregiver" in the rest of the survey for ease of reference).
- ☐ I am a healthcare professional who cares for people with sleep apnea
- ☐ None of the above

2 How many years since sleep apnea first affected your life?

- ☐ Within the past 12 months
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 5-10 years
- ☐ 11-20 years
- ☐ More than 20 years

Please comment more here (if you'd like):

3 What is your age (or the age of the person with sleep apnea)?

	Age 10 or younger	11-17	18-24	25-34	35-44	45-54	55-64	65-74	75 or older
Current age	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Age at onset of sleep apnea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4 The person with sleep apnea about whom you are responding describes themselves as:

- | | |
|--|---|
| <input type="radio"/> Male | <input type="radio"/> Transgender female |
| <input type="radio"/> Female | <input type="radio"/> Fluid, questioning, or unsure |
| <input type="radio"/> Transgender male | <input type="radio"/> Prefer not to answer |

5 Where do you (the respondent) live (most of the year)?

- | | |
|--|--|
| <input type="radio"/> Northeast United States | <input type="radio"/> Mountain region of United States |
| <input type="radio"/> Mid-Atlantic United States | <input type="radio"/> Western region of United States |
| <input type="radio"/> Midwest United States | <input type="radio"/> Outside United States |
| <input type="radio"/> Southern United States | <input type="radio"/> Prefer not to answer |

3. Diagnosis

Please tell us about the diagnosis of sleep apnea.

6 Has the diagnosis of sleep apnea been made (or confirmed) by a physician?

- ☐ Yes
- ☐ No
- ☐ I am in the process of getting diagnostic testing
- ☐ I don't know
- ☐ I prefer not to answer

Please comment more here (if you'd like):

7 How long did it take for the person with sleep apnea to get diagnosed with sleep apnea?

- ☐ I have not yet been diagnosed (or the person in my life who has sleep apnea has not yet been diagnosed)
- ☐ Within 12 months of recognition of symptoms
- ☐ 1-2 years after recognizing symptoms
- ☐ 3-5 years after recognizing symptoms
- ☐ 6-10 years after recognizing symptoms
- ☐ More than 10 years after recognizing symptoms

Please comment more here (if you'd like):

8 Were any of the following used to help determine the diagnosis? Check all that apply, answering to the best of your knowledge.

- | | |
|--|---|
| <input type="checkbox"/> A formal diagnosis has not (yet) been made | <input type="checkbox"/> Electrocardiogram (EKG/ECG) |
| <input type="checkbox"/> Overnight sleep study in a sleep lab (also called "attended polysomnography") | <input type="checkbox"/> Physical exam |
| <input type="checkbox"/> Home sleep study | <input type="checkbox"/> Family history |
| <input type="checkbox"/> Electroencephalogram (EEG) | <input type="checkbox"/> Epworth Sleepiness Scale (ESS) |

Please comment more here (if you'd like):

9 What was the **primary** motivating factor for pursuing a formal diagnosis?

- ☐ Symptom level was bothersome or intolerable
- ☐ Family member or friend expressed concern
- ☐ Medical professional expressed concern
- ☐ Episode where patient's life (or someone else's life) was in jeopardy
- ☐ None of the above
- ☐ Not applicable or choose not to answer

Please describe another motivation or comment more here (if you'd like):

10 Sleep apnea is often accompanied by other medical conditions. Please indicate below any other conditions that may affect you (or the person who has sleep apnea). Check as many as apply.

- | | |
|--|---|
| <input type="checkbox"/> Chronic obstructive pulmonary disease (COPD) | <input type="checkbox"/> Narcolepsy |
| <input type="checkbox"/> Congestive heart failure (CHF) | <input type="checkbox"/> Upper airway resistance syndrome (UARS) |
| <input type="checkbox"/> Diabetes | <input type="checkbox"/> Idiopathic hypersomnia |
| <input type="checkbox"/> Atrial fibrillation or another heart dysrrhythmia | <input type="checkbox"/> Major depressive disorder (MDD) |
| <input type="checkbox"/> High blood pressure (or systemic hypertension) | <input type="checkbox"/> Mood disorder other than depression |
| <input type="checkbox"/> Pulmonary hypertension | <input type="checkbox"/> Attention deficit disorder (ADD) or attention deficit with hyperactivity disorder (ADHD) |
| <input type="checkbox"/> Parkinson's disease | <input type="checkbox"/> Acromegaly (high growth hormone) |
| <input type="checkbox"/> Restless leg syndrome or periodic limb movement | <input type="checkbox"/> Hypothyroidism |
| <input type="checkbox"/> Chronic pain or fibromyalgia | <input type="checkbox"/> Allergic rhinitis (allergies) |
| <input type="checkbox"/> Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) | <input type="checkbox"/> Gastroesophageal reflux disease (GERD), acid reflux, and/or silent reflux |
| <input type="checkbox"/> Migraine | <input type="checkbox"/> None of the above |

Please specify other conditions not listed here or comment more (if you'd like):

11 Some physical features are considered to be associated with sleep apnea. Do any of these apply to you (or for caregivers, the person with sleep apnea)? Check all that might apply.

- | | |
|---|--|
| <input type="checkbox"/> Large neck circumference (19 inches or more) | <input type="checkbox"/> Overweight or body mass index between 25-30 |
| <input type="checkbox"/> Recessed lower jaw or "overbite" | <input type="checkbox"/> Obese or body mass index over 30 |
| <input type="checkbox"/> Narrow lower jaw | <input type="checkbox"/> None of the above |
| <input type="checkbox"/> Ankyloglossia or "tongue tie" | |

4. Symptoms

Tell us about the symptoms experienced in relation to sleep apnea.

12 In general, how would you describe the impact of sleep apnea symptoms on the person living with sleep apnea's daily life?

	MILD: Does not interfere with daily activities	MODERATE: Causes some limitation in daily activities	SEVERE: Significantly impacts daily activities
WITHOUT the current treatment routine (or untreated, if no treatment is presently being used)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
WITH the current treatment routine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please comment more here (if you'd like):

13

Mark each of the symptoms that has had a **moderate or severe impact** on daily activities. A "moderate" impact refers to some limitation on daily activities. A "severe" impact indicates major limitation on daily activities.

- | | |
|--|--|
| <input type="checkbox"/> Daytime sleepiness | <input type="checkbox"/> Nighttime bladder control issues, including frequent nighttime urination |
| <input type="checkbox"/> Fatigue | <input type="checkbox"/> Morning headaches |
| <input type="checkbox"/> Nasal congestion | <input type="checkbox"/> Dry mouth in the morning |
| <input type="checkbox"/> Loud, habitual snoring | <input type="checkbox"/> Cognitive difficulties including feeling in a fog, forgetfulness, memory loss, short-term memory problems, poor concentration |
| <input type="checkbox"/> Unintentional daytime sleep episodes | <input type="checkbox"/> Depressed mood or depression |
| <input type="checkbox"/> Unrefreshing sleep | <input type="checkbox"/> Irritability |
| <input type="checkbox"/> Insomnia | <input type="checkbox"/> Anxiety |
| <input type="checkbox"/> Awakening with breath-holding, gasping, or choking | <input type="checkbox"/> Hyperactivity |
| <input type="checkbox"/> Report of another person that you hold your breath, gasp, or choke during sleep | <input type="checkbox"/> Attention deficit |
| <input type="checkbox"/> Hypoventilation (or shallow breathing) | <input type="checkbox"/> Decreased libido |
| <input type="checkbox"/> Frequent movements, restlessness during sleep | <input type="checkbox"/> For males, erectile dysfunction |

List other symptoms or comment more here (if you'd like):

14 Of the symptoms related to sleep apnea, which **1-3** have the **MOST SIGNIFICANT impact** on your life?

- | | |
|--|--|
| <input type="checkbox"/> Daytime sleepiness | <input type="checkbox"/> Nighttime bladder control issues, including frequent nighttime urination |
| <input type="checkbox"/> Fatigue | <input type="checkbox"/> Morning headaches |
| <input type="checkbox"/> Nasal congestion | <input type="checkbox"/> Dry mouth in the morning |
| <input type="checkbox"/> Loud, habitual snoring | <input type="checkbox"/> Cognitive difficulties including feeling in a fog, forgetfulness, memory loss, short-term memory problems, poor concentration |
| <input type="checkbox"/> Unintentional daytime sleep episodes | <input type="checkbox"/> Depressed mood or depression |
| <input type="checkbox"/> Unrefreshing sleep | <input type="checkbox"/> Irritability |
| <input type="checkbox"/> Insomnia | <input type="checkbox"/> Hyperactivity |
| <input type="checkbox"/> Awakening with breath-holding, gasping, or choking | <input type="checkbox"/> Attention deficit |
| <input type="checkbox"/> Report of another person that you hold your breath, gasp, or choke during sleep | <input type="checkbox"/> Anxiety |
| <input type="checkbox"/> Hypoventilation (or shallow breathing) | <input type="checkbox"/> Decreased libido |
| <input type="checkbox"/> Frequent movements, restlessness during sleep | <input type="checkbox"/> Erectile dysfunction |

List other symptoms or comment more here (if you'd like):

15 How has the condition changed over time? Check as many as apply.

- ☐ It is more stable and better managed now than when symptoms first became evident
- ☐ It is worse and more unpredictable now than when symptoms first became evident
- ☐ It is generally about the same as when symptoms first became evident
- ☐ I am better informed and prepared to manage my condition but the symptoms and severity are about the same
- ☐ I feel more overwhelmed and less prepared to manage my condition compared to when it first became evident
- ☐ None of the above/prefer not to answer

Please comment more here (if you'd like):

16 Do symptoms come and go? Check as many as apply.

- ☐ Symptoms are present on a daily basis
- ☐ Symptoms vary from day-to-day or week-to-week
- ☐ Go through periods when not bothered by the symptoms and other periods when they impact life
- ☐ Level of symptoms varies according to how well treatment approach(es) is/are working
- ☐ Level of symptoms varies according to other factors in life (ex., stress, seasonal allergies, etc.)
- ☐ None of the above/prefer not to answer

Please comment more here (if you'd like):

5. Life Impacts

Please tell us about the impact of sleep apnea on your life.

17 Are there specific activities that are important to you (the person with sleep apnea) but that you (he/she) cannot do at all or as fully as you would like because of sleep apnea? Check all that apply.

- | | |
|--|---|
| <input type="checkbox"/> Sleep through the night | <input type="checkbox"/> Socializing/interacting with family and friends |
| <input type="checkbox"/> Awaken feeling rested, ready to start the day | <input type="checkbox"/> Drive a car or other vehicle (without limitations) |
| <input type="checkbox"/> Get through the day without falling asleep | <input type="checkbox"/> Start a family |
| <input type="checkbox"/> Perform as I'd like to at work or at school | <input type="checkbox"/> Share a bed/bedroom with a spouse/partner |
| <input type="checkbox"/> Perform self-care the way I'd like to | <input type="checkbox"/> None of the above/prefer not to answer |
| <input type="checkbox"/> Perform household responsibilities like caring for home/family, cooking, cleaning | |

Please list other impacts or comment more (if you'd like):

18

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired? Answer as best you can. Caregivers answer for the person with sleep apnea, as best you can.

	Would NEVER doze	SLIGHT chance of dozing	MODERATE chance of dozing	HIGH chance of dozing
Sitting and reading	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Watching television	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sitting, inactive in a public place (e.g., theatre or a meeting)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
As a passenger in a car for an hour without a break	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lying down to rest in the afternoon when circumstances permit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sitting and talking to someone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sitting quietly after lunch (without alcohol)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In a car, while stopped for a few minutes in traffic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

19 What are your **top 1-2 concerns** about living with sleep apnea?
Please answer for yourself, the respondent.

- ☐ The impact of symptoms on daily activities
- ☐ The impact of symptoms on relationships and well-being
- ☐ The effect of symptoms on physical and/or mental performance
- ☐ The risk of having or causing an accident while driving or at work
- ☐ The potential long-term consequences on health and lifespan
- ☐ The difficulty of accessing or sticking with therapy
- ☐ The burden of treating sleep apnea
- ☐ The stigma of having or treating sleep apnea

Please list other concerns or comment more (if you'd like):

20 Describe the biggest impact sleep apnea has on your life
(answering for yourself as the respondent, either patient or family member):

6. Treatment

Tell us about ways in which you're attempting to manage sleep apnea.

21 Which of the following **ventilation and airway-related therapies** have been used to help manage your (or your family member's) sleep apnea?

	Current	Past (but not now)	Never	Prefer not to answer/Don't know
Positive airway pressure (CPAP, APAP, or BiPAP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oral appliances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nasal expiratory resistance device (Provent or Theravent)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Upper airway stimulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Supplemental oxygen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

22 If positive airway pressure is used:

How many nights a week (on average)?

How many hours per night (on average)?

23 If an oral appliance is used:

How many nights a week (on average)?

How many hours per night (on average)?

24 Which of the following **medications** have been used to help manage the symptoms or conditions you (or loved one) experience related to sleep apnea?

	Current	Past (but not now)	Never	Prefer not to answer/Don't know
Nasal corticosteroids (such as Flonase or Nasalcort)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Current	Past (but not now)	Never	Prefer not to answer/Don't know
Wakefulness-promoting agents (modafinil or armodafinil (Provigil or Nuvigil))	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tricyclic antidepressants (such as amitriptyline, Vivactil or Tryptil (protriptyline), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Selective serotonin reuptake inhibitors and other antidepressants (such as Prozac (fluoxetine), Zoloft (sertraline), Cymbalta (duloxetine), Desyrel (trazodone), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anticonvulsants (such as Neurontin (gabapentin), Tegretol (carbamazepine), Klonopin (clonazepam), Valium (diazepam), Ativan (lorazepam), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antianxiety agents (such as BuSpar (buspirone), Vistaril (hydroxyzine), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prescription stimulants (such as Concerta (methylphenidate HCl), Adderall (dextroamphetamine-sulfate), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypnotics/sedatives (such as Ambien (zolpidem), Lunesta (eszopiclone), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Current	Past (but not now)	Never	Prefer not to answer/Don't know
Estrogen preparations (such as Delestrogen, Elestrin, EstroGel (estradiol), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Decongestants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vasodilators (such as Viagra (sildenafil), Cialis (tadalafil), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Leukotrein inhibitors (such as Accolate (zafirlukast), Singulair (montelukast), etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other medications (please specify):

25 Which of the following **surgical approaches** have been used to help manage your (family member's) sleep apnea?

- | | |
|---|---|
| <input type="checkbox"/> Upper airway surgery | <input type="checkbox"/> Palatable implants |
| <input type="checkbox"/> Laser-assisted uvuloplasty (LAUP) | <input type="checkbox"/> Bariatric or other obesity-related surgeries |
| <input type="checkbox"/> Uvulopalatopharyngoplasty (UPPP) | <input type="checkbox"/> Tracheostomy |
| <input type="checkbox"/> Tonsillectomy and/or adenoidectomy | <input type="checkbox"/> None of the above |

Other surgical approaches (please specify):

26

Which of the following **supportive strategies** have been used to help manage your (family member's) sleep apnea?

	Current	Past (but not now)	Never	Prefer not to answer/Don't know
Sleep position training (side sleeping)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increased caffeine intake	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Alcohol avoidance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Weight loss through diet and/or increased physical activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oro-myofunctional or orofacial therapy/training (to retrain mouth and tongue)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Extending sleeping time with regular naps and/or earlier bedtime/later waking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Relief of nasal congestion with nasal strips, nettie pot, and/or other non-medical approaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cognitive behavioral therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Meditation and/or mindfulness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yoga and/or Tai chi	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Massage or other types of bodywork	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other supportive strategies (please specify):

27 What have you found that helps the condition most?

28 What have you found makes the condition worse?

29 What barriers do you (or your loved one) encounter sticking with (or seeking out) treatment approaches that seem to help manage sleep apnea? Check all that apply.

☐ Inconvenient

☐ Uncomfortable

☐ Stigmatizing

☐ Side effects

☐ Concerns about long-term use

☐ Financial (including lack of insurance, lack of insurance coverage or high out of pocket costs)

☐ Access to healthcare or knowledgeable healthcare

☐ Other conditions make it hard to follow treatment plan

Please describe:

30 Assuming there is no complete cure for sleep apnea, what would be **the most important** result that a treatment could provide you (or your loved one)?

- ☐ Feel better and go about daily life more easily
- ☐ Experience a significant improvement of the symptoms that present the biggest problems
- ☐ Fewer long-term health problems
- ☐ Longer life expectancy
- ☐ Overall treatment plan is easier (few medications, fewer routines to follow, fewer doctor/hospital visits)
- ☐ Overall treatment plan costs less

Please comment more here (if you'd like):

31 What is your experience with participating in research about sleep apnea? Check all that apply. (Caregivers reply on behalf of the person with sleep apnea.)

- ☐ I have never been asked to participate in a research study.
- ☐ I am interested in learning more about research opportunities.
- ☐ I have participated in one or more research studies for sleep apnea.
- ☐ I have participated in one or more research studies for another condition that I have.
- ☐ I am not interested in participating in research at this time.
- ☐ Choose not to answer.

Other (please specify)

32 Is there anything else you'd like us to know about your experience with sleep apnea?

This concludes the AWAKE Sleep Apnea survey. Thank you for your important contribution this initiative.
Please visit www.awakesleepapnea.org for additional information and updates!



Raising our voices for progress in treatment and care

AWAKE Sleep Apnea is a strategic initiative of the American Sleep Apnea Association

641 S Street, N.W., Third Floor
Washington, D.C. 20001-5196
Phone: 888-293-3650
Email: info@sleepapnea.org
Web: www.sleepapnea.org



The American Sleep Apnea Association, founded in 1990, is a patient-led 501(c)(3) nonprofit organization that promotes sleep health and awareness of sleep apnea, works for continuing improvements in treatments and care, and advocates for the interests of sleep apnea patients.